

Official Journal of the European Union

L 174



English edition

Legislation

Volume 63

3 June 2020

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I

(Legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2020/686

of 17 December 2019

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Article 94(3), Article 97(2), Article 101(3), Article 106(1), Article 122(1) and (2), Article 131(1), Article 160(1) and (2), Article 161(6), Article 162(3) and (4), Article 163(5), Article 164(2), Article 165(3) and Article 279(2) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans. Those rules provide, inter alia, for the registration and approval of germinal product establishments, and for the traceability and animal health requirements for movements of consignments of germinal products within the Union. Regulation (EU) 2016/429 also empowers the Commission to adopt rules to supplement certain non-essential elements of that Regulation by means of delegated acts. It is therefore appropriate to adopt such rules in order to ensure the smooth functioning of the system in the new legal framework established by Regulation (EU) 2016/429.
- (2) The rules laid down in this Regulation are required to supplement those laid down in Chapters 1, 2 and 5 of Title I of Part IV of Regulation (EU) 2016/429, as regards the approval of germinal product establishments, the registers of germinal product establishments to be kept by the competent authorities, the record-keeping obligations of operators, the traceability and animal health requirements, and animal health certification and notification requirements for movements within the Union of consignments of germinal products of certain kept terrestrial animals in order to prevent the spread of transmissible animal diseases within the Union by those products.
- (3) These rules are substantively linked and many are intended to be applied in tandem. In the interests of simplicity and transparency, as well as to facilitate their application and to avoid a multiplication of rules, they therefore should be laid down in a single act rather than in a number of separate acts with many cross-references and the risk of duplication.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

- (4) Indeed, Regulation (EU) 2016/429 aims at providing a simpler and more flexible regulatory framework than previously existed, while at the same time ensuring a more risk-based approach to animal health requirements, enhanced disease preparedness, prevention and control of animal diseases. It was also adopted in order to ensure that the rules concerning animal diseases were laid down mainly in a single act, as opposed to being scattered in a number of different acts. The rules laid down in this Regulation concerning germinal products also follow the same approach.
- (5) Prior to the adoption of Regulation (EU) 2016/429, Union rules on germinal products were laid down in Council Directives 88/407/EEC ⁽²⁾, 89/556/EEC ⁽³⁾, 90/429/EEC ⁽⁴⁾ and 92/65/EEC ⁽⁵⁾. Regulation (EU) 2016/429 repeals and replaces those four Directives with effect from 21 April 2021. Those Directives laid down the animal health conditions for trade within the Union and for the entry into the Union of consignments of semen, ova and embryos of bovine, ovine, caprine, porcine and equine animals and in principle of certain other animal species. The rules laid down in those Directives have proven to be effective in preventing the spread of transmissible animal diseases within the Union. Accordingly, the main substance of those rules should be maintained, but updated to take account of the experience gained in their application and current scientific knowledge.
- (6) Germinal products, and in particular semen, but also to a lesser extent oocytes and embryos may represent an important risk for the spread of animal diseases. They are collected or produced from a limited number of donors, but are used widely in the general animal population so they can, if not handled properly or not classified with the correct health status, be a source of disease for a large number of animals. Such cases have occurred in the past and have caused substantial economic losses.
- (7) To prevent the risk of the spread of disease, Regulation (EU) 2016/429 provides that germinal products should be collected, produced, processed and stored at specialised germinal product establishments and be subject to special animal health and hygiene regimes. At the same time, in order for animals to be admitted into those germinal product establishments and be classified as donors of germinal products which may be moved between Member States, they are required to comply with higher animal health standards than those applicable to the general animal population. Regulation (EU) 2016/429 also lays down specific procedures to ensure the traceability of those germinal products and a special set of animal health requirements apply to their movements within the Union. Within this framework, it is appropriate to lay down in this Regulation rules with regard to the movements of consignments of germinal products on the basis of several empowering provisions laid down in Regulation (EU) 2016/429 which provide for the Commission to adopt delegated acts, and in particular those laid down in Part IV thereof.
- (8) Article 160(1) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts laying down animal health requirements for movements to other Member States of germinal products of bovine, porcine, ovine, caprine and equine animals. One of the conditions for such movements is that those germinal products must come from a germinal product establishment approved for that purpose in accordance with conditions to be laid down in a delegated act. Furthermore, Article 94(3)(c) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts concerning the special rules for the cessation of activities of germinal product establishments previously approved in accordance with the conditions laid down in a delegated act. At the same time, Article 101(3) of that Regulation provides for the Commission to adopt delegated acts on the detailed information to be included in the registers of registered and approved germinal product establishments kept by the competent authority, which will also include germinal product establishments which have ceased their activity.
- (9) As the animal health requirements and derogations to be adopted pursuant to those provisions of Regulation (EU) 2016/429 all relate to movements of germinal products of kept terrestrial animals within the Union, albeit pertaining to a number of different species, in the interests of simplification of Union rules, they should be laid down in a single delegated act, rather than scattered in a number of different delegated acts.

⁽²⁾ Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species (OJ L 194, 22.7.1988, p. 10).

⁽³⁾ Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (OJ L 302, 19.10.1989, p. 1).

⁽⁴⁾ Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (OJ L 224, 18.8.1990, p. 62).

⁽⁵⁾ Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

- (10) Article 162(1) of Regulation (EU) 2016/429 lays down requirements concerning the minimum information to be included in animal health certificates for movements between Member States of germinal products of bovine, porcine, ovine, caprine and equine animals. They must include information on the marking of the germinal products, when so required by Article 121(1) of that Regulation or by any rules laid down in delegated acts adopted pursuant to Article 122(1) thereof, and the information needed to demonstrate that the germinal products fulfil the movement requirements as provided for in Articles 157 and 159 of that Regulation or by rules set out in delegated acts adopted pursuant to Article 160 thereof. Article 162(3) of that Regulation provides for delegated acts to be adopted concerning the information to be contained in the animal health certificates. At the same time, Article 163(5) thereof provides for delegated acts to be adopted on the notification requirements for movements between Member States of germinal products of certain kept terrestrial animals, accompanied by an animal health certificate whose content is to be established in accordance with Article 162(3) and (4) of that Regulation.
- (11) Article 94(1) of Regulation (EU) 2016/429 provides that germinal products of bovine, porcine, ovine, caprine and equine animals may be moved to another Member State if those germinal products were collected at germinal product establishments which have been approved by the competent authorities in accordance with Article 97(1) thereof. Such approval may only be granted if those germinal product establishments comply with particular requirements relating to quarantine, isolation and other biosecurity measures, surveillance, facilities and equipment, as well as responsibilities, competence and specialised training of personnel and veterinarians. Therefore, based on those requirements, it is necessary to set out in this Regulation the detailed rules and conditions for the approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals may be moved to another Member State.
- (12) Directive 92/65/EEC provides that semen of ovine and caprine animals, which is to be moved to another Member State, may be collected at the establishment of origin of those animals instead of at a semen collection centre. This Regulation should provide for a similar derogation. However, special conditions for movements of consignments of such semen, including the purpose of such movements and the consent of the Member State of destination, should be established. Therefore, based on the possible risk posed by the movement of such semen, the rules and conditions authorising such derogations should be laid down in this Regulation.
- (13) The collection of equine semen has its own particular characteristics due to the special breeding system of equine animals which takes account of the participation of such animals in dedicated equine competitions, shows and other equestrian events. Currently, Directive 92/65/EEC provides for three types of residency of stallions at semen collection centres. The main rules laid down in the current system provided for in that Directive should be maintained in this Regulation. However, the conditions for the testing programme as specified in point 1.6(b) of Chapter II(I) of Annex D to Directive 92/65/EEC for donors which may leave the semen collection centre occasionally and for the testing programme as specified in point 1.6(c) of Chapter II(I) of Annex D to Directive 92/65/EEC for 'walk-in stallions', should be improved and strengthened in this Regulation.
- (14) This Regulation should also provide for germinal product storage centres storing germinal products of any type and originating from more than one species, under one unique approval number and subject to rules that ensure traceability, as there are no animal health reasons requiring separate storage centres per type of germinal product or per species. Information on the types and species of stored germinal products should be specified in the approval of such establishments and in the publicly available register of approved germinal product establishments kept by the competent authorities. This Regulation should also lay down specific provisions on the storage of fresh, chilled and frozen semen.
- (15) The continual progress in germinal products processing techniques has led to the establishment of specialised units for that purpose. Those units not only process germinal products, including sex-sorting of semen, but they also prepare the final product ready for use or for storage. Therefore, such units should be considered to be germinal product establishments where the processing and storage of germinal products takes place. However, as equipment for sex-sorting of semen is costly, semen collection centres may use services of other operators for processing, including sex-sorting, of semen. In that case, semen is sent out for processing and is then returned to the semen collection centre of origin. Therefore, it is appropriate to lay down in this Regulation rules for the processing of germinal products, including the possibility for their processing at germinal product processing establishments, as well as detailed rules for the transport and the marking of semen and other germinal products to and from such germinal product processing establishments. Where semen is processed at a germinal product processing establishment, a marking on the straw or another package should include the approval or registration number of both the semen collection centre and the germinal product processing establishment in order to ensure traceability of the semen.

- (16) While antibiotics should be used prudently, at the same time, in particular with a view to possible international trade, the inclusion of antibiotics in semen diluents should be in line with the provisions of Article 4.6.7 of the Terrestrial Animal Health Code ('the Code') of the World Organisation for Animal Health (OIE), Edition 2017 ⁽⁶⁾. In accordance with Directive 88/407/EEC, there is an obligation to add to bovine semen antibiotics that are effective against campylobacters, leptospires and mycoplasmas, and in accordance with Directive 90/429/EEC there is an obligation to add to porcine semen antibiotics which are effective against leptospires, while Directive 92/65/EEC provides for the voluntary use of antibiotics. This Regulation should maintain the rules for the usage of antibiotics laid down in Directives 88/407/EEC, 90/429/EEC and 92/65/EEC, as well as those recommended by the OIE. Where antibiotics are added to semen, information about the active substance(s) and their concentration should be indicated in the accompanying health certificate.
- (17) Article 101(1) of Regulation (EU) 2016/429 provides that each competent authority should establish and keep up-to-date registers of registered germinal product establishments and of approved germinal product establishments which should be made available to the Commission and the competent authorities of the Member States. In addition, the register of approved germinal product establishments should be made available to the public. Therefore, it is appropriate to lay down in this Regulation the detailed information which should be included in those registers and the public availability of the register of the approved germinal product establishments.
- (18) Due to the lengthy stocking capabilities for semen, oocytes and embryos, it is necessary to lay down in this Regulation special rules for the storage and movement of germinal products collected by approved germinal product establishments which cease their activity. Information concerning such germinal product establishments should be retained in the register of approved germinal product establishments of the Member State concerned and dates when the activity was stopped should be included. In addition, the date of withdrawal of the approval should be indicated in that register. The period for retaining information concerning such germinal product establishments in that register should also be established.
- (19) In addition, this Regulation should also lay down rules to ensure that operators of approved germinal product establishments who cease their activity, prior to the date of withdrawal of the approval of their germinal product establishment, move the semen, oocytes or embryos collected or produced and stored in those germinal product establishments for further storage to a germinal product storage centre, or for reproduction purposes to an establishment where bovine, porcine, ovine, caprine or equine animals are kept, or for safe disposal or use as animal by-products in accordance with Article 13 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽⁷⁾.
- (20) Article 121 of Regulation (EU) 2016/429 lays down traceability requirements for germinal products of bovine, ovine, caprine, porcine and equine animals and detailed rules in relation to the marking of those germinal products should be laid down in this Regulation. The current system for the marking of straws and other packages with germinal products is well established. Account should also be taken of the recommendations of the International Committee for Animal Recording (ICAR) ⁽⁸⁾ in this respect.
- (21) The collection and processing of semen of ovine and caprine animals also have particular characteristics. Some semen collection centres freeze semen in pellets, while others place fresh or chilled semen for a short time in receptacles, such as tubes. The individual marking of such pellets and tubes is time consuming and onerous. In order to allow the movement to other Member States of semen of ovine and caprine animals, while at the same time ensuring its traceability, group identification of pellets of frozen semen or tubes or straws with fresh or chilled semen should be available. Therefore, it is necessary to lay down in this Regulation rules for the marking of collective packages, such as goblets, where pellets of frozen semen, or tubes or straws with fresh or chilled semen of ovine and caprine animals are placed.
- (22) Traceability requirements for germinal products of bovine, ovine, caprine, porcine and equine animals laid down in this Regulation are to be supplemented by the rules concerning technical requirements and specifications for marking of straws and other packages which will be laid down in Commission Implementing Regulation adopted in accordance with Article 123 of Regulation (EU) 2016/429.

⁽⁶⁾ http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_coll_semen.htm

⁽⁷⁾ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

⁽⁸⁾ <https://www.icar.org/>

- (23) An increasing number of germinal products of dogs and cats, of terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments and of animals of the families *Camelidae* and *Cervidae* are moved between Member States. Therefore, it is appropriate to establish harmonised rules on the marking of straws and other packages containing such germinal products. Additional rules on the traceability of germinal products of kept terrestrial animals of species other than those of the bovine, porcine, ovine, caprine and equine species should be laid down in this Regulation.
- (24) Article 159 of Regulation (EU) 2016/429 lays down rules concerning the authorisation of movements to other Member States of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species. In order to make those rules operational, it is necessary to lay down in this Regulation detailed rules for the collection, production, processing, storage and transport of germinal products, and animal health requirements for kept donor animals from which germinal products are collected and concerning isolation and quarantine for such animals, and requirements for the laboratory and other tests to be carried out on kept donor animals and germinal products, as well as animal health requirements for the collection, production, processing, storage or other procedures and transport of those germinal products.
- (25) In addition, Directives 88/407/EEC, 90/429/EEC and 92/65/EEC provided for derogations, under certain conditions, from testing obligations for donor animals of the bovine, porcine, ovine and caprine species when those animals are moved between semen collection centres. As such derogations decrease the procedural and economic burdens for operators of semen collection centres and are justified from an animal health point of view, it is appropriate to maintain in this Regulation such derogations from certain animal health requirements for donor animals of the bovine, ovine, caprine and porcine species moved between approved semen collection centres.
- (26) Based on current scientific knowledge, the transport of different types of germinal products of a single species in one container does not pose a risk for the contamination of germinal products if they are transported under certain conditions. These conditions include being transported in physically separated compartments of the transport container or with the use of double-bag system protecting the commodity of one type from the other. Therefore, it is appropriate to lay down rules in this Regulation permitting the transport of germinal products of different types of a single species in one container under certain conditions.
- (27) The sealing of containers in which germinal products are transported from approved germinal product establishments to other Member States or nationally from approved germinal product establishments to germinal product processing establishments and germinal product storage centres ensures that the animal health conditions for the transport of germinal products are not compromised. The centre veterinarian or team veterinarian responsible for the germinal product establishment, whose name is specified in the approval of that establishment, should ensure that such seal is applied on the transport container. An official veterinarian certifying a consignment of germinal products should have the possibility of breaking that seal for the purpose of verifying the content of the transport container and later on re-sealing the transport container. Those arrangements should be taken into account in the rules laid down in this Regulation.
- (28) Directive 89/556/EEC lays down conditions for intra-Union trade in and imports into the Union of embryos of animals of the bovine species. However, it is also necessary to lay down in this Regulation rules on movements within the Union of bovine oocytes as well as ovaries.
- (29) Union legislation in force prior to the adoption of Regulation (EU) 2016/429 and this Regulation laid down the rules on trade in semen covering situations where each dose of the consignment consists of ejaculates of one particular donor. However, due to the fact that mixed or pooled semen from several donors may increase fertility and such semen is commonly used, this Regulation should lay down rules on movements of mixed or pooled semen of bovine, porcine, ovine and caprine animals, provided that mixing of semen is restricted only to one semen collection centre where the semen was collected and a mark on each straw or other package in which mixed semen is placed allows tracing the individual identification numbers of all donor animals. In addition, the operator should have procedures in place as regards the processing of mixed semen and should include, in its records, details of movements of such semen from semen collection centre.

- (30) Article 13 of Directive 92/65/EEC lays down rules for trade in semen, ova and embryos of animals of species susceptible to the diseases listed in Annex A or B thereto which are consigned to and from bodies, institutes or centres approved in accordance with Annex C thereto. Annex E to that Directive sets out the model animal health certificate for trade which should accompany the consignments of such semen, ova or embryos. Articles 95 and 137 of Regulation (EU) 2016/429 establish the concept of 'a confined establishment' which is equivalent to 'approved body, institute or centre' defined in Article 2(1)(c) of Directive 92/65/EEC. Given that genetic material of animals is currently exchanged between approved bodies, institutes and centres, it is necessary to maintain the possibility for such intra-Union movements in this Regulation. It is therefore appropriate to lay down in this Regulation the animal health requirements for movements to other Member States of germinal products of terrestrial animals kept at confined establishments. This Regulation should thus provide for a possibility for operators of confined establishments to move to other Member States consignments of germinal products collected from animals kept at those establishments without a need for additional approval as germinal product establishment. High animal health requirements for the approval as a confined establishment, controlled management of animals at those establishments, specific surveillance requirements and targeted movement of consignments of germinal products to another confined establishment should provide for sufficient guarantees to prevent the spread of animal diseases.
- (31) Article 162 of Regulation (EU) 2016/429 lays down rules concerning the minimum information which must be included in animal health certificates for movements between Member States of germinal products of kept terrestrial animals of the bovine, porcine, ovine, caprine and equine species. Therefore, this Regulation should specify the detailed information that should be contained in such certificates.
- (32) Article 163 of Regulation (EU) 2016/429 provides that operators should inform the competent authority in their Member State of origin in advance of the intended movement to another Member State of germinal products of kept terrestrial animals of the bovine, porcine, ovine, caprine and equine species and should provide all the necessary information to enable that competent authority to notify the movement of germinal products to the competent authority of the Member State of destination. Therefore, it is necessary to lay down in this Regulation detailed rules concerning the requirements for the advance notification by operators, the information necessary to notify such movements and the emergency procedures for such notifications.
- (33) Article 163(2) of Regulation (EU) 2016/429 provides that Traces should be used for the notification purposes when consignments of germinal products are intended to be moved to other Member States. Traces is the integrated computerised veterinary system as provided for in Commission Decisions 2003/24/EC ⁽⁹⁾ and 2004/292/EC ⁽¹⁰⁾. Article 131 of Regulation (EU) 2017/625 of the European Parliament and of the Council ⁽¹¹⁾ provides for the establishment of an information management system for official controls (IMSOC) which will incorporate functionalities of Traces. IMSOC should therefore be referred to in this Regulation instead of Traces.
- (34) Article 165 of Regulation (EU) 2016/429 provides that the competent authority of the place of destination may, subject to agreement of the competent authority of the place of origin, authorise for scientific purposes movements of germinal products into its territory where those movements do not fulfil the standard requirements for movements of germinal products. In order to allow such movements, it is appropriate to lay down in this Regulation the rules for the granting of derogations by the competent authorities for movements between Member States of germinal products for scientific purposes.

⁽⁹⁾ Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system (OJ L 8, 14.1.2003, p. 44).

⁽¹⁰⁾ Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC (OJ L 94, 31.3.2004, p. 63).

⁽¹¹⁾ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

- (35) A national gene bank plays an important role in storing the genetic material of animal populations that are particular to that Member State. The objective of such national gene banks is *ex situ* conservation and sustainable use of animal genetic resources. Germinal products stored at the national gene banks are often of unknown animal health status or were collected, produced, processed and stored in accordance with a different animal health regime than it is currently applicable in accordance with Union and national legislation. As such germinal products have a particular value, as they are often genetic material of endangered breeds as defined in point (24) of Article 2 of Regulation (EU) 2016/1012 of the European Parliament and of the Council ⁽¹²⁾, or breeds that are extinct since collection of the germinal products, and Member States have expressed their interest in exchanging such germinal products amongst themselves, special conditions for granting derogations by the competent authorities for the movement of germinal products stored in national gene banks to other Member States should be laid down in this Regulation. As a general rule, this Regulation should lay down the conditions for movements of those germinal products between national gene banks of different Member States, while rules for national distribution of germinal products from national gene banks to operators should be left to the competent authorities of Member States. Special attention should also be paid to the animal health conditions for such movements, where testing for particular diseases may be required.
- (36) This Regulation refers to Commission Implementing Regulation (EU) 2018/1882 ⁽¹³⁾ and Commission Delegated Regulations (EU) 2019/2035 ⁽¹⁴⁾, (EU) 2020/689 ⁽¹⁵⁾ and (EU) 2020/688 ⁽¹⁶⁾ which were also adopted under Regulation (EU) 2016/429. The references to those Regulations are necessary as they lay down requirements on surveillance, eradication programmes and disease free statuses, identification and registration, traceability and movements within the Union and entry into the Union of animals, which are also applicable to germinal product donor animals.
- (37) In order to ensure a smooth transition to the new legal framework for semen collection or storage centres or embryo collection or production teams approved under acts adopted pursuant to Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC, which are repealed by Regulation (EU) 2016/429 with effect from 21 April 2021, carrying out activities related to the collection, production, processing, storing and transport of germinal products, they should be deemed to be approved in accordance with this Regulation. Member States should ensure that those operators comply with all the rules provided for in this Regulation, in particular by submitting them to regular and risk-based official controls. In the event of non-compliance, the competent authorities should ensure that those operators take the necessary measures to remedy that non-compliance and, where necessary, suspend or withdraw their approval.
- (38) In order to ensure a smooth transition for germinal products collected and produced before the date of application of this Regulation, straws and other packages in which such semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, and which are marked before 21 April 2021 in accordance with the legislation adopted pursuant to Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC, should be considered to have been marked in accordance with this Regulation and eligible for movement between Member States.
- (39) This Regulation should be applicable from 21 April 2021 in accordance with the date of application of Regulation (EU) 2016/429,

⁽¹²⁾ Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding ('Animal Breeding Regulation') (OJ L 171, 29.6.2016, p. 66).

⁽¹³⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

⁽¹⁴⁾ Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115).

⁽¹⁵⁾ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (See page 211 of this Official Journal).

⁽¹⁶⁾ Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (See page 140 of this Official Journal).

HAS ADOPTED THIS REGULATION:

PART I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation supplements the rules laid down in Regulation (EU) 2016/429 as regards registered and approved germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals.
2. Chapter 1 of Part II lays down the requirements for the approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State in relation to:
 - (a) quarantine, isolation and other biosecurity measures;
 - (b) surveillance requirements;
 - (c) facilities and equipment;
 - (d) responsibilities, competence and specialised training of personnel and veterinarians for the activity of germinal product establishments;
 - (e) responsibilities of the competent authority approving germinal product establishments;
 - (f) special rules for the cessation of activities of those germinal product establishments.
3. Chapter 2 of Part II lays down the requirements on:
 - (a) the information to be included by the competent authority in the register of registered germinal product establishments;
 - (b) the information to be included by the competent authority in the register of the of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals; and the rules for the availability to the public of that register when germinal products of those animals are to be moved between Member States.
4. Chapter 3 of Part II lays down:
 - (a) the rules for the record-keeping obligations on operators of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals, and the requirements for record-keeping in respect of the germinal products collected, produced or processed in such an establishment after it has ceased its activities;
 - (b) the traceability requirements for germinal products of:
 - (i) bovine, porcine, ovine, caprine and equine animals;
 - (ii) dogs (*Canis lupus familiaris*) and cats (*Felis silvestris catus*);
 - (iii) terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments;
 - (iv) animals of the families *Camelidae* and *Cervidae*.
5. Chapter 1 of Part III lays down the animal health requirements, including derogations, for movements between Member States of germinal products of bovine, porcine, ovine, caprine and equine animals, specifying:
 - (a) the rules for the collection, production, processing and storage of germinal products in the approved germinal product establishments;
 - (b) the animal health requirements for donor animals from which germinal products were collected, and concerning isolation or quarantine for those animals;

- (c) the laboratory and other tests to be carried out on donor animals and germinal products;
 - (d) the animal health requirements for the collection, production, processing, storage and other procedures, and for the transport of germinal products.
6. Chapter 2 of Part III, for movements between Member States of germinal products of bovine, porcine, ovine, caprine and equine animals, lays down:
- (a) the rules on animal health certification;
 - (b) the information to be contained in the animal health certificate;
 - (c) the requirements concerning self-declaration document;
 - (d) the notification requirements.
7. Chapter 3 of Part III lays down the animal health, certification and notification requirements for movements between Member States of germinal products of:
- (a) dogs and cats;
 - (b) terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments;
 - (c) animals of the families *Camelidae* and *Cervidae*.
8. Chapter 4 of Part III lays down rules for the granting of derogations by competent authorities for movements between Member States of germinal products for scientific purposes and germinal products stored at gene banks.
9. Part IV lays down certain transitional measures regarding Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC in relation to:
- (a) the approval of semen collection centres, semen storage centres, embryo collection teams and embryo production teams;
 - (b) the marking of straws and other packages in which semen, oocytes or embryos are placed, stored and transported.
10. This Regulation shall not apply to germinal products of wild animals.

Article 2

Definitions

For the purposes of this Regulation, in addition to the definitions laid down in Article 1 of Implementing Regulation (EU) 2018/1882, the following definitions shall apply:

- (1) 'registered germinal product establishment' means a germinal product establishment, other than an approved germinal product establishment, registered with the competent authority in accordance with point (a) of the first subparagraph of Article 93 of Regulation (EU) 2016/429;
- (2) 'approved germinal product establishment' means a semen collection centre, an embryo collection team, an embryo production team, a germinal product processing establishment or a germinal product storage centre, approved in accordance with Article 97 of Regulation (EU) 2016/429;
- (3) 'bovine animal' or 'animal of the bovine species' means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species;
- (4) 'porcine animal' or 'animal of the porcine species' means an animal of the ungulate species of *Sus scrofa*;
- (5) 'ovine animal' or 'animal of the ovine species' means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species;

- (6) 'caprine animal' or 'animal of the caprine species' means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species;
- (7) 'equine animal' or 'animal of the equine species' means an animal of the species of solipeds belonging to genus *Equus* (including horses, asses, and zebras) and the offspring of crossings of those species;
- (8) 'animal health certificate' means a document issued by the competent authority of the Member State of origin to accompany a consignment of germinal products to their place of destination as referred to in Article 161(4) of Regulation (EU) 2016/429;
- (9) 'self-declaration document' means a document issued by the operator to accompany a consignment of germinal products to their place of destination as referred to in Articles 32 and 46;
- (10) 'gene bank' means a repository of animal genetic material for *ex situ* conservation and sustainable use of genetic resources of kept terrestrial animals, held by a host institution authorised or recognised by the competent authority to fulfil these tasks;
- (11) 'semen collection centre' means a germinal product establishment approved by the competent authority for the collection, processing, storage and transport of semen of bovine, porcine, ovine, caprine or equine animals intended for movement to another Member State, as referred to in Article 4;
- (12) 'embryo collection team' means a germinal product establishment comprised of a group of professionals or a structure approved by the competent authority for the collection, processing, storage and transport of *in vivo* derived embryos of bovine, porcine, ovine, caprine or equine animals intended for movement to another Member State, as referred to in Article 4;
- (13) 'embryo production team' means a germinal product establishment comprised of a group of professionals or a structure approved by the competent authority for the collection, processing, storage and transport of oocytes, and the *in vitro* production, where applicable with stored semen, processing, storage and transport of embryos, of bovine, porcine, ovine, caprine or equine animals both intended for movement to another Member State, as referred to in Article 4;
- (14) 'semen' means the ejaculate of an animal or animals, either in the unaltered state or prepared or diluted;
- (15) 'oocytes' means the haploid stages of the ootidogenesis including secondary oocytes and ova;
- (16) 'embryo' means the initial stage of development of an animal while it is capable of being transferred to a recipient dam;
- (17) 'consignment of germinal products' means a quantity of semen, oocytes, *in vivo* derived embryos or *in vitro* produced embryos dispatched from a single approved germinal product establishment covered by a single animal health certificate;
- (18) 'germinal product processing establishment' means a germinal product establishment approved by the competent authority for the processing, including semen sex-sorting where appropriate, and the storage of semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals of one or more species, or any combination of types of germinal products or species, intended for movement to another Member State, as referred to in Article 4;
- (19) 'germinal product storage centre' means a germinal product establishment approved by the competent authority for the storage of semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals of one or more species, or any combination of types of germinal products or species, intended for movement to another Member State, as referred to in Article 4;
- (20) 'centre veterinarian' means the veterinarian responsible for the activities carried out at the semen collection centre, at the germinal product processing establishment or at the germinal product storage centre as laid down in this Regulation;
- (21) 'team veterinarian' means the veterinarian responsible for the activities carried out by an embryo collection team or by an embryo production team as laid down in this Regulation;
- (22) 'unique approval number' means a number assigned by the competent authority;

- (23) 'withdrawal date of the approval' means the date on which the competent authority has suspended or withdrawn the approval of an approved germinal product establishment in accordance with Article 100 of Regulation (EU) 2016/429;
- (24) 'unique registration number' means a number assigned to a registered germinal product establishment;
- (25) 'quarantine accommodation' means a facility authorised by the competent authority for the purpose of the isolation of bovine, porcine, ovine or caprine animals for a period of at least 28 days before they are admitted to a semen collection centre;
- (26) 'establishment free from (disease)' means an establishment granted the status in accordance with the requirements set out in Article 20 of Delegated Regulation (EU) 2020/689;
- (27) 'official laboratory' means a laboratory, situated in a Member State or third country or territory, designated in accordance with Article 37 of Regulation (EU) 2017/625 by the competent authority to carry out the tests provided for in Articles 24 and 25 of this Regulation;
- (28) 'IMSOC' means an information management system for official controls for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls and other official activities are managed, handled, and automatically exchanged as referred to in Article 131 of Regulation (EU) 2017/625 and is the system now used instead of Traces;
- (29) 'endangered breed' means a local breed, recognised by a Member State to be endangered, genetically adapted to one or more traditional production systems or environments in that Member State and where the endangered status is scientifically established by a body possessing the necessary skills and knowledge in the area of endangered breeds as referred to in Article 2(24) of Regulation (EU) 2016/1012;
- (30) 'approved eradication programme' means a disease eradication programme implemented in a Member State or zone thereof as approved by the Commission in accordance with Article 31(3) of Regulation (EU) 2016/429;
- (31) 'batch of donor animals' means a group of animals of the same health status from which germinal products are collected and processed at the same time, and transported together.

PART II

APPROVAL OF GERMINAL PRODUCT ESTABLISHMENTS, REGISTERS, RECORD-KEEPING AND TRACEABILITY

CHAPTER 1

Approval of germinal product establishments

Article 3

Requirements for the approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals

Operators of the following germinal product establishments for bovine, porcine, ovine, caprine and equine animals shall apply in accordance with Article 94(1)(b) of Regulation (EU) 2016/429 to the competent authority for approval for the purpose of moving consignments of germinal products of those animals to other Member States:

- (a) the establishment where semen of bovine, porcine, ovine, caprine or equine animals is collected, processed and stored for approval as a semen collection centre;
- (b) the group of professionals or the structure supervised by a team veterinarian competent to perform the collection, processing and storage of embryos of bovine, porcine, ovine, caprine or equine animals for approval as a embryo collection team;

- (c) the group of professionals or the structure supervised by a team veterinarian competent to perform the collection, processing and storage of oocytes and production, processing and storage of embryos of bovine, porcine, ovine, caprine or equine animals for approval as an embryo production team;
- (d) the establishment where fresh, chilled or frozen semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals are processed and stored for approval as a germinal product processing establishment;
- (e) the establishment where fresh, chilled or frozen semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals are stored for approval as a germinal product storage centre.

Article 4

Approval by the competent authority of germinal product establishments for bovine, porcine, ovine, caprine and equine animals

1. The competent authority shall only grant approval of a germinal product establishment for bovine, porcine, ovine, caprine or equine animals as referred to in Article 97 of Regulation (EU) 2016/429 after it has ensured that it complies with the following requirements:

- (a) the operator has appointed:
 - (i) a centre veterinarian responsible for the activities set out in:
 - point 1 of Part 1 of Annex I, in the case of an application for approval of a germinal product establishment referred to in point (a) of Article 3 as a semen collection centre,
 - point 1 of Part 4 of Annex I, in the case of an application for approval of a germinal product establishment referred to in point (d) of Article 3 as a germinal product processing establishment,
 - point 1 of Part 5 of Annex I, in the case of an application for approval of a germinal product establishment referred to in point (e) of Article 3 as a germinal product storage centre; or
 - (ii) a team veterinarian responsible for the activities set out in:
 - point 1 of Part 2 of Annex I, in the case of an application for approval of a germinal product establishment referred to in point (b) of Article 3 as a embryo collection team,
 - point 1 of Part 3 of Annex I, in the case of an application for approval of a germinal product establishment referred to in point (c) of Article 3 as a embryo production team;
- (b) the facilities, equipment and operational procedures for the activity in question comply with the requirements set out in:
 - (i) point 2 of Part 1 of Annex I, in respect of the collection, processing, storage and transport of semen of bovine, porcine, ovine, caprine or equine animals;
 - (ii) point 2 of Part 2 of Annex I, in respect of the collection, processing, storage and transport of embryos of bovine, porcine, ovine, caprine or equine animals;
 - (iii) point 2 of Part 3 of Annex I, in respect of the collection of oocytes and of the production, processing, storage and transport of embryos of bovine, porcine, ovine, caprine or equine animals, including the processing and storage of semen and oocytes used for the embryo production;
 - (iv) point 2 of Part 4 of Annex I, in respect of the processing, storage and transport of fresh, chilled or frozen semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals;
 - (v) point 2 of Part 5 of Annex I, in respect of the storage and transport of fresh, chilled or frozen semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals.

2. When granting approval of a germinal product establishment for bovine, porcine, ovine, caprine and equine animals, as referred to in Articles 97 and 99 of Regulation (EU) 2016/429, the competent authority shall assign it with a unique approval number, which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted.

*Article 5***Special rules for the cessation of activities of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals**

1. Where the operator of an approved germinal product establishment for bovine, porcine, ovine, caprine and equine animals ceases its activity, that operator shall ensure that prior to the withdrawal date of the approval all consignments of semen, oocytes or embryos collected or produced and stored in that germinal product establishment have been moved:

- (a) to a germinal product storage centre for further storage; or
- (b) for reproduction purposes to an establishment where bovine, porcine, ovine, caprine or equine animals are kept; or
- (c) for safe disposal or use as animal by-products in accordance with Article 13 of Regulation (EC) No 1069/2009.

2. Where consignments of semen, oocytes or embryos are not moved from the approved germinal product establishment prior the withdrawal date of the approval as referred to in paragraph 1, such consignments shall not be moved to another Member State.

*CHAPTER 2***Registers to be kept by the competent authority of registered and approved germinal product establishments***Article 6***Register to be kept by the competent authority of registered germinal product establishments**

1. The competent authority shall draw up and keep up-to-date a register of registered germinal product establishments.
2. The competent authority shall include at least the following information in the register referred to in paragraph 1, for each registered germinal product establishment:
 - (a) the name, contact details and, where available, the Uniform Resource Locator (URL) of the website of the registered germinal product establishment;
 - (b) the address of the registered germinal product establishment;
 - (c) the type of germinal products and animal species for which it was registered;
 - (d) the unique registration number assigned by the competent authority and the date of the registration;
 - (e) if activities of the registered germinal product establishment have ceased, the date of cessation of those activities.

*Article 7***Register to be kept by the competent authority of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals**

1. The competent authority shall draw up and keep up to date a register of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals.
2. The competent authority shall include at least the following information in the register referred to in paragraph 1 for each approved germinal product establishment:
 - (a) the name, contact details and, where available, the URL of the website of the germinal product establishment;
 - (b) the address of the germinal product establishment;
 - (c) the name of the centre veterinarian or the team veterinarian;
 - (d) the type of germinal products, the type of the germinal product establishment and animal species for which the approval has been granted;
 - (e) the unique approval number assigned by the competent authority and the date of the approval.

3. Where, based on requirements provided for in Article 4, a germinal product processing establishment or a germinal product storage centre is approved by the competent authority for the storage and, in respect of the germinal product processing establishment, the processing, of germinal products of more than one type or of more than one animal species, the competent authority shall include information on the type of the germinal products and on the animal species thereof stored and, if applicable, processed at the approved germinal product establishment in its register of approved germinal product establishments.

4. Where the competent authority has suspended or withdrawn the approval of an approved germinal product establishment in accordance with Article 100(2) of Regulation (EU) 2016/429, it shall, without undue delay:

- (a) indicate that suspension or withdrawal in its register of approved germinal product establishments;
- (b) specify in the case of the suspension of the approval, the commencement and end date, and in the case of withdrawal, the withdrawal date of the approval.

5. Where an approved germinal product establishment has ceased its activity as referred to in Article 5, the competent authority shall, without undue delay, indicate the date of cessation of those activities in its register of approved germinal product establishments.

6. The competent authority shall make the register referred to in paragraph 1 available to the public on its website, where germinal products are to be moved between Member States and notify the URL of that website to the Commission.

Where the URL of the website of a competent authority has been changed it shall notify, without undue delay, the new URL of that website to the Commission.

CHAPTER 3

Record-keeping and traceability

Section 1

Record keeping

Article 8

Record-keeping obligations of operators of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals

1. Operators of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals shall keep and maintain records containing at least the following information:

- (a) in respect of a semen collection centre:
 - (i) the species, breed, date of birth and identification of each donor animal present at the semen collection centre;
 - (ii) the dates of any movement of donor animals to and from the semen collection centre and, where those animals are accompanied by any document, the reference to those documents;
 - (iii) the health status, the results of clinical and diagnostic tests and the laboratory techniques used, treatments and vaccinations carried out on the donor animals;
 - (iv) the date of semen collection and, where relevant, the date and the place of processing of semen;
 - (v) the identification of semen and details of its destination;
- (b) in respect of an embryo collection team, an embryo production team or an embryo collection and production team:
 - (i) the species, breed, date of birth and identification of each donor animal from which oocytes or embryos were collected;
 - (ii) the health status, the results of clinical and diagnostic tests and the laboratory techniques used, treatments and vaccinations carried out on donor animals of oocytes or embryos;

- (iii) the date and place of oocytes or embryos collection, examination, and processing;
 - (iv) the identification of oocytes or embryos and details of their destination;
 - (v) where micromanipulation is being performed on the embryos, the details of micromanipulation techniques used which involve penetration of the *zona pellucida* or, in case of equine embryos, the embryonic capsule;
 - (vi) the origin of semen used for artificial insemination of donor animals or to fertilise oocytes for *in vitro* production of embryos;
- (c) in respect of a germinal product processing establishment or a germinal product storage centre:
- (i) the type of germinal products either processed and stored or stored at the approved germinal product establishment with reference to the species of the donor animal;
 - (ii) the dates of movement of germinal products to and from the approved germinal product establishment with the reference to the documents which accompanied those germinal products;
 - (iii) the documents, including an animal health certificate and a self-declaration document, confirming that the health status of the donor animals whose germinal products are either processed and stored or stored at the approved germinal product establishment complies with the requirements of this Regulation;
 - (iv) the identification of germinal products that are either processed and stored or stored at the approved germinal product establishment.

2. Where a germinal product establishment, referred to in paragraph 1(c), is approved by the competent authority for either processing and storage or storage of germinal products of more than one type or of more than one animal species, the operator shall keep and maintain records separately for each type of germinal product and germinal products of each animal species either processed and stored or stored.

Article 9

Record-keeping obligations of operators of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals that cease their activity

1. Where an approved germinal product establishment for bovine, porcine, ovine, caprine and equine animals ceases its activity as referred to in Article 5, the operator of that establishment shall only move consignments of stored germinal products to a germinal product storage centre if such consignments are accompanied by originals or copies of the records required in accordance with Article 8(1).
2. The operator of the germinal product storage centre receiving the consignment of germinal products from the establishment that has ceased its activity as referred to in paragraph 1 shall record the entry and details of the germinal products based on the accompanying records required in accordance with Article 8(1)(c).

Section 2

Traceability

Article 10

Traceability requirements for germinal products of bovine, porcine, ovine, caprine and equine animals

1. Operators collecting, producing, processing or storing germinal products of bovine, porcine, ovine, caprine or equine animals shall mark each straw or other package in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, in such a way that the following information can be readily established:
 - (a) the date of collection or production of those germinal products;
 - (b) the species and identification of the donor animal(s);

- (c) the unique approval number of the germinal product establishment of collection or production, processing and storage of those germinal products;
 - (d) any other relevant information.
2. In case of sex-sorting of semen at a germinal product processing establishment, the operator of the semen collection centre shall supplement the information referred to in paragraph 1 with information which permits the identification of the unique approval number of the germinal product processing establishment where that semen was sex-sorted.
3. Where a single straw or another package contains semen of bovine, porcine, ovine or caprine animals collected from more than one donor animal, the operator shall ensure that the information referred to in paragraph 1 permits the identification of all donor animals that have contributed to the dose of semen used for insemination.
4. By way of derogation from paragraph 1, where the semen of ovine or caprine animals is
- (a) frozen in pellets, the operator may mark the goblet containing the semen pellets of a single donor instead of marking each individual pellet in that goblet;
 - (b) fresh or chilled semen, the operator may mark the goblet containing the semen tubes or straws of a single donor instead of marking each individual tube or straw in that goblet.
5. By way of derogation from paragraph 1(c), the operator shall ensure that the marking of each straw or other package in which semen, oocytes or embryos are placed, stored and transported, is carried out in such a way that it permits the identification of:
- (a) in the case of semen of ovine and caprine animals which has been collected at the establishment where the donor animals are kept as referred to in Article 13, the unique registration number of that establishment; or
 - (b) in the case of germinal products of bovine, porcine, ovine, caprine or equine animals which have been collected or produced at a confined establishment referred to in Article 14, the unique approval number of that confined establishment.

Article 11

Traceability requirements for germinal products of dogs and cats, terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments, and animals of the families *Camelidae* and *Cervidae*

1. Operators collecting, producing, processing or storing germinal products of dogs or cats, of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae* shall mark each straw or other package in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported in such a way that the following information can be readily established:
- (a) the date of collection or production of those germinal products;
 - (b) the species, where necessary subspecies, and identification of the donor animal(s);
 - (c) one of the following:
 - (i) the address of the establishment of collection or production, processing and storage of those germinal products;
 - (ii) where the establishment of collection or production, processing and storage of those germinal products was assigned with a unique registration number, the unique registration number which shall include the ISO 3166-1 alpha-2 code of the country in which the establishment is registered;
 - (iii) where the establishment of collection or production, processing and storage of those germinal products is a confined establishment, the unique approval number which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted;
 - (d) any other information.
2. In case of sex-sorting of semen at an establishment other than the establishment of its collection or production, the operator of the establishment of collection or production of that semen shall supplement the information referred to in paragraph 1 with information which permits the identification of the establishment where that semen was sex-sorted.

3. By way of derogation from paragraph 1, where the semen of the animals referred to in paragraph 1 is frozen in pellets, the operator may mark the goblet containing semen pellets of a single donor instead of marking each individual pellet in that goblet.

4. Where a single straw or another package contains semen collected from more than one donor animal, the operator shall ensure that the information, referred to in paragraph 1, includes the identification of all donor animals.

PART III

MOVEMENTS OF GERMINAL PRODUCTS BETWEEN MEMBER STATES

CHAPTER 1

Animal health requirements for movements of germinal products of bovine, porcine, ovine, caprine and equine animals

Section 1

Rules for the collection, production, processing and storage of germinal products of bovine, porcine, ovine, caprine and equine animals in approved germinal product establishments

Article 12

Rules for movements to other Member States of germinal products of bovine, porcine, ovine, caprine and equine animals from approved germinal product establishments

Operators shall only move to another Member State semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals, which were collected, produced, processed and stored in approved germinal product establishments.

Article 13

Derogation for the movements to other Member States of semen of ovine and caprine animals from the establishments where those animals are kept

By way of derogation from Article 12, operators may move to other Member States consignments of semen of ovine and caprine animals which were collected, processed and stored at the establishment where those donor animals are kept, provided that those operators:

- (a) obtain the prior consent of the competent authority of the Member State of destination to accept the consignment;
- (b) ensure that the donor animals have been clinically examined by a veterinarian prior to semen collection and showed no symptoms suggesting the presence of any of the category D diseases or of the emerging diseases relevant for the ovine and caprine animals or clinical signs of such category D or emerging diseases, on the day the semen was collected;
- (c) ensure that the donor animals come from establishments which fulfil the animal health requirements laid down in Article 15(1), (2), (3) and (4) of Delegated Regulation (EU) 2020/688;
- (d) ensure that the donor animals have undergone the following tests with negative results carried out on samples taken during the period of isolation which must commence at least 30 days prior to the date of collection of the semen:
 - (i) a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688 for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*;
 - (ii) in the case of ovine animals, a serological test for ovine epididymitis (*Brucella ovis*);
 - (iii) in the case of caprine animals kept together with ovine animals, a serological test for ovine epididymitis (*Brucella ovis*);

- (e) ensure that the donor animals are identified in accordance with Article 45(2) or (4), or Article 46(1), (2) or (3) of Regulation (EU) 2019/2035;
- (f) ensure that the semen has been marked in accordance with the requirements provided for in Article 10;
- (g) keep records at the establishment which must include at least the information provided for in Article 8(1)(a);
- (h) ensure that the consignment of semen is transported in accordance with Articles 28 and 29.

Article 14

Derogation for movements to other Member States of germinal products of bovine, porcine, ovine, caprine and equine animals kept at confined establishments

By way of derogation from Article 12, operators of confined establishments may move to other Member States consignments of semen, oocytes and embryos collected at those establishments from bovine, porcine, ovine, caprine and equine animals, provided that those operators:

- (a) only move consignments of those germinal products to another confined establishment;
- (b) ensure that the donor animals:
 - (i) do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for bovine, porcine, ovine, caprine or equine animals;
 - (ii) come from an establishment where none of the category D diseases relevant for bovine, porcine, ovine, caprine or equine animals have been reported for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;
 - (iii) have remained in a single confined establishment of origin for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;
 - (iv) have been clinically examined by the establishment veterinarian responsible for the activities carried out at confined establishment, and showed no symptoms suggesting the presence of any of the category D diseases referred to in point (ii) or of the emerging diseases or clinical signs of such diseases, on the day of collection of the semen, oocytes or embryos;
 - (v) as much as possible, were not used for natural breeding during a period of at least 30 days prior to the date of first collection and during the period of collection of the semen, oocytes or embryos intended for movement to another Member State;
 - (vi) are identified in accordance with requirements laid down in Regulation (EU) 2019/2035;
 - for bovine animals in Article 38,
 - for porcine animals in Article 52(1) or 54(2),
 - for ovine and caprine animals in Article 45(2) or (4), or Article 46(1), (2) or (3),
 - for equine animals in Article 58(1) or 59(1) or 62(1);
- (c) ensure that the germinal products have been marked in accordance with the requirements provided for in Article 10;
- (d) ensure that the germinal products are transported in accordance with Articles 28 and 29.

Section 2

Animal health requirements for donor animals from which germinal products were collected, and isolation and quarantine requirements for those animals

Sub-Section I

General animal health requirements for donor bovine, porcine, ovine, caprine and equine animals*Article 15***Responsibilities of operators for compliance with the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals from which germinal products were collected**

Operators shall only move to another Member State consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals which comply with the following requirements:

- (a) the germinal products were collected from animals which did not show symptoms or clinical signs of transmissible animal diseases on the day of collection;
- (b) the movement was authorised respectively by the centre or team veterinarian.

*Article 16***Responsibilities of centre veterinarians and team veterinarians for compliance with the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals from which germinal products were collected**

Centre veterinarians, as regards donor animals of semen, or team veterinarians, as regards donor animals of oocytes and embryos, shall ensure that the donor bovine, porcine, ovine, caprine and equine animals comply with the following requirements:

- (a) they were born and have remained since birth in the Union, or have entered the Union in accordance with the requirements for entry into the Union;
- (b) they come from establishments in a Member State or zone thereof, or from establishments under official control by the competent authority in a third country or territory, or a zone thereof, each of which fulfils the animal health requirements laid down in Delegated Regulation (EU) 2020/688:
 - (i) for bovine animals in Article 10(1), Article 11(1), (2) and (3) and Article 12(1), (2) and (3);
 - (ii) for porcine animals in Article 19(1) and Article 20(1) and (2);
 - (iii) for ovine and caprine animals in Article 15(1), (2), (3) and (4);
 - (iv) for equine animals in Article 22(1) and (2);
- (c) they have been identified in accordance with requirements laid down in Regulation (EU) 2019/2035:
 - (i) for bovine animals in Article 38;
 - (ii) for porcine animals in Article 52(1) or 54(2);
 - (iii) for ovine and caprine animals in Article 45(2) or (4), or Article 46(1), (2) or (3);
 - (iv) for equine animals in Article 58(1) or 59(1) or 62(1);

- (d) for a period of at least 30 days prior to the date of the first collection of the germinal products and during the collection period:
 - (i) they have been kept in establishments which are not situated in a restricted zone established due to the occurrence in bovine, porcine, ovine, caprine or equine animals of a category A disease or of an emerging disease relevant for those animals;
 - (ii) they have been kept in establishments where no category D diseases relevant for those animals have been reported;
 - (iii) they have not been in contact with animals from establishments situated in a restricted zone referred to in point (i) or from establishments which do not meet the conditions referred to in point (ii);
 - (iv) they have not been used for natural breeding;
- (e) they showed neither symptoms nor clinical signs of any of the category D diseases referred to in point (d)(ii) or of the emerging diseases on the day of collection of the semen, oocytes or embryos;
- (f) they comply with the additional animal health requirements set out:
 - (i) for bovine animals in Article 20, and in Part 1 and Chapters I, II and III of Part 5 of Annex II;
 - (ii) for porcine animals in Article 21, and in Part 2 and Chapters I and IV of Part 5 of Annex II;
 - (iii) for ovine and caprine animals in Article 22, and in Part 3 and Chapters I, II and III of Part 5 of Annex II;
 - (iv) for equine animals in Article 23, and in Part 4 of Annex II.

Article 17

Responsibilities of centre veterinarians and team veterinarians for compliance with the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals from which germinal products were collected from establishments subject to movement restrictions on animal health grounds

Centre veterinarians, as regards donor animals of semen, or team veterinarians, as regards donor animals of oocytes and embryos, shall ensure that semen, oocytes and embryos, collected at either a semen collection centre or an establishment which is subjected to movement restrictions on animal health grounds concerning the diseases referred to in Article 16(b), 20, 21, 22 or 23, comply with the following requirements:

- (a) they must be kept in separate storage;
- (b) they must not be moved between Member States until the movement restrictions applied to either the semen collection centre or the establishment where the semen was collected has been removed by the competent authorities; and
- (c) the semen, oocytes and embryos stored must have undergone the appropriate official investigations to rule out the presence in the semen, oocytes and embryos of animal pathogens causing the diseases for which the movement restrictions were established.

Article 18

Additional responsibilities of centre veterinarians for compliance with the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals from which semen was collected

Centre veterinarians shall ensure that donor bovine, porcine, ovine, caprine and equine animals comply with the following requirements:

- (a) they showed neither symptoms nor clinical signs of any of the category D diseases referred to in Article 16(d)(ii) on the day of their admission to a semen collection centre;

- (b) in the case of donor bovine, porcine, ovine and caprine animals, prior to the day of their admission to a semen collection centre, they were kept in a quarantine accommodation which on that day complied with the following conditions:
 - (i) none of the category D diseases relevant for the bovine, porcine, ovine or caprine animals has been reported for a period of at least the preceeding 30 days;
 - (ii) it was not situated in a restricted zone established due to the occurrence in bovine, porcine, ovine or caprine animals of a category A disease or of an emerging disease relevant for those animals;
- (c) they are kept at the semen collection centre which:
 - (i) during a period which comprises at least 30 days prior to date of collection and at least 30 days following the date of collection of the semen or, in the case of fresh semen, until the date of dispatch of the consignment of semen, none of the category D diseases relevant for bovine, porcine, ovine, caprine or equine animals have been reported;
 - (ii) it is not situated in a restricted zone established due to the occurrence in bovine, porcine, ovine, caprine or equine animals of a category A disease or of an emerging disease relevant for those animals.

Article 19

Derogation from the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals moved between semen collection centres

1. By way of derogation from point (b) of Article 18, operators may move donor bovine, porcine, ovine and caprine animals, and donor equine animals subjected to the testing programme for certain diseases as referred to in point 1(b)(i) of Chapter I of Part 4 of Annex II, directly from one semen collection centre to another semen collection centre:

- (a) without quarantine or testing, before and after the movement, as referred to in Annex II for the following animals:
 - (i) for bovine animals, in Part 1 and Chapters I, II and III of Part 5 thereof;
 - (ii) for porcine animals, in Part 2 and Chapters I and IV of Part 5 thereof;
 - (iii) for ovine and caprine animals, in Part 3 and Chapters I, II and III of Part 5 thereof;
 - (iv) for equine animals, in point 1(a) of Chapter I of Part 4 thereof; and
- (b) provided that the donor animals:
 - (i) show no disease symptoms or signs of any of the category D diseases relevant for the bovine, porcine, ovine, caprine or equine animals on the day of that movement;
 - (ii) before that movement, they were permanently present since the date of their admission at the semen collection centre and were subjected to the following tests relevant for the bovine, porcine, ovine, caprine or equine animals referred to in paragraph 1(a), with negative results:
 - all compulsory routine tests referred to in Annex II in the period of the preceding 12 months prior to date of that movement, or
 - where the compulsory routine tests have not yet been carried out at the semen collection centre, all tests required before admission to a semen collection centre carried out during the period immediately preceding quarantine and during the quarantine period.

2. Operators shall only move donor animals, as referred to in the introductory phrase of paragraph 1, where the movement is authorised by the competent authority of the semen collection centre of origin and with the prior consent of the centre veterinarian of the semen collection centre of destination.

3. Operators shall ensure that donor animals referred to in the introductory phrase of paragraph 1 do not come into direct or indirect contact with animals of a lower health status during the movement and the means of transport used have been cleansed and disinfected before use.

4. Operators of semen collection centres of destination shall subject donor animals referred to in the introductory phrase of paragraph 1 to all compulsory routine tests referred to in paragraph 1(a) not later than 12 months following the date the last compulsory routine tests were carried out on those animals.

Sub-Section II

Additional animal health requirements for certain species of ungulates

Article 20

Additional animal health requirements for donor bovine animals from which semen, oocytes and embryos were collected

1. The centre veterinarian, as regards donor animals of semen, or the team veterinarian, as regards donor animals of oocytes and embryos, shall ensure that donor bovine animals comply with the following requirements:
 - (a) they came from an establishment, in the case of donor animals of semen prior to their admission to a quarantine accommodation, that was free from the following diseases and have never been kept previously in any establishment of a lower health status:
 - (i) infection with *Mycobacterium tuberculosis complex* (*M. bovis*, *M. caprae* and *M. tuberculosis*);
 - (ii) infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*;
 - (iii) enzootic bovine leukosis;
 - (iv) infectious bovine rhinotracheitis/infectious pustular vulvovaginitis;
 - (b) they fulfil the additional animal health requirements laid down in Part 1 and Chapters I, II and III of Part 5 of Annex II.
2. By way of derogation from paragraph 1(a)(iii), the centre veterinarian may accept that a donor animal of semen came from an establishment which was not free from enzootic bovine leukosis provided that the animal either:
 - (a) is less than 2 years of age and has been produced by a dam which was subjected, with negative results, to a serological test for enzootic bovine leukosis after removal of that animal from its dam; or
 - (b) has reached the age of 2 years and was subjected, with negative results, to a serological test for enzootic bovine leukosis.
3. By way of derogation from paragraph 1(a)(iii), the team veterinarian may accept a donor animal of oocytes and embryos that was less than 2 years of age which came from an establishment which was not free from enzootic bovine leukosis provided that the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of enzootic bovine leukosis during a period of at least the preceding 3 years.
4. By way of derogation from paragraph 1(a)(iv),
 - (a) the centre veterinarian, as regards donor animals of semen, may accept a donor animal which came from an establishment which was not free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis provided that the animal has undergone the test required in accordance with point 1(b)(iv) of Chapter I of Part 1 of Annex II, or
 - (b) the team veterinarian, as regards donor animals of oocytes and embryos, may accept a donor animal which came from an establishment which was not free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis provided that the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis during a period of at least the preceding 12 months.

Article 21

Additional animal health requirements for donor porcine animals from which semen, oocytes and embryos were collected

1. The centre veterinarian, as regards donor animals of semen, or the team veterinarian, as regards donor animals of oocytes and embryos, shall ensure that donor porcine animals comply with the following requirements:
 - (a) they came from an establishment, in the case of donor animals of semen prior their admission to a quarantine accommodation, where no clinical, serological, virological or pathological evidence of infection with Aujeszky's disease virus had been detected during a period of at least the preceding 12 months;
 - (b) they fulfil additional animal health requirements laid down in Part 2 and Chapters I and IV of Part 5 of Annex II.

2. The centre veterinarian shall ensure that donor porcine animals of semen comply with the following requirements:
- (a) prior to their admission to a quarantine accommodation, they came from an establishment which was free from infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* in accordance with the requirements laid down in Chapter IV of Part 5 of Annex II;
 - (b) they were kept at the quarantine accommodation which on the day of admission was free from infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* for the period of at least the preceding 3 months;
 - (c) they are kept in a semen collection centre where no clinical, serological, virological or pathological evidence of infection with Aujeszky's disease virus has been reported for a period comprising at least 30 days prior to the date of admission and at least 30 days immediately prior to the date of collection;
 - (d) they have not been vaccinated against infection with porcine reproductive and respiratory syndrome virus and were kept, since birth or for a period comprising at least 3 months prior to the date of entry into the quarantine accommodation, in an establishment where no animals have been vaccinated against infection with porcine reproductive and respiratory syndrome virus and no infection with porcine reproductive and respiratory syndrome virus was detected during that period.

Article 22

Additional animal health requirements for donor ovine and caprine animals from which semen, oocytes and embryos were collected

The centre veterinarian, as regards donor animals of semen, or the team veterinarian, as regards donor animals of oocytes and embryos, shall ensure that donor ovine and caprine animals comply with the following requirements:

- (a) they did not come from an establishment, nor have been in contact with animals from an establishment, in the case of donor animals of semen prior to their admission to a quarantine accommodation, which has been the subject to movement restrictions as regards infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*. The movement restrictions concerning the establishment are lifted after the period comprising of at least 42 days from the date of slaughter or killing and the disposal of the last animal infected or susceptible to that disease;
- (b) they came from an establishment, in the case of donor animals of semen prior to their admission to a quarantine accommodation, which was free from infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* and have never been kept previously in any establishment of a lower health status;
- (c) they fulfil additional animal health requirements laid down in Part 3 and Chapters I, II and III of Part 5 of Annex II.

Article 23

Additional animal health requirements for donor equine animals from which semen, oocytes and embryos were collected

1. The centre veterinarian shall ensure that equine animals admitted to a semen collection centre and the team veterinarian shall ensure that equine animals used for the collection of oocytes and embryos or the production of embryos comply with the following requirements prior to the collection of the germinal products:

- (a) they come from an establishment:
 - (i) where surra (*Trypanosoma evansi*) has not been reported during the period of the preceding 30 days, or where surra (*Trypanosoma evansi*) has been reported during the period of the preceding 2 years and following the last outbreak the affected establishment remained under movement restrictions until:
 - the infected animals have been removed from the establishment, and
 - the remaining animals in the establishment have been subjected to a test for surra (*Trypanosoma evansi*) with one of the diagnostic methods provided for in Part 3 of Annex I to Delegated Regulation (EU) 2020/688, with negative results carried out on samples taken at least 6 months after the last infected animal has been removed from the establishment;

- (ii) where dourine has not been reported during the period of the preceding 6 months, or where dourine has been reported during the period of the preceding 2 years and following the last outbreak the affected establishment remained under movement restrictions until:
 - the infected animals have been killed and destroyed or slaughtered, or the infected entire male equine animals have been castrated, and
 - the remaining equine animals in the establishment, with the exception of the castrated male equine animals referred to in the first indent kept apart from female equine animals, have been subjected to a test for dourine with one of the diagnostic methods provided for in Part 8 of Annex I to Delegated Regulation (EU) 2020/688, with negative results, carried out on samples taken at least 6 months after the measures described in the first indent have been completed;
- (iii) where equine infectious anaemia has not been reported during the period of the preceding 90 days, or where equine infectious anaemia has been reported during the period of the preceding 12 months and following the last outbreak the affected establishment remained under movement restrictions until:
 - the infected animals have been killed and destroyed or slaughtered, and
 - the remaining equine animals in the establishment have been subjected to a test for equine infectious anaemia with one of the diagnostic methods provided for in Part 9 of Annex I to Delegated Regulation (EU) 2020/688, with negative results, carried out on samples taken on two occasions at least 3 months apart after the measures described in the first indent have been completed and the establishment was cleaned and disinfected;
- (b) in the case of semen donors, they were kept for a period of 30 days prior to the date of semen collection in establishments where no equine animal has shown any clinical sign of infection with equine arteritis virus or of contagious equine metritis during that period;
- (c) they fulfil the additional animal health requirements laid down in Part 4 of Annex II.

2. By way of derogation from paragraph 1(a), the movement restrictions referred to in paragraph 1(a)(i) to (iii) must remain in place for a period of at least 30 days, beginning on the day on which all the animals on the establishment of species listed for the respective disease referred to in paragraph 1(a)(i) to (iii) were either killed and destroyed or slaughtered, where allowed in accordance with paragraph 1(b), and the establishment was cleaned and disinfected.

Section 3

Laboratory and other tests to be carried out on kept donor animals of the bovine, porcine, ovine, caprine and equine species and germinal products thereof

Article 24

Laboratory and other tests to be carried out on donor bovine, porcine, ovine, caprine and equine animals and germinal products thereof

Operators shall ensure that:

- (a) donor animals whose germinal products are to be moved to other Member States have undergone the following tests:
 - (i) for bovine animals, in Part 1 and as applicable in Chapters I, II and III of Part 5 of Annex II;
 - (ii) for porcine animals, in Part 2 and as applicable Chapters I and IV of Part 5 of Annex II;
 - (iii) for ovine and caprine animals, in Part 3 and as applicable in Chapters I, II and III of Part 5 of Annex II;
 - (iv) for equine animals, in Part 4 of Annex II;
- (b) all the tests referred to in point (a) are carried out in official laboratories.

*Article 25***Authorisation for laboratory tests to be carried out on donor animals of the bovine, porcine, ovine and caprine species in quarantine accommodation**

1. The competent authority may authorise the following tests referred to in Annex II to be carried out on samples taken in the quarantine accommodation:
 - (a) for bovine animals, the tests referred to in point 1(b) of Chapter I of Part 1 thereof;
 - (b) for porcine animals, the tests referred to in point 1(b) of Chapter I of Part 2 thereof;
 - (c) for ovine and caprine animals, the tests referred to in point 1(c) of Chapter I of Part 3 thereof.
2. Where the competent authority has granted the authorisations referred to in paragraph 1, the following conditions shall be met:
 - (a) the period of quarantine in the quarantine accommodation must not commence before the date of sampling for the purpose of testing referred to in paragraph 1(a), (b) and (c);
 - (b) where results of any of the tests referred to in paragraph 1 are positive, the animal concerned must be immediately removed from the quarantine accommodation;
 - (c) in the case of quarantine of a group of animals, if any of the animals prove positive for a test referred to in paragraph 1, the quarantine in the quarantine accommodation must not commence for the remaining animals until the animal which proved positive has been removed from the quarantine accommodation.

*Section 4***Animal health requirements for the collection, production, processing, storage and other procedures of germinal products of bovine, porcine, ovine, caprine and equine animals***Article 26***Obligations on operators as regards the animal health requirements for the collection, production, processing and storage of germinal products of bovine, porcine, ovine, caprine and equine animals**

Operators shall ensure that consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals are only moved to other Member States if those consignments fulfil the animal health requirements for the collection, production, processing and storage of germinal products set out in Annex III.

*Section 5***Animal health requirements for the transport of germinal products of bovine, porcine, ovine, caprine and equine animals***Article 27***Responsibilities of centre veterinarians and team veterinarians for compliance with the animal health requirements for the transport of germinal products of bovine, porcine, ovine, caprine and equine animals**

1. Where germinal products of bovine, porcine, ovine, caprine and equine animals are moved to another Member State or to a germinal product processing establishment or a germinal product storage centre within the same Member State, the centre veterinarian or the team veterinarian shall ensure that:
 - (a) the transport containers are sealed and numbered prior to their dispatch from the approved germinal product establishment;

- (b) the mark on the straws or other packages, applied in accordance with Article 10, corresponds with the number provided either in the animal health certificate or in the self-declaration document and on the container in which they are transported.
2. The seal referred to in paragraph 1(a) applied under the responsibility of the centre veterinarian or the team veterinarian may be replaced by the official veterinarian.

Article 28

Responsibilities of operators for compliance with the animal health requirements for the transport of germinal products of bovine, porcine, ovine, caprine and equine animals

1. Operators shall only move semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals to other Member States subject to compliance with the following conditions:
- (a) only one type of germinal product of one species has been placed in the transport container;
 - (b) the transport container, referred to in point (a):
 - (i) has been cleaned and either disinfected or sterilised before use, or is a new single-use container;
 - (ii) has been filled in with the cryogenic agent which has not been previously used for other products.
2. By way of derogation from paragraph 1, operators may place in one transport container semen, oocytes and embryos of the same species provided that:
- (a) straws or other packages in which germinal products are placed are securely and hermetically sealed;
 - (b) the germinal products of different types are separated from each other by physical compartments or by being placed in secondary protective bags.
3. By way of derogation from paragraphs 1 and 2, operators may place in one transport container semen, oocytes and embryos of ovine and caprine animals.

Article 29

Additional responsibilities on operators for the transport of semen of bovine, porcine, ovine and caprine animals

Where operators move to another Member State consignments of semen of bovine, porcine, ovine or caprine animals which has been collected from more than one donor animal and placed in a single straw or another package, the operators shall:

- (a) ensure that the semen is collected and dispatched from a single semen collection centre or, in the case of the derogations provided for in Articles 13 and 14, a single establishment where it was collected;
- (b) have procedures in place as regards the processing of that semen in order to ensure its traceability in accordance with Articles 10 and 19.

CHAPTER 2

Animal health certification, self-declaration and movement notification for germinal products of bovine, porcine, ovine, caprine and equine animals

Article 30

Rules on animal health certification

1. Before issuing an animal health certificate for movements between Member States of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals, the official veterinarian shall carry out:
- (a) a visual examination of the transport container in order to verify if the requirements referred to in Article 28 have been fulfilled and to check:

- (i) the seal and number applied by the centre or team veterinarian on the transport container as referred to in Article 27(1)(a); or
 - (ii) if necessary, the germinal products placed in the transport container and to seal and number the transport container after that check;
 - (b) a documentary check of the data submitted by the centre or team veterinarian to ensure that:
 - (i) the information to be certified is supported by the records kept in accordance with Article 8;
 - (ii) the mark on the straws or other packages, applied in accordance with Article 10, corresponds with the number provided in the animal health certificate and on the container in which they are transported;
 - (iii) the requirements referred to in Chapter 1 of Part III have been fulfilled.
2. The official veterinarian shall carry out the checks and examinations as provided for in paragraph 1 and issue the animal health certificate within the period of 72 hours preceding the time of dispatch of the consignment of germinal products.
3. The animal health certificate shall be valid for a period of 10 days from the date of issuing.

Article 31

Information to be contained in the animal health certificate for germinal products of bovine, porcine, ovine, caprine and equine moved between Member States

The animal health certificates for movements between Member States of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals, shall contain at least the information set out in point 1 of Annex IV.

Article 32

Requirements concerning the self-declaration document for movements to and from germinal product processing establishments of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals

1. Where an operator of an approved germinal product establishment of bovine, porcine, ovine, caprine and equine animals arranges for germinal products to be processed by a germinal product processing establishment, that operator shall ensure that a self-declaration document accompanies the consignment of the germinal products during the transport to and from that germinal product processing establishment.
2. An operator of an approved germinal product establishment shall ensure that the self-declaration document referred to in paragraph 1 includes at least the following information:
- (a) the name and address of the approved germinal product establishment of the collection or production of the germinal products;
 - (b) the name and address of the germinal product processing establishment to which the germinal products are moved for processing;
 - (c) the dates of movement of the consignment of the germinal products to and from a germinal product processing establishment;
 - (d) the type and the quantity of the germinal products;
 - (e) the marking of the germinal products, as required by Article 10.

*Article 33***Requirement for advance notification by operators of movements of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals between Member States**

Where consignments of germinal products of bovine, porcine, ovine, caprine and equine animals are moved to another Member State, operators of approved germinal product establishments, establishments where ovine and caprine animals are kept as referred to in Article 13 or confined establishments as referred to in Article 14 shall notify the competent authority in their Member State of origin in advance of the intended movement of those consignments of germinal products.

*Article 34***Information necessary to notify movements of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals between Member States**

Operators notifying the competent authority in their Member State of origin in accordance with Article 33, shall provide that competent authority with the information concerning each consignment of germinal products to be moved to another Member State provided for in:

- (a) points 1(a) to (f) of Annex IV, where the germinal products are accompanied by an animal health certificate; or
- (b) Article 32(2), where the germinal products are accompanied by a self-declaration document.

*Article 35***Emergency procedures for the notification of movements of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals between Member States in the event of power cuts and other disturbances of IMSOC**

1. In the event of power cuts and other disturbances of IMSOC, the competent authority of the place of origin of the consignment of germinal products of bovine, porcine, ovine, caprine and equine animals to be moved to another Member State shall notify the Commission and the competent authority of the place of destination of the movement of that consignment by fax or email.
2. The notification, referred to in paragraph 1, shall be done by the competent authority of the place of origin of the consignment of germinal products in accordance with the contingency arrangements to be applied in the event of unavailability of any of the functionalities IMSOC.

*CHAPTER 3****Animal health requirements, animal health certification and notification for germinal products of animals other than bovine, porcine, ovine, caprine and equine animals****Article 36***Animal health requirements for movements to other Member States of germinal products of dogs and cats**

Operators shall only move to other Member States semen, oocytes and embryos collected from dogs (*Canis lupus familiaris*) and cats (*Felis silvestris catus*) which:

- (a) have been born and remained since birth in the Union, or have entered the Union in accordance with the requirements for entry into the Union;
- (b) come from an establishment where infection with rabies virus has not been confirmed for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;
- (c) showed no disease symptoms on the day of collection of the semen, oocytes or embryos;

- (d) are marked by the implantation of a transponder or by a clearly readable tattoo in accordance with Article 17(1) of Regulation (EU) No 576/2013 of the European Parliament and of the Council ⁽¹⁷⁾ or identified in accordance with Article 70 of Regulation (EU) 2019/2035;
- (e) have received an anti-rabies vaccination that complies with the validity requirements set out in Part 1 of Annex VII to Delegated Regulation (EU) 2020/688;
- (f) comply with any preventive health measure for diseases or infections other than rabies set out in Part 2 of Annex VII to Delegated Regulation (EU) 2020/688;
- (g) were not used for natural breeding during a period of at least 30 days prior to the date of collection of semen, oocytes or embryos and during the collection period.

Article 37

Animal health requirements for movements to other Member States between confined establishments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals

Operators of confined establishments shall only move germinal products of terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at those establishments to confined establishments in other Member States when the donor animals:

- (a) have been born and remained since birth in the Union, or have entered the Union in accordance with the requirements for entry into the Union;
- (b) have remained in a single confined establishment of origin for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;
- (c) do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for the species in those kept terrestrial animals;
- (d) come from an establishment where no category D disease relevant for that species has been reported for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;
- (e) are identified and registered in accordance with the rules of that confined establishment;
- (f) as much as possible, were not used for natural breeding during a period of at least 30 days prior to the date of first collection and during the period of collection of the semen, oocytes or embryos intended for movement to another Member State;
- (g) have been clinically examined by the establishment veterinarian responsible for the activities carried out at confined establishment, and show no disease symptoms on the day the semen, oocytes or embryos are collected.

Article 38

Animal health requirements for movements to other Member States of germinal products of animals of the families *Camelidae* and *Cervidae*

Operators shall only move to another Member State germinal products collected from animals of the family *Camelidae* or *Cervidae* which:

- (a) have been born and remained since birth in the Union, or have entered the Union in accordance with the requirements for entry into the Union;

⁽¹⁷⁾ Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

- (b) have remained in a single establishment of origin for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;
- (c) do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for the species in those kept terrestrial animals;
- (d) come from an establishment where during a period of at least the preceding 12 months prior to the date of collection of the semen, oocytes or embryos:
 - (i) a surveillance programme to detect infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) has been carried out in accordance with Part 2 or 3 of Annex II to Delegated Regulation (EU) 2020/688;
 - (ii) no animals of the family *Camelidae* or *Cervidae* which do not fulfil the requirements referred to in point (i) has been introduced;
 - (iii) in case of suspicion of infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), investigations were carried out and the disease was ruled out;
- (e) come from an establishment:
 - (i) where infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* has not been reported during the period of at least the preceding 42 days prior to the date of collection of the semen, oocytes or embryos;
 - (ii) in case of animals of the family *Camelidae*, where all animals present have been subjected to a test for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* as referred to in Part 1 of Annex I to Delegated Regulation (EU) 2020/688 with negative results carried out on samples taken during the period of the preceding 30 days prior to the date of collection of the semen, oocytes or embryos;
- (f) come from an establishment where infectious bovine rhinotracheitis/infectious pustular vulvovaginitis has not been reported during the period of at least the preceding 30 days prior to the date of collection of the semen, oocytes or embryos;
- (g) come from an establishment where infection with epizootic haemorrhagic disease virus has not been reported during a period of at least the preceding 2 years prior to the date of collection of the semen, oocytes or embryos within a radius of 150 km around the establishment;
- (h) come from an establishment where infection with rabies virus has not been confirmed during the period of at least the preceding 30 days prior to the date of collection of the germinal products;
- (i) come from an establishment where anthrax has not been reported during the period of at least the preceding 15 days prior to the date of collection of the semen, oocytes or embryos collection;
- (j) come from an establishment where surra (*Trypanosoma evansi*):
 - (i) has not been reported during a period of at least the preceding 30 days prior to the date of collection of the semen, oocytes or embryos; or
 - (ii) has been confirmed during the preceding 2 years, but following the last outbreak of that disease the establishment has remained under movement restrictions until:
 - the infected animals were removed from the establishment, and
 - the remaining animals on the establishment were subjected to a test for surra (*Trypanosoma evansi*) referred to in Part 3 of Annex I to Delegated Regulation (EU) 2020/688, with negative result, carried out on samples taken at least 6 months after the infected animals were removed from the establishment;

- (k) fulfil animal health requirements as regards infection with bluetongue virus (serotypes 1-24) laid down in Chapter II of Part 5 of Annex II;
- (l) have not been in contact with animals which did not comply with the requirements set out in point (a) and in points (c) to (k) during the residency period of at least 30 days set out in point (b);
- (m) have been clinically examined by a veterinarian and showed no disease symptoms on the day of collection of the semen, oocytes or embryos;
- (n) are identified in accordance with Article 73(1) or (2) or Article 74 of Regulation (EU) 2019/2035;
- (o) were not used for natural breeding during a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos and during the collection period.

Article 39

Rules concerning animal health certification

1. Before signing an animal health certificate for movements between Member States of consignments of germinal products of dogs or cats, the official veterinarian shall carry out:

- (a) a visual examination of the transport container in order to check:
 - (i) the seal and number applied by the operator on the transport container; or
 - (ii) if necessary, the germinal products placed in the transport container and to seal and number the transport container after that check;
- (b) a documentary check of the data submitted by the operator to ensure that:
 - (i) the information to be certified is supported by the records kept at the establishment;
 - (ii) the mark on the straws or other packages, applied in accordance with Article 11, corresponds with the number provided in the animal health certificate and on the container in which they are transported;
 - (iii) the requirements referred to in Article 36 have been fulfilled.

2. Before signing an animal health certificate for movements between Member States of consignments of germinal products of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments, the official veterinarian shall carry out:

- (a) a visual examination of the transport container in order to check:
 - (i) the seal and number applied by the establishment veterinarian responsible for the activities carried out at confined establishment on the transport container; or
 - (ii) if necessary, germinal products placed in the transport container and to seal and number the transport container after that check;
- (b) a documentary check of the data submitted by the establishment veterinarian responsible for the activities carried out at confined establishment to ensure that:
 - (i) the information to be certified is supported by the records kept at the confined establishment;
 - (ii) the mark on the straws or other packages, applied in accordance with Article 11, corresponds with the number provided in the animal health certificate and on the container in which they are transported;
 - (iii) the requirements referred to in Article 37 have been fulfilled.

3. Before signing an animal health certificate for movements between Member States of consignments of germinal products of animals of the family *Camelidae* or *Cervidae*, the official veterinarian shall carry out:

- (a) a visual examination of the transport container in order to check:
 - (i) the seal and number applied by the operator on the transport container; or

- (ii) if necessary, the germinal products placed in the transport container and to seal and number the transport container after that check;
 - (b) a documentary check of the data submitted by the operator to ensure that:
 - (i) the information to be certified is supported by the records kept at the establishment;
 - (ii) the mark on the straws or other packages, applied in accordance with Article 11, corresponds with the number provided in the animal health certificate and on the container in which they are transported;
 - (iii) the requirements referred to in Article 38 have been fulfilled.
4. The official veterinarian shall carry out the checks and examinations as provided for in paragraphs 1, 2 and 3 and issue the animal health certificate within the period of 72 hours preceding the time of dispatch of the consignment of germinal products.
5. The animal health certificate provided for in paragraphs 1, 2 and 3 shall be valid for 10 days from the date of issuing.

Article 40

Animal health certification requirements for movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals between Member States

The animal health certificates for movements between Member States of consignments of germinal products of dogs and cats, and of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae*, shall contain at least the information set out in point 2 of Annex IV.

Article 41

Requirement for advance notification by operators of movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals between Member States

Where consignments of germinal products of dogs or cats, of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae* are moved to another Member State, the operator shall notify the competent authority in the Member State of origin of the consignments in advance of the intended movement of those consignments of germinal products.

Article 42

Information necessary to notify movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals between Member States

Operators required to notify the competent authority in the Member State of origin of the consignments in accordance with Article 41, shall provide that competent authority with the information concerning each consignment of germinal products to be moved to another Member State provided for in point 2(a) to (f) of Annex IV.

Article 43

Emergency procedures for the notification of movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals between Member States in the event of power cuts and other disturbances of IMSOC

1. In the event of power cuts and other disturbances of IMSOC, the competent authority of the place of origin of the consignment of germinal products of dogs or cats, of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae*, to be moved to another Member State, shall notify the Commission and the competent authority of the place of destination of the movement of that consignment by fax or email.

2. The notification, referred to in paragraph 1, shall be carried out by the competent authority of the place of origin of the consignment of the germinal products in accordance with the contingency arrangements to be applied in the event of unavailability of any of the functionalities of IMSOC.

CHAPTER 4

Additional rules for the granting of derogations by competent authorities for germinal products

Article 44

Additional rules for the granting of derogations by competent authorities for germinal products intended for scientific purposes

1. The competent authorities of the Member States of origin may grant derogation for the movement to another Member State of germinal products intended for scientific purposes which do not fulfil the animal health requirements provided for in Chapter 1 or 3, provided the operator of the establishment of dispatch has obtained the prior written consent of the competent authority of the Member State of destination to accept the consignment of germinal products.
2. The competent authority of the Member State of destination shall only consent to accept the consignment of germinal products referred to in paragraph 1, where the operator of the establishment of destination intended to receive those germinal products ensures that the germinal products are only used for scientific purposes under conditions that prevent the spread of category D diseases.

Article 45

Additional rules for the granting of derogations by competent authorities for germinal products moved to gene banks in another Member State

1. The competent authorities of the Member States of origin may grant derogations for movements to gene banks in another Member State of germinal products, provided that the operator of the establishment of dispatch has obtained the prior written consent of the competent authority of the Member State of destination to accept the consignment of germinal products, of:
 - (a) endangered breeds which do not fulfil the animal health requirements provided for in Chapter 1; or
 - (b) terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments which do not fulfil the animal health requirements provided for in Article 37.
2. The competent authority of the Member State of destination shall only consent to accept the consignment of germinal products referred to in paragraph 1, provided that:
 - (a) the operator of the gene bank intended to receive those germinal products ensures that the germinal products are only used for the *ex situ* conservation and sustainable use of genetic resources of kept terrestrial animals for which the receiving gene bank was established;
 - (b) it has sufficient information, including information provided by the competent authority of the Member State of origin or results of testing, or carries out treatment of the germinal products enabling it to prevent the spread of foot-and-mouth disease, infection with rinderpest virus and other listed diseases.

Article 46

Rules on and information to be contained in the self-declaration document for germinal products intended for scientific purposes or to be moved to gene banks in another Member State

1. Where germinal products intended for scientific purposes or for storage at gene banks are to be moved to another Member State, the operator of the establishment of dispatch shall ensure that a self-declaration document accompanies the germinal products during the transport to the place of destination.

2. The operator of the establishment of dispatch shall ensure that the self-declaration document provided for in paragraph 1 includes at least the following information:

- (a) the name and address of the consignor and the consignee;
- (b) the name and address of the place of dispatch and the place of destination;
- (c) where the germinal products were moved to and from a germinal product processing establishment, the dates of those movements;
- (d) the type of the germinal products and the species of donor animals;
- (e) the number of straws or other packages in the consignment to be dispatched;
- (f) the following information allowing the identification of germinal products:
 - (i) the marking applied on the straws or other packages;
 - (ii) the place and date of their collection or production;
- (g) available results of the tests referred to in Article 45(2)(b).

Article 47

Advance notification by operators of movements of germinal products intended for scientific purposes or to gene banks between Member States

Where germinal products intended for scientific purposes or for storage at gene banks are moved to another Member State, the operator of the establishment of dispatch shall notify the competent authority in the Member State of origin of the consignment in advance of the intended movement of those germinal products and provide the information listed in Article 46(2)(a) to (g).

Article 48

Emergency procedures for the notification of movements between Member States of germinal products intended for scientific purposes or to gene banks in the event of power cuts and other disturbances of IMSOC

1. In the event of power cuts and other disturbances of IMSOC, the competent authority of the place of origin of the consignment of germinal products intended for scientific purposes or for storage at gene banks, to be moved to another Member State, shall notify the Commission and the competent authority of the place of destination of the movement of that consignment by fax or email.

2. The notification, referred to in paragraph 1, shall be done by the competent authority of the place of origin of the consignment of the germinal products in accordance with the contingency arrangements to be applied in the event of unavailability of any of the functionalities of IMSOC.

PART IV

FINAL PROVISIONS

Article 49

Transitional measures

1. Semen collection centres, semen storage centres, embryo collection teams and embryo production teams which have been approved before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC referred to in the 6th, 7th, 8th and 12th indents of Article 270(2) of Regulation (EU) 2016/429 shall be considered to have been approved in accordance with this Regulation.

In all other respects, they shall be subject to the rules provided for in this Regulation, and in Regulation (EU) 2016/429.

2. Straws and other packages in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, marked before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC shall be considered to have been marked in accordance with this Regulation.
3. Animal health certificates issued before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC shall be considered to have been issued in accordance with this Regulation.

Article 50

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 December 2019.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

RULES FOR THE COLLECTION, PRODUCTION, PROCESSING AND STORAGE OF GERMINAL PRODUCTS OF BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS AS REFERRED TO IN CHAPTER 1 OF PART II

PART 1

REQUIREMENTS FOR SEMEN COLLECTION CENTRES REFERRED TO IN ARTICLE 4

1. The responsibilities of the centre veterinarian, as referred to in Article 4(1)(a)(i), shall be the following:
 - (a) the centre veterinarian shall ensure that:
 - (i) at the semen collection centre, only animals which have not been used for natural breeding for a period of at least 30 days prior to the date of the first semen collection and during the collection period are kept;
 - (ii) at the semen collection centre, records are kept in accordance with the requirements laid down in Article 8(1)(a);
 - (iii) the entry of unauthorised persons is prevented;
 - (iv) authorised visitors comply with the animal health and biosecurity requirements referred to in point (c)(i);
 - (v) each individual dose of semen is clearly marked in accordance with the requirements laid down in Article 10;
 - (vi) the collection, processing and storage of semen takes place only on the premises set aside for that purpose and under strict hygiene conditions;
 - (vii) only semen collected at a semen collection centre is processed and stored at that semen collection centre, and it must not come into contact with any other consignment of germinal products of lesser health status;
 - (viii) all instruments which come into contact with the semen or the donor animal during the collection and processing of semen are cleaned and either disinfected or sterilised prior to use, except for new single-use instruments;
 - (ix) where, in the case of equine animals, the semen collection centre is located within the perimeters of a registered establishment which also hosts an artificial insemination or service centre, there is a strict separation between the instruments and equipment coming into contact with donor animals, their semen and other animals kept in the semen collection centre and the semen, instruments and equipment used for artificial insemination or natural service;
 - (x) any biological product originating from animals used in the processing of semen, including diluents, additives or extenders, is obtained from sources which present no animal health risk or which are treated prior to use so that such risk is prevented;
 - (xi) before the commencement of each filling operation, the storage containers and transport containers are cleaned and either disinfected or sterilised, except for new single-use containers;
 - (xii) the cryogenic agents used for the preservation or storage of semen have not previously been used for other products;
 - (xiii) the staff employed at the semen collection centre have received adequate training on disinfection and hygiene techniques to prevent the spread of diseases;
 - (b) by way of derogation from point (a)(vii), the centre veterinarian may authorise semen that was not collected at a semen collection centre to be processed at the semen collection centre provided that the following conditions are met:

- (i) such semen is collected from animals which fulfil the following requirements set out in Annex II
 - in respect of bovine animals, the requirements set out in point 1(b) of Chapter I of Part 1, and as applicable in Chapters I, II and III of Part 5 thereof,
 - in respect of porcine animals, the requirements set out in point 1(b) of Chapter I of Part 2, and as applicable in Chapters I and IV of Part 5 thereof,
 - in respect of ovine and caprine animals, the requirements set out in point 1(c) of Chapter I of Part 3, and as applicable in Chapters I, II and III of Part 5 thereof,
 - in respect of equine animals, in point 1(a) of Chapter I of Part 4 thereof;
 - (ii) processing is carried out with separate equipment or at a different time from semen intended to be moved to another Member State, and the equipment in the latter case must be cleaned and sterilised after use;
 - (iii) such semen is not moved to another Member State and does not at any time come into contact with, or is stored with, semen intended to be moved to another Member State;
 - (iv) such semen is identifiable by a marking which must be different from that referred to in point (a)(v);
- (c) the centre veterinarian shall:
- (i) lay down the animal health and biosecurity requirements for the operation of the semen collection centre and the measures to ensure compliance with those requirements;
 - (ii) only accept into the semen collection centre animals of species whose semen is to be collected;
- (d) by way of derogation from point (c)(ii), the centre veterinarian may authorise kept animals other than bovine, porcine, ovine, caprine or equine animals to be admitted to the semen collection centre, provided that they present no risk of infection to those species whose semen is to be collected, and they comply with the animal health and biosecurity requirements referred to in point (c)(i);
- (e) the centre veterinarian of a semen collection centre for equine animals, located within the perimeters of a registered establishment which also hosts an artificial insemination or service centre, shall ensure that equine animals entering the establishment meet the requirements of Article 23(1)(a) to (c) and may decide that where direct contact of donor male equine animals with female equine animals or castrated male equine animals for teasing or with uncastrated male equine animals used on the establishment outside the semen collection centre for natural service cannot be excluded, those female and male equine animals must meet all the requirements of Article 23(1).
2. The requirements for the facilities, equipment and operational procedures of the semen collection centre, as referred to in Article 4(1)(b)(i), shall be the following:
- (a) the semen collection centre must have at least:
- (i) lockable animal accommodation and, if required, an exercise area for equine animals which is physically separated from the semen collection facilities, the semen processing room and the storage room;
 - (ii) isolation facilities for animals which have failed tests referred to in Annex II of this Regulation or which show symptoms or signs of any of the category D diseases relevant for the bovine, porcine, ovine, caprine or equine animals, and which have no direct connection with the regular animal accommodation referred to in point (i);
 - (iii) semen collection facilities that may be open air provided that they are protected from adverse weather effects and are equipped with slip-proof flooring at and around the place of semen collection;
 - (iv) a separate room for the cleansing and disinfection or sterilisation of equipment;
 - (v) a semen processing room, separated from the semen collection facilities and the room for cleansing equipment referred to in point (iv), which need not necessarily be on the same site;

- (vi) a semen storage room, which need not necessarily be on the same site; the semen storage room must be furnished with the necessary installation to store germinal products, which must be so constructed that it protects those germinal products and the installation from adverse weather and environment effects;
- (b) the semen collection centre must be so constructed or isolated that contact with outside livestock is prevented;
- (c) the semen collection centre must be so constructed that, except for the office rooms and, in the case of equine animals, the exercise area, it can be readily cleansed and disinfected;
- (d) the semen collection centre must be so constructed that unauthorised access of people is effectively prevented.

PART 2

REQUIREMENTS FOR THE APPROVAL OF AN EMBRYO COLLECTION TEAM REFERRED TO IN ARTICLE 4

1. The responsibilities of the team veterinarian of an embryo collection team, as referred to in Article 4(1)(a)(ii), shall be the following:
 - (a) the team veterinarian shall be responsible for all embryo collection team operations, including, amongst others, the following:
 - (i) the verification of the identity and health status of donor animals;
 - (ii) the clinical examination and surgery of donor animals;
 - (iii) the disinfection and hygiene procedures, including procedures ensuring the transport of embryos to the laboratory in a hygienic and safe manner;
 - (iv) record-keeping in accordance with the requirements laid down in Article 8(1)(b);
 - (v) the marking of straws and other packages where embryos are placed in accordance with the requirements set out in Article 10(1) and (5);
 - (vi) the training of members of the embryo collection team on disinfection and hygiene techniques to prevent the spread of diseases;
 - (b) the team veterinarian shall lay down the animal health and biosecurity requirements for the operation of the embryo collection team and the measures to ensure compliance with those requirements, including the testing of samples within a quality control scheme.
2. The facilities, equipment and operational procedures of the embryo collection team, as referred to in Article 4(1)(b)(ii), shall comply with the following points (a) and (b):
 - (a) the embryo collection team must have at its disposal a laboratory where embryos can be examined, processed and packaged with adequate equipment, and that laboratory must be either:
 - (i) a permanently located laboratory, which must have the following:
 - a room where embryos can be processed which is physically separated from the area used to handle the donor animals during collection,
 - a room or area for cleansing and sterilising instruments used for embryo collection and processing, except when using only new single-use equipment,
 - a room for the storing of embryos;

or

(ii) a mobile laboratory, which must:

- have a specially equipped part of the vehicle consisting of two separate sections: one section for the examination and processing of embryos, which must be the clean section; and another section for accommodating equipment and materials used in contact with the donor animals,
- use only new single-use equipment, unless the sterilisation of its equipment and the provision of fluids and other products necessary for the collection and processing of embryos is carried out at a permanently located laboratory.

The laboratories referred to in points (i) and (ii) must be designed and have a layout so as to prevent the cross-contamination of embryos, and team operations shall be carried out in a manner that prevents such cross-contamination;

(b) the embryo collection team must have at its disposal storage premises which comply with the following conditions:

- (i) they comprise at least one lockable room for the storage of embryos;
- (ii) they must be easy to cleanse and disinfect;
- (iii) they must have permanent records of all incoming and outgoing embryos;
- (iv) they must have storage containers for embryos.

PART 3

REQUIREMENTS FOR THE APPROVAL OF AN EMBRYO PRODUCTION TEAM REFERRED TO IN ARTICLE 4

1. In addition to the responsibilities listed in point 1 of Part 2 of this Annex, the team veterinarian of an embryo production team, referred to in Article 4(1)(a)(ii), shall ensure that the embryo production team members have received adequate training on disease control and laboratory techniques, particularly on procedures for working in sterile conditions.
2. In addition to the requirements listed in point 2 of Part 2 of this Annex, the facilities, equipment and operational procedures of an embryo production team, referred to in Article 4(1)(b)(iii), shall comply with the following requirements:
 - (a) the embryo production team must have at its disposal a permanently located laboratory which must have:
 - (i) adequate equipment and facilities, including separate rooms or areas for:
 - the recovery of oocytes from ovaries,
 - the processing of oocytes and embryos, and
 - the storing of embryos and semen;
 - (ii) a laminar flow facility or other suitable facilities where all technical operations associated with specific sterile conditions (namely, the processing of oocytes, embryos and semen) are conducted; however, the centrifugation of semen may be carried out outside the laminar flow facility or other facility as long as full hygiene precautions are taken;
 - (b) where oocytes and other tissues are to be collected in a slaughterhouse, the embryo production team must have at its disposal suitable equipment for the collection and transport of the ovaries and other tissues to the processing laboratory in a hygienic and safe manner;
 - (c) the embryo production team may outsource the collection of oocytes to a group of specialised professionals provided that their activity is included in the approval by the competent authority of the embryo production team and the responsibilities of the team veterinarian referred to in point 1 are extended to their activities;

- (d) the embryo production team shall use semen which:
 - (i) meets the requirements of this Regulation;
 - (ii) is stored for the operation of the embryo production team in separate storage containers in the premises referred to in point 2(b) of Part 2 for the storing of produced embryos.

PART 4

REQUIREMENTS FOR THE APPROVAL OF A GERMINAL PRODUCT PROCESSING ESTABLISHMENT REFERRED TO IN ARTICLE 4

1. The responsibilities of the centre veterinarian, referred to in Article 4(1)(a)(i), shall be the following:
 - (a) the centre veterinarian shall ensure that:
 - (i) at the germinal product processing establishment records are kept in accordance with the requirements laid down in Article 8(1)(c);
 - (ii) the entry of unauthorised persons is prevented;
 - (iii) authorised visitors comply with the animal health and biosecurity requirements referred to in point (b)(i);
 - (iv) each individual dose of semen, oocytes or embryos is clearly marked in accordance with the traceability requirements set out in Article 10;
 - (v) the processing and storage of germinal products takes place only on the premises set aside for that purpose and under strict hygiene conditions;
 - (vi) all instruments which come into contact with the germinal products are cleansed and either disinfected or sterilised prior to use, except for new single-use instruments;
 - (vii) before the commencement of each filling operation, the storage containers and transport containers are cleansed and either disinfected or sterilised, except for new single-use containers;
 - (viii) cryogenic agents used for the preservation or storage of germinal products have not previously been used for other products;
 - (ix) the staff of the germinal product processing establishment have received adequate training:
 - on disinfection and hygiene techniques to prevent the spread of diseases,
 - for the purpose of processing germinal products, on laboratory techniques and particularly on procedures for working in sterile conditions;
 - (b) the centre veterinarian shall:
 - (i) lay down the animal health and biosecurity requirements for the operation of the germinal product processing establishment and the measures to ensure compliance with those requirements;
 - (ii) only accept into a germinal product processing establishment semen, oocytes or embryos collected, produced, processed and stored in an approved germinal product establishment, and transported under conditions that ensure that cross-contamination of semen, oocytes or embryos is prevented, as they have had no contact with germinal products which do not comply with the rules laid down in this Regulation.
2. The requirements for the facilities, equipment and operational procedures of a germinal product processing establishment, referred to in Article 4(1)(b)(iv), shall be the following:
 - (a) the germinal product processing establishment must have at least:
 - (i) a germinal products processing room, separated from the germinal products storage room referred to in point (ii) and the room used for cleansing equipment referred to in point (iii);

- (ii) a germinal products storage room, which need not necessarily be on the same site, furnished with the necessary installation to store germinal products, and which is so constructed that it protects those germinal products and the installation from adverse weather and environment effects;
 - (iii) a separate room for the cleansing and disinfection or sterilisation of equipment;
- (b) where processing is not limited to germinal products delivered from one approved germinal product establishment or is not limited to a germinal product of one type or of a single species, the germinal product processing establishment must have procedures in place to ensure that:
 - (i) the processing of each consignment of germinal products is separated in time; and
 - (ii) the equipment is cleansed and disinfected between the processing of different consignments;
- (c) where storage is not limited to a germinal product of one type or of a single species,
 - (i) the germinal product processing establishment must have distinct storage containers assigned for each type and species of germinal product that is stored in the germinal products storage room referred to in point (a)(ii), and
 - (ii) the handling of stored germinal products of different types and species must be carried out by separate staff or at a different time;
- (d) the germinal product processing establishment must be so constructed that, except the office rooms, it can be readily cleansed and disinfected;
- (e) the germinal product processing establishment must be so constructed that unauthorised access of people is effectively prevented.

PART 5

REQUIREMENTS FOR THE APPROVAL OF A GERMINAL PRODUCT STORAGE CENTRE REFERRED TO IN ARTICLE 4

1. The responsibilities of the centre veterinarian, referred to in Article 4(1)(a)(i), shall be the following:

- (a) the centre veterinarian shall ensure that:
 - (i) at the germinal product storage centre records are kept in accordance with the requirements laid down in Article 8(1)(c);
 - (ii) the entry of unauthorised persons is effectively prevented;
 - (iii) authorised visitors comply with the animal health and biosecurity requirements referred to in point (b)(i);
 - (iv) each individual dose of semen, oocytes or embryos is clearly marked in accordance with the requirements set out in Article 10;
 - (v) storage of germinal products takes place only on the premises set aside for that purpose and under strict hygiene conditions;
 - (vi) all instruments which come into contact with the germinal products are cleansed and either disinfected or sterilised prior to use, except for new single-use instruments;
 - (vii) before the commencement of each filling operation, the storage containers and transport containers are cleansed and either disinfected or sterilised, except for new single-use containers;
 - (viii) cryogenic agents used for preservation or storage of germinal products have not previously been used for other products;

- (ix) the staff employed at the germinal product storage centre have received adequate training on disinfection and hygiene techniques to prevent the spread of diseases;
 - (b) the centre veterinarian shall:
 - (i) lay down the animal health and biosecurity requirements for the operation of the germinal product storage centre and the measures to ensure compliance with those requirements;
 - (ii) only accept into a germinal product storage centre semen, oocytes or embryos collected, produced, processed and stored in an approved germinal product establishment, and transported in conditions which ensure that cross-contamination of semen, oocytes or embryos is prevented, as they have had no contact with germinal products which do not comply with the rules laid down in this Regulation.
2. The requirements for the facilities, equipment and operational procedures of a germinal product storage centre, referred to in Article 4(1)(b)(v), shall be the following:
- (a) the germinal product storage centre must have a storage room furnished with necessary installation to store germinal products, which is so constructed that it protects those germinal products and the installation from adverse weather and environment effects;
 - (b) where storage is not limited to a germinal product of one type or of a single species,
 - (i) the germinal product storage centre must have distinct storage containers assigned for each type and species of germinal product that is stored at the centre, and
 - (ii) the handling of stored germinal products of different types and species must be carried out by separate staff or at a different time;
 - (c) the germinal product storage centre must be so constructed that, except the office rooms, it can be readily cleansed and disinfected;
 - (d) the germinal product storage centre must be so constructed or isolated that contact with outside livestock is prevented;
 - (e) the germinal product storage centre must be so constructed that unauthorised access of people is effectively prevented.
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ANNEX II

ADDITIONAL ANIMAL HEALTH REQUIREMENTS FOR BOVINE, OVINE, CAPRINE, PORCINE AND EQUINE ANIMALS FROM WHICH GERMINAL PRODUCTS ARE COLLECTED, AND CONCERNING QUARANTINE AND LABORATORY OR OTHER TESTS OF THOSE ANIMALS AS REFERRED TO IN SECTION 2 OF CHAPTER 1 OF PART III

PART 1

ADDITIONAL ANIMAL HEALTH REQUIREMENTS FOR BOVINE ANIMALS FROM WHICH GERMINAL PRODUCTS ARE COLLECTED, AND CONCERNING QUARANTINE AND LABORATORY OR OTHER TESTS OF THOSE ANIMALS, AS REFERRED TO IN ARTICLE 20

Chapter I

Additional animal health requirements for bovine animals from which semen is collected, and concerning quarantine and laboratory or other tests for those animals

1. For all bovine animals admitted to a semen collection centre, the following requirements shall apply:
 - (a) the animals must have been subjected to quarantine in quarantine accommodation where only other cloven-hoofed animals with at least the same health status were present;
 - (b) within the period of 30 days prior to the commencement of the quarantine referred to in point (a), the animals must have been subjected to the following tests with a negative result in each case, except for the bovine viral diarrhoea antibody test referred to in point (v):
 - (i) for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), an intradermal tuberculin test referred to in point 1 of Part 2 of Annex I to Delegated Regulation (EU) 2020/688;
 - (ii) for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688;
 - (iii) for enzootic bovine leukosis, a serological test referred to in point (a) of Part 4 of Annex I to Delegated Regulation (EU) 2020/688, using the derogation provided for in Article 20(2)(a);
 - (iv) for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, a serological test (whole virus) on a blood sample if the animals do not come from an establishment free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis;
 - (v) for bovine viral diarrhoea:
 - a virus isolation test, a test for virus genome or a test for virus antigen, and
 - a serological test to determine the presence or absence of antibodies;
 - (c) during the quarantine referred to in point (a), and for a period of at least 21 days, or 7 days in the case of the tests required in accordance with points (iv) and (v), after being admitted to the quarantine accommodation, the animals must have been subjected to the following tests with a negative result in each case, except for the bovine viral diarrhoea antibody test referred to in point (iii):
 - (i) for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688;
 - (ii) for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, a serological test (whole virus) on a blood sample.

If any animals prove positive, these animals shall be removed immediately from the quarantine accommodation and the other animals of the same group shall remain in quarantine and be retested, with negative results, not earlier than on the 21st day from the date of the removal of the positive animal(s);

(iii) for bovine viral diarrhoea:

- a virus isolation test, a test for virus genome or a test for virus antigen, and
- a serological test to determine the presence or absence of antibodies.

Any seronegative or seropositive animal shall only be allowed to enter the semen collection centre if no seroconversion occurs in animals which tested seronegative before entry into the quarantine accommodation.

If seroconversion occurs, all animals that remain seronegative shall be kept in quarantine accommodation over a prolonged period until there is no longer seroconversion in the group of animals for a period of 3 weeks. Serologically positive animals may be allowed to enter the semen collection centre;

(iv) for bovine genital campylobacteriosis (*Campylobacter fetus* ssp. *venerealis*):

- in the case of animals less than 6 months old or kept since that age in a single sex group without contact with females prior to the quarantine referred to in point (a), a single test carried out on a sample of artificial vagina washings or preputial specimen, or
- tests carried out on samples of artificial vagina washings or preputial specimens taken on three occasions at intervals of at least 7 days;

(v) for trichomonosis (*Trichomonas foetus*):

- in the case of animals less than 6 months old or kept since that age in a single sex group without contact with females prior to the quarantine referred to in point (a), a single test carried out on a sample of preputial specimen, or
- tests carried out on preputial specimens taken on three occasions at intervals of at least 7 days.

If any of the tests referred to in point (c) prove positive, the animal concerned shall be removed immediately from the quarantine accommodation. In the event of the quarantine of a group of animals, the competent authority shall take all necessary measures to re-establish the eligibility of the remaining animals for entry into the semen collection centre in accordance with Chapter I of Part 1 of this Annex;

(d) prior to the initial dispatch of semen from bovine viral diarrhoea serologically positive bulls, a semen sample from each animal shall be subjected to a virus isolation or virus antigen enzyme-linked immunosorbent assay (ELISA) for bovine viral diarrhoea. In the event of a positive result, the bull shall be removed from the semen collection centre and all of its semen shall be destroyed.

2. All bovine animals kept at a semen collection centre shall be subjected at least once a year to the following tests (compulsory routine tests), with negative results:

- (a) for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), an intradermal tuberculin test referred to in point 1 of Part 2 of Annex I to Delegated Regulation (EU) 2020/688;
- (b) for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688;
- (c) for enzootic bovine leukosis, a serological test referred to in point (a) of Part 4 of Annex I to Delegated Regulation (EU) 2020/688;
- (d) for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, a serological test (whole virus) on a blood sample;

- (e) for bovine viral diarrhoea, a serological test for the detection of an antibody which is applied only to seronegative animals.

In the event that an animal becomes serologically positive, every ejaculate of that animal collected since the last negative test shall be either discarded or tested for virus or virus genome with negative results;

- (f) for bovine genital campylobacteriosis, a test on a sample of preputial specimen. Only bulls in semen production or having contact with bulls in semen production shall be required to be tested. Bulls returning to collection after a lay-off period of more than 6 months shall be tested during a period of 30 days prior to resuming production;
- (g) for trichomonosis, a test on a sample of preputial specimen. Only bulls in semen production or having contact with bulls in semen production shall be required to be tested. Bulls returning to collection after a lay-off period of more than 6 months shall be tested during a period of 30 days prior to resuming production.

3. If any of the tests referred to in point 2 prove positive, the animal shall be isolated and the semen collected from it since the last negative test shall not be moved to another Member State, with the exception, for bovine viral diarrhoea, of semen from every ejaculate which has been tested negative for either bovine viral diarrhoea virus or virus genome.

The animal referred to in the first subparagraph shall be removed from the semen collection centre.

Semen collected from all other animals at the semen collection centre since the date when the last sample was taken that gave a negative result in one of the tests described in point 2 shall be kept in separate storage and shall not be subject to movement between Member States until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens that cause diseases referred to in point 2.

Chapter II

Additional animal health requirements for bovine animals which are *in vivo* derived embryos donors, and concerning the quarantine of those animals

1. Donor bovine animals must have been clinically examined by the team veterinarian or a team member and certified to be free of symptoms or signs of any of the category D diseases relevant for the animals of the bovine species on the day of embryo collection.
2. Semen used to inseminate donor bovine animals artificially must have been collected, processed and stored in accordance with the requirements of Chapter I of Part 1 of Annex II, and of Part 1 of Annex III.

Chapter III

Additional animal health requirements for bovine animals from which oocytes for *in vitro* production of embryos are collected, and concerning quarantine of those animals

1. When oocytes are recovered from individual live bovine animals (either by aspiration from surgically excised ovaries ('ovariectomy') or by ultrasonographically guided transvaginal aspiration ('ovum pick-up'), the requirements laid down in Chapter II shall apply to the donor animals of such oocytes.
2. In the case of donor bovine animals of ovaries and other tissues to be collected after slaughter in a slaughterhouse, those animals must not have been designated for slaughter as part of an approved eradication programme, nor have come from an establishment situated in a restricted zone established due to an outbreak of a category A disease or of an emerging disease in accordance with Article 6 of Regulation (EU) 2016/429 in donor bovine animals.
3. The slaughterhouse where the ovaries and other tissues are collected must not be situated in a restricted zone established due to an outbreak of a category A disease or of an emerging disease in accordance with Article 6 of Regulation (EU) 2016/429 in donor bovine animals.

4. Semen used to fertilise oocytes of bovine animals for *in vitro* production of embryos must have been collected, processed and stored in accordance with the requirements of Chapter I of Part 1 of Annex II, and of Part 1 of Annex III.

PART 2

ADDITIONAL ANIMAL HEALTH REQUIREMENTS FOR PORCINE ANIMALS FROM WHICH GERMINAL PRODUCTS ARE COLLECTED, AND CONCERNING QUARANTINE AND LABORATORY OR OTHER TESTS OF THOSE ANIMALS, AS REFERRED TO IN ARTICLE 21

Chapter I

Additional animal health requirements for porcine animals from which semen is collected, and concerning quarantine and laboratory or other tests of those animals

1. For all porcine animals admitted to a semen collection centre, the following requirements shall apply:
 - (a) the animals must have been subjected to quarantine in quarantine accommodation where only other cloven-hoofed animals with at least the same health status were present;
 - (b) within a period of 30 days prior to entering the quarantine accommodation referred to in point (a), the animals must have been subjected to the following tests, with negative results:

- (i) as regards infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a buffered Brucella antigen test (rose Bengal test), a competitive ELISA or an indirect ELISA for the detection of antibodies to smooth *Brucella* species.

If any of the animals prove positive in the serological tests detecting antibodies to smooth *Brucella* species (including *Brucella abortus*, *Brucella melitensis* and *Brucella suis*), animals with negative results in the same establishment shall not be admitted into the quarantine accommodation until a disease-free status of the infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* of the establishments of origin of the animals that proved positive has been confirmed;

- (ii) as regards infection with Aujeszky's disease virus:

- in the case of non-vaccinated animals, an ELISA to detect antibodies to the whole Aujeszky's disease virus or to glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD) of the virus or a serum neutralisation test,
- in the case of animals vaccinated with a gE deleted vaccine, an ELISA to detect antibodies to glycoprotein E (ADV-gE) of Aujeszky's disease virus.

The serological tests for infection with Aujeszky's disease virus must meet the standards set out in Part 7 of Annex I to Delegated Regulation (EU) 2020/688;

- (iii) as regards classical swine fever, an antibody ELISA or serum neutralisation test, in case of animals coming from a Member State or zone thereof where classical swine fever has been reported or vaccination against this disease has been practiced for the period of the preceding 12 months;
 - (iv) as regards infection with porcine reproductive and respiratory syndrome virus, a serological test (the immunoperoxidase monolayer assay (IPMA), immunofluorescence assay (IFA), or ELISA);
 - (c) the animals have been subjected to the following tests carried out on samples taken during a period of at least 21 days after being admitted to the quarantine accommodation referred to in point (a):
 - (i) as regards infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a buffered Brucella antigen test (rose Bengal test), a competitive ELISA or an indirect ELISA for the detection of antibodies to smooth *Brucella* species.

Animals which proved positive in a test referred to in the first subparagraph are to be removed from the quarantine accommodation, unless the suspicion of infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* has been ruled out in accordance with point (d);

(ii) as regards infection with Aujeszky's disease virus:

- in the case of non-vaccinated animals, an ELISA to detect antibodies to the whole Aujeszky's disease virus or to glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD) of the virus or a serum neutralisation test,
- in the case of animals vaccinated with a gE deleted vaccine, an ELISA to detect antibodies to glycoprotein E (ADV-gE) of Aujeszky's disease virus.

If any of the animals prove positive in the tests for infection with Aujeszky's disease virus, those animals shall be removed immediately from the quarantine accommodation;

(iii) as regards classical swine fever, an antibody ELISA or serum neutralisation test, in case of animals coming from a Member State or zone thereof where classical swine fever has not been reported and vaccination against this disease has not been practiced for the period of the preceding 12 months;

(iv) as regards infection with porcine reproductive and respiratory syndrome virus, a serological test (IPMA, IFA, or ELISA) and a test for virus genome (reverse-transcription polymerase chain reaction (RT-PCR), nested set RT-PCR, real-time RT-PCR).

If any of the animals prove positive in the tests for infection with porcine reproductive and respiratory syndrome virus, those animals shall be removed immediately from the quarantine accommodation.

Where a group of animals is quarantined, the competent authority shall take all necessary measures to ensure that the remaining animals which have proved negative in the tests referred to in points (i), (ii), (iii) and (iv) have a satisfactory health status before they are admitted to the semen collection centre in accordance with this Chapter;

(d) the following measures shall be taken in the case of a suspicion of infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*:

(i) the following protocol shall be implemented with regard to animals which have proved positive for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* in a test referred to in point (c)(i):

- the positive sera are subjected to at least one of the alternative tests set out in point (c)(i) which has not been carried out on the samples referred to in point (c),
- an epidemiological enquiry is carried out on the establishment(s) of origin of the animals which have proved positive in the test for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*,
- not earlier than 7 days following the date of the collection of the samples referred to in point (c), samples are taken from all the animals which have proved positive in the tests referred to in point (c)(i) and in the first indent of point (d)(i) and subjected to a serological test provided for in point (c)(i), or all animals referred to in point (c) are subjected to a brucelin skin test;

(ii) the suspicion of infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* shall be ruled out provided that the epidemiological enquiry on the establishment(s) of origin did not reveal the presence of infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* and either:

- the repeat testing referred to in the first indent of point (d)(i) or the test referred to in the third indent of point (d)(i) were carried out with a negative result,

or

- all animals which proved positive in the tests referred to in the first or third indent of point (d)(i) have been subjected to a *post-mortem* inspection and agent detection test (PCR or bacteriological culture) for smooth *Brucella* species (including *Brucella abortus*, *Brucella melitensis* and *Brucella suis*), with a negative result in each case;

(iii) after the suspicion of infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* is ruled out, all of the animals from the quarantine accommodation referred to in the second paragraph of point (c) may be admitted to the semen collection centre.

2. Compulsory routine testing of porcine animals kept at semen collection centres shall be carried out as follows:

(a) all porcine animals kept at the semen collection centre shall be subjected to the following tests with negative results:

(i) as regards infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a buffered Brucella antigen test (rose Bengal test), or a competitive ELISA or an indirect ELISA;

(ii) as regards infection with Aujeszky's disease virus:

— in the case of non-vaccinated animals, an ELISA to detect antibodies to the whole Aujeszky's disease virus or to glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD) of the virus or a serum neutralisation test,

— in the case of animals vaccinated with a gE deleted vaccine, an ELISA to detect antibodies to glycoprotein E (ADV-gE) of Aujeszky's disease virus;

(iii) as regards classical swine fever, an antibody ELISA or serum neutralisation test;

(iv) as regards infection with porcine reproductive and respiratory syndrome virus, a serological test (IPMA, IFA, or ELISA);

(b) the tests set out in point (a) shall be carried out on samples taken from:

(i) all animals immediately prior to leaving the semen collection centre, or upon arrival at the slaughterhouse, and in no case later than 12 months from the date of admission to the semen collection centre;

or

(ii) at least:

— 25 % of the animals in the semen collection centre every 3 months to test for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, infection with Aujeszky's disease virus and classical swine fever and from at least 10 % of the animals in the semen collection centre every month to test for infection with porcine reproductive and respiratory syndrome virus,

or

— 10 % of the animals in the semen collection centre every month to test for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, infection with Aujeszky's disease virus, classical swine fever and infection with porcine reproductive and respiratory syndrome virus.

In the case of sampling carried out in accordance with the two options listed in point (ii), the centre veterinarian shall ensure that the sampled animals are representative of the total population of that centre, in particular with respect to age groups and housing;

(c) where the testing is carried out in accordance with point 2(b)(ii), the centre veterinarian shall ensure that all animals are tested for the diseases referred to in point 2(a) at least every 12 months from the date of admission to the semen collection centre.

3. If any of the tests set out in point 2(a) prove positive, the animal shall be isolated and the semen collected from them since the last negative test shall not be the subject of movement between Member States.

The animal referred to in the first subparagraph shall be removed immediately from the semen collection centre.

Semen collected from all other animals present at the semen collection centre since the date when the last sample was taken that gave a negative result in one of the tests described in point 2(a) shall be kept in separate storage and shall not be the subject of movement between Member States until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens that cause diseases referred to in point 2(a).

Chapter II

Additional animal health requirements for porcine animals from which oocytes and embryos are collected, and concerning the quarantine of those animals

1. Donor porcine animals must have been clinically examined by the team veterinarian or a team member and certified to be free of symptoms or signs of any of the category D diseases relevant for the porcine animals on the day of oocyte or embryo collection.
2. In addition to the requirements referred to in point 1, donor porcine females shall, except donors of *in vivo* derived embryos subject to trypsin treatment, come from a Member State or zone thereof which is free from infection with Aujeszky's disease virus or where an approved eradication programme for infection with Aujeszky's disease virus is carried out.
3. As regards infection with porcine reproductive and respiratory syndrome virus, the donor porcine females of *in vivo* derived embryos shall be subjected to a serological test for infection with porcine reproductive and respiratory syndrome virus, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within a period of 15 days prior to embryo collection.
4. Semen used to inseminate donor porcine animals artificially must have been collected, processed and stored in accordance with the requirements of Chapter I of Part 2 of Annex II, and of Part 1 of Annex III.

PART 3

ADDITIONAL ANIMAL HEALTH REQUIREMENTS FOR OVINE AND CAPRINE ANIMALS FROM WHICH GERMINAL PRODUCTS ARE COLLECTED, AND CONCERNING THE QUARANTINE AND LABORATORY OR OTHER TESTS OF THOSE ANIMALS, AS REFERRED TO IN ARTICLE 22

Chapter I

Additional animal health requirements for ovine and caprine animals from which semen is collected, and concerning the quarantine and laboratory or other tests of those animals

1. For all ovine and caprine animals admitted to a semen collection centre, the following requirements shall apply:
 - (a) the animals must have been subjected to quarantine in quarantine accommodation where only other cloven-hoofed animals with at least the same health status were present;
 - (b) in the case of ovine animals, they must come from an establishment where, during the period of 60 days prior to their stay in the quarantine accommodation referred to in point (a), they have been subjected to a serological test for ovine epididymitis (*Brucella ovis*) or any other test with an equivalent documented sensitivity and specificity.

In the case where ovine animals are kept together with caprine animals, those caprine animals shall also be subjected to a serological test for ovine epididymitis (*Brucella ovis*) with negative results;
 - (c) the animals have been subjected to the following tests carried out on a blood sample taken within a period of 30 days preceding the commencement of the period of quarantine referred to in point (a), with a negative result in each case:
 - (i) for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688;
 - (ii) in the case of ovine animals, for ovine epididymitis (*Brucella ovis*), a serological test or any other test with an equivalent documented sensitivity and specificity.

In the case where ovine animals are kept together with caprine animals, those caprine animals shall also be subjected to a serological test for ovine epididymitis (*Brucella ovis*) with negative results;
 - (d) the animals have been subjected to the following tests carried out on samples taken during the period of quarantine referred to in point (a), and within a period of at least 21 days from the date of being admitted to the quarantine accommodation, with negative results:
 - (i) for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688;

- (ii) in the case of ovine animals, for ovine epididymitis (*Brucella ovis*), a serological test or any other test with an equivalent documented sensitivity and specificity.

In the case where ovine animals are kept together with caprine animals, those caprine animals shall also be subjected to a serological test for ovine epididymitis (*Brucella ovis*) with negative results.

2. All ovine and caprine animals kept at an approved semen collection centre shall be subjected at least once a year to the following tests (compulsory routine tests), with negative results:
 - (a) for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688;
 - (b) in the case of ovine animals, for ovine epididymitis (*Brucella ovis*) a serological test or any other test with an equivalent documented sensitivity and specificity.

In the case where ovine animals are kept together with caprine animals, those caprine animals shall also be subjected to a serological test for ovine epididymitis (*Brucella ovis*) with negative results.

3. If any of the tests described in point 2 prove positive, the animal shall be isolated and the semen collected from it since the date of the last negative test shall not be moved between Member States.

The animal referred to in the first subparagraph shall be removed from the semen collection centre.

Semen collected from all other animals present at the semen collection centre since the date when the last sample was taken that gave a negative result in one of the tests described in point 2 shall be kept in separate storage and shall not be moved between Member States until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens that cause diseases referred to in point 2.

Chapter II

Additional animal health requirements for ovine and caprine animals from which oocytes and embryos are collected, and concerning the quarantine of those animals

1. Donor ovine and caprine animals must have been clinically examined by the team veterinarian or a team member and certified to be free of symptoms or signs of any of the category D diseases relevant for the animals of the ovine and caprine species on the day of collection of the oocytes or embryos.
2. Semen used to inseminate donor ovine and caprine animals artificially must have been collected, processed and stored in accordance with the requirements of Chapter I of Part 3 of Annex II, and of Part 1 of Annex III.

PART 4

ADDITIONAL ANIMAL HEALTH REQUIREMENTS FOR EQUINE ANIMALS FROM WHICH GERMINAL PRODUCTS ARE COLLECTED, AND CONCERNING THE QUARANTINE AND LABORATORY OR OTHER TESTS OF THOSE ANIMALS, AS REFERRED TO IN ARTICLE 23

Chapter I

Additional animal health requirements for equine animals from which semen is collected, and concerning the quarantine and laboratory or other tests of those animals

1. In order to be used for the collection of semen, the donor equine animal shall, to the satisfaction of the centre veterinarian, meet the following requirements:
 - (a) the animal shall be subjected to the following tests, in accordance with one of the testing programmes provided for in point (b):
 - (i) an agar-gel immuno-diffusion test (Coggins test) or an ELISA for equine infectious anaemia with a negative result;

- (ii) a test for the isolation of the equine arteritis virus or the detection of its genome by polymerase chain reaction (PCR) or real-time PCR carried out with a negative result on an aliquot of the entire semen of the donor stallion, unless the donor stallion has been subjected to a serum neutralisation test for equine viral arteritis where a negative result was obtained at a serum dilution of one in four;
- (iii) an agent identification test for contagious equine metritis (*Taylorella equigenitalis*), carried out with a negative result in each case on three specimens (swabs) taken from the donor stallion on two occasions with an interval of not less than 7 days, and in any case no earlier than 7 days (systemic treatment) or 21 days (local treatment) after the possible antimicrobial treatment of the donor stallion, from at least the following sites:
 - the penile sheath (prepuce),
 - the urethra,
 - the fossa glandis.

The specimens shall be placed in a transport medium with activated charcoal, such as Amies medium, before being dispatched to the laboratory.

The specimens shall be subjected to at least one of the following tests:

- culture under microaerophilic conditions for a period of at least 7 days for the isolation of *Taylorella equigenitalis*, set up within 24 hours from the time of taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport,
- or
- PCR or real-time PCR for the detection of genome of *Taylorella equigenitalis*, carried out within 48 hours from the time of taking the specimens from the donor animal;

(b) the animal shall be subjected to one of the following testing programmes:

- (i) if the donor stallion is continuously resident at the semen collection centre for a period of at least 30 days prior to the date of the first semen collection and during the collection period, and no equine animals in the semen collection centre come into direct contact with equine animals of a lower health status than the donor stallion, the tests required in accordance with point (a) shall be carried out on samples taken from the donor stallion at least once a year (compulsory routine tests) at the beginning of the breeding season or prior to the first collection of semen intended for movement to another Member State as fresh, chilled or frozen semen and not less than 14 days following the date of the commencement of the residence period of at least 30 days prior to the date of first semen collection;
- (ii) if the donor stallion is resident at the semen collection centre for a period of at least 30 days prior to the date of the first semen collection and during the collection period, but it may leave the semen collection centre occasionally, under the responsibility of the centre veterinarian, for a total period of less than 14 days during the collection period, or other equine animals in the semen collection centre come into direct contact with equine animals of a lower health status, the tests required in accordance with point (a) shall be carried out as follows:

- at least once a year on samples taken from the donor stallion at the beginning of the breeding season or prior to the first collection of semen intended for movement to another Member State as fresh, chilled or frozen semen and not less than 14 days following the date of the commencement of the residence period of at least 30 days prior to the date of first semen collection,

and

- during the period of collection of semen intended for movement to another Member State as fresh, chilled or frozen semen as follows:
 - the test required in point (a)(i) on samples taken not more than 90 days prior to the date of the collection of semen intended for movement to another Member State,
 - the test required in point (a)(ii) on samples taken not more than 30 days prior to the date of the collection of semen intended for movement to another Member State, unless the non-shedder state of the donor stallion is confirmed by a virus isolation test, PCR or real-time PCR carried out on samples of an aliquot of the entire semen taken not more than 6 months prior to the date of the collection of semen intended for movement to another Member State and the donor stallion has been subjected to a serum neutralisation test for equine viral arteritis with a positive result at a serum dilution of at least one in four,

- the test required in point (a)(iii) on samples taken not more than 60 days prior to the date of the collection of semen intended for movement to another Member State, which in the case of PCR or real-time PCR may be carried out on three specimens (swabs) taken on a single occasion;
- (iii) if the donor stallion does not meet the conditions set out in points (i) and (ii) and the semen is collected for movement to another Member State as frozen semen, the tests required in accordance with point (a) shall be carried out on samples taken from the donor stallion as follows:
- at least once a year at the beginning of the breeding season,
 - during the storage period provided for in point 2(b) of Part 1 of Annex III and before the semen is removed from the semen collection centre or used, on samples taken not earlier than 14 days and not later than 90 days following the date of collection of the semen.

By way of derogation from the second indent of point (iii), post-collection sampling and testing for equine viral arteritis as described in point (a)(ii) shall not be required where the non-shedder state of a seropositive donor stallion is confirmed by a virus isolation test, PCR or real-time PCR carried out with a negative result on samples of an aliquot of the entire semen of the donor stallion taken twice a year at an interval of at least 4 months and the donor stallion has been subjected to a serum neutralisation test for equine viral arteritis with a positive result at a serum dilution of at least one in four;

- (c) if any of the tests provided for in point (b) prove positive, the donor stallion shall be isolated and the semen collected from it since the date of the last negative test shall not be moved between Member States with the exception, for equine viral arteritis, of semen from every ejaculate which has undergone the equine arteritis virus isolation test with a negative result.

Semen collected from all other stallions at the semen collection centre since the date when the last sample was taken that gave a negative result in one of the tests provided for in point (b) shall be kept in separate storage and shall not be moved between Member States until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens that cause diseases referred to in point (b).

Chapter II

Additional animal health requirements for equine animals from which oocytes and embryos are collected, and concerning the quarantine and laboratory or other tests of those animals

1. Donor equine animals must have been clinically examined by the team veterinarian or a team member and certified to be free of symptoms or signs of any of the category D diseases relevant for the animals of the equine species on the day of oocyte or embryo collection.
2. In addition to the requirements referred to in point 1, donor equine animals shall:
 - (a) not be used for natural breeding during a period of at least 30 days prior to the date of collection of oocytes or embryos and between the date of the first sample referred to in points (b) and (c) and the date of the collection of oocytes and embryos;
 - (b) be subjected with a negative result to an agar-gel immuno-diffusion test (Coggins test) or an ELISA for equine infectious anaemia carried out on a blood sample taken not less than 14 days following the date of the commencement of the period of at least 30 days referred to in point (a) and not more than 90 days prior to the date of the collection of oocytes or embryos for movement between Member States;
 - (c) be subjected to an agent identification test for contagious equine metritis (*Taylorella equigenitalis*), carried out with a negative result in each case on at least two specimens (swabs) taken from the donor animal, which must in any case not be earlier than 7 days (systemic treatment) or 21 days (local treatment) after the possible antimicrobial treatment of the donor animal, from at least the following sites:
 - the mucosal surfaces of the clitoral fossa,
 - the clitoral sinuses.

The specimens shall be taken during the period of at least 30 days referred to in point (a) on two occasions with an interval of not less than 7 days in the case of the test referred to in point (i) below, or on one occasion in the case of the test referred to in point (ii) below.

The specimens shall be placed in a transport medium with activated charcoal, such as Amies medium, before being dispatched to the laboratory.

The specimens shall be subjected to at least one of the following tests:

- (i) culture under microaerophilic conditions for a period of at least 7 days for the isolation of *Taylorella equigenitalis*, set up within 24 hours from the time of taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport;

or

- (ii) PCR or real-time PCR for the detection of genome of *Taylorella equigenitalis*, carried out within 48 hours from the time of taking the specimens from the donor animal.

3. Semen used to inseminate donor animals artificially must have been collected, processed and stored in accordance with the requirements of Chapter I of Part 4 of Annex II, and of Part 1 of Annex III.

PART 5

OTHER ANIMAL HEALTH REQUIREMENTS FOR BOVINE, PORCINE, OVINE AND CAPRINE ANIMALS AND ANIMALS OF THE FAMILIES CAMELIDAE AND CERVIDAE FROM WHICH GERMINAL PRODUCTS ARE COLLECTED, AND CONCERNING THE QUARANTINE AND LABORATORY OR OTHER TESTS OF THOSE ANIMALS, AS REFERRED TO IN ARTICLES 20, 21, 22 AND 38

Chapter I

Requirements for bovine, porcine, ovine and caprine animals as regards foot-and-mouth disease

1. The bovine, porcine, ovine and caprine animals which are semen, oocyte or embryo donors must:
 - (a) come from establishments:
 - (i) situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the establishment for a period of at least 30 days immediately prior to the date of collection;
 - (ii) in which foot-and-mouth disease has not been reported during a period of at least 3 months immediately prior to the date of collection;
 - (b) have not been vaccinated against foot-and-mouth disease during the period of 12 months immediately prior to the date of collection.
2. The centre veterinarian shall ensure that:
 - (a) the bovine, porcine, ovine and caprine animals which are semen donors are only admitted to the semen collection centre after they have undergone isolation in the quarantine accommodation, which on the day of admission of the animals to the semen collection centre must:
 - (i) be situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the quarantine accommodation for a period of at least 30 days;
 - (ii) have had no outbreak of foot-and-mouth disease reported during the period of 3 months preceding the date of admission of the animals into the semen collection centre;
 - (b) semen is only moved to another Member State subject to compliance with the following conditions:
 - (i) the semen collection centre is situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the semen collection centre for a period of at least 30 days;

- (ii) the semen collection centre has been free from foot-and-mouth disease for a period of at least 3 months prior to the date of collection of the semen and 30 days from the date of collection or, in the case of fresh semen, until the date of dispatch of the consignment of semen to another Member State;
 - (iii) in the case of fresh semen, the donor animal has been kept at the semen collection centre referred to in point (i) for a continuous period of at least 30 days immediately prior to the date of collection of the semen.
3. By way of derogation from point 1(b), the centre veterinarian may authorise the dispatch of semen collected from a kept donor animal which has been vaccinated against foot-and-mouth disease during the period of 12 months immediately prior to the date of collection, provided that:
- (a) the donor animal has not been vaccinated against foot-and-mouth disease within the period of at least 30 days immediately prior to the date of collection;
 - (b) 5 % (with a minimum of five straws) of each quantity of semen taken from a donor animal at any time is submitted to a virus isolation test for foot and mouth disease with negative results.
4. By way of derogation from point 1(b), the team veterinarian may authorise the dispatch, to another Member State, of *in vivo* derived embryos collected from a donor animal which has been vaccinated against foot-and-mouth disease during the 12-month period immediately prior to the date of collection, provided that:
- (a) the female donor animal has not been vaccinated against foot-and-mouth disease within the period of at least 30 days immediately prior to the date of collection;
 - (b) the semen used for fertilisation was collected from a male donor that complies with the conditions set out in point 1(b) or the semen complies with the conditions set out in point 2;
 - (c) prior to freezing, the embryos have been subjected to trypsin washing carried out in accordance with the recommendations of the IETS Manual ⁽¹⁾;
 - (d) the embryos are stored deep frozen for a period of at least 30 days from the date of collection, and during this period the donor animal has not shown clinical signs of foot-and-mouth disease.

Chapter II

Requirements for bovine, ovine and caprine animals and for animals of the families *Camelidae* and *Cervidae* as regards infection with bluetongue virus (serotypes 1-24)

1. The bovine, ovine and caprine animals and animals of the families *Camelidae* and *Cervidae* which are semen donors must fulfil at least one of the following conditions:
- (a) they have been kept in a Member State or zone thereof free from infection with bluetongue virus (serotypes 1-24) for a period of at least 60 days prior to and during collection of the semen;
 - (b) they have been kept in a seasonally disease-free zone, during the seasonally disease-free period, for a period of at least 60 days prior to and during collection of the semen, in a Member State or zone thereof:
 - (i) with an approved eradication programme against infection with bluetongue virus (serotype 1-24); or
 - (ii) where the competent authority of the place of origin of the consignment of semen has obtained the prior written consent of the competent authority of the Member State of destination to the conditions for establishment of that seasonally disease-free zone and to accept the consignment of semen;
 - (c) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the semen;
 - (d) they have been subjected to a serological test to detect antibodies to the bluetongue virus serogroup 1-24, with negative results, between 28 and 60 days from the date of each collection of the semen;

⁽¹⁾ Manual of the International Embryo Transfer Society – A procedural guide and general information for the use of embryo transfer technology emphasising sanitary procedures, published by the International Embryo Transfer Society 1 111 North Dunlap Avenue, Savoy, Illinois 61 874 USA (<http://www.iets.org/>).

- (e) they have been subjected to an agent identification test for bluetongue virus (serotypes 1-24), with negative results, on blood samples taken at commencement and final collection of the semen and during collection of the semen at intervals of:
 - (i) at least every 7 days, in the case of the virus isolation test;
 - or
 - (ii) at least every 28 days, in the case of PCR.
- 2. The ovine and caprine animals and animals of the families *Camelidae* and *Cervidae* which are *in vivo* derived embryo donors and bovine, ovine and caprine animals and animals of the families *Camelidae* and *Cervidae* which are oocyte donors for the *in vitro* production of embryos must fulfil at least one of the following conditions:
 - (a) they have been kept in a Member State or zone thereof free from infection with bluetongue virus (serotypes 1-24) for a period of at least 60 days prior to and during collection of the oocytes or embryos;
 - (b) they have been kept in a seasonally disease-free zone, during the seasonally disease-free period, for a period of at least 60 days prior to and during collection of the oocytes or embryos, in a Member State or zone thereof:
 - (i) with an approved eradication programme against infection with bluetongue virus (serotype 1-24); or
 - (ii) where the competent authority of the place of origin of the consignment of oocytes or embryos has obtained the prior written consent of the competent authority of the Member State of destination to the conditions for establishment of that seasonally disease-free zone and to accept the consignment of oocytes or embryos;
 - (c) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the oocytes or embryos;
 - (d) they have been subjected to a serological test to detect antibodies to the bluetongue virus serogroup 1-24, with negative results, on a blood sample taken between 28 and 60 days from the date of collection of the oocytes or embryos;
 - (e) they have been subjected to an agent identification test for bluetongue virus (serotypes 1-24), with negative results, on a blood sample taken on the date of collection of the oocytes or embryos.
- 3. The semen used to fertilise the oocytes must be collected from animals which comply with the requirements set out in point 1.

Chapter III

Requirements for bovine, ovine and caprine animals as regards infection with the epizootic haemorrhagic disease virus (serotypes 1-7)

- 1. The bovine, ovine and caprine animals which are semen donors must fulfil at least one of the following conditions:
 - (a) they have been kept for a period of at least 60 days prior to and during collection of the semen in a Member State or zone thereof where infection with epizootic haemorrhagic disease virus (serotypes 1-7) (EHDV 1-7) has not been reported for a period of at least the preceding 2 years within a radius of 150 km of the establishment;
 - (b) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the semen;
 - (c) they have been subjected to a serological test to detect antibodies to EHDV 1-7, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days from the date of the final collection of the semen;
 - (d) they have been subjected to an agent identification test for EHDV 1-7, with negative results, on blood samples taken at the commencement and final collection of the semen and during the collection of the semen at intervals of:
 - (i) at least every 7 days, in the case of virus isolation test;
 - or
 - (ii) at least every 28 days, in the case of PCR.

2. The ovine and caprine animals which are *in vivo* derived embryo donors and bovine, ovine and caprine animals which are oocyte donors for the *in vitro* production of embryos must fulfil at least one of the following conditions:
 - (a) they have been kept for a period of at least 60 days prior to and during collection of the oocytes or embryos in a Member State or zone where EHDV 1-7 has not been reported for a period of at least the preceding 2 years within a radius of 150 km of the establishment;
 - (b) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the oocytes or embryos;
 - (c) they have been subjected to a serological test to detect antibodies to EHDV 1-7, with negative results, on a blood sample taken between 28 and 60 days from the date of collection of the oocytes or embryos;
 - (d) they have been subjected to an agent identification test for EHDV 1-7, with negative results, on a blood sample taken on the date of collection of the oocytes or embryos.
3. The semen used to fertilise the oocytes must be collected from animals which comply with the requirements set out in point 1.

Chapter IV

Requirements for an establishment to be considered free from infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* in porcine animals

To qualify as free from infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, an establishment of porcine animals must satisfy the following requirements:

- (a) infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* must be a notifiable disease in porcine animals in the Member State;
 - (b) infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* has not been confirmed in the establishment for a period of at least the preceding 3 years;
 - (c) animals showing clinical signs consistent with infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* such as abortions or orchitis are subjected to the necessary diagnostic tests with negative results;
 - (d) no porcine animals belonging to the establishment have been vaccinated against infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* for at least the preceding 3 years;
 - (e) porcine animals which have been introduced to the establishment:
 - (i) either come from establishments free from infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* for a period of at least the preceding 3 years, or were tested on a sample taken within a period of 30 days prior to the date of dispatch with negative results;
- and
- (ii) have not been vaccinated against infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* for a period of at least the preceding 3 years;
 - (f) for a period of at least the preceding 3 years, there has been no evidence of infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* in other epidemiological units of the same establishment, or measures have been implemented to prevent any transmission of infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* from those other epidemiological units.
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ANNEX III

ANIMAL HEALTH REQUIREMENTS FOR THE COLLECTION, PRODUCTION, PROCESSING AND STORAGE OF GERMINAL PRODUCTS OF BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS AS REFERRED TO IN ARTICLE 26

PART 1

ANIMAL HEALTH REQUIREMENTS FOR THE COLLECTION, PROCESSING AND STORAGE OF FRESH, CHILLED OR FROZEN SEMEN OF BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS, AND FOR THE TRANSPORT OF THAT SEMEN

1. All instruments used for the collection, processing, preservation or freezing of semen shall be cleansed and either disinfected or sterilised before use, except for new single-use instruments.
2. Frozen semen shall:
 - (a) be placed and stored in storage containers:
 - (i) which have been cleansed and either disinfected or sterilised before use, or which are new single-use containers;
 - (ii) with a cryogenic agent, which must not have previously been used for other biological products originating from animals;
 - (b) prior to dispatch or use, be stored in approved conditions for a minimum period of 30 days from the date of collection.
3. Where necessary, the antibiotics or mixtures of antibiotics with a bactericidal activity at least equivalent to that of the following antibiotics or their mixtures in each ml of semen, may be added to semen or contained in semen diluents:
 - (a) in the case of semen of bovine and porcine animals, a mixture of lincomycin-spectinomycin (150/300 µg), penicillin (500 IU) and streptomycin (500 µg); or
 - (b) in the case of semen of ovine and caprine animals, gentamicin (250 µg) or a mixture of penicillin (500 IU) and streptomycin (500 µg); or
 - (c) a mixture of gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg), penicillin (500 IU) and streptomycin (500 µg); or
 - (d) a mixture of amikacin (75 µg) and divekacin (25 µg).
4. In respect of semen of bovine animals, antibiotics referred to in point 3(a), (c) and (d), or semen diluents containing such antibiotics or mixtures of antibiotics, shall be added and be effective in particular against campylobacters, leptospire and mycoplasmas.
5. In respect of semen of porcine animals, antibiotics or mixtures of antibiotics referred to in point 3(a), (c) and (d), or semen diluents containing such antibiotics or mixtures of antibiotics, shall be added and be effective in particular against leptospire.
6. Where an antibiotic or a mixture of antibiotics is(are) added to semen:
 - (a) the name(s) of the antibiotic(s) added and its(their) concentration or the commercial name of the semen diluent containing antibiotics shall be stated in the animal health certificate accompanying the consignment;
 - (b) it(they) shall be added to the semen after final dilution or to the diluent;
 - (c) in the case of frozen semen, it(they) shall be added before the semen is frozen.
7. For frozen or chilled semen, immediately after the addition of the antibiotics, the diluted semen shall be kept at:
 - (a) a temperature of at least 5 °C, except in the case of semen of porcine animals, which may be kept at a temperature of at least 15 °C for a period of not less than 45 minutes; or
 - (b) a time-temperature regime with a documented equivalent bactericidal activity.

PART 2

**ANIMAL HEALTH REQUIREMENTS FOR THE COLLECTION AND PROCESSING OF IN VIVO DERIVED EMBRYOS
OF BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS**

In vivo derived embryos shall be collected, processed and preserved in accordance with the following requirements:

1. Embryos shall be collected and processed by an embryo collection team, without coming into contact with any other consignment of embryos not complying with the requirements of this Regulation.
2. Embryos shall be collected in a place which is separated from other parts of the premises or establishment and which shall be kept in good repair and constructed with materials which permit its effective and easy cleansing and disinfection.
3. Embryos shall be processed (examined, washed, treated and placed in straws or other packages) in either a permanently located laboratory or a mobile laboratory.
4. All equipment used to collect, handle, wash, freeze and store embryos shall be cleansed and either disinfected or sterilised before use, according to the IETS Manual, or be a new single-use equipment.
5. Any biological product originating from animals used in the media and solutions for the collection, processing, washing or storage of embryos shall be free from pathogenic microorganisms. Media and solutions used in the collection, freezing and storage of embryos shall be sterilised by methods approved in accordance with the IETS Manual and handled in such a manner as to ensure sterility.
6. Where, according to the IETS Manual, antibiotics or a mixture of antibiotics are added to the collection, processing, washing and storage media, the names of the antibiotics added and their concentration shall be stated in the animal health certificate accompanying the consignment.
7. The cryogenic agents used for the preservation or storage of embryos shall not have previously been used for other biological products originating from animals.
8. The embryos shall be washed according to the IETS Manual and have an intact *zona pellucida* or, in the case of equine embryos, the embryonic capsule, before and immediately after washing. Each embryo shall be washed at least 10 times in a special fluid for embryos, which shall be changed each time. Each wash shall be a 100-fold dilution of the previous wash and a sterile micropipette shall be used to transfer the embryo on each occasion.

The standard washing procedure shall be modified to include additional washes with the enzyme trypsin, according to the IETS Manual, when inactivation or removal of certain pathogens is required.

9. Embryos from different donor animals shall not be washed together.
10. The *zona pellucida* or, in the case of equine embryos, the embryonic capsule of each embryo shall be examined over its entire surface area at not less than 50× magnification and certified to be intact and free of adherent material.
11. Embryos that have successfully undergone the examination set out in point 10 shall be placed in a cleansed and either disinfected or sterile, except for a new single-use, straw or another package which is marked in accordance with Article 10(1) and (5) and which shall be sealed immediately.
12. Each embryo shall, where appropriate, be frozen as soon as possible and stored in a storage premises, referred to in point 2(b) of Part 2 of Annex I, which is under the responsibility of the team veterinarian.

13. Where there is no other procedure to verify the health status of the donor animals, or in order to verify compliance with the animal health and biosecurity requirements laid down by the team veterinarian, including in the framework of the quality control scheme referred to in point 1(b) of Part 2 of Annex I, the embryo collection team shall, in accordance with the IETS Manual, submit to an official or authorised by the competent authority laboratory routine samples of non-viable embryos or oocytes, flushing fluids or washing fluids resulting from its activities for the detection of bacterial and viral contamination at a frequency to be established by the team veterinarian.

PART 3

ANIMAL HEALTH REQUIREMENTS FOR THE COLLECTION AND PROCESSING OF OOCYTES, OVARIES AND OTHER TISSUES FOR IN VITRO PRODUCTION OF EMBRYOS OF BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS

In addition to the requirements set out in Part 2, the following additional requirements shall apply to the collection, processing and transport of oocytes, ovaries and other tissues for use in *in vitro* fertilisation and *in vitro* culture:

1. The ovaries and other tissues collected at a slaughterhouse, either from an individual donor animal or from a batch of donor animals, shall be collected in a slaughterhouse approved in accordance with Article 148 of Regulation (EU) 2017/625.

Those potential donor animals must have undergone *ante-mortem* and *post-mortem* inspections carried out by a veterinarian at the slaughterhouse who must have certified them to be free of symptoms and signs of any of the category A, B, C and D diseases relevant for the bovine, porcine, ovine, caprine or equine animals.

The slaughterhouse must be situated in an area where foot-and-mouth disease has not been reported within a 10-km radius for a period of at least the preceding 30 days before the date of collection of the ovaries and other tissues.

2. Ovaries shall not be brought into the laboratory of an embryo production team for processing until a *post-mortem* inspection of donor animals is completed with satisfactory results.

If a disease referred to in point 1 is found in the individual donor animal, the batch of donor animals or in any animals slaughtered in that slaughterhouse on that day, all ovaries and other tissues from those donor animals shall be traced and discarded.

3. Equipment for the removal and transport of ovaries and other tissues shall be cleansed and either disinfected or sterilised before use, except for new single-use equipment, and exclusively used for those purposes.

Separate equipment shall be used to handle oocytes and embryos from different individual donor animals and from different batches of donor animals.

PART 4

ANIMAL HEALTH REQUIREMENTS FOR THE PROCESSING OF IN VITRO PRODUCED EMBRYOS OF BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS

In addition to the requirements set out in Part 2, the following additional requirements shall apply to the processing of *in vitro* produced embryos:

1. After the *in vitro* culture period is completed, but prior to the freezing, storage and transport of the embryos, they shall be washed and undergo the treatments referred to in points 7, 10 and 11 of Part 2.
2. Embryos from different individual donor animals or from different batches of donor animals, referred to in point 1 of Part 3, shall not be washed together.
3. Embryos from different individual donor animals or from different batches of donor animals shall not be placed in the same straw or other package.

PART 5

ANIMAL HEALTH REQUIREMENTS FOR THE PROCESSING OF MICROMANIPULATED EMBRYOS OF BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS

Prior to any micromanipulation which compromises the integrity of the *zona pellucida* or, in the case of equine embryos, the embryonic capsule, all embryos or oocytes shall be collected and processed in accordance with the animal health requirements set out in Parts 2, 3 and 4.

In addition, the following requirements shall apply:

1. Where micromanipulation of the embryo which involves penetration of the *zona pellucida* or, in the case of equine embryos, the embryonic capsule, this shall be carried out in a laboratory referred to in point 2(a) of Part 3 of Annex I, which is under the responsibility of the team veterinarian.
2. Each embryo production team shall keep records of its activities in accordance with Article 8(1)(b).

In the case of embryos produced by *in vitro* fertilisation, the identification of the embryos may be done on the basis of a batch of donor animals, but shall contain details of the date and place of collection of ovaries and oocytes. It shall also allow the establishment of origin of the donor animals to be traced.

3. Any micromanipulation which involves penetration of the *zona pellucida* or, in the case of equine embryos, the embryonic capsule, shall be carried out in the facilities approved for that purpose, and after the last wash and examination.

Such micromanipulation may only be carried out on an embryo with an intact *zona pellucida* or, in the case of equine embryos, an intact embryonic capsule.

PART 6

ANIMAL HEALTH REQUIREMENTS FOR THE STORAGE OF *IN VIVO* DERIVED AND *IN VITRO* PRODUCED EMBRYOS, AND OF OOCYTES OF BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS

1. Each embryo collection team and embryo production team shall ensure that the embryos and oocytes are stored at suitable temperatures in storage premises referred to in point 2(b) of Part 2 of Annex I.
2. Only embryos collected by an embryo collection team, or oocytes collected by and embryos produced by an embryo production team, and transported in conditions ensuring that cross-contamination of embryos and oocytes is prevented, as they have had no contact with embryos and oocytes which do not comply with the requirements laid down in this Regulation, may be brought into the storage premises referred to in point 2(b) of Part 2 of Annex I.

In vivo derived embryos, *in vitro* produced embryos and oocytes shall be stored in distinct storage containers assigned for each type of germinal product and the handling of stored germinal products of different types and species must be carried out by separate staff or at a different time.

3. The team veterinarian may decide that embryos not collected by an embryo collection team, or oocytes not collected and embryos not produced by an embryo production team, may be processed by the embryo collection team or the embryo production team provided that:

(a) such oocytes and embryos are collected from animals which fulfil the conditions laid down:

- (i) in respect of bovine animals, in point 1 of Chapter II of Part 1 of Annex II and as applicable in Chapters I, II and III of Part 5 of Annex II;
- (ii) in respect of porcine animals, in points 1, 2 and 3 of Chapter II of Part 2 of Annex II and as applicable in Chapters I and IV of Part 5 of Annex II;
- (iii) in respect of ovine and caprine animals, in point 1 of Chapter II of Part 3 of Annex II and as applicable in Chapters I to III of Part 5 of Annex II;
- (iv) in respect of equine animals, in points 1 and 2 of Chapter II of Part 4 of Annex II;

- (b) processing is carried out with separate equipment or at a different time from oocytes and embryos intended to be moved to another Member State, the equipment in the latter case being cleaned and sterilised after use;
 - (c) such oocytes and embryos shall not be moved to another Member State and shall not at any time come into contact with, or be stored with, oocytes and embryos intended to be moved to another Member State;
 - (d) such oocytes and embryos must be identifiable by a marking which is different from that referred to in point 1(a)(v) of Part 1 of Annex I.
4. Frozen embryos or oocytes shall, prior to dispatch to another Member State, be stored in storage premises referred to in point 2(b) of Part 2 of Annex I for a period of at least 30 days from the date of their collection or production.
 5. Only embryos or oocytes from an individual donor animal or from one batch of donor animals, referred to in point 1 of Part 3, shall be placed in the same straw or another package.
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ANNEX IV

**INFORMATION TO BE CONTAINED IN THE ANIMAL HEALTH CERTIFICATE FOR GERMINAL PRODUCTS
MOVED BETWEEN MEMBER STATES AS REFERRED TO IN ARTICLES 31 AND 40**

1. The animal health certificate for germinal products of bovine, porcine, ovine, caprine and equine animals moved between Member States, referred to in Article 31, shall contain at least the following information:
 - (a) the name and address of the consignor and the consignee;
 - (b) the name and address of the establishment of dispatch, and
 - (i) the unique approval number of that establishment, where the establishment of dispatch is an approved germinal product establishment or a confined establishment, referred to in Article 14;or
 - (ii) the unique registration number of that establishment, where the establishment of dispatch is an establishment where ovine and caprine animals are kept, referred to in Article 13;
 - (c) the name and address of the establishment of destination, and
 - (i) the unique approval number of that establishment, where the establishment of destination is an approved germinal product establishment or a confined establishment;or
 - (ii) the unique registration number of that establishment, where the establishment of destination is a registered germinal product establishment or any other registered establishment;
 - (d) the type of germinal products and the species of donor animals;
 - (e) the number of straws or other packages to be dispatched;
 - (f) the information allowing identification of germinal products:
 - (i) the species, breed and identification of the donor animals in accordance with the requirements laid down in Title I, II, III or IV of Part III of Regulation (EU) 2019/2035 from which germinal products were collected;
 - (ii) the marking applied to the straws or other packages in accordance with the requirements provided for in Article 10;
 - (iii) the place and date of their collection or production;
 - (g) the number on the seal applied to the transport container;
 - (h) the information on the animal health situation, additional guarantees and, where necessary, test results in relation to:
 - (i) the Member State or zone thereof;
 - (ii) the establishment of origin of the donor animals;
 - (iii) the germinal product establishment or, in the case provided for in Article 14, the confined establishment of germinal products collection or production, processing and storage;
 - (iv) the donor animals from which germinal products were collected;
 - (v) the germinal products to be dispatched;
 - (i) the date and place of issue of the animal health certificate, the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.
2. The animal health certificate for the germinal products of dogs and cats, and of terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments and of animals of the families *Camelidae* and *Cervidae* moved between Member States, referred to in Article 40, shall contain at least the following information:
 - (a) the name and address of the consignor and the consignee;

- (b) the name and address of the establishment of dispatch, and
 - (i) the unique registration number, where the establishment of dispatch was assigned with such registration number;
 - or
 - (ii) the unique approval number of that confined establishment, where the establishment of dispatch is a confined establishment;
 - (c) the name and address of the establishment of destination and, where the establishment of destination is a confined establishment, the unique approval number of that confined establishment;
 - (d) the type of germinal products and the species of donor animals;
 - (e) the number of straws or other packages to be dispatched;
 - (f) the information allowing identification of germinal products:
 - (i) the species, where necessary the subspecies, and identification of the donor animals from which germinal products were collected,
 - in the case of dogs and cats, in accordance with Article 17(1) of Regulation (EU) No 576/2013 or Article 70 of Regulation (EU) 2019/2035,
 - or
 - in the case of terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments, in accordance with the rules of that confined establishment,
 - or
 - in the case of animals of the families *Camelidae* and *Cervidae*, in accordance with Article 73(1) or (2) or Article 74 of Regulation (EU) 2019/2035;
 - (ii) the marking applied to the straws or other packages in accordance with Article 11;
 - (iii) the place and date of their collection or production;
 - (g) the number on the seal applied to the transport container;
 - (h) the information on the animal health situation, additional guarantees and, where necessary, test results in relation to:
 - (i) the Member State or zone thereof;
 - (ii) the establishment of origin of the donor animals;
 - (iii) the donor animals from which germinal products were collected;
 - (iv) the germinal products to be dispatched;
 - (i) the date and place of issue of the animal health certificate, the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.
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COMMISSION DELEGATED REGULATION (EU) 2020/687**of 17 December 2019****supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (the 'Animal Health Law') ⁽¹⁾, and in particular Article 47(1), Article 53(2), Article 54(3), Article 55(2), Article 58(2), the first paragraph of Article 63, Article 64(4), the first paragraph of Article 67, Article 68(3), Article 70(3), Article 72(2), Article 73(3), Article 74(4), Article 76(5), Article 77(2) and Article 272(2) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans, including rules on disease awareness, preparedness and control. In particular, Regulation (EU) 2016/429 lays down disease-specific rules for the prevention and control of diseases referred to in its Article 5. Regulation (EU) 2016/429 also provides that those disease-specific rules apply to species and groups of animal species that pose a considerable risk for the spread of specific diseases and which are listed as such in Commission Implementing Regulation (EU) 2018/1882 ⁽²⁾.
- (2) It is necessary to lay down rules supplementing the rules on disease control measures set out in Title II of Part III of Regulation (EU) 2016/429 for certain listed diseases. Those supplementing rules and the rules set out in Regulation (EU) 2016/429 are closely linked and should be applied in tandem. In the interest of simplicity, transparency and ease of application, the supplementing rules should be laid down in a single act rather than in a number of separate acts with many cross-references and risks of duplication.
- (3) Article 53, Article 54(3), Article 55(2), Article 58(2), and Articles 63, 64, 67, 68 and 70 in Chapter 1 of Title II of Regulation (EU) 2016/429 relate to various technical aspects of the measures to be taken if there is suspicion and confirmation of diseases referred to in Article 9(1)(a) of that Regulation. Similarly, Article 72(2), Article 73(3), Article 74(4), Article 76(5) and Article 77 in Chapter 2 of Title II of Regulation (EU) 2016/429 relate to technical aspects of the measures to be taken if there is suspicion and confirmation of diseases referred to in Article 9(1)(b) and (c) of that Regulation.
- (4) The rules to be laid down pursuant to Articles in Title II are interrelated as they apply to disease control measures for different categories of listed diseases in Regulation (EU) 2016/429. Therefore, for the effective application of those rules and in the interests of clarity, they should be laid down in a single delegated act providing a comprehensive set of technical measures for the control of listed diseases and contributing to the overall simplification of the legal framework on animal disease control.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

- (5) Previous disease control provisions were laid down in a number of directives, each of which contained rules for one or few animal diseases. Some of those rules have been replaced by Regulation (EU) 2016/429, while others need to be replaced by this Delegated Regulation in order to simplify and remove possible inconsistencies. This will provide clear, harmonised and detailed rules to control animal diseases throughout the Union. This will also enable the application of the relevant provisions by competent authorities and operators, and will increase the transparency of the rules and therefore will ensure a better response to animal disease risks.
- (6) To eradicate an outbreak of a category A disease as soon as possible and to ensure a high level of animal health and animal welfare protection, it is necessary to provide for disease control measures at Union level.
- (7) The scope of this Regulation should therefore include disease control measures for category A diseases in terrestrial and aquatic animals, as well as certain disease control measures for category B and C diseases. In the case of category B and C diseases, those disease control measures should be applied in conjunction with the rules on surveillance and eradication set out in Commission Delegated Regulation (EU) 2020/689 ⁽³⁾.
- (8) The disease control measures set out in this Delegated Regulation should apply to animals and to products obtained from animals, including products of animal origin, germinal products, animal by-products and derived products. These animal by-products are subject to public and animal health rules set out in Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽⁴⁾. The rules for safe collection, disposal and processing of animal by-products and derived products laid down in that Regulation apply in the event of the onset of a category A disease. However, that Regulation does not include disease control measures and restrictions intended to apply in such events. Therefore, those rules should be provided for in this Delegated Regulation.
- (9) Directive 2008/68/EC of the European Parliament and of the Council ⁽⁵⁾ lays down rules for the safe transport of dangerous goods. When transporting infected animal by-products or other infected material which may be considered as dangerous goods, competent authorities should comply with the rules laid down in that Directive.
- (10) It is appropriate to follow a single approach for the measures to apply in the event of a category A disease. However, the epidemiology of diseases should be taken into account to establish the appropriate moment for the competent authority to apply control measures and to carry out investigations if there is suspicion or confirmation of those diseases. Therefore 'monitoring periods' should be provided, as reference time frames for each category A disease affecting terrestrial animals based on incubation periods and other relevant elements that may affect the spread of the disease.
- (11) Article 54 of Regulation (EU) 2016/429 requires the competent authority to carry out investigations on the occurrence of a category A disease at different stages: (i) when the disease is suspected; (ii) when the disease is confirmed; and (iii) when it is necessary to rule out its spreading to epidemiologically linked establishments and locations as well as neighbouring establishments and zones. Those investigations include clinical examination and sampling for laboratory testing. It is appropriate to lay down general rules on sampling in order to ensure the validity of sampling procedures, diagnostic methods and biosecurity measures.
- (12) Article 43 of Regulation (EU) 2016/429 requires the competent authority to draw up and update contingency plans and, where necessary, provide detailed instruction manuals on implementing of measures to be taken in case of a category A disease as provided for in Part III of that Regulation. The measures set out in this Delegated Regulation supplement those laid down in Part III of Regulation (EU) 2016/429 and it is therefore necessary that they be implemented in accordance with the contingency plans provided for in Regulation (EU) 2016/429.

⁽³⁾ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (see page 211 of this Official Journal).

⁽⁴⁾ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 ('Animal by-products Regulation') (OJ L 300, 14.11.2009, p. 1).

⁽⁵⁾ Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

- (13) Articles 53 and 55 of Regulation (EU) 2016/429 lay down obligations on operators and competent authorities in the case of a suspicion of a category A disease. The aim is to prevent the spread of the disease from affected animals and establishments under their responsibility to unaffected animals or to humans even before the disease has been confirmed. The disease control and biosecurity measures provided for in Regulation (EU) 2016/429 should be applied at this early stage in the affected establishment as regards movements of animals and products from and to that establishment and its surroundings. It is also necessary to detail those measures in order to ensure their effectiveness and proportionality.
- (14) Article 54 of Regulation (EU) 2016/429 requires the competent authority to conduct an official investigation if there is a suspicion of a category A disease, to either confirm or rule out the presence of the disease. In order to establish a standard operating procedure for such official investigations in all Member States, it is necessary to detail the circumstances which justify the conduct of an investigation, the minimum investigation tasks to be performed by official veterinarians and the way those tasks should be carried out.
- (15) Regulation (EU) 2016/429 requires that, if there is a suspicion or confirmation of a category A disease, disease control measures be applied not only in establishments keeping animals but also in food and feed businesses, in animal by-products establishments or in other locations that may pose a risk of spreading of diseases. It is necessary to specify which control measures apply in those cases, in particular in the case of border control posts and means of transport.
- (16) Regulation (EU) 2016/429 requires that the confirmation of a category A disease is the starting point for the competent authority to implement stricter disease control measures than those applied in the suspicion phase and to carry out further investigations. It is therefore necessary to specify when a category A disease should be considered confirmed. This confirmation should be done in accordance with Union acts adopted pursuant to Regulation (EU) 2016/429 on surveillance of diseases, eradication programmes and disease-free status.
- (17) Regulation (EU) 2016/429 lays down the basic rules on the disease control measures to apply in the affected establishments in the event of an outbreak of a category A disease. At the same time, it provides competent authorities with a certain flexibility in deciding which of those measures should apply. In order to allow competent authorities to take the most proportionate and efficient control measures and ensure a harmonised implementation of the measures taken by Member States, it is appropriate to establish detailed decision making criteria based on epidemiological circumstances, type and location of establishments, species and categories of animals and economic or social conditions of the area affected by the disease.
- (18) The competent authority should have the possibility to grant, in justified cases and under supplementary guarantees if necessary, derogations from certain disease control measures, in particular from the requirement to kill the animals in the affected establishment, taking into account epidemiological factors and after carrying out an accurate risk assessment. Such derogations could be granted for confined establishments, for animals kept for scientific purposes or for purposes related to conservation of protected or endangered species and for officially registered rare breeds or for animals with a justified high genetic, cultural or educational value. In such cases, the application of general measures could have undesirable and disproportioned consequences.
- (19) In order to adapt the disease control measures to each specific situation, the competent authority should have the possibility to apply disease control measures that are not specifically provided for in Regulation (EU) 2016/429 or in this Delegated Regulation, taking into consideration epidemiological factors and after carrying out a risk assessment.
- (20) Cleaning and disinfection in the affected establishment is one of the basic disease control measures provided for in Regulation (EU) 2016/429 to minimise the risk of spreading a confirmed category A disease. Preliminary cleaning and disinfection are the most effective measures to reduce the disease agent load in the affected establishment once the affected animals have been taken off. The competent authority should therefore have the obligation to check the performance of the immediate preliminary cleaning and disinfection and, when necessary, the control of insects and rodents. It is appropriate to detail the cleaning and disinfection procedure, specifying when it must be initiated and the criteria for selecting the biocidal products to be used.

- (21) Article 62 of Regulation (EU) 2016/429 requires the competent authority to extend the disease control measures applied in the affected establishments to other establishments, epidemiological units therein, food and feed businesses, or animal by-products establishments or any other location of relevance, including means of transport, where epidemiological evidences give reason to suspect the spread of the category A disease to, from or through them. It is necessary to specify the traceability investigation which the competent authority must perform, under the epidemiological enquiry provided for in Regulation (EU) 2016/429, in order to properly identify those epidemiological links.
- (22) It is also appropriate to detail the control measures to apply in identified linked establishments and locations. In order to be effective, those measures should be flexible and proportionate, without imposing unnecessary burdens on operators or competent authorities. The competent authorities should consequently be allowed to derogate from general provisions in exceptional circumstances, after carrying out a risk assessment.
- (23) Article 64 of Regulation (EU) 2016/429 requires competent authorities to establish a restricted zone around the affected establishment when an outbreak of a category A disease is confirmed, in order to prevent any further spread of the disease. The restricted zone may include a protection zone and a surveillance zone. It is appropriate to set supplementary rules on how to establish and modify, if necessary, the restricted zone, including details on the protection zone, on the surveillance zone and on the possibility to establish further restricted zones depending on the epidemiology of the disease. It is also appropriate to provide for specific derogations for those cases where the establishment of restricted zones would not contribute to control the spreading of the disease or would impose an unjustified burden on operators and competent authorities.
- (24) Article 65 of Regulation (EU) 2016/429 lists the measures that the competent authority may take in the restricted zone to prevent the spreading of the disease. In order to allow competent authorities to take the most proportionate and efficient control measures and ensure a harmonised implementation of the measures in all Member States, it is appropriate to establish detailed decision making criteria based on epidemiological circumstances, type and location of production establishments, species and categories of animals and economic or social conditions of the area affected by the disease.
- (25) It is necessary to specify the prohibitions of movements of animals and products within, from or through the protection and surveillance zone and the prohibitions of other activities that can pose a risk of spreading a category A disease. Those prohibitions should be proportional to the risk of spreading the disease linked to each activity and commodity. Consequently, they need to be established taking into account the epidemiological disease profile. This is especially important in respect of prohibitions concerning products since there are certain products that should be exempted, in particular those considered safe commodities in relation to the risk of spreading certain diseases.
- (26) The prohibitions of activities in the restricted zone should be limited as far as possible. For that reason, there should be the possibility for the competent authority to grant derogations from the prohibitions when certain risk-mitigating measures are taken and certain procedural conditions are met. Such derogations may be granted, in particular, when the competent authority can check the reinforcement of biosecurity measures and when general and specific conditions, related to the relevant animals, products obtained from those animals, or other substances and materials that may be contaminated, are fulfilled.
- (27) Movements of ungulates should be limited to transports to a slaughterhouse. Poultry movements should be limited to the transport to slaughterhouses and to younger animals such as day-old-chicks and ready-to-lay poultry. Movements of products of animal origin should be allowed if the products have been produced before the high-risk period determined for the disease. Movements of products of animal origin and by-products produced within or after the high risk period should be allowed if the products have been subjected to specific treatments that inactivate the disease agent. Those treatments should be in line with existing Union legislation, international standards and new scientific evidence.
- (28) The competent authority should be able to visit establishments and to examine animals. To prevent the further spread of the disease, requirements should be set and be met before the measures applying to the protection zone can be lifted. Once those measures are lifted, the measures applying to the surveillance zone should be implemented, for an additional period, in the area previously covered by the protection zone, to ensure that the disease is controlled.

- (29) The provisions on control measures applicable within the surveillance zone should include general and specific rules for animals, products obtained from those animals, or other substances and materials that may be contaminated. They should also include derogations to allow a proportional application of the control measures. The intensity of the control measures and the derogations for their proportional application should reflect the lower risk that the surveillance zone poses for the spread of the disease but should ensure that the control measures are sufficient to avoid any risk of a further spread of the disease.
- (30) The competent authority should: (i) authorise the repopulation of the affected establishments with animals; (ii) ensure that a final cleaning and disinfection of the establishment is carried out; and, if relevant, (iii) carry out a check for vectors to ensure that diseases do not reappear. The competent authority should have the flexibility needed to decide on the most appropriate repopulation measures taking into account epidemiological circumstances and specific risk mitigation conditions.
- (31) Wild animals of listed species could also be affected by category A diseases. Control measures for those wild animals are essential in preventing the spread of the diseases and in ensuring their eradication. As for diseases occurring in kept animals, the competent authority should consider control measures for diseases in wild animals as part of the contingency plans provided for by the Regulation (EU) 2016/429. The control measures should apply to suspected and confirmed cases of a disease affecting wild animals within an infected zone. Measures restricting the movement of kept animals that are listed species from the infected zone should be applied with flexibility in mind, based on the epidemiological situation. This is to ensure robust control measures while avoiding unnecessary burdens for operators and competent authorities.
- (32) The collection and safe disposal of dead bodies of wild animals contributes to preventing the spread of category A diseases. It is appropriate to supplement Regulation (EU) 2016/429 with rules ensuring the safe collection and disposal of animal by-products from wild terrestrial and aquatic animals affected by category A diseases or subject to restriction measures imposed in response to those diseases in line with Regulation (EC) No 1069/2009.
- (33) Article 43 of Regulation (EU) 2016/429 requires the competent authority to establish an operational expert group as part of the contingency plans. These plans are designed to ensure a high level of disease awareness and preparedness and to provide a rapid response in case of an outbreak of a category A disease. The main task of the operational expert group in the case of an outbreak of diseases in terrestrial animals is to support the competent authority assessing the relevant measures for the control or eradication of the disease. The operational expert group for diseases in wild terrestrial animals should be multidisciplinary and have representatives of relevant government departments such as environmental and forests authorities, as well as stakeholders concerned, local authorities, police or other organisations that can provide advice to the competent authority on possible actions and their implementation to control or eradicate the category A disease.
- (34) Council Directive 2006/88/EC ⁽⁶⁾ includes provisions on animal health requirements for aquaculture animals and products and on the prevention and control of certain diseases in aquatic animals. The provisions in this Delegated Regulation should be based on the provisions from previous Union legislation that have worked well and have been revised and aligned, as far as possible, with the knowledge and experience gained in the past, and updated in accordance with new evidence and international standards.
- (35) Article 61 of Regulation (EU) 2016/429 provides for the application of disease control measures in establishments and other locations upon confirmation of category A diseases. One of those measures is the killing of animals that may be contaminated or may contribute to the spread of the disease. The possibility to apply such preventive killing should be detailed in this Delegated Regulation as a disease control measure aimed at reducing the infective pressure of a category A disease and to facilitate its control.
- (36) Article 62 of Regulation (EU) 2016/429 includes criteria for extending the disease control measures applied in an affected establishment to epidemiologically linked establishments and locations. The analysis of the hydrodynamic and topographic conditions, including data from water catchments, barriers in watercourses or water flow conditions, allows predicting the possible passive spread of a category A disease to other establishments or locations and this prediction may contribute to minimise the impact of a category A disease. The result of such an analysis permits the implementation of better-informed disease control measures, which should avoid or minimise the spread of a category A disease from a high-risk to a disease free area.

⁽⁶⁾ Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

- (37) The competent authority should be able to derogate from restrictions applicable upon confirmation of a category A disease in order to allow the use of aquaculture animals for human consumption, provided they do not show clinical signs of the disease and are processed in a way that reduces the risk of spreading the disease by infective material. The derogation should be aimed at reducing economic losses while minimising the risk of the disease spreading.
- (38) Article 37 of Regulation (EU) 2016/429 provides for the recognition of a disease-free status of compartments for listed diseases. Compartments include different establishments with common and efficient biosecurity systems permitting those establishments to have a distinct animal health status. Therefore, if a category A disease is suspected or confirmed in an aquaculture establishment within a compartment, the disease control measures should be extended to other establishments within that compartment resulting in a more efficient control of the disease.
- (39) Fallowing for aquatic animals is a disease control measure already included in previous Union legislation on prevention and control of diseases in aquaculture animals and should continue to be applied. The main objective of fallowing is to prevent or minimise the risk of re-infection of establishments with the category A disease, after cleaning and disinfection has been completed, and before introducing a new population of aquatic animals. Synchronous fallowing in areas with multiple infected establishments strengthens the disease control measures and contributes to a higher success rate. Different fallowing periods should be established for different category A diseases to reduce the fallowing time to a minimum while ensuring the effectiveness of this disease control measure.
- (40) When an aquaculture establishment has been affected by a category A disease which does not pose a risk to human health, the placing on the market of products from that establishment should be allowed after risk-mitigating measures have been taken. For fish, those measures should include slaughtering and evisceration. Crustaceans should be processed to non-viable products before they are dispatched. The products should be used for direct human consumption or undergo further processing in an establishment approved under Article 179 of Regulation (EU) 2016/429. Those measures are effective in controlling and avoiding the further spread of the disease while allowing those products to be used for human consumption rather than unnecessarily wasted.
- (41) Article 64 of Regulation (EU) 2016/429 provides that, when a category A disease breaks out in aquatic animals, restricted zones be established as an effective measure to control the disease. Restricted zones may include a protection zone around establishments that have an increased risk of being affected by a category A disease. To ensure an effective disease control and to prevent the further spread of the disease, the introduction of aquaculture animals for farming in establishments located in the protection zone should be prohibited. To avoid re-infection, the protection zone should be maintained until the infected aquaculture establishments are emptied of animals, cleaned and disinfected and the fallowing period has been completed.
- (42) Control measures applied in a protection zone established for disease in aquatic animals should be lifted only if a series of conditions are met. Those conditions should include depopulation, cleaning, disinfection and fallowing of the affected establishments. Furthermore, the results of regular visits carried out in all establishments located in the protection zone must be satisfactory. When all those conditions are met, the protection zone should become a surveillance zone. That surveillance zone should be maintained until the surveillance period for the relevant category A disease has elapsed and there are no elements to suspect the presence of the disease.
- (43) Article 43 of Regulation (EU) 2016/429 requires the competent authority to establish an operational expert group as part of the contingency plans designed to ensure a high level of disease awareness and preparedness and to provide a rapid response in case of an outbreak of a category A disease. The main task of the operational expert group in the case of an outbreak of diseases in aquatic animals is to support the competent authority in assessing the relevant measures for the control or eradication of the disease. The operational expert group for diseases in wild aquatic animals should be multidisciplinary and include representatives of government departments such as environmental and fisheries authorities, as well as stakeholders concerned, local authorities, police or other organisations that can provide advice to the competent authority on possible actions to control or eradicate the category A disease.
- (44) Article 6 of Regulation (EC) No 1069/2009 provides for the implementation of general health restrictions in the case of a serious transmissible disease. When a category A disease is present in aquaculture animals, the competent authority may impose stricter rules for animal by-products originating from certain establishments. Those rules are intended to deal with situations where public health restrictions may not address the animal health risk. It is necessary, in particular, that animal by-products from such establishments must be processed or disposed of as category 2 material in compliance with Article 13 of Regulation (EC) No 1069/2009.

- (45) Article 270 of Regulation (EU) 2016/429 repealed Council Directives 92/66/EEC ⁽⁷⁾, 2001/89/EC ⁽⁸⁾, 2002/60/EC ⁽⁹⁾, 2003/85/EC ⁽¹⁰⁾ and 2005/94/EC ⁽¹¹⁾, which contained rules for the control of animal diseases. Article 272 of Regulation (EU) 2016/429 provides that the repealed Directives continue to apply for three years after the date of application of that Regulation or an earlier date to be determined by the Commission in a delegated act. In order to ensure a harmonised and simplified approach across species and diseases, this Regulation should apply from the date of application of Regulation (EU) 2016/429 and the repealed Directives should cease to apply from the same date,

HAS ADOPTED THIS REGULATION:

PART I

GENERAL PROVISIONS

Article 1

Subject matter and scope

This Regulation supplements the rules on disease awareness, preparedness and control to be applied with regard to the listed diseases referred to in Article 9(1)(a), (b) and (c) of Regulation (EU) 2016/429.

Those rules cover the following:

- (a) Part II covers kept and wild terrestrial animals, and in particular:
- (i) Chapter I lays down supplementing rules on disease control measures in the event of suspicion and official confirmation of a category A disease in kept animals as referred to in Articles 53, 54, 55, 58 and 63 of Regulation (EU) 2016/429;
 - (ii) Chapter II lays down supplementing rules regarding the establishment of restricted zones in the event of official confirmation of a category A disease in kept animals as referred to in Article 64 and 67 of Regulation (EU) 2016/429;
 - (iii) Chapter III lays down supplementing rules regarding the repopulation of the restricted zone with kept animals in the event of official confirmation of a category A disease as referred to in Articles 63 and 68 of Regulation (EU) 2016/429;
 - (iv) Chapter IV lays down supplementing rules regarding disease control measures in the event of suspicion and official confirmation of a category A disease in wild animals as referred to in Article 70 of Regulation (EU) 2016/429;
 - (v) Chapter V lays down supplementing rules on disease control measures in the event of suspicion and official confirmation of category B and C diseases in terrestrial animals as referred to in Article 74 and 77 of Regulation (EU) 2016/429;
- (b) Part III covers kept and wild aquatic animals, and in particular:
- (i) Chapter I lays down supplementing rules on disease control measures in the event of suspicion and official confirmation of a category A disease in aquatic animals as referred to in Articles 53, 54, 55, 58 and 63 of Regulation (EU) 2016/429;

⁽⁷⁾ Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease (OJ L 260, 5.9.1992, p. 1).

⁽⁸⁾ Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (OJ L 316, 1.12.2001, p. 5).

⁽⁹⁾ Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever (OJ L 192, 20.7.2002, p. 27).

⁽¹⁰⁾ Council Directive 2003/85/EC of 29 of September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1).

⁽¹¹⁾ Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16).

- (ii) Chapter II lays down supplementing rules regarding the establishment of restricted zones in the event of official confirmation of a category A disease in aquaculture animals as referred to in Article 64 and 67 of Regulation (EU) 2016/429;
 - (iii) Chapter III lays down supplementing rules regarding disease control measures in the event of suspicion and official confirmation of a category A disease in wild aquatic animals as referred to in Article 70 of Regulation (EU) 2016/429;
 - (iv) Chapter IV lays down supplementing rules on disease control measures in the event of suspicion and official confirmation of category B and C diseases in aquatic animals as referred to in Article 74 and 77 of Regulation (EU) 2016/429;
- (c) Part IV covers final provisions.

Article 2

Definitions

For the purposes of this Regulation, definitions laid down in Regulation (EU) 2018/1882 and Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽¹²⁾ shall apply, except where those definitions cover terms that are defined in the second paragraph of this Article.

In addition, the following definitions shall also apply:

- (1) 'means of transport' means road or rail vehicle, vessels and aircrafts;
- (2) 'day-old chicks' means poultry less than 72 hours old;
- (3) 'semen' means the ejaculate of an animal or animals, either in the unaltered state or prepared or diluted;
- (4) 'oocytes' means the haploid stages of the ootidogenesis including secondary oocytes and ova;
- (5) 'embryo' means the initial stage of development of an animal while it is capable of being transferred to a recipient dam;
- (6) 'fresh meat' means meat, minced meat and meat preparations, including vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any process other than chilling, freezing or quick-freezing;
- (7) 'carcass of an ungulate' means the whole body of a slaughtered or killed ungulate after:
 - bleeding, in the case of slaughtered animals,
 - evisceration,
 - removal of the limbs at the carpus and tarsus,
 - removal of the tail, the udder, the head and the skin, except in porcine animals;
- (8) 'offal' means fresh meat other than that of the carcass as defined in (7), even if it remains naturally connected to the carcass;
- (9) 'meat products' means processed products, including treated stomachs, bladders, intestines, rendered fats, meat extracts and blood products, resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat;
- (10) 'casings' means the bladders and intestines that after cleaning have been processed by tissue scraping, defatting and washing and have been dried after salting;
- (11) 'colostrum' means the fluid secreted by the mammary glands of kept animals up to five days post parturition that is rich in antibodies and minerals, and precedes the production of raw milk.
- (12) 'colostrum-based products' means processed products resulting from the processing of colostrum or from the further processing of such processed products;
- (13) 'safe commodity' means a commodity that can be moved without the need for risk mitigation measures specifically directed against a particular listed disease regardless of the status of the Member State or zone of origin for that disease;

⁽¹²⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

- (14) 'supply chain' means an integrated production chain of a common health status as regards listed diseases consisting of a collaborative network of specialised establishments approved by the competent authority for the purpose of Article 45, between which animals are moved to complete the production cycle;
- (15) 'infected zone' means a zone in which restrictions on the movements of kept and wild animals or products and other disease control and biosecurity measures may be applied with the view to preventing the spread of a category A disease in the event of official confirmation of the disease in wild animals.

Article 3

Clinical examinations, sampling procedures and diagnostic methods

1. Where clinical examinations of animals are required pursuant to this Regulation in order to confirm or rule out the presence of a category A disease, the competent authority shall ensure that:

- (a) the sampling of animals for clinical examination is carried out in accordance with:
 - (i) point A.1 of Annex I for terrestrial animals; and
 - (ii) point 1 of Annex XII for aquatic animals;
- (b) the clinical examination comprises:
 - (i) an initial general evaluation of the animal health status of the establishment which comprises all the animals of listed species kept in the establishment; and
 - (ii) an individual examination of the animals included in the sample referred to in point (a).

2. Where laboratory examinations are required pursuant to this Regulation in order to confirm or rule out the presence of a category A disease, the competent authority shall ensure that:

- (a) the sampling of animals for laboratory examination is carried out in accordance with:
 - (i) point A.2 of Annex I for terrestrial animals; and
 - (ii) point 1(b), (c), (d) and (e) of Annex XII for aquatic animals;
- (b) the diagnostic methods for laboratory examinations fulfil the requirements set out in:
 - (i) point B of Annex I for terrestrial animals; and
 - (ii) point 2 of Annex XII for aquatic animals;
- (c) the samples are sent:
 - (i) without delay to an official laboratory designated in accordance with Article 37 of Regulation (EU) 2017/625 of the European Parliament and of the Council ⁽¹³⁾;
 - (ii) in accordance with point C of Annex I for terrestrial animals and point 1(f) of Annex XII for aquatic animals; and
 - (iii) following any other instruction from the competent authority and from the laboratory regarding biosecurity and biosafety conditions to prevent the spread of category A disease agents;
- (d) in the case of kept animals:
 - (i) an inventory of all kept animals on the establishment and their species and categories is compiled; for poultry and aquaculture animals the number of animals may be estimated; and
 - (ii) an identification mark of each sampled animal of listed species, or in the case of poultry and aquaculture animals the batch number, is recorded.

⁽¹³⁾ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (OJ L 95, 7.4.2017, p. 1).

*Article 4***Contingency plans**

The competent authority shall implement the measures laid down in this Regulation in accordance with the contingency plan referred to in Article 43 of Regulation (EU) 2016/429.

PART II

TERRESTRIAL ANIMALS

CHAPTER I

Disease control measures for category A diseases in kept terrestrial animals

Section 1

Preliminary disease control measures in the event of suspicion of a category A disease in kept animals*Article 5***Obligations on operators in the event of suspicion of a category A disease in kept animals in an establishment**

In the event of suspicion of a category A disease in kept animals, operators shall take the following disease control measures in order to prevent the spread of the category A disease from the affected animals and establishments under their responsibility to other unaffected animals or to humans until the competent authority rules out the presence of the category A disease:

- (a) isolate all animals suspected of being infected with the category A disease;
- (b) keep the manure, including litter and used bedding, and any product, material or substance likely to be contaminated with and to transmit category A diseases isolated and protected from insects and rodents, kept animals of non-listed species and wild animals to the extent technically and practically feasible;
- (c) implement the appropriate additional biosecurity measures to avoid any risk of spread of the category A disease;
- (d) cease all movements of kept animals of listed species from or to the establishment;
- (e) prevent non-essential movements of animals of non-listed species, products, materials, substances, persons and means of transport from or to the establishment;
- (f) ensure that production, health and traceability records of the establishment are updated;
- (g) provide the competent authority, on its request, with any relevant information regarding the category A disease; and
- (h) follow any instructions given by the competent authority regarding the control of the category A disease, in accordance with Regulation (EU) 2016/429 and this Regulation.

*Article 6***Investigation by the competent authority in the event of suspicion of a category A disease in kept animals in an establishment**

1. In the event of suspicion of a category A disease in kept animals in an establishment, in accordance with Article 9(1), (3) and (4) of Delegated Regulation (EU) 2020/689, the competent authority shall immediately conduct an investigation to confirm or rule out the presence of the suspected listed disease.

2. In the course of the investigation referred to in paragraph 1 the competent authority shall ensure that official veterinarians perform at least:

- (a) clinical examinations of kept animals of listed species at the establishment; and
- (b) collection of samples for laboratory examinations.

Article 7

Preliminary restriction and biosecurity measures in the event of suspicion of a category A disease in kept animals in an establishment

1. In the event of suspicion of a category A disease in an establishment, the competent authority shall place the establishment under official surveillance and immediately impose the following preliminary restriction and biosecurity measures, in order to prevent the spread of the category A disease from the affected animals and the establishment to other unaffected animals or to humans:

- (a) prohibition of movements of kept animals of listed species into and from the establishment;
- (b) prohibition of movements of kept animals of non-listed species into and from the establishment;
- (c) prohibition of movements of any product, material or substance likely to be contaminated with or likely to transmit category A diseases from the establishment;
- (d) isolation of kept animals of listed species and protection from wild animals, animals of non-listed species and, when necessary, from insects and rodents;
- (e) prohibition of killing of animals of listed species, unless authorised by the competent authority; and
- (f) prohibition of non-essential movements of products, materials, substances, persons and means of transport into the establishments.

2. By way of derogation from point 1(a), (b) and (c) the competent authority may authorise movements of animals and products from the establishment where a category A disease is suspected, after carrying out a risk assessment and provided that:

- (a) the movements of animals and products comply with all conditions and biosecurity measures necessary in order to avoid the spread of the disease;
- (b) in the establishment of destination there are not other kept animals of listed species; and
- (c) the establishment of destination is not a slaughterhouse.

3. Where derogations provided for in paragraph 2 are granted, the competent authority may impose the disease control measures provided for in paragraph 1 in the establishment of destination.

4. The competent authority may order preventive killing, in accordance with Article 12(1) and (2), of animals of listed species in the establishment where a category A disease is suspected when the epidemiological situation so requires.

5. All animal by-products from dead animals, which have died or have been killed in the establishment where a category A disease is suspected shall be processed or disposed of in accordance with Regulation (EC) No 1069/2009 to ensure that the suspected disease agent is inactivated and to prevent the spread of the disease to unaffected animals or to humans.

Article 8

Inventory and records analysis in the event of suspicion of a category A disease in kept animals in an establishment

1. In the event of suspicion of a category A disease, the competent authority shall order and verify that, without delay, operators of the establishments where a category A disease is suspected compile and maintain an up-to-date inventory of the following:

- (a) the species, categories and number of animals kept on the establishment; for poultry, the number of animals may be estimated;

- (b) the individual identification number of all the animals of species for which the individual identification is compulsory in accordance with Commission Delegated Regulation (EU) 2019/2035 ⁽¹⁴⁾;
 - (c) the species, categories and number of kept animals of listed species which have been born, died, showed clinical signs or are likely to be infected or contaminated with the category A disease in the establishment;
 - (d) any product, material or substance likely to be contaminated with or likely to transmit the relevant category A disease in the establishment; and
 - (e) when relevant, all places likely to enable the survival of the vectors of the relevant category A disease in the establishment.
2. Where the establishment consists of several epidemiological units, the information in paragraph 1 shall be specified for each epidemiological unit.
3. In the framework of the epidemiological enquiry, as referred to in Article 57 of Regulation (EU) 2016/429, the competent authority shall analyse at least the following records of the establishment where a category A disease is suspected:
- (a) the inventory referred to in paragraph 1;
 - (b) the records concerning the origin and date of arrival and departure at or from the establishment of kept animals of listed species;
 - (c) the records concerning the origin and date of arrival and departure at or from the establishment of other relevant transport movements;
 - (d) the production records; and
 - (e) the records concerning to visits to the establishment, if available.
4. The records analysis referred to in paragraph 3 shall cover, at least, the monitoring period set out in Annex II for the relevant disease, calculated backwards from the date on which the suspicion was notified.

Article 9

Temporary restricted zones in the event of suspicion of a category A disease in kept terrestrial animals in an establishment

1. In the event of suspicion of a category A disease in kept animals in an establishment, the competent authority may establish a temporary restricted zone taking into account the following circumstances:
- (a) the location of the establishment in an area with a high density of kept animals of listed species for which a category A disease is suspected;
 - (b) the movement of animals or persons in contact with kept animals of listed species for which a category A disease is suspected;
 - (c) the delay in confirming the category A disease pursuant to Article 11;
 - (d) the insufficient information on the possible origin and routes of introduction of the suspected category A disease; and
 - (e) the disease profile, in particular the routes and speed of transmission of the disease and the persistence of the disease in the animal population.
2. In the establishments within the temporary restricted zone the competent authority shall apply at least the measures provided for in Article 7.
3. The competent authority may maintain the temporary restricted zone until the moment that the presence of the category A disease has been ruled out in the establishment where it was suspected or the presence of that disease has been confirmed and a restricted zone is established pursuant to Article 21.

⁽¹⁴⁾ Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115).

4. The competent authority may order preventive killing, in accordance with Article 12(1) and (2), or slaughtering of animals of listed species, in the temporary restricted zones when the epidemiological situation so requires.

Article 10

Measures to apply in the event of suspicion of a category A disease in food and feed businesses, border control posts, animal by-products establishments or any other location of relevance, including means of transport

1. In the event of suspicion of a category A disease in accordance with Article 9(1), (3) and (4) of Delegated Regulation (EU) 2020/689 in food and feed businesses, border control posts, animal by-products establishments or any other location of relevance, including means of transport, the competent authority shall apply:

- (a) the relevant provisions laid down in Articles 5 to 9; and
- (b) if needed, additional measures adapted to the specific situation in order to prevent the spread of the category A disease to unaffected animals or to humans.

2. The competent authority shall also apply provisions laid down in Articles 5 to 9 in the establishments of origin of the animals or products present in the establishments and locations referred to in paragraph 1 which are suspected to be infected.

Section 2

Disease control measures in the event of the official confirmation of a category A disease in kept animals

Article 11

Official confirmation of a category A disease in kept terrestrial animals

The competent authority shall officially confirm an outbreak of a category A disease in kept terrestrial animals when a case is confirmed in accordance with Article 9(2), (3) and (4) of Delegated Regulation (EU) 2020/689.

Article 12

Disease control measures in the event of official confirmation of an outbreak of a category A disease in kept animals in an establishment

1. Following the official confirmation of an outbreak of a category A disease in an establishment in accordance with Article 11, the competent authority shall order that, in addition to measures provided for in Article 7, the following disease control measures are immediately applied under the supervision of official veterinarians:

- (a) all animals of listed species kept in the affected establishment shall be killed as soon as possible on the spot, within the establishment, in such a way as to avoid any risk of spreading the relevant category A disease agent during and after killing;
- (b) all appropriate and necessary biosecurity measures shall be taken to avoid any possible spread of the category A disease to unaffected kept or wild animals or to humans;
- (c) bodies or parts of kept animals of listed species which have died or which have been killed pursuant to point (a) of this paragraph shall be disposed of in accordance with Regulation (EC) No 1069/2009;
- (d) all potentially contaminated products, materials or substances present in the establishment shall be isolated until:
 - (i) they are disposed of or processed in accordance with Regulation (EC) No 1069/2009, in the case of animal by-products (including those resulting from the killing and products of animal origin and germinal products);
 - (ii) cleaning and disinfection measures are completed in accordance with the Article 15, in the case of other materials and substances fit for cleaning and disinfection;
 - (iii) disposal is completed under the supervision of official veterinarians, in the case of feeding stuff and other materials unfit for cleaning and disinfection.

2. The competent authority shall order and supervise that:
 - (a) the transport from the affected establishment of animal by-products referred to in paragraphs 1(c) and 1(d)(i) complies with the provisions of Regulation (EC) No 1069/2009;
 - (b) the transport from the affected establishment of materials or substances referred to in paragraph 1(d)(iii) complies with its instructions regarding biosecurity and biosafety conditions to prevent the spread of category A disease agent.
3. The competent authority shall collect samples for laboratory examination from kept animals of listed species, before or when they are killed or dead, for the purposes of the epidemiological enquiry referred to in Article 57 of Regulation (EU) 2016/429.
4. By way of derogation of point (a) of paragraph 1, the competent authority may, after carrying out a risk assessment and taking into account the possibility of applying other risk-mitigating measures, decide:
 - (a) to order the killing of kept animals of listed species at the nearest suitable place in such a way as to avoid any risk of spreading the category A disease during killing or transport; or
 - (b) postpone the killing of kept animals of listed species, provided that those animals are subject to emergency vaccination as provided for in Article 69 of Regulation (EU) 2016/429.

Article 13

Specific derogations from Article 12(1)(a)

1. In the event of an outbreak of a category A disease in establishments keeping animals of listed species in two or more epidemiological units, the competent authority may grant derogation from Article 12(1)(a) to the epidemiological units in which the disease has not been confirmed, after carrying out a risk assessment, and, when necessary, after obtaining favourable results in laboratory examinations, and provided that:
 - (a) the epidemiological enquiry referred to in Article 57 of Regulation (EU) 2016/429 has not revealed any epidemiological link between the epidemiological units in which the category A disease has been confirmed and those in which the disease has not been confirmed, to suspect the spread of the category A disease between them; and
 - (b) the competent authority has confirmed that, at least during the monitoring period, set out in Annex II for the relevant disease, before the confirmation of the category A disease, the epidemiological units in which the disease has not been confirmed were kept completely separated and handled by different personnel.
2. The competent authority may grant derogation from Article 12(1)(a) to the following categories of animals provided that the conditions in paragraph 3 are fulfilled:
 - (a) animals kept in a confined establishment;
 - (b) animals kept for scientific purposes or purposes related to conservation of protected or endangered species;
 - (c) animals officially registered in advance as rare breeds; and
 - (d) animals with a duly justified high genetic, cultural or educational value.
3. The competent authority shall ensure that the following conditions are fulfilled when granting the derogation provided for in paragraph 2:
 - (a) the competent authority has carried out an assessment of the effects of granting such derogation and, in particular, of the effects on the animal health status of the Member State concerned and of the adjacent countries and the outcome of this assessment indicated that the animal health status is not endangered;
 - (b) appropriate biosecurity measures are applied to prevent the risk of transmission of the category A disease to unaffected kept animals or to wild animals or to humans taking into account:
 - (i) the disease profile; and
 - (ii) the affected species of animals;

- (c) the animals are subject to appropriate isolation and clinical surveillance, including laboratory examinations, until the competent authority can ensure that the animals do not pose a risk of transmission of the category A disease.
4. The competent authority may grant specific derogations from Article 12(1)(a) to equine animals kept in establishments where an outbreak of the category A diseases referred to in Annex III has been confirmed under the conditions set out in that Annex.

Article 14

Additional disease control measures in the event of an outbreak of a category A disease in kept terrestrial animals in an establishment

1. The competent authority may establish, in addition to the measures provided for in Article 12, sampling procedures for kept animals of non-listed species and wild animals of listed species, based on the information obtained from the epidemiological enquiry referred to in Article 57 of the Regulation (EU) 2016/429.
2. The competent authority may, after carrying out a risk assessment of the further spread of the relevant category A disease and taking into account the possibility of applying other risk-mitigating measures, order the killing of kept animals of non-listed species and wild animals in such a way as to avoid any risk of spreading the category A disease during killing, transport and until disposal of the entire bodies or parts of the dead animals.

Article 15

Preliminary cleaning and disinfection and control of insects and rodents in the affected establishment

1. Immediately after the completion of the measures provided for in Article 12, and when relevant in Article 14, the competent authority shall order and supervise a preliminary cleaning and disinfection and, when relevant, control of insects and rodents, in the affected establishment in order to avoid spreading of the category A disease.
2. The preliminary cleaning, disinfection and control referred to in paragraph 1 shall be:
 - (a) performed in accordance with the procedures set out in points A and B of Annex IV using the appropriate biocidal products to ensure destruction of the relevant category A disease agent; and
 - (b) adequately documented.
3. When the competent authority grants one of the derogations provided for in Article 13(2) and (4), it shall order the preliminary cleaning, disinfection and the control referred to in paragraph 1 adapting the procedures referred to in point 2(a) to the specific situation without detriment to the control of spreading of the category A disease from the affected animals and affected establishments and locations to other unaffected animals or to humans.
4. In addition to the measures referred to in paragraphs 1 and 2, the competent authority shall order and supervise that the means of transport used for the transport of animals to and from the affected establishment are properly cleaned and disinfected and, where relevant, subjected to measures ensuring the control of insects and rodents.

Article 16

Derogations and special rules for the preliminary cleaning and disinfection and control of vectors

The competent authority may grant derogation to the requirement regarding cleaning and disinfection and control of insects and rodents set out in Article 15 in the case of:

- (a) pastures epidemiologically linked to the affected establishment, under specific procedures to ensure effective inactivation of the relevant category A disease agent taking into account the disease profile, the type of establishment and the climatic conditions; and
- (b) manure, including litter and used bedding, from the affected establishment, under specific procedures to ensure effective inactivation of the relevant category A disease agent in accordance with scientific evidence.

*Article 17***Identification of epidemiologically linked establishments and other locations of relevance, including means of transport**

1. In the frame of the epidemiological enquiry, as referred to in Article 57 of the Regulation (EU) 2016/429, and in order to identify all the epidemiologically linked establishments and other locations of relevance, including means of transport, the competent authority shall trace all kept animals present in the establishment where an outbreak of a category A disease has been confirmed and any products, materials, substances, means of transport or people likely to spread the relevant category A disease including:

- (a) those dispatched into and from the establishment; and
- (b) those that have entered into contact with the establishment.

2. The tracing referred to in paragraph 1 shall cover at least the monitoring period, set out in Annex II for the relevant disease, calculated backwards from the date the suspicion was notified.

3. After carrying out a risk assessment, the competent authority may exclude from the tracing referred to in paragraph 1 those products considered as safe commodities, as provided for in Annex VII.

*Article 18***Measures to be applied in the epidemiologically linked establishments and other locations of relevance, including means of transport**

1. When the tracing provided for in Article 17(1) demonstrates that animals of listed species were dispatched from or to the affected establishment during the period referred to in paragraph 2 of that Article, the competent authority shall:

- (a) carry out investigations and impose restriction and biosecurity measures in accordance with Article 6, Article 7 and Article 8 in the establishments of destination or origin of the movement; or
- (b) immediately extend the measures in Article 12 to the establishment of origin or the establishment of destination of the movement in the case that there is epidemiological evidence of spreading of the disease to, from or through that establishment.

2. The competent authority shall apply the measures referred to in paragraph 1 in other establishments and locations of relevance, including means of transport, likely to be contaminated as a result of contact with animals, products, materials, substances, persons or means of transport from the affected establishment identified in the frame of the tracing referred to in Article 17 or based on any other relevant information from the epidemiological enquiry, as referred to in Article 57 of the Regulation (EU) 2016/429.

*Article 19***Measures to be applied to the products identified by the tracing**

1. The competent authority shall order and supervise that semen, oocytes and embryos identified as contaminated by the tracing referred to in Article 17 are disposed of in accordance with Regulation (EU) No 1069/2009.

2. The competent authority shall order and supervise the treatment, processing or disposing of the products identified by the tracing referred to in Article 17, at least up to:

- (a) the first food processing establishment in the case of products of animal origin;
- (b) the hatchery or the establishment where eggs were sent for hatching, in the case of hatching eggs which did not yet hatch; and
- (c) the first establishment of processing in the case of animal by products, except manure; or
- (d) the location where it is stored, in the case of manure, including litter and used bedding.

3. The competent authority shall establish official surveillance on poultry hatched during the tracing period referred to in Article 17(2) from hatching eggs originating from the affected establishment; this surveillance shall be established in all the establishments of destination of the hatching eggs and shall be maintained for a period of time of 21 days after hatching.
4. The competent authority shall order and supervise that the transport from the establishments of animal by-products is subject to the provisions laid down in Regulation (EC) No 1069/2009.
5. The competent authority shall order and supervise that materials or substances likely to be contaminated or likely to transmit the relevant category A disease comply with its instructions regarding biosecurity and biosafety conditions to prevent the spread of category A disease agent.

Article 20

Measures to be applied in the event of official confirmation of an outbreak of a category A disease in food and feed businesses, border control posts, animal by-products establishments and any other location of relevance, including means of transport

1. In the event of official confirmation of an outbreak in accordance with Article 11 in food and feed businesses, border control posts, animal by-products establishments or any other locations of relevance, including means of transport, the competent authority shall apply:
 - (a) the relevant provisions laid down in Articles 12 to 19; and
 - (b) if needed, additional measures adapted to the specific situation in order to prevent the spread of the category A disease from the affected animals and affected establishments and locations to other unaffected animals or to humans.
2. The competent authority shall apply provisions laid down in Articles 12 to 19 also in the establishments of origin of the affected animals or products present in the establishments and locations referred to in paragraph 1.

CHAPTER II

Disease control measures for category A diseases of kept terrestrial animals in the restricted zones

Section 1

General disease control measures in the restricted zone

Article 21

Establishment of a restricted zone

1. In the event of an outbreak of a category A disease in an establishment, food and feed business, animal by-products establishment or other locations, including means of transport, the competent authority shall immediately establish around the affected establishment or location a restricted zone, which comprises:
 - (a) a protection zone based on the minimum radius from the outbreak set out for the relevant category A disease in Annex V;
 - (b) a surveillance zone based on the minimum radius from the outbreak set out for the relevant category A disease in Annex V; and
 - (c) if necessary, on the basis of the criteria set out in paragraph 1 of Article 64 of Regulation (EU) 2016/429, further restricted zones around or adjacent to the protection and surveillance zones, where the competent authority shall apply the same measures as those provided for in Section 3 of this Chapter for the surveillance zone.
2. The competent authority shall adapt the boundaries of the initial restricted zone, including the boundaries of the protection, surveillance and the further restricted zones, in the case of the overlapping of two or more restricted zones due to further outbreaks of the category A disease.

3. By way of derogation of paragraph 1, and after carrying out a risk assessment taking into account the disease profile, the competent authority may not establish a restricted zone when an outbreak of a category A disease occurs in the following locations:

- (a) establishments keeping animals referred to Article 13(2);
- (b) hatcheries;
- (c) food and feed businesses, border control posts, animal by-products establishments;
- (d) means of transport;
- (e) locations where assembly operations or temporal exhibition or veterinary assistance of animals take place; and
- (f) any other location which is not an establishment.

Article 22

Measures to be applied in the restricted zone

1. The competent authority shall without delay compile and keep up to date an inventory of all establishments keeping animals of listed species located in the restricted zone including the species, categories and number of animals in each establishment; for poultry, the number of animals may be estimated.

2. The competent authority may, in order to prevent the spreading of the disease and based on epidemiological information or other evidence, implement preventive killing, in accordance with Article 12(1) and (2), or slaughtering of kept animals of listed species in the establishments located in the restricted zone.

3. The competent authority shall order and supervise that all movements of entire bodies or parts of dead wild and kept animals of listed species from the restricted zone are destined for processing or disposal in accordance with Regulation (EC) No 1069/2009 in a plant approved for those purposes:

- (a) within the territory of the Member State; or
- (b) in another Member State in accordance with Article 48(1) and (3) of Regulation (EC) No 1069/2009, where it is not feasible to process or dispose the entire bodies or parts of dead animals in an approved plant in the territory of the Member State where the outbreak occurred.

4. The competent authority shall impose specific conditions for the transport of animals and products through the restricted zone in order to ensure that they are performed:

- (a) without stopping or unloading in the restricted zone;
- (b) prioritising major highways or mainline railways; and
- (c) avoiding the vicinity of establishments keeping animals of listed species.

5. Animal by-products originating from and moved outside the restricted zone shall be accompanied by an animal health certificate issued by an official veterinarian stating that they are allowed to be moved from the restricted zone under the conditions established by the competent authority in accordance with this Chapter.

6. The competent authority may decide that the certificate referred to in paragraph 5 shall not be issued for movements of animal by-products within the Member State concerned when that authority considers that an alternative system is in place ensuring that consignments of such products are traceable and that products fulfil the animal health requirements for such movements.

7. Any collection of samples in the establishments in the restricted zone keeping animals of listed species for purposes other than to confirm or rule out the presence of the relevant category A diseases must be authorised by the competent authority.

*Article 23***Derogations from measures to be applied in the restricted zone**

The competent authority may grant derogations from the provisions set out in this Chapter concerning the measures to be applied in restricted zones, to the extent necessary and after carrying out a risk assessment:

- (a) in the further restricted zones referred to in Article 21(1)(c);
- (b) in the case that the competent authority decides to establish a restricted zone when an outbreak of a category A disease occurs in establishments and locations referred to in Article 21(3);
- (c) in the case that the outbreak occurs in an establishment keeping up to 50 captive birds; or
- (d) in establishments and locations referred to in Article 21(3) located in a restricted zone.

*Article 24***Requirements for the means of transport of kept animals of listed species and products thereof**

1. The competent authority shall ensure that the means of transport used for movements of kept animals of listed species and products thereof within, from, to and through the restricted zone have been:

- (a) constructed and maintained in such a way to avoid any leakage or escape of animals, products or any item representing an animal health risk;
- (b) cleaned and disinfected immediately after every transport of animals, products or any item representing an animal health risk and, if necessary, subsequently disinfected again, and in any case dried or allowed to dry, before any new loading of animals or products; and
- (c) where relevant, subjected to measures for the control of insects and rodents before the transport.

2. The cleaning and disinfection of the means of transport referred to in paragraph 1 shall be performed:

- (a) in accordance with the instructions or procedures provided for by the competent authority using the appropriate biocidal products to ensure the destruction of the relevant category A disease agent; and
- (b) adequately documented.

*Section 2***Disease control measures in the protection zone***Article 25***Measures to be applied in establishments keeping animals of listed species in the protection zone**

1. The competent authority shall order without delay the application of the following measures in establishments in the protection zone keeping animals of listed species, other than the establishment in which the category A disease has been confirmed:

- (a) to keep animals of listed species separate from wild animals and animals of non-listed species;
- (b) to implement additional surveillance in order to identify any further spread of the category A disease to the establishments, including any increased morbidity or mortality or significant drop in production data; any such increase or drop shall be immediately notified to the competent authority;
- (c) when appropriate, to implement adequate means of controlling insects and rodents and other disease vectors in and around the establishment;
- (d) to use appropriate means of disinfection at the entrances and exits of the establishment;

- (e) to apply appropriate biosecurity measures to all persons in contact with kept animals of listed species or entering or leaving the establishment as well as to means of transport in order to avoid any risk of spread of the relevant category A disease;
 - (f) to keep records of all persons visiting the establishment, maintain them up to date in order to facilitate disease surveillance and control and made them available to the competent authority upon request;
 - (g) to dispose entire bodies or parts of dead or killed kept animals of listed species according to Article 22(3).
2. By way of derogation of point (f) of paragraph 1 the records on visitors are not required in establishments where animals referred to in Article 13(2) are kept, if visitors have no access to the areas where the animals are kept.

Article 26

Visits by official veterinarians in establishments in the protection zone

1. The competent authority shall ensure that official veterinarians carry out at least one visit to all the establishments referred to in Article 25, as soon as possible and without unjustified delay, after the official confirmation of an outbreak of a category A disease.
2. When carrying out the visits referred to in paragraph 1, official veterinarians shall perform at least the following activities:
 - (a) documentary checks, including production, health and traceability records analysis;
 - (b) verification of the implementation of the measures applied to prevent the introduction or spread of the relevant category A disease in accordance with Article 25;
 - (c) clinical examination of kept animals of listed species; and
 - (d) if necessary, collection of samples of animals for laboratory examination in order to confirm or rule out the presence of the relevant category A disease.
3. The competent authority may require further veterinary visits to the establishments in the protection zone to follow up on the situation.
4. The competent authority shall keep a record of activities and visits referred to in paragraph 1, 2 and 3 and the findings thereof.
5. By way of derogation from paragraph 1, where the radius of the protection zone set in Annex V is larger than 3 km, the competent authority may decide to require not the visit to all the establishments referred to in Article 25 but the visit of a representative number of those establishments in accordance with point A.3 of Annex I.

Article 27

Prohibitions in relation to activities, including movements, concerning animals, products and other material within, from or to the protection zone

1. The competent authority shall prohibit the activities, including movements, concerning animals of listed species and their products and other materials within, from and to the protection zone in accordance with the table in Annex VI.
2. The competent authority may extend the prohibitions provided for in paragraph 1 to:
 - (a) animals of non-listed species and products from such animals; and
 - (b) activities, including movements, other than those set out in Annex VI.
3. The following products are exempted from prohibitions provided for in paragraphs 1 and 2:
 - (a) products of animal origin considered as safe commodities, in accordance with Annex VII, as regards the relevant disease;

- (b) products of animal origin which have undergone the relevant treatment in accordance with Annex VII;
 - (c) products or other materials likely to spread the disease obtained or produced before the monitoring period set out in Annex II for the relevant disease calculated backwards from the date on which the suspicion was notified;
 - (d) products produced in the protection zone which have been obtained from kept animals of listed species:
 - (i) kept outside the protection zone;
 - (ii) kept and slaughtered outside the protection zone; or
 - (iii) kept outside the protection zone and slaughtered in the protection zone;
 - (e) derived products.
4. Prohibitions provided for in paragraph 1 and 2 shall apply to products referred to in paragraph 3 if:
- (a) the products were not clearly separated, during the production process, storage and transport, from products not eligible for dispatch outside the restricted zone pursuant to this Regulation; or
 - (b) the competent authority has epidemiological evidences of spreading of the disease to, from or through those products.

Article 28

General conditions to grant derogations from prohibitions in the protection zone

1. By way of derogation from prohibitions provided for in Article 27, the competent authority may authorise movements of animals and products in the cases covered by Articles 29 to 38 and under the specific conditions provided for in those Articles and the general conditions laid down in paragraphs 2 to 7 of this Article.

Prior to granting the authorisation, the competent authority shall assess the risks deriving from that authorisation and the assessment must indicate that the risk of spreading the category A disease is negligible.

2. All authorised movements must be performed:

- (a) exclusively via designated routes,
- (b) prioritising major highways or mainline railways,
- (c) avoiding the vicinity of establishments keeping animals of listed species; and
- (d) without unloading or stopping, until the unloading in the establishment of destination.

3. The competent authority of the establishment of origin shall designate the establishment of destination for movements from or to the protection zone. If the competent authority of the establishment of origin is different from the competent authority of the establishment of destination, it shall inform the competent authority of the establishment of destination about such designation.

4. The competent authority of the establishment of origin shall verify that the establishment of destination agrees to be designated and to receive each consignment of animals or products.

5. When authorising movements of animals from the protection zone, the competent authority shall ensure that such movements do not pose a risk of spreading of the category A disease based on:

- (a) a clinical examination, with favourable results, of animals kept in the establishment, including those animals to be moved;
- (b) if necessary, a laboratory examination, with favourable results, of animals kept in the establishment, including those animals to be moved; and
- (c) the outcome of the visits referred to in Article 26.

6. When authorising the transport of products from the protection zone, the competent authority shall order and supervise that:

- (a) during the whole production process and their storage, products were clearly separated from products not eligible for dispatch outside the restricted zone in accordance with this Regulation; and
- (b) products will not be transported with products not eligible for dispatch outside the restricted zone pursuant to this Regulation.

7. When granting an authorisation pursuant to paragraph 1, the competent authority shall ensure that supplementary biosecurity measures are applied from the moment of loading, during all transport operations and until the unloading in the designated establishment of destination in accordance with its instructions.

Article 29

Specific conditions for authorising movements for slaughter of kept animals of listed species in the protection zone

1. The competent authority may authorise movements of kept animals of listed species from establishments located in the protection zone to a slaughterhouse located:

- (a) as near as possible to the establishment of origin, within the protection zone;
- (b) in the surveillance zone, when it is not possible to slaughter the animals in the protection zone; or
- (c) as near as possible to the surveillance zone when it is not possible to slaughter the animals in the restricted zone.

2. The competent authority shall only grant authorisations provided for in paragraph 1 under the following conditions:

- (a) the means of transport must be sealed at the moment of loading by the competent authority of dispatch or under its supervision;
- (b) the competent authority of the slaughterhouse shall:
 - (i) be informed in advance by the slaughterhouse operator of the intention to receive kept animals of listed species;
 - (ii) confirm the absence of any signs indicative of the category A disease during the *ante* and *post mortem* inspections;
 - (iii) supervise the slaughterhouse operator having effective procedures in place to ensure that kept animals of listed species originating in the protection zone are kept separately and slaughtered separately from such animals or at different times, preferably at the end of the working day of arrival;
 - (iv) confirm the slaughter of the animals to the competent authority of the establishment of origin of the animals;
 - (v) supervise the slaughterhouse operator cleaning and disinfecting the premises where the animals have been kept and slaughtered and the completion of the cleaning and disinfection is completed before other kept animals of listed species are kept or slaughtered in those premises; and
 - (vi) supervise the obtaining of meat from such animals complying with the conditions laid down in Article 33.

3. The competent authority may authorise movements of kept animals of listed species from establishments located outside the protection zone to a slaughterhouse located in the protection zone if:

- (a) the animals are kept separately from other animals originating from the protection zone and are slaughtered separately from those animals or at a different time;
- (b) the fresh meat obtained is cut, transported and stored separately from fresh meat obtained from animals originating in the protection zone; and
- (c) the cleaning and disinfection of the means of transport referred to in Article 24 takes place under official supervision after unloading the animals.

4. By way of derogation of Article 9 of Regulation (EC) No 1069/2009 the competent authority may authorise the processing and use of animal by-products, obtained from animals slaughtered in accordance with paragraphs 1, 2 and 3 as category 3 material in accordance with Regulation (EC) No 1069/2009 in a plant approved for processing or disposal of animal by-products, located on its territory, or in another Member State, where it is not feasible to process or dispose them in an approved plant in the territory of the Member State where the outbreak occurred.

In case the animal by-products referred to in the first subparagraph are moved to a plant located in another Member State, the Member State of destination and the Member States of passage shall authorise such dispatch and the competent authority of destination shall authorise the processing and use of those animal by-products as category 3 material in accordance with Regulation (EC) No 1069/2009.

Article 30

Specific conditions for authorising certain movements of poultry from establishments located in the protection zone

1. The competent authority may authorise movements of day-old-chicks from an establishment located in the protection zone to an establishment located in the same Member State but, if possible, outside the restricted zone, provided that:

- (a) in the case of day-old-chicks hatched from eggs originating in the restricted zone:
 - (i) the means of transport is sealed at the moment of loading by the competent authority or under its supervision;
 - (ii) the establishment of destination is placed under official surveillance by the official veterinarians following the arrival of the animals; and
 - (iii) if moved outside the restricted zone, the poultry remain in the establishment of destination at least for a period of 21 days.
- (b) in the case of day-old-chicks hatched from eggs originating outside the restricted zone, the hatchery of dispatch can ensure that no contact has occurred between those eggs and any other hatching eggs or day-old chicks originating in the restricted zone.

2. The competent authority may authorise movements of ready-to-lay poultry from establishments located in the protection zone to establishments located in the same Member State and, if possible, within the restricted zone, provided that:

- (a) in the establishment of destination there is no other kept animal of listed species;
- (b) the means of transport is sealed at the moment of loading by the competent authority or under its supervision;
- (c) the establishment of destination is placed under official surveillance by the official veterinarians following the arrival of the animals; and
- (d) if moved outside the restricted zone, the animals remain on the establishment of destination at least for a period of 21 days.

Article 31

Specific conditions for authorising certain movements of hatching eggs in the protection zone

1. The competent authority may authorise movements of hatching eggs either:

- (a) from an establishment located in the protection zone to a hatchery located in the same Member State; or
- (b) from an establishment located in the same member State to a hatchery located in the protection zone.

2. The authorisation provided for in paragraph 1(a) shall be subject to the following conditions:

- (a) the parent flocks from which the hatching eggs are derived have undergone a clinical examination and have been sampled for laboratory examination with favourable results;

- (b) the hatching eggs and their packaging are disinfected before dispatch and the tracing back of the hatching eggs can be ensured; and
 - (c) the hatching eggs must be transported in means of transport sealed by the competent authority.
3. The competent authority may authorise movements of hatching eggs from an establishment located in the protection zone to an establishment for in-house hatching located in the same Member State, if:
- (a) the parent flocks from which the hatching eggs are derived have undergone a clinical examination and have been sampled for laboratory examination with favourable results;
 - (b) the establishment of destination is placed under official supervision until 21 days following hatching of the eggs;
 - (c) the poultry must remain on the establishment of destination during the period referred to in (b); and
 - (d) the requirements referred to in paragraph 2(b) and (c) are complied with.

Article 32

Specific conditions for authorising movements of semen from approved germinal product establishments in the protection zone

The competent authority may authorise movements of semen collected from animals of listed species kept in approved germinal product establishments, excluding hatcheries, located in the protection zone after the estimated date of earliest infection of the affected establishment subject to the following conditions:

- (a) all the disease control measures relating to the category A disease have been lifted in the protection zone in accordance with Article 39;
- (b) all kept animals of listed species in the semen collection centre have undergone a clinical examination and have been sampled for laboratory examination in order to rule out the presence of the category A disease in the semen collection centre; and
- (c) the donor animal has been subjected with favourable result to a laboratory examination on a sample taken not earlier than seven days after the monitoring period set out in Annex II for the relevant disease, calculated forwards from the date on which the semen was collected.

Article 33

Specific conditions for authorising movements of fresh meat and raw milk obtained from kept animals of listed species from establishments in the protection zone

1. The competent authority may authorise movements of fresh meat and raw milk obtained from animals of listed species kept in establishments located in the protection zone if:
- (a) they are moved to a processing establishment to undergo one of the relevant risk-mitigating treatments set out in Annex VII; or
 - (b) in the case of fresh meat of poultry:
 - (i) it has been marked in accordance with paragraph 1 of Annex IX from the moment it was obtained in the slaughterhouse; and
 - (ii) it is not intended to another Member State.
2. The competent authority shall ensure that movements to a processing establishment referred to in paragraph 1(a) comply with the following conditions:
- (a) fresh meat must be marked in accordance with point 2 of Annex IX in the slaughterhouse after the post-mortem inspection and must bear such mark until it is treated;
 - (b) the movement of fresh meat and raw milk from the establishment of origin to the processing establishment must be carried out in sealed containers; and

- (c) the processing establishment must be located in the same restricted zone or as near as possible to the restricted zone and must operate under the supervision of official veterinarians.

Article 34

Specific conditions for authorising movements of eggs for human consumption from establishments located in the protection zone

The competent authority may authorise the movement of eggs for human consumption from establishments located in the protection zone to the following destinations within the same Member State:

- (a) to a packing centre, provided that they are packed in:
 - (i) a disposable packaging; or
 - (ii) a packaging which can be cleaned and disinfected in such way as to destroy the relevant category A disease agent;
- (b) to an establishment for the manufacture of egg products as set out in Chapter II of Section X of Annex III to Regulation (EC) No 853/2004, in order to be handled and treated in accordance with Chapter XI of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽¹⁵⁾.

Article 35

Specific conditions for authorising movements of manure, including litter and used bedding from establishments located in the protection zone to a landfill

The competent authority may authorise movements of manure, including litter and used bedding, from establishments located in the protection zone for the purpose of their disposal in a designated landfill located within the same Member State only after processing in accordance with Article 13(c) of Regulation (EU) No 1069/2009.

Article 36

Specific conditions for authorising the movement of feed materials of plant origin and straw from the protection zone

The competent authority may authorise movements of feed materials of plant origin and straw produced in the protection zone provided that:

- (a) they were produced in locations not keeping animals of listed species;
- (b) they were produced in feed processing establishments not keeping animals of listed species and the raw plant material originates:
 - (i) from locations referred to in point (a); or
 - (ii) from outside the protection zone;
- (c) they are intended for use within the protection zone; or
- (d) they have undergone at least one of the risk-mitigating treatments in accordance with Annex VIII.

Article 37

Specific conditions for authorising movements of kept animals of listed species and products to an animal by-products approved plant

1. The competent authority may authorise movements of kept animals of listed species from establishments located in the protection zone to a plant approved for processing or disposal of animal by-products in which:

- (a) the kept animals are immediately killed; and
- (b) the resulting animal by-products are disposed of in accordance with Regulation (EC) No 1069/2009.

⁽¹⁵⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

2. The competent authority may authorise movements of products from establishments and locations in the protection zone to a plant approved for processing or disposal of animal by-products, in which the products are disposed of or processed in accordance with Regulation (EC) No 1069/2009.

Article 38

Measures to be applied in food and feed businesses, border control posts, animal by-products establishments or any other location of relevance in the protection zone, including means of transport

1. The competent authority shall apply the relevant measures referred to in Article 25, and Articles 27 to 38 in food and feed businesses, border control posts, animal by-products establishments or any other location of relevance in the protection zone, including means of transport.
2. In the establishments and locations referred to in paragraph 1, the competent authority may apply additional measures adapted to the specific situation in order to prevent the spread of the category A disease within and from the protection zone.

Article 39

Duration of the disease control measures in the protection zone

1. The competent authority may lift the measures provided for in Section 1 and 2 of this Chapter only if the minimum period set out in Annex X has elapsed and the following conditions are fulfilled:
 - (a) the preliminary cleaning and disinfection and, where relevant, control of insects and rodents, has been performed in accordance with Article 15 in the affected establishment; and
 - (b) in all establishments keeping animals of listed species in the protection zone, animals of listed species have undergone, with favourable results, clinical and when necessary laboratory examinations in accordance with Article 26.
2. Where the relevant category A disease is transmitted by a listed vector, as referred to in Regulation (EU) 2018/1882, the competent authority may:
 - (a) establish the duration of the measures in the protection zone on a case by case basis, taking into account any factor influencing the risk of the disease spreading; and
 - (b) provide for the introduction of sentinel animals.
3. After the lifting of the measures referred to in paragraph 1, the measures provided for in Section 3 of this Chapter shall apply in the protection zone for at least the additional period set out in Annex X.

Section 3

Disease control measures in the surveillance zone

Article 40

Measures to be applied in establishments in the surveillance zone

The competent authority shall order the application, without delay, of the measures provided for in Article 25 in all the establishments in the surveillance zone keeping animals of listed species.

Article 41

Visits by the official veterinarians in establishments in the surveillance zone

The competent authority shall ensure that official veterinarians carry out visits to a sample of establishments keeping animals of listed species in the surveillance zone in accordance with Article 26 and point A.3 of Annex I.

*Article 42***Prohibitions in relation to activities, including movements, concerning animals, products and other material within, from or to the surveillance zone**

The competent authority shall apply prohibitions, exemptions and derogations to activities, including movements concerning animals of listed species, the products thereof and other material, from and to the surveillance zone in accordance with Article 27.

*Article 43***General conditions for granting derogations from prohibitions provided for in Article 42**

1. By way of derogation from Article 42, the competent authority may authorise movements of animals and products only in the cases covered by Articles 44 to 52, under the specific conditions provided for in those Articles and the general conditions laid down in paragraphs 2 to 7 of this Article.

Prior to granting the authorisation, the competent authority shall assess the risks deriving from that authorisation. The assessment must indicate that the risk of spreading the category A disease is negligible.

2. All authorised movements shall be performed:

- (a) prioritising major highways or mainline railways;
- (b) avoiding the vicinity of establishments keeping animals of listed species; and
- (c) without unloading or stopping, until the unloading in the establishment of destination.

3. The competent authority of the establishment of origin shall designate the establishment of destination for movements from or to the surveillance zone. If the competent authority is not the same as in the establishment of destination, it shall inform the competent authority of the establishment of destination about such designation.

4. The competent authority of the establishment of origin shall verify that the establishment of destination agrees to be designated and to receive each consignment of animals or products.

5. When authorising movements of animals from the surveillance zone, the competent authority shall ensure that such movements do not pose a risk of spreading the category A disease based on:

- (a) a clinical examination with favourable results of animals kept in the establishment, including those animals to be moved;
- (b) if necessary, a laboratory examination with favourable results of animals kept in the establishment, including those animals to be moved; and
- (c) the outcome of the visits referred to in Article 41, if available.

6. When authorising the transport of products from the surveillance zone, the competent authority must ensure that:

- (a) during the whole production process and storage, products were clearly separated from products not eligible for dispatch outside the restricted zone pursuant this Regulation;
- (b) products will not be transported with products not eligible for dispatch outside the restricted zone pursuant this Regulation.

7. When granting derogations provided for in paragraph 1, the competent authority shall ensure that supplementary biosecurity measures are applied from the moment of loading, during all transport operations and until the unloading in the designated establishment of destination in accordance with its instructions.

*Article 44***Specific conditions for authorising movements for slaughter of kept animals of listed species within, from and to the surveillance zone**

1. The competent authority may authorise movements of kept animals of listed species originating in the surveillance zone to a slaughterhouse located:
 - (a) as near as possible to the establishment of origin, within the restricted zone; or
 - (b) outside the restricted zone, as near as possible to the surveillance zone, when it is not possible to slaughter the animals in the restricted zone, and after carrying out a risk assessment.
2. The meat obtained from animals referred to in paragraph 1 shall be subject to the measures provided for in Article 49.
3. The competent authority may authorise movements of kept animals of listed species originating outside the surveillance zone to a slaughterhouse situated in the surveillance zone.
4. The competent authority may authorise the processing and use of animal by-products, obtained from animals slaughtered in accordance with paragraphs 1, 2 and 3 as category 3 material in accordance with Regulation (EC) No 1069/2009 in a plant approved for processing or disposal of animal by-products, located on their territory, or in another Member State, where it is not feasible to process or dispose them in an approved plant in the territory of the Member State where the outbreak occurred.

In case the animal by-products referred to in the first subparagraph are moved to a plant located in another Member State, the Member State of destination and the Member States of passage shall authorise such dispatch and the competent authority of destination shall authorise the processing and use of those animal by-products as category 3 material in accordance with Regulation (EC) No 1069/2009.

*Article 45***Specific conditions for authorising certain movements of kept ungulates of listed species from establishments in the surveillance zone**

1. The competent authority may authorise the movement of kept ungulates of listed species to pastures situated within the surveillance zone, provided that:
 - (a) a period of 15 days has elapsed after the preliminary cleaning and disinfection referred to in Article 15 has been completed and approved; and
 - (b) the animals do not come into contact with animals of listed species from other establishments.
2. The competent authority may, after carrying out a risk assessment, authorise the movement of kept animals of listed species of ungulates to an establishment belonging to the same supply chain, located in or outside the surveillance zone, to complete the production cycle before slaughter. If the establishment of destination is located outside the surveillance zone, the competent authority shall apply in that establishment the measures provided for in Articles 40, Article 41 and Article 42 as long as the disease control measures in the surveillance zone of origin are maintained as provided for in Article 55.

*Article 46***Specific conditions for authorising certain movements of poultry from establishments located in the surveillance zone**

1. The competent authority may authorise movements of day-old chicks originating in the surveillance zone:
 - (a) to establishments in the same Member State where they were hatched from eggs originating from establishments within the surveillance zone, if:
 - (i) the establishment of destination is placed under official surveillance following the arrival of the animals; and
 - (ii) if moved outside the restricted zone, the animals remain in the establishments of destination for at least 21 days;

- (b) to establishments in the same Member State where they were hatched from eggs originating outside the restricted zone, if the hatchery of dispatch can ensure that no contact has occurred between those eggs and any other hatching eggs or day-old chicks obtained from animals kept within the restricted zone.
2. The competent authority may authorise movements of ready-to-lay poultry from establishments in the surveillance zone to establishments in the same Member State, if:
- (a) in the establishment of destination there is no other kept animal of listed species;
 - (b) the establishment of destination is placed under official surveillance following the arrival of the ready-to-lay poultry; and
 - (c) the poultry remain on the establishment of destination for at least 21 days.

Article 47

Specific conditions for authorising certain movements of hatching eggs to and from establishments in the surveillance zone

1. The competent authority may authorise movements of hatching eggs from an establishment located in the same Member State to:
- (a) a hatchery located in the surveillance zone; or
 - (b) an establishment for in-house hatching located in the surveillance zone.
2. The competent authority may authorise movements of hatching eggs from an establishment located in the surveillance zone to a hatchery in the same Member State or to an establishment for in-house hatching located in the same Member State, only if the hatching eggs and their packaging are disinfected before dispatch and the tracing back of these eggs can be ensured.

Article 48

Specific conditions for authorising movements of semen from approved germinal product establishments in the surveillance zone

The competent authority may authorise movements of semen collected from animals of listed species kept in approved germinal product establishments, excluding hatcheries, located in the surveillance zone after the estimated date of earliest infection of the affected establishment provided that:

- (a) all the disease control measures relating to the relevant category A disease have been lifted in the surveillance zone in accordance with Article 55;
- (b) all the kept animals of listed species in the semen collection centre have undergone a clinical examination and have been sampled for laboratory examinations in order to rule out the presence of the category A disease in the semen collection centre;
- (c) the donor animal has been subjected with favourable results to a laboratory examination on a sample taken not earlier than seven days after the monitoring period set out in Annex II for the relevant disease, calculated forwards from the date on which the semen was collected.

Article 49

Specific conditions for authorising movements of fresh meat and raw milk obtained from kept animals of listed species from establishments located in the surveillance zone

1. The competent authority may authorise movements of fresh meat and raw milk obtained from animals of listed species kept in establishments located in the surveillance zone if, either:
- (a) the fresh meat or the raw milk is moved to a processing establishment to undergo one of the risk-mitigating treatments set out in Annex VII; or
 - (b) the fresh meat is obtained from poultry.

2. The competent authority shall ensure that fresh meat and the raw milk moved pursuant paragraph 1(a), comply with the following:

- (a) fresh meat is marked in accordance with Annex IX when it is obtained in the slaughterhouse and keeps such mark until it is treated; and
- (b) the treatment is applied in an establishment situated in the same restricted zone or as near as possible of the restricted zone, which operates under the supervision of official veterinarians.

Article 50

Specific conditions for authorising movements of eggs for human consumption from establishments in the surveillance zone

1. The competent authority may authorise movements of eggs for human consumption from establishments in the surveillance zone to a packing centre located in the same Member State provided that they are packed in:

- (a) a disposable packaging; or
- (b) a packaging which can be cleaned and disinfected in such way as to destroy the category A disease agent.

2. The competent authority may authorise movements of eggs for human consumption from establishments located in the surveillance zone to an establishment for the manufacture of egg products located in the same Member State if:

- (a) the establishment for the manufacture of egg products complies with Chapter II of Section X of Annex III to Regulation (EC) No 853/2004; and
- (b) the eggs are moved to the establishment for the manufacture of egg products in order to be handled and treated in accordance with Chapter XI of Annex II to Regulation (EC) No 852/2004.

Article 51

Specific conditions for authorising movements of manure, including litter and used bedding, from establishments in the surveillance zone

The competent authority may authorise the movement of manure, including litter and used bedding, from establishments located in the surveillance zone:

- (a) without processing, to a landfill, previously authorised for that purpose by the competent authority, located in the same surveillance zone; or
- (b) following processing, to a landfill, previously authorised for that purpose by the competent authority, located in the territory in the Member State.

Article 52

Specific conditions for authorising the movement of feed materials of plant origin and straw from the surveillance zone

The competent authority may authorise movements of feed materials of plant origin or straw produced in the surveillance zone provided that the feed materials or the straw:

- (a) were produced in locations not keeping animals of listed species, other than feed processing establishments;
- (b) were produced in feed processing establishments not keeping animals of listed species and the raw plant material originates:
 - (i) from locations referred to in paragraph (a); or
 - (ii) from outside the surveillance zone;

- (c) are intended for use within the surveillance zone;
- (d) have undergone at least one of the risk-mitigating treatments set out in Annex VIII.

Article 53

Specific conditions for authorising movements of kept animals of listed species and products to an approved plant

1. The competent authority may authorise movements of kept animals of listed species from establishments located in the surveillance zone to a plant approved for processing or disposal of animal by-products where:
 - (a) the kept animals are immediately killed; and
 - (b) the resulting animal by-products are disposed of in accordance with Regulation (EC) No 1069/2009.
2. The competent authority may authorise movements of products from establishments and other locations in the surveillance zone to a plant approved for processing or disposal of animal by-products where they are disposed of or processed in accordance with Regulation (EC) No 1069/2009.

Article 54

Measures to be applied in food and feed businesses, border control posts, animal by-products establishments or any other location of relevance in the surveillance zone, including means of transport

1. The competent authority shall apply the relevant measures referred to in Article 40, and Articles 42 to 53 in food and feed businesses, border control posts, animal by-products establishments or any other location of relevance in the surveillance zone, including means of transport.
2. In the establishments and locations referred to in paragraph 1, the competent authority may apply additional measures adapted to the specific situation in order to prevent the spread of the category A disease within and from the surveillance zone.

Article 55

Duration of the disease control measures in the surveillance zone

1. The competent authority may lift the disease control measures applied in the surveillance zone pursuant to Sections 1 and 3 of this Chapter only if the period set out in Annex XI has elapsed and the following conditions are fulfilled:
 - (a) the requirements provided for in Article 39 have been met in the protection zone; and
 - (b) a representative number of establishments keeping animals of listed species have undergone, with favourable results, visits carried out by official veterinarians, in accordance with Article 41.
2. Where the relevant category A disease is transmitted by a listed vector, in accordance with Regulation (EU) 2018/1882, the competent authority may:
 - (a) set the duration of the measures in the surveillance zone on a case by case basis taking into account factors influencing the risk of spreading the disease; and
 - (b) provide for the introduction of sentinel animals.

Section 4

Derogations applicable in the restricted zone in the case of further disease outbreaks*Article 56***Derogations from prohibitions of movements of animals within the restricted zones when restriction measures are maintained**

1. Where prohibitions of movement of animals provided for in Articles 27 and Article 42 are maintained beyond the period set out in Annex XI because of the official confirmation of further outbreaks of the category A disease, the competent authority may, under exceptional circumstances, authorise the movement of kept animals of listed species from an establishment within the restricted zone in cases not covered by derogations provided for in Articles 27 and Article 42, if:
 - (a) the operator has submitted a reasoned application for that authorisation;
 - (b) the risks derived from authorising such movements have been assessed prior to the authorisation and the assessment indicates that the risk of spreading of the category A disease is negligible;
 - (c) official veterinarians have carried out clinical examinations and have collected samples for laboratory examinations from animals of listed species, including those to be moved, which have yielded favourable results.
2. Where movements of animals are authorised pursuant paragraph 1, the competent authority shall ensure that the transport complies with the requirements laid down in Article 24.

CHAPTER III

Repopulation with terrestrial animals of establishments in restricted zones*Article 57***Conditions to authorise the repopulation of the affected establishment**

1. The competent authority shall only authorise the repopulation of the affected establishment if the following requirements are met:
 - (a) a final cleaning and disinfection and, when relevant, control of insects and rodents has been:
 - (i) carried out, in accordance with the procedures set out in points A and C of Annex IV, using the appropriate biocidal products to ensure destruction of the relevant category A disease agent; and
 - (ii) adequately documented;
 - (b) the monitoring period set out in Annex II for the relevant disease, calculated forwards from the date on which the final cleaning and disinfection provided for in point (a) was carried out, has elapsed.
2. The competent authority shall supervise that the final cleaning and disinfection and, when relevant, control of insects and rodents in the affected establishment is carried out in compliance with the requirements in paragraph 1(a).
3. The competent authority shall not allow access to a pasture of kept animals of listed species during the period of time during which it is considered contaminated; this period of time shall be established after carrying out a risk assessment.
4. Where for duly justified reasons the final cleaning and disinfection and, when relevant, the control of insects and rodents referred to in paragraph 1, have not been entirely accomplished in the affected establishment, the competent authority may authorise the repopulation by way of derogation from paragraph 1, provided that:
 - (a) a period of at least 3 months has elapsed since the preliminary cleaning and disinfection, as referred to in Article 15, was performed; and

- (b) prior to granting the authorisation, the competent authority has assessed the risks deriving from that authorisation and the assessment indicates that the risk of spreading the category A disease is negligible.

Article 58

Derogation from the requirement provided for in Article 55(1)(b)

In the event of the official confirmation of an outbreak of a category A disease in food and feed businesses, assembly centres, border control posts, animal by-products establishments or any other location of relevance, including means of transport, the competent authority may authorise the reintroduction of kept animals of listed species for slaughter, assembly operations, inspection or transport, 24 hours after completion of:

- (a) the measures referred to in Articles 12, Article 14, Article 15, Article 17, Article 18 and Article 57(1)(a); and
- (b) any additional measure applied by the competent authority adapted to the specific situation.

Article 59

Requirements for the repopulation of the affected establishment with kept animals of listed species

1. The competent authority shall supervise the repopulation with kept animals of listed species of the affected establishment complying with the provisions of this Article.

2. Kept animals of listed species intended for repopulation shall:

- (a) not originate from an establishment subject to the restrictions provided for in Chapter III; and
- (b) be sampled for laboratory examination to rule out the presence of the disease with favourable results prior to their introduction into the establishment.

3. For the purposes of paragraph 2(b), samples shall be collected from:

- (a) a representative number of all the animals to be introduced in the establishment, if they are all introduced at the same time and from the same establishment of origin; or
- (b) a representative number of animals of each consignment, if animals are all to be introduced at different times or from different establishments of origin.

In the case of day-old-chicks, the competent authority may decide not to perform the sampling for laboratory examination referred to in paragraph 2(b).

4. Kept animals of listed species intended for repopulation shall be introduced in the establishments as follows:

- (a) in all the epidemiological units and buildings of the affected establishment;
- (b) preferably at the same time or within the monitoring period set out in Annex II for the relevant disease, calculated forwards from the date on which the first animal was introduced; or
- (c) in case of open-air farming establishments or when the requirement set out in point (a) is impractical, by using sentinel animals which have been sampled for laboratory examinations with favourable results for the relevant category A disease before being introduced in the establishment.

5. Official veterinarians shall carry out at least a visit to the affected establishment on the last day of the monitoring period set out in Annex II for the relevant disease, calculated forwards from the date on which the animals were placed in the establishment, and in any case before 30 days have elapsed since that day, performing at least:

- (a) documentary checks, including production, health and traceability records analysis;
- (b) clinical examination of kept animals of listed species; and
- (c) collection of samples of animals for laboratory examination in order to confirm or rule out the presence of the relevant category A disease.

6. Any person entering or leaving the establishment shall comply with appropriate biosecurity measures aimed at preventing the spread of the relevant category A disease.
7. Kept animals of listed species shall only leave the establishment under the authorisation of the competent authority and only after obtaining favourable results from the laboratory examination referred to in paragraph 5(c).
8. From the date that the animals were placed in the establishment until the end of the repopulation, in accordance with Article 61, the operator shall:
 - (a) keep up to date the records of health and production data for kept animals of listed species; and
 - (b) immediately notify to the competent authority any significant change in production data and any other abnormalities.
9. If unusual mortalities or clinical signs of the relevant category A disease are notified to the competent authority during the period referred to in paragraph 8, the official veterinarians shall without delay collect samples for laboratory examination to rule out the presence of the relevant category A disease.
10. The competent authority may exempt confined establishments from one or more of the provisions laid down in paragraphs 1 to 9 after assessing the risks deriving from that exemption and the assessment indicates that the risk of spreading the category A disease is negligible.

Article 60

Additional requirements for the repopulation of the affected establishment

1. The competent authority shall authorise the repopulation of the affected establishment with animals other than kept listed species taking into account the risk of spreading the relevant category A disease and the risk of vector persistence.
2. The competent authority may extend some or all the provisions provided for in Articles 57 and 59 if preventive killing as provided for in paragraph 4 of Articles 7 and 9 is applied.

Article 61

End of the repopulation of the affected establishment and lifting of disease control measures in the affected establishment

1. The repopulation of the affected establishment shall be considered finalised when the measures provided in Articles 57 and 59, and when relevant in Article 60, have been successfully completed.
2. The competent authority shall lift all the disease control measures applied in the affected establishment in accordance with this Regulation when the repopulation is considered finalised as provided for in paragraph 1.

CHAPTER IV

Disease control measures in wild animals of listed species

Article 62

Measures in the event of suspicion of a category A disease in wild animals of listed species

1. In the event of suspicion of a category A disease in wild animals of listed species in accordance with Article 9(1), (3), and (4) of Delegated Regulation (EU) 2020/689, the competent authority shall immediately conduct an investigation to confirm or rule out the presence of the suspected listed disease.
2. In the course of the investigation referred to in paragraph 1 the competent authority shall at least organise post-mortem examinations and the collection of samples for laboratory examination of wild animals of listed species shot dead or found dead to confirm or rule out the presence of the category A disease.

3. As regards the bodies of dead wild animals in which the relevant category A disease is suspected, whether the wild animals were killed or found dead, the competent authority shall ensure that:

- (a) the entire bodies of the dead wild animals or parts thereof are disposed of or processed in accordance with Regulation (EC) No 1069/2009; and
- (b) where feasible, any material or substance likely to be contaminated by contact with the bodies of dead wild animals or animal by-products obtained therefrom undergoes cleaning and disinfection or is disposed of following the instructions and under the supervision of official veterinarians.

Article 63

Measures in the event of an outbreak of a category A disease in wild animals of listed species

1. In the event of an official confirmation of an outbreak of a category A disease in wild animals of listed species in accordance with Article 9(2), (3) and (4) of Delegated Regulation (EU) 2020/689, the competent authority may determine an infected zone in order to prevent the further spread of the disease based on:

- (a) the disease profile;
- (b) the estimated population of wild animals of listed species;
- (c) the risk factors contributing to the spread of the relevant category A disease, in particular, the risk of the introduction of a category A disease into establishments keeping animals of listed species;
- (d) sampling results; and
- (e) other relevant factors.

2. As regards the bodies of wild animals in which the relevant category A disease has been confirmed, whether the wild animals were killed or found dead, the competent authority shall ensure that:

- (a) their entire bodies of the dead wild animals or parts thereof are disposed of or processed in accordance with Regulation (EC) No 1069/2009; and
- (b) where feasible, any material or substance likely to be contaminated by contact with the bodies of dead wild animals or animal by-products therefrom undergoes cleaning and disinfection or is disposed of following the instructions and under the supervision of official veterinarians.

3. The competent authority may adapt the boundaries of the initial infected zone:

- (a) in order to control the further spread of the relevant category A disease; and
- (b) in the case of confirmation of further outbreaks of the category A disease in wild animals.

4. The competent authority shall immediately inform operators, clinical veterinarians, hunters, other relevant competent authorities and any other natural or legal person concerned about the outbreak of the disease and the control measures adopted.

Article 64

Measures to be applied in the infected zone

1. In the infected zone determined in accordance with Article 63, the competent authority shall organise post-mortem examinations of wild animals of listed species shot dead or found dead, including when necessary sampling for laboratory examination.

2. In the infected zone the competent authority shall at least:

- (a) implement risk mitigation and reinforced biosecurity measures in order to prevent the spread of the category A disease from the affected animals and infected zone to unaffected animals or to humans;

- (b) prohibit movements of wild animals of listed species and products of animal origin thereof as provided for in Commission Delegated Regulation (EU) 2020/688 ⁽¹⁶⁾; and
- (c) ensure that all bodies of dead wild animals of listed species, whether the animals were killed or found dead, or parts thereof, are disposed of or processed in accordance with in Regulation (EC) No 1069/2009.

Article 65

Additional measures to apply in the infected zone

In order to avoid the spreading of the category A disease, in the infected zone the competent authority may:

- (a) regulate movements of kept animals of listed species;
- (b) regulate hunting activities and other outdoors activities;
- (c) restrict the feeding of wild animals of listed species; and
- (d) develop and implement an eradication plan for the category A disease in wild animals of listed species if the epidemiological situation so requires.

Article 66

Operational expert group

In the event of an officially confirmed outbreak of a category A disease in wild animals of listed species and in the case that the competent authority determines an infected zone in accordance with Article 63, the competent authority shall establish an operational expert group as referred to in Article 43 of Regulation (EU) 2016/429 to assist the competent authority in:

- (a) assessing the epidemiological situation and its evolution;
- (b) defining the infected zone;
- (c) establishing the appropriate measures to be applied in the infected zone in accordance with this Chapter and their duration; and
- (d) developing an eradication plan, when relevant.

Article 67

Duration of measures in the infected zone

The competent authority shall maintain the measures applied in the infected zone in accordance with this Chapter until the epidemiological information indicates that the relevant wild population no longer poses a risk of introduction of a category A disease into establishments keeping animals of listed species and the operational group recommends lifting of the measures.

CHAPTER V

Disease control measures for category B and C diseases of terrestrial animals

Article 68

Preliminary disease control measures to be applied when a category B or C disease is suspected by the competent authority in Member States or zones that have been granted with the disease free status

In the event of suspicion of a category B or C disease in accordance with Article 9(1), (3) or (4) of Delegated Regulation (EU) 2020/689, in Member States or zones that have been granted the disease free status pursuant to Article 36(4) of Regulation (EU) 2016/429 or Article 84(1) of Delegated Regulation (EU) 2020/689, the competent authority shall apply the measures laid down in:

⁽¹⁶⁾ Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (see page 140 of this Official Journal).

- (a) Articles 21, 22, 23 of Delegated Regulation (EU) 2020/689 for infection with *Brucella abortus*, *B. melitensis*, *B. suis*, infection with *Mycobacterium tuberculosis complex*, enzootic bovine leucosis, infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, infection with Aujeszky's disease virus and bovine viral diarrhoea;
- (b) Article 35 of Delegated Regulation (EU) 2020/689 for infection with rabies virus; and
- (c) Article 41 of Delegated Regulation (EU) 2020/689 for infection with bluetongue virus (serotype 1-24).

Article 69

Disease control measures to be applied when a category B or C disease is confirmed

In the event of confirmation of a category B or C disease in accordance with point (2) of Article 9 of Delegated Regulation (EU) 2020/689 in Member States or zones that have been granted the disease free status in with paragraph 4 of Article 36 of Regulation (EU) 2016/429 or paragraph 1 Article 84 of Delegated Regulation (EU) 2020/689, the competent authority shall apply the measures laid down in:

- (a) Articles 24 to 31 of Delegated Regulation (EU) 2020/689 for infection with *Brucella abortus*, *B. melitensis*, *B. suis*, infection with *Mycobacterium tuberculosis complex*, enzootic bovine leucosis, infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, infection with Aujeszky's disease virus and bovine viral diarrhoea;
- (b) Article 36 of Delegated Regulation (EU) 2020/689 for infection with rabies virus; and
- (c) Article 42 of Delegated Regulation (EU) 2020/689 for infection with bluetongue virus (serotype 1-24).

PART III

AQUATIC ANIMALS

CHAPTER I

Disease control measures for category A diseases in aquaculture animals

Section 1

Preliminary disease control measures in the event of suspicion of a category A disease in aquaculture animals

Article 70

Obligations on operators in the event of suspicion of category A disease in aquaculture animals in establishments

In the event of suspicion of a category A disease in aquaculture animals of listed species, operators shall take the following disease control measures in order to prevent the spread of the category A disease from the affected animals and aquaculture establishments under their responsibility to other unaffected aquatic animals until the competent authority rules out the presence of the category A disease:

- (a) isolate, where technically possible, all aquaculture animals in the establishment suspected of being infected with the category A disease;
- (b) prevent movements of aquaculture animals into and from the establishment;
- (c) keep records of all visits and movements from and to the establishment;
- (d) keep any product, piece of equipment, material or substance likely to be contaminated with and to transmit category A diseases isolated and as far as practicable protected from vectors and other aquatic animals;
- (e) implement the appropriate biosecurity measures to avoid spread of the category A disease;
- (f) provide the competent authority, on its request, with any relevant information regarding the category A disease; and
- (g) follow any instructions given by the competent authority regarding the control of category A disease, in accordance with Regulation (EU) 2016/429 and this Regulation.

*Article 71***Investigation by the competent authority of the suspicion of a category A disease in aquaculture animals in an establishment**

1. In the event of the suspicion of a category A disease in aquaculture animals in an establishment in accordance with Article 9(1), (3) and (4) of Delegated Regulation (EU) 2020/689, the competent authority shall immediately conduct an investigation to confirm or rule out the presence of the suspected listed disease.
2. In the course of the investigation referred to in paragraph 1 the competent authority shall ensure that the official veterinarians perform at least:
 - (a) clinical examinations of aquaculture animals; and
 - (b) the collection of samples for laboratory examination.

*Article 72***Preliminary restriction and biosecurity measures to be applied in the event of the suspicion of a category A disease in aquaculture animals**

1. In the event of suspicion of a category A disease in an establishment, the competent authority shall place the establishment under official surveillance and immediately impose the following preliminary restriction and biosecurity measures, in order to prevent the spread of the category A disease from the affected aquaculture animals and the establishment to unaffected aquatic animals:
 - (a) prohibition of movements of aquaculture animals into and from the establishment;
 - (b) prohibition of non-essential movements from the establishment of means of transport and equipment;
 - (c) prohibition of slaughter of aquaculture animals for human consumption;
 - (d) where technically feasible and regarded necessary, order the isolation of all aquaculture animals; and
 - (e) when practicable, implement adequate means and measures to control birds and other predators.
2. The competent authority may order preventive killing of listed species at the affected establishment where a category A disease is suspected provided that all necessary biosecurity and other risk-mitigating measures are applied to prevent the spread of the category A disease from the establishment.
3. The competent authority shall by way of derogation from Article 10(i) of Regulation (EC) No 1069/2009 and after carrying out a risk assessment, authorise movements of aquaculture animals for the sole purpose of immediate killing in a disease control aquatic food establishment or a plant approved for processing or disposal of as animal-by-products of category 1 or category 2 in accordance with that Regulation. The authorisation may only be granted when the necessary biosecurity and other risk-mitigating measures are applied to prevent the spread of the category A disease.
4. All animal by-products from dead aquaculture animals which have died or have been killed in accordance with this Article, including molluscs shells with meat, shall by way of derogation from Article 10(i) of Regulation (EC) No 1069/2009 be processed or disposed of as category 1 or category 2 material in accordance with that Regulation to ensure that the relevant disease agent is inactivated and to prevent the transmission of the disease to other aquatic animals.

*Article 73***Inventory and record analysis in the event of the suspicion of a category A disease in aquaculture animals**

1. In the event of suspicion of a category A disease, the competent authority shall order and verify that, without delay, operators of the establishments where a category A disease is suspected compile and maintain an up-to-date inventory of the following:
 - (a) the species, categories and quantities (numbers, volume or weight) of all aquaculture animals kept in the establishment;

- (b) any product, material or substance likely to be contaminated with or likely to transmit the category A disease; and
- (c) the mortality in each epidemiological unit within the establishment, recorded on a daily basis.

2. In the framework of the epidemiological enquiry, as referred to in Article 57 of Regulation (EU) 2016/429 and carried out in establishments where the disease is suspected, the official veterinarians shall analyse at least the records listed in paragraph 1 of Article 186 of Regulation (EU) 2016/429.

Article 74

Extension of disease control measures in the event of the suspicion of a category A disease to other establishments

In order to prevent the spread of a category A disease the competent authority shall conduct an investigation as provided for in Article 71 and, after carrying out a risk assessment, extend the relevant measures provided for in Articles 72 and 73 to:

- (a) establishments situated in the same compartment as the establishment where the disease is suspected, or which, due to distance, hydrodynamic conditions or topographic conditions, have an increased risk for contracting the relevant disease agent from the establishment where the disease is suspected;
- (b) any establishment other than those referred to in point (a) which has a direct epidemiological link with the establishment where the disease is suspected.

Article 75

Temporary restricted zones around the establishment

The competent authority may establish a temporary restricted zone around the establishment where there is a suspicion of category A disease and where preliminary disease control measures are applied as referred to in Article 72 and Article 73 taking into account the following circumstances:

- (a) the location of the establishment in an area with other establishments keeping aquaculture animals of listed species for which a category A disease is suspected;
- (b) the movement of animals in the vicinity of the suspected establishment;
- (c) the delay in confirming the category A disease pursuant to Article 77;
- (d) the insufficient information on the possible origin and routes of introduction of the suspected category A disease; and
- (e) the disease profile, in particular the routes and speed of transmission of the disease and the persistence of the disease in the relevant population of aquaculture animals of listed species.

Article 76

Measures to apply in the event of suspicion of a category A disease in food and feed businesses, purification centre, dispatch centre, border control posts, animal by-products establishments or any other location of relevance, including means of transport

1. In the event of suspicion of a category A disease in accordance with Article 9(1), (3) and (4) of Delegated Regulation (EU) 2020/689 in food and feed businesses, purification centres, dispatch centres, border control posts, animal by-products establishments or any other location of relevance, including means of transport, the competent authority shall apply:

- (a) the measures provided for in Articles 71 to 75; and
- (b) if needed, additional measures adapted to the specific situation in order to prevent the spread of the category A disease from the animals and establishments or locations under suspicion to unaffected animals.

2. The competent authority shall apply provisions laid down in Articles 71 to 75 also in the establishments of origin of the animals or products present in the establishments and locations referred to in paragraph 1.

Section 2

Disease control measures in the event of official confirmation of A category A disease in aquaculture animals*Article 77***Official confirmation of a category A disease in aquaculture animals**

The competent authority shall officially confirm an outbreak of a category A disease in aquaculture animals when the conditions set out in Article 9(2), (3) and (4) of Delegated Regulation (EU) 2020/689 are met.

*Article 78***Disease control measures in the event of official confirmation of an outbreak of category A disease in an establishment**

1. Following the official confirmation of an outbreak of a category A disease in accordance with Article 77, the competent authority shall in addition to the measures provided for Article 72 and Article 73, order that the following disease control measures are immediately applied under the supervision of the official veterinarians, to the establishment where the official confirmation of an outbreak of a category A disease has occurred:

- (a) fish and crustaceans of listed species shall be killed as soon as possible and molluscs of listed species shall be removed from water as soon as possible;
- (b) animals referred to in (a) shall by way of derogation from Article 10(i) of Regulation (EC) No 1069/2009 be disposed of as category 1 or category 2 material in accordance with that Regulation;
- (c) the measures provided for in point (a) and (b) shall be carried out either:
 - (i) in the establishment where the official confirmation of an outbreak of a category A disease has occurred with subsequent processing on site; or
 - (ii) in a disease control aquatic food establishment, or in a plant approved in accordance with Regulation (EC) No 1069/2009 for processing or disposal in a way that prevents risk of spreading the category A disease;
- (d) aquaculture animals of non-listed species shall, as soon as possible, be killed or slaughtered for human consumption or, in case of molluscs, removed from water in accordance with paragraph 1(b);
- (e) appropriate measures shall be applied to limit any possible spread of the category A disease to and from any wild aquatic animals that might be in epidemiological contact with the establishment;
- (f) all potentially contaminated products, materials or substances shall be isolated until:
 - (i) they are disposed of in accordance with Regulation (EC) No 1069/2009, in the case of animal by-products;
 - (ii) by way of derogation from Article 10(i) of Regulation (EC) No 1069/2009 they are disposed of or processed as category 1 or category 2 material in accordance with that Regulation, in the case of products of animal origin;
 - (iii) cleaning and disinfection measures have been completed in accordance with the provisions in Article 80, in the case of materials and substances which are fit for cleaning and disinfection; and
 - (iv) they are removed from the establishment and disposed of under the supervision of official veterinarians, in the case of feeding stuff and other materials unfit for cleaning and disinfection.

2. The competent authority shall order and supervise:

- (a) the transport from the affected establishment of animal by-products referred to in paragraph 1(f)(i) and of the products of animal origin referred to in paragraph 1(f)(ii) being in compliance with the provisions of Regulation (EC) No 1069/2009; and
- (b) the transport from the affected establishment of materials or substances referred to in paragraph 1(f)(iv) being in compliance with its instructions regarding biosecurity and biosafety conditions to prevent the spread of category A disease agent.

3. By way of derogation from paragraph 1(a), the competent authority may, after carrying out a risk assessment, allow slaughter of fish or crustaceans or in case of molluscs removal from water, for human consumption, at the establishment or in a disease aquatic control food establishment, provided that appropriate biosecurity and other necessary risk-mitigating measures to prevent the spread of the category A disease are taken. All animal by-products resulting from that derogation shall, by way of derogation from Article 10(i) of Regulation (EC) No 1069/2009, be processed or disposed of as category 1 or category 2 material in accordance with that Regulation.

4. By way of derogation from paragraph 1(d), the competent authority may, after carrying out a risk assessment, decide not to kill, slaughter or remove from water aquaculture animals of non-listed species provided that appropriate risk-mitigating measures are applied to prevent any risk of spreading of the relevant category A disease from the establishment.

5. By way of derogation from paragraph 1(f)(ii), the competent authority may, after carrying out a risk assessment, allow the placing on the market of products of animal origin in accordance with Article 83.

Article 79

Specific derogations from control measures in establishments where listed species are kept for scientific purposes or purposes related to conservation of endangered species

1. The competent authority may grant derogations from the measures provided for in Article 78(1)(a) and (c) in the event of an official confirmation of a category A disease in establishments where listed species are kept for scientific purposes or purposes related to conservation of endangered species, provided that:

- (a) the animal health status of the concerned Member State, or of other Member States, is not jeopardised; and
- (b) all appropriate biosecurity measures as listed in Article 78 are taken to prevent any risk of spreading of the category A disease agent.

2. Where a derogation is granted pursuant to paragraph 1, the competent authority shall ensure that aquaculture animals of listed species covered by the derogation are:

- (a) kept in premises where appropriate biosecurity measures to avoid spread of the relevant category A disease are implemented; and
- (b) subjected to further surveillance and laboratory examination and are not moved from the establishment until the laboratory tests have indicated that they do not pose a risk of further spread of the relevant category A disease.

Article 80

Cleaning and disinfection

1. The competent authority shall order the operators to carry out, immediately after the completion of the disease control measures provided for in Article 78, the cleaning and disinfection of:

- (a) the establishment, as far as the competent authority considers it is technically possible;
- (b) any husbandry-related equipment including but not limited to feeding, grading, treatment, vaccination and workboats;
- (c) any production-related equipment including but not limited to cages, netting, trestles, bags and long-lines;
- (d) any protective clothing or safety equipment used by operators and visitors; and
- (e) all means of transport including tanks and other equipment used to move infected animals or personnel who have been in contact with infected animals.

2. The cleaning and disinfection as provided for in paragraph 1 shall be carried out:

- (a) in accordance to a protocol previously agreed between the competent authority and the operator; and
- (b) under the supervision of official veterinarians.

*Article 81***Fallowing of the affected establishment**

The competent authority shall order operators to carry out, after the completion of the cleaning and disinfection provided for in Article 80, the fallowing of the affected establishment for the period of time laid down in Annex XIII.

*Article 82***Extension of disease control measures in the event of confirmation of a category A disease**

In order to prevent the spread of a category A disease the competent authority shall conduct an investigation provided for in Article 71 and after carrying out a risk assessment, extend some or all of the measures provided for in Articles 78, 80 and 81 to:

- (a) establishments of the same compartment or which due to distance, hydrodynamic conditions or topographic conditions, have an increased risk for contracting the relevant disease agent from the suspected establishment where the disease is confirmed;
- (b) any establishment which as a result of the enquiry provided for in Article 57 of Regulation (EU) 2016/429, has shown a direct epidemiological link with the establishment where the disease is confirmed.

*Article 83***Placing on the market of products of animal origin from aquaculture animals of listed species produced in infected establishments**

1. When granting a derogation pursuant Article 78(5), the competent authority may allow the placing on the market of products of animal origin only if the following conditions are fulfilled:

- (a) fish must be slaughtered and eviscerated before dispatch;
- (b) molluscs and crustaceans must be fully traceable and processed to non-viable products unable to survive if returned to the water, before dispatch.

When purification is required before processing and placing on the market, it shall be conducted at a disease control aquatic food establishment or in a bio-secure purification centre.

2. The products of animal origin referred to in paragraph 1 shall be intended for:

- (a) to the final consumer directly; or
- (b) for further processing in a disease control aquatic food establishment.

*Article 84***Measures to be applied in the event of confirmation of category A diseases in, food and feed businesses, purification centre, dispatch centre, border control posts or any other location of relevance, including means of transport**

1. In the event of confirmation of a category A disease in food and feed businesses, purification centre, dispatch centre, border control posts or any other location of relevance, including means of transport, in accordance with Article 77, the competent authority shall apply:

- (a) the measures provided for in Articles 78, Article 80 and Article 81; and
- (b) if needed, additional measures adapted to the specific situation in order to prevent the spread of the category A disease from the affected animals and establishments or locations to unaffected animals.

2. The competent authority shall apply provisions laid down in Articles 78, Article 80 and Article 81 also in the establishments of origin of the animals or products present in the establishments and locations referred to in paragraph 1.

CHAPTER II

Disease control measures for category A diseases of aquaculture animals in the restricted zone

Section 1

General disease control measures in the restricted zone

Article 85

Establishment of a restricted zone

1. In the event of the official confirmation of an outbreak of a category A disease in an establishment, food and feed business, animal by-products establishment or any other location of relevance, including means of transport, the competent authority shall immediately establish a restricted zone around the affected establishment or location, including:
 - (a) a protection zone around the establishment or location where the category A disease is confirmed;
 - (b) a surveillance zone around the protection zone; and
 - (c) if necessary, on the basis of the criteria set out in Article 64(1) of Regulation (EU) 2016/429, further restricted zones around or adjacent to the protection and surveillance zones.
2. The extent of the zones shall be set on a case-to-case basis, taking into account factors influencing the risk of spreading the disease. To that end, the competent authority shall consider the following data and criteria:
 - (a) data from the epidemiological enquiry in accordance with Article 57 in Regulation (EU) 2016/429;
 - (b) relevant hydrodynamic data;
 - (c) criteria listed in Article 64(1) of Regulation (EU) 2016/429; and
 - (d) criteria provided for in Annex XIV to this Regulation.
3. The competent authority shall adapt the boundaries of the initial restricted zone, including the boundaries of the protection, surveillance and the further restricted zones, in the case of the overlapping of two or more restricted zones due to further outbreaks of the category A disease.
4. By way of derogation from paragraph 1, the competent authority may due to specific geographical, hydrodynamic and epidemiological circumstances, and after carrying out a risk assessment taking into account the disease profile:
 - (a) not establish the restricted zone as provided for in paragraph 1 around the infected establishment or location;
 - (b) establish a restricted zone consisting of a protection zone without any adjacent surveillance zone; and
 - (c) not establish a restricted zone when a category A disease is confirmed in food and feed businesses, purification centre, dispatch centre, border control posts, animal by-products establishments or any other location of relevance, including means of transport.
5. The competent authority may derogate, to the extent necessary and after carrying out a risk assessment taking into account geographical, hydrodynamic, epidemiological circumstances and the disease profile, from the provisions of this Chapter:
 - (a) in the further restricted zones; and
 - (b) in the case that the competent authority decides to establish the restricted zone when an outbreak of a category A disease occurs in establishments or any other locations of relevance referred to in paragraph 4(c).

Article 86

Measures to be applied in the restricted zone

1. The competent authority shall without delay compile and keep an up-to-date inventory of all establishments keeping aquaculture animals of listed species located in the restricted zone, including the species, categories and the estimated number of animals in each establishment.

2. In the establishments located within the restricted zone, the competent authority may, on the basis of epidemiological information or other relevant evidence and after carrying out a risk assessment, implement preventive killing or, slaughtering for human consumption or, in the case of molluscs, removal from water, of aquaculture animals of listed species pursuant to Article 78(1)(a) and (2).

3. Any collection of samples, in establishments in the restricted zone keeping aquaculture animals of listed species, for purposes other than to confirm or rule out the presence of the relevant category A disease, shall be authorised by the competent authority.

Section 2

Disease control measures in the protection zone

Article 87

Measures to be applied in establishments keeping aquaculture animals in the protection zone

1. The competent authority shall order operators of establishments keeping aquaculture animals of any species in the protection zone, other than the establishment in which the category A disease has been confirmed, to carry out at least the following measures in order to prevent and control the spread of the disease:

- (a) without delay update the records of the inventory provided for in Article 73(1);
- (b) when practicable, implement appropriate measures to limit any possible spread of the category A disease to and from any wild aquatic animals that might be in epidemiological contact with the establishment;
- (c) prevent aquaculture animals from being removed from the establishment in which they are kept unless authorised by the competent authority;
- (d) implement appropriate biosecurity measures to any product, piece of equipment, material or substance likely to spread the relevant category A disease;
- (e) reduce the number of visitors to those which are strictly necessary to operate the establishment in a proper manner; and
- (f) where practicable, implement appropriate means of cleaning and disinfection at the entry and exit of the establishment.

2. The competent authority shall order and supervise that the operator has processed or disposed of as the relevant category material in accordance with Regulation (EC) No 1069/2009 animal by-products from aquaculture animals of listed species that have died or have been killed, including molluscs shells with meat, in establishments keeping listed species within the protection zone.

3. The competent authority may decide after carrying out a risk assessment that Articles 87 and 88 only apply to aquaculture animals of listed species.

Article 88

Visits by official veterinarians in establishments in the protection zone

1. The competent authority shall ensure that official veterinarians carry out at least one visit to all the establishments referred to in Article 87 as soon as possible and without delay after the official confirmation of an outbreak of category A disease, with priority directed to establishments that the competent authority has assessed as posing a high risk as regards contracting or spreading disease.

2. When carrying out the visits referred to in paragraph 1, official veterinarians shall perform at least the following activities:

- (a) documentary checks and record analysis;

- (b) verification of the implementation of the measures intended to prevent the introduction or spread of the relevant category A disease in accordance with to Article 87;
 - (c) clinical examination of aquaculture animals of listed species; and
 - (d) if necessary, collection of samples for laboratory examination in order to confirm or rule out the presence of the relevant category A disease.
3. The competent authority may require further veterinary visits to the establishments to follow up on the situation.
4. The competent authority shall keep a record of activities and visits referred to in paragraph 1, 2 and 3, and the findings thereof.

Article 89

Prohibitions in relation to movements of aquaculture animals, products from aquaculture animals, other substances and material within, from or to the protection zone

1. The competent authority shall prohibit the following movements within the protection zone:
- (a) movement of aquaculture animals of listed species between establishments in the protection zone;
 - (b) movement of aquaculture animals of listed species from or to the protection zone;
 - (c) any movements from the establishments within the protection zone of means of transport and any equipment, product, material or substance likely to transmit the relevant category A disease;
 - (d) transport of aquaculture animals by well-boats through the protection zone; and
 - (e) dispatch of unprocessed animal by-products from aquaculture animals of any species from establishments in the protection zone.
2. The competent authority may, after carrying out a risk assessment, extend the prohibitions provided for in paragraph 1(a) to 1(d) to animals of non-listed species and their products.

Article 90

General conditions to grant derogations from prohibitions of movement and transport concerning aquatic animals and products in the protection zone

1. By way of derogation from prohibitions provided for in Article 89(1), the competent authority may authorise the movement and transport of aquatic animals and products in the cases covered by Articles 91 to 94 under the specific conditions provided for in those Articles and the general conditions laid down in paragraph 2 of this Article.
2. When granting the authorisations provided for in paragraph 1, the competent authority shall ensure that the following conditions are met:
- (a) all movements must be carried out exclusively via designated routes, agreed with the competent authority, without unloading or stopping;
 - (b) any exchange of water and discharges of water during the transportation must be carried out in areas, establishments or water exchange points approved by the competent authority;
 - (c) the means of transport must be constructed and maintained in such a way that they can undergo proper cleaning and disinfection;

- (d) the means of transport are cleaned and disinfected:
 - (i) prior to the transport operations; and
 - (ii) after transport operations under the supervision of the official veterinarian;
- (e) any other supplementary biosecurity measure considered necessary by the competent authority must be taken in relation to transport operations.

Article 91

Specific conditions for slaughter, and movements for slaughter or processing of aquaculture animals from listed species from establishments in the protection zone

1. Aquaculture animals from establishments keeping listed species in the protection zone may be:
 - (a) slaughtered within the establishment in compliance with biosecurity measures provided for by the competent authority; or
 - (b) moved for immediate slaughter for human consumption in a disease control aquatic food establishment; or
 - (c) in the case of molluscs, removed from water and moved to a disease control aquatic food establishment for purification if necessary and further processing.
2. The competent authority may, after carrying out a risk assessment based on relevant epidemiological data, limit the application of the measures provided for in paragraph 1 to establishments keeping solely aquaculture animals of species listed in the third column of the Annex to Commission Implementing Regulation (EU) 2018/1882.
3. When authorising the movements of aquaculture animals referred to in paragraph 1(b), the competent authority responsible for the disease control aquatic food establishment shall:
 - (a) be informed of the intention to send aquaculture animals of listed species to the disease control aquatic food establishment;
 - (b) agree to receive the aquaculture animals in question;
 - (c) supervise and confirm the slaughter of the animals to the competent authority of dispatch;
 - (d) ensure that the aquaculture animals of listed species originating from the protection zone are kept separately from aquaculture animals of listed species originating from outside the protection zone, and slaughtered or processed separately from those animals;
 - (e) monitor the slaughtering or processing;
 - (f) ensure that the cleaning and disinfection of the premises is completed before aquaculture animals from establishments outside the protection zone are slaughtered or processed;
 - (g) ensure that products of animal origin obtained from the aquaculture animals comply with the specific conditions for placing on the market provided for in Article 92; and
 - (h) ensure that animal by-products from slaughter or other processes referred to in paragraph 1, are processed or disposed of in accordance with Regulation (EC) No 1069/2009.

Article 92

Specific conditions for placing on the market of products of animal origin from aquaculture animals of listed species produced in non-affected establishments in the protection zone

1. The competent authority may authorise placing on the market of products of animal origin obtained from aquaculture animals of listed species in non-affected establishments in the protection zone, provided that the following conditions are fulfilled:
 - (a) fish must be slaughtered and eviscerated before dispatch; and
 - (b) molluscs and crustaceans must be fully traceable and processed to non viable products unable to survive if returned to the water, before dispatch.

2. The products of animal origin referred to in paragraph 1 shall be intended:
 - (a) for direct supply to the final consumer; or
 - (b) for further processing in a disease control aquatic food establishment.

Article 93

Special conditions for authorising transport of unprocessed animal by-products from establishments located in the protection zone

The competent authority may authorise the transport of unprocessed animal by-products of aquaculture animals of listed species from establishments in the protection zone to a plant for further processing in accordance with Regulation (EC) No 1069/2009.

Article 94

Risk-mitigating measures concerning certain activities related to aquatic animals within the protection zone

1. The competent authority may, after carrying out a risk assessment, implement risk- mitigating measures as regards:
 - (a) commercial and recreational fishing activities in the protection zone;
 - (b) other activities that are related to aquatic animals in the protection zone and that might pose a risk of spreading the disease; and
 - (c) transport of service boats used for maintenance activities and treatment of aquatic animals in the protection zone.
2. In the framework of the measures provided for in paragraph 1, the competent authority may, as relevant, order the cleaning and disinfection of equipment, which has been used in waters covered by the protection zone.

Article 95

Measures to be applied in food and feed businesses, purification centre, dispatch centres, border control posts, animal by-products establishments or any other location of relevance in the protection zone, including means of transport

1. The competent authority shall apply the measures provided for in Articles 87 to 93 in food and feed businesses, purification centre, dispatch centres, border control posts, animal by-products establishments or any other location of relevance in the protection zone, including means of transport.
2. In the establishments and locations referred to in paragraph 1, the competent authority may apply additional measures adapted to the specific situation in order to prevent the spread of the category A disease within and from the protection zone.

Article 96

Removal of aquaculture animals from affected establishments and subsequent risk- mitigating measures

1. The competent authority shall determine a point in time by which aquaculture animals in all infected establishments shall be removed.
2. The competent authority may decide, after carrying out a risk assessment, that paragraph 1 also applies to establishments in the protection zone in which the category A disease has not been confirmed in order to control and prevent the possible spread of the diseases.

3. After the removal of aquaculture animals as provided for in paragraph 1, cleaning, disinfection and fallowing shall be carried out in accordance with Articles 80 and 81.
4. The competent authority shall order synchronous fallowing of the affected establishments and the establishments selected in accordance with paragraph 2.
5. The synchronous fallowing referred to in paragraph 4 shall last for the period of time laid down in Annex XIII.

Article 97

Duration of disease control measures in the protection zone, repopulation of establishments covered by the protection zone

1. The competent authority shall maintain the disease control measures in the protection zone provided for in Section 2 of this Chapter until:
 - (a) the measures in Article 96 are carried out and completed; and
 - (b) the competent authority has, based on the outcome of the investigations conducted in accordance with Article 88, ruled out any occurrence of the relevant category A disease in the other establishments within the protection zone.
2. When the conditions set out in paragraph 1 are met:
 - (a) the competent authority shall apply the measures provided for in Section 3 of this Chapter in the protection zone for the period of time set out in Article 101; and
 - (b) the establishments referred to in Article 96(1) and (2) and previously covered by the protection zone may be repopulated.

Section 3

Disease control measures in the surveillance zone

Article 98

Measures to be applied in establishments in the surveillance zone

1. In the surveillance zone, the competent authority shall order that the measures provided for in Article 87 are applied in all establishments keeping aquaculture animals of listed species.
2. Official veterinarians shall visit the establishments referred to in paragraph 1 and carry out the activities provided for in Article 88(2) as appropriate.
3. The establishments within the surveillance zone shall undergo surveillance comprising visits and samplings as described in point 1 of Annex XV.
4. The surveillance provided for in paragraph 3 shall be carried out by the competent authority.

Article 99

Measures in relation to the movement and transport of aquaculture animals within from or to the surveillance zone

1. The competent authority shall prohibit any movements of aquaculture animals from establishments within the surveillance zone for slaughter, further farming or release into the wild outside the surveillance zone.

2. The competent authority shall ensure that any transport of aquaculture animals of listed species within or into the surveillance zone shall be conducted under conditions as set out in Article 90(a) to (e) and in Article 91.
3. The competent authority may order appropriate supplementary biosecurity measures to be applied to transport operations, including the unloading in the designated establishment of destination in order to control and prevent the possible spread of the diseases.
4. By way of derogation from paragraph 1, and in agreement with the competent authority of the place of destination, the competent authority may authorise movements of aquaculture animals provided that appropriate biosecurity measures to prevent the spreading of the category A disease are applied.

Article 100

Measures to be applied in food and feed businesses, purification centre, dispatch centres, border control posts, animal by-products establishments or any other location of relevance in the surveillance zone, including means of transport

1. The competent authority shall order without delay that the measures provided for in Articles 98 and 99 be applied in food and feed businesses, purification centre, dispatch centres, border control posts, animal by-products establishments or any other location of relevance in the surveillance zone, including means of transport.
2. In the locations referred to in paragraph 1, the competent authority may apply additional measures adapted to the specific situation in order to prevent the spread of the category A disease within and from the surveillance zone.

Article 101

Duration of disease control measures in the surveillance zone

The competent authority shall lift the disease control measures provided for in this Section when the period of surveillance, set out in point 2 of Annex XV, for the relevant category A disease has elapsed with favourable results.

CHAPTER III

Disease control measures in wild aquatic animals

Article 102

Measures in the event of a suspect case of a category A disease in wild aquatic animals of listed species

In the event of a suspect case of a category A disease in wild aquatic animals of listed species in accordance with Article 9(1), (3) and (4) in Delegated Regulation (EU) 2020/689, the competent authority shall:

- (a) immediately conduct an investigation of wild aquatic animals of listed species fished, caught, collected or found dead to confirm or rule out the presence of the category A disease in accordance with Article 71(2);
- (b) ensure that all animal by-products obtained from the wild aquatic animals of listed species suspected to be infected, including molluscs shells with meat, are processed or disposed of as category 1 or category 2 material in accordance with Regulation (EC) No 1069/2009;
- (c) ensure that, where practicable any material or substance likely to be contaminated by animals suspected to be affected or by the animal by-products obtained from those animals undergoes cleaning and disinfection or is disposed of following the instructions and under the supervision of official veterinarians; and
- (d) provide relevant information to the operators or authorities in charge of the management of the relevant animal population.

*Article 103***Measures in the event of an outbreak of a category A disease in wild aquatic animals of listed species**

1. In the event of an officially confirmed case of a category A disease in wild aquatic animals of listed species, the competent authority shall determine an infected zone on the basis of:
 - (a) relevant hydrodynamic, topographic and epidemiological conditions;
 - (b) the disease profile and the estimated population of aquatic animals of listed species; and
 - (c) the risk factors contributing to the spread of the relevant category A disease, in particular those associated with the risk of introducing the disease into establishments keeping aquatic animals of listed species.
2. The competent authority may adapt the boundaries of the initial infected zone:
 - (a) in order to control the further spread of the relevant category A disease; and
 - (b) in the case of confirmation of further outbreaks of the category A disease in wild animals.
3. The competent authority shall immediately inform operators, other relevant competent authorities, relevant veterinarians, and any other natural or legal person concerned, about the outbreak of the diseases and the control measures adopted.

*Article 104***Measures to be applied in the infected zone**

1. In the infected zone established in accordance with Article 103 the competent authority shall:
 - (a) implement risk mitigation and reinforced biosecurity measures, in order to prevent the spread of the category A disease from the affected animals and infected zone to unaffected animals and areas;
 - (b) prohibit any movement by humans of wild aquatic animals of listed species and products of animal origin obtained from those animals from the infected zone;
 - (c) by way of derogation from Article 10(i) of Regulation (EC) No 1069/2009 ensure that all animal by-products obtained from the wild aquatic animals of listed species in the infected zone including molluscs shells, with meat are processed or disposed of as category 1 or category 2 material in accordance with that Regulation;
 - (d) ensure, where practicable, that any material or substance likely to be contaminated by wild aquatic animals of listed species in the infected zone or animal by-products obtained from those animals undergoes cleaning and disinfection or is disposed of following the instructions and under the supervision of official veterinarians; and
 - (e) prohibit bringing into establishments keeping aquaculture animals of listed species both within and outside the infected zone or to water catchment or coastal areas outside the infected zone any parts of aquatic animals of listed species whether, fished, caught, collected or found dead in the infected zone as well as any product, material or substance which is likely to be contaminated with a category A disease in the infected zone.
2. By way of derogation from paragraph 1(b) and for the purpose of preserving valuable genetic material, the competent authority may authorise movements of wild aquatic animals of listed species from the infected zone to an establishment authorised by the competent authority for that purpose, provided that appropriate biosecurity measures to prevent the spread of the category A disease are applied. The establishment of destination shall be considered as an establishment located in the infected zone for the purposes of Article 108.

*Article 105***Additional measures to be applied in the infected zone**

1. After carrying out a risk assessment, the competent authority shall determine the additional measures necessary to control or eradicate the relevant category A disease.

2. As part of the control or eradication of the relevant category A disease the competent authority may:
 - (a) suspend restocking, fishing, collecting and catching activities;
 - (b) order mandatory cleaning and disinfection of fishing equipment and boats and other equipment likely to be contaminated; and
 - (c) increase fishing, collecting and catching activities or implement other relevant measures to eradicate the disease.
3. The measures provided for in paragraph 1 shall be implemented after consultations and in cooperation with the operational expert group referred to in Article 107 and other authorities and stakeholders.

Article 106

Extension of measures

The competent authority may decide that relevant measures in Articles 102 to 105 also apply to aquatic animals of non-listed species.

Article 107

Operational expert group

1. In the event of a confirmed case of a category A disease in wild aquatic animals of listed species, the competent authority shall establish an operational expert group as referred to in Article 43(2)(d)(iii) of Regulation (EU) 2016/429.
2. The operational expert group shall assist the competent authority in:
 - (a) assessing the epidemiological situation and its evolution;
 - (b) determining the infected zone; and
 - (c) establishing the appropriate measures to be applied in the infected zone and their duration.

Article 108

Measures in the establishments within the infected zone

1. In the establishments keeping aquaculture animals of listed species within the infected zone, the competent authority shall apply the measures provided for in Article 87.
2. In addition to the measures provided for in Article 87, the competent authority shall prohibit the movement of aquaculture animals kept in establishments within the infected zone:
 - (a) out of the infected zone; or
 - (b) to other establishments in the infected zone.
3. The competent authority may, after carrying out a risk assessment, limit the prohibition in paragraph 2 to aquaculture animals of listed species.
4. By way of derogation from paragraph 2, the competent authority may authorise after carrying out a risk assessment and in agreement with the competent authority of the place of destination, the movement of animals of listed species out of the infected zone or to other establishments in the infected zone.

Article 109

Duration of the measures in the infected zone

The competent authority shall maintain the measures provided for in this Chapter until the epidemiological information indicates that the relevant wild population no longer poses a risk of spreading the disease and the operational group recommends lifting the measures.

CHAPTER IV

Disease control measures for category B and C diseases of aquatic animals

Article 110

Preliminary disease control measures to be applied when a category B or C disease is suspected by the competent authority in Member States, zones or compartments that have been granted a disease free status

The competent authority shall apply the measures laid down in Articles 55, Article 56 and Article 57 of Delegated Regulation (EU) 2020/689 in the event of suspicion of a category B or C disease in accordance with Article 9(1), (3) or (4) of Delegated Regulation (EU) 2020/689, in Member States, zones or compartments that have been granted a disease free status as provided for in Article 36(4) and Article 37(4) of Regulation (EU) 2016/429, or Article 83, Article 84(1)(h) to (m) or Article 84(2)(b) to (g) of Delegated Regulation (EU) 2020/689.

Article 111

Disease control measures to be applied when a category B or C disease is confirmed

The competent authority shall apply the measures laid down in the Articles 58 to 65 of Delegated Regulation (EU) 2020/689 in the event of confirmation of a category B or C disease in accordance with Article 9(2), (3) or (4) of Delegated Regulation (EU) 2020/689 in Member States or zones or compartments that have been granted the disease free status as provided for in Article 36(4) and Article 37(4) of Regulation (EU) 2016/429, or Article 83, Article 84(1)(h) to (m) or Article 84(2)(b) to (g) of Delegated Regulation (EU) 2020/689:

PART IV

FINAL PROVISIONS

Article 112

Repeals

Directive 92/66/EEC, Directive 2001/89/EC, Directive 2003/85/EC and Directive 2005/94/EC as well as the acts adopted on the basis thereof, shall cease to apply with effect from 21 April 2021.

Article 113

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 December 2019.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

**CLINICAL EXAMINATIONS, SAMPLING PROCEDURES, DIAGNOSTIC METHODS OF CATEGORY A DISEASES
AND TRANSPORT OF SAMPLES**

(as referred to in Article 3 of this Regulation)

A. Sampling procedures**A.1 SAMPLING OF ANIMALS FOR CLINICAL EXAMINATIONS**

1. Clinical examinations must include, if possible:
 - (a) animals showing clinical signs of category A diseases;
 - (b) animals likely to have recently died from the suspected/confirmed disease;
 - (c) animals with epidemiological link to a suspected or confirmed case; and
 - (d) animals that obtained positive or non-conclusive results in previous laboratory examinations.
2. Animals to examine must be selected at random, in a number large enough to allow the detection of the disease, if present, where there are no obvious signs of disease or post-mortem lesions suggesting category A diseases.
3. The animals to examine and the sampling method must be chosen in accordance with the instructions of the competent authority and with the relevant contingency plan as referred to in Article 43 of Regulation (EU) 2016/429. The animals to examine and the sampling method must take into account the disease profile and:
 - (a) the purpose of the sampling;
 - (b) the listed species kept in the establishment;
 - (c) the number of animals of listed species kept in the establishment;
 - (d) the category of the kept animals;
 - (e) the available production, health and traceability records of the kept animals relevant for the investigation;
 - (f) the type of establishment and the husbandry practices;
 - (g) the level of exposure risk:
 - (i) likelihood of exposure to the disease agent or to the vector;
 - (ii) absence of immunisation of the animals due to vaccination or maternal immunity; and
 - (iii) history of residence in the establishment;
 - (h) other relevant epidemiological factors.
4. The minimum number of animals to examine must be in accordance with the instructions of the competent authority and with the relevant contingency plan as referred to in Article 43 of Regulation (EU) 2016/429. The minimum number of animals to examine must take into account the disease profile and in particular:
 - (a) the expected prevalence in the establishment;
 - (b) the level of confidence desired of the survey results, which in any case must not be lower than 95 %; and
 - (c) international standards and available scientific evidence.

A.2 SAMPLING OF ANIMALS FOR LABORATORY EXAMINATIONS

1. Sampling for laboratory examinations must take into account the outcome of the clinical examinations referred to in point A.1 and, if possible, must include animals referred to in paragraph 1 of point A.1.

2. If there are no obvious signs of disease or post-mortem lesions suggesting category A diseases, samples must be collected at random in each epidemiological unit of the establishment and must allow the detection of the disease, if present.
3. The animals to sample, the nature of the samples to collect and the sampling method must be in accordance with the instructions of the competent authority and with the relevant contingency plan as referred to in Article 43 of the Regulation (EU) 2016/429. The animals to sample, the nature of the samples to collect and the sampling method must take into account the disease profile and the criteria set out in paragraph 3 of point A.1.
4. The minimum number of animals to sample must be in accordance with the instructions of the competent authority and the relevant contingency plan as referred to in Article 43 of the Regulation (EU) 2016/429. The minimum number of animals to sample must take into account the criteria set out in paragraph 4 of point A.1 and the performance of the tests used.
5. In the case of wild animals, samples must be collected from animals shot, found dead or purposely trapped or must be obtained on the basis of non-invasive methods such as salt licks and chewing ropes or baits. The minimum number and the nature of the samples must take into account the estimated size of the wild population and the relevant criteria set out in paragraph 3 and 4 of point A.1.

A.3 SAMPLING OF ESTABLISHMENTS FOR VISITS

1. The choice of establishments to sample and the sampling method must be in accordance with the instructions of the competent authority and with the relevant contingency plan as referred to in Article 43 of the Regulation (EU) 2016/429. The choice of establishments to sample and the sampling method must take into account the disease profile and the criteria set out in paragraph 3 of point A.1.
2. The minimum number of establishments to visit must be in accordance with the instructions of the competent authority and with the relevant contingency plan, as referred to in Article 43 of the Regulation (EU) 2016/429.

B. Diagnostic methods

The techniques, reference materials, their standardisation and the interpretation of the results of tests carried out using the relevant diagnostic methods for category A diseases must comply with Article 6 and Part III of Annex VI to Delegated Regulation (EU) 2020/689.

The diagnostic methodology must aim to maximise the sensitivity of the surveillance. In certain circumstances this surveillance may include the use of laboratory examinations in order to assess previous exposure to disease.

C. Transport of samples

1. All samples taken to confirm or rule out the presence of a category A disease must be sent, with a proper labelling and identification, to an official laboratory which has been informed of their arrival. These samples must be accompanied by the appropriate forms, in accordance with the requirements established by the competent authority and the laboratory receiving the samples. These forms must include at least:
 - (a) the establishment of origin of the sampled animals;
 - (b) information on the species, age and category of the sampled animals;
 - (c) the clinical history of the animals, if available and relevant;
 - (d) the clinical signs and post-mortem findings; and
 - (e) any other relevant information.

2. All samples must be:
 - (a) stored in watertight and unbreakable containers and packages and in accordance with applicable international standards;
 - (b) kept at the most appropriate temperature and other conditions during transport taking into account the factors that may affect the sample quality.
 3. The exterior of the package must be labelled with the address of the recipient laboratory and the following message must be prominently displayed:

‘Animal pathological material; perishable; fragile; do not open outside the laboratory of destination.’
 4. The person responsible in the official laboratory receiving the samples must be informed in due time of the arrival of the samples.
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ANNEX II

MONITORING PERIOD

(as referred to in Articles 8, 17, 27, 32, 48, 57 and 59 of this Regulation)

Category A diseases	Monitoring period
Foot and mouth disease (FMD)	21 days
Infection with rinderpest virus (RP)	21 days
Infection with Rift Valley fever virus (RVFV)	30 days
Infection with lumpy skin disease virus (LSD)	28 days
Infection with <i>Mycoplasma mycoides subsp. mycoides SC</i> (Contagious bovine pleuropneumonia) (CBPP)	45 days
Sheep pox and goat pox (SPGP)	21 days
Infection with peste des petits ruminants virus (PPR)	21 days
Contagious caprine pleuropneumonia (CCPP)	45 days
African horse sickness (AHS)	14 days
Infection with <i>Burkholderia mallei</i> (Glanders)	6 months
Classical swine fever (CSF)	15 days
African swine fever (ASF)	15 days
Highly pathogenic avian influenza (HPAI)	21 days
Infection with Newcastle disease virus (NCD)	21 days

ANNEX III

CONDITIONS FOR CERTAIN DEROGATIONS FROM ARTICLE 12(1)(a) IN EQUINE ANIMALS

(as referred to in Article 13(4))

1. In the event of an outbreak of African horse sickness the competent authority may derogate from Article 12(1)(a) the affected and the unaffected animals, provided that:
 - (a) the affected animals subject to the derogation are isolated in vector-protected premises which avoid any transmission of the disease agent from the animals to the relevant vectors until 40 days, corresponding to the infective period established in the relevant Chapter of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), have elapsed after the entry of the animals into the vector protected premises; and
 - (b) surveillance, including if needed laboratory examinations, carried out by the competent authority, indicates that none of the animals in the vector protected premises poses a risk of virus transmission.
 2. In the event of an outbreak of infection with *Burkholderia mallei* (Glanders) the competent authority may derogate from Article 12(1)(a) the unaffected animals, provided that the animals subject to the derogation are quarantined until:
 - (a) the affected animals have been killed and destroyed;
 - (b) after the killing, the cleaning and disinfection of the establishment has been completed as provided for in Article 15; and
 - (c) the remaining animals have been subjected to a complement fixation test carried with negative result at a serum dilution of 1 in 5 on samples taken at least 6 months after the cleaning and disinfection referred to in point (b).
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ANNEX IV

PROCEDURES FOR CLEANING, DISINFECTION AND WHEN NECESSARY CONTROL OF INSECTS AND RODENTS

(as referred to in Articles 12, 15, 16, 39, 45 and 57 of this Regulation)

A. General requirements

1. The choice of biocidal products and procedures for cleaning and disinfection operations must take into account:
 - (a) the causal agent of infection;
 - (b) the nature of the establishments, vehicles, objects and materials which are to be treated; and
 - (c) the applicable legislation.
2. The conditions under which biocidal products are used must ensure that their efficacy is not impaired. In particular technical parameters provided by the manufacturer, such as pressure, temperature, required contact time or storage must be observed. The activity of the disinfectant must not be compromised by interaction with other substances.
3. Re-contamination of the previously cleaned parts must be avoided, in particular where washing is carried out with liquids applied under pressure.
4. The water used for cleaning operations must be contained and disposed of in a way that avoids any risk of spreading category A disease agents.
5. Biocidal products must be used in a way that reduces as much as possible any adverse impact on the environment and on public health that may arise from their use.

B. Preliminary cleaning and disinfection

For preliminary cleaning and disinfection under Article 15, to avoid spreading the category A disease:

- (a) entire bodies or parts of dead kept animals of listed species must be sprayed with disinfectant and removed from the establishment, in closed and leak-proof vehicles or containers for processing and disposal;
- (b) any tissue or blood which may have been spilled during killing, slaughter or post-mortem examination must be carefully collected and disposed of;
- (c) as soon as the entire bodies or parts of dead kept animals of listed species have been removed for processing or disposal, the parts of the establishment in which these animals were kept and any parts of other buildings, surfaces or equipment contaminated during killing or post-mortem examination must be sprayed with disinfectant;
- (d) manure, including litter and used bedding, must be thoroughly soaked with disinfectant;
- (e) the disinfectant must remain on the treated surface for at least 24 hours;
- (f) equipment, containers, consumption utensils, surfaces or any material likely to be contaminated after the washing and disinfecting must be destroyed.

C. Final cleaning and disinfection:

For final cleaning and disinfection for the purpose of Article 57:

1. Manure, including litter and used bedding, must be removed and treated as follows:
 - (a) the solid phase of manure, including litter and used bedding, must either:
 - (i) undergo a steam treatment at a temperature of at least 70 °C;
 - (ii) be destroyed by burning;

- (iii) be buried deep enough to prevent access by animals; or
 - (iv) be stacked to heat, sprayed with disinfectant and left for at least 42 days, during which the stack must be either covered or re-stacked to ensure thermic treatment of all layers;
 - (b) the liquid phase of manure must be stored for at least 42 days, and in the case of highly pathogenic avian influenza 60 days, after the last addition of infective material.
2. Buildings, surfaces and equipment must be thoroughly washed and cleaned by removing the remaining grease and dirt and sprayed with disinfectants.
 3. After 7 days the establishments must be cleaned and disinfected again.
-

ANNEX V

MINIMUM RADIUS OF PROTECTION AND SURVEILLANCE ZONES

(as referred to in Article 21 of this Regulation)

Indicated as radius of a circle centred on the establishment

Category A diseases	Protection Zone	Surveillance Zone
Foot and mouth disease	3 km	10 km
Infection with rinderpest virus	3 km	10 km
Infection with Rift Valley fever virus	20 km	50 km
Infection with lumpy skin disease virus	20 km	50 km
Infection with <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> SC (Contagious bovine pleuropneumonia)	Establishment	3 km
Sheep pox and goat pox	3 km	10 km
Infection with peste des petits ruminants virus	3 km	10 km
Contagious caprine pleuropneumonia	Establishment	3 km
African horse sickness	100 km	150 km
Infection with <i>Burkholderia mallei</i> (Glanders)	Establishment	Establishment
Classical swine fever	3 km	10 km
African swine fever	3 km	10 km
Highly pathogenic avian influenza	3 km	10 km
Infection with Newcastle disease virus	3 km	10 km

ANNEX VI

PROHIBITIONS IN THE RESTRICTED ZONE

(as referred to in Article 27 of this Regulation)

Table: Prohibitions of activities concerning animals of listed species and products from those animals

PROHIBITIONS OF ACTIVITIES CONCERNING ANIMALS AND PRODUCTS	FMD ⁽¹⁾	RP	RVFV	LSD	CBPP	SPCP	PPR	CCPP	CSF	ASF	AHS	GLAND	HPAI	NCD
Movements of kept animals of listed species from establishments in the restricted zone	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Movements of kept animals of listed species to establishments in the restricted zone	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Restocking of game animals of listed species	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Fairs, markets, shows and other gatherings of kept animals of listed species including collection and dispersion of those species	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Movements of semen, oocytes and embryos obtained from kept animals of listed species from establishments in the restricted zone	X	X	X	X (*)	X	X	X	X	X	X	X	NA	NA	NA
Collection of semen, oocytes and embryo from kept animals of listed species	X	X	X	X	X	X	X	X	X	X	NP	NA	NA	NA
Itinerant artificial insemination of kept animals of listed species	X	X	X	X	X	X	X	X	X	X	X	NA	NA	NA
Itinerant natural service of kept animals of listed species	X	X	X	X	X	X	X	X	X	X	X	NA	NA	NA
Movements of hatching eggs from establishments in the restricted zone	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	X	X
Movements of fresh meat excluding offal from kept and wild animals of listed species from slaughterhouses or game handling establishments in the restricted zone	X	X	X	NP	NP	X	X	NP	X	X	NP	NA	X	X

⁽¹⁾ Disease abbreviations in accordance with Annex II.

NA = Not applicable.

X = prohibition.

NP = Not prohibited.

(*) only oocytes and embryo.

PROHIBITIONS OF ACTIVITIES CONCERNING ANIMALS AND PRODUCTS	FMD (*)	RP	RVFV	LSD	CBPP	SPCP	PPR	CCPP	CSF	ASF	AHS	GLAND	HPAI	NCD
Movements of offal from kept and wild animals of listed species from slaughterhouses or game handling establishments in the restricted zone	X	X	X	X	X	X	X	X	X	X	NP	NA	X	X
Movements of meat products obtained from fresh meat of listed species from establishments in the restricted zone	X	X	X	NP	NP	NP	X	NP	X	X	NP	NA	X	X
Movement of raw milk and colostrum obtained from kept animals of listed species from establishments in the restricted zone	X	X	X	X	NP	X	X	NP	NA	NA	NP	NA	NA	NA
Movement of dairy products and colostrum based products from establishments in the restricted zone	X	X	X	X	NP	X	X	NP	NA	NA	NP	NA	NA	NA
Movement of eggs for human consumption from establishments in the restricted zone	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	X	X
Movement of manure, including litter and used bedding from kept animals of listed species from establishments in the restricted zone	X	X	X	X	NP	X	X	NP	X	X	NP	NA	X	X
Movement of hides, skins, wool, bristles and feathers from kept animals of listed species from establishments in the restricted zone	X	X	X	X	NP	X	X	NP	X	X	NP	NA	X	X
Movement of feed material of plant origin and straw obtained in the protection zone (*)	X	X	NP	NP	NP	NP	NP	NP	NP	NP	NP	NA	NP	NP

(*) only oocytes and embryo.

ANNEX VII

RISK-MITIGATING TREATMENTS FOR PRODUCTS OF ANIMAL ORIGIN FROM THE RESTRICTED ZONE

(as referred to in Articles 27, 33 and 49 of this Regulation)

Treatment	FMD ⁽¹⁾	RP	RVFV	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHV	HPAI	NCV
MEAT													
Heat treatment in an hermetically sealed container, to achieve a minimum F_0 ⁽²⁾ value of 3	x						X		X	X		X	X
Heat treatment to achieve a core temperature of 80 °C	X						X		X	X		X	X
Heat treatment to achieve a core temperature of 70 °C	X						X		X			X	X
Heat treatment (to meat previously de-boned and defatted) to achieve a core temperature of 70 °C for a minimum of 30 minutes	X						X		X				
In an hermetically sealed container, applying 60 °C for a minimum of 4 hours	X						X		X	X			
Core temperature of 73,9 °C for a minimum of 0,51 seconds ⁽³⁾	X											X	X
Core temperature of 70,0 °C for a minimum of 3,5 seconds ⁽³⁾												X	X
Core temperature of 65,0 °C for a minimum of 42 seconds ⁽³⁾												X	X
Core temperature of 60 °C for a minimum of 507 seconds ⁽³⁾												X	X
Heat treatment to achieve desiccation to maximum values of A_w of 0,93 and pH of 6													
Heat treatment to achieve a core temperature of 65 °C for a period of time to achieve a minimum pasteurisation value of 40							X						

⁽¹⁾ Disease abbreviations in accordance with Annex II.

⁽²⁾ F_0 is the calculated killing effect on bacterial spores. An F_0 value of 3 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121 °C (250 °F) in three minutes with instantaneous heating and chilling.

⁽³⁾ Only for poultry meat.

Treatment	FMD ⁽¹⁾	RP	RVFV	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	HPAI	NCD
Natural fermentation and maturation for bone-in meat: minimum 9 months, to achieve maximum values of Aw of 0,93 and pH of 6	X								X				
Natural fermentation and maturation for de-boned meat: minimum 9 months, to achieve maximum values of Aw of 0,93 and pH of 6	X								X	X			
Natural fermentation for loins: minimum 140 days to achieve maximum values of Aw of 0,93 and pH of 6 ⁽⁴⁾									X	X			
Natural fermentation for hams: minimum 190 days to achieve maximum values of Aw of 0,93 and pH of 6 ⁽⁴⁾									X	X			
Drying after salting Italian style bone-in hams: minimum 313 days ⁽⁴⁾									X				
Drying after salting Spanish style bone-in hams and loins ⁽⁴⁾ : — Iberian hams: minimum 252 days — Iberian shoulders: minimum 140 days — Iberian loins: minimum 126 days — Serrano hams: minimum 140 days	X								X	X			
Maturation of carcasses at a minimum temperature of 2 °C for a minimum of 24 hours following slaughter			X										
Removal of offal				X	X			X					
CASINGS													
Salting with sodium chloride (NaCl) either dry or as saturated brine (Aw < 0,80), for a continuous period of 30 days or longer at an ambient temperature of 20 °C or above	X								X	X			
Salting with phosphate supplemented salt 86,5 % NaCl, 10,7 % Na ₂ HPO ₄ and 2,8 % Na ₃ PO ₄ either dry or as saturated brine (Aw < 0,80) for a continuous period of 30 days or longer at an ambient temperature of 20 °C or above	X			SC ⁽⁵⁾			X		X	X			
Salting with sodium chloride (NaCl) minimum 30 days ⁽⁶⁾													

⁽⁴⁾ Only for porcine animals.⁽⁵⁾ Safe commodity.⁽⁶⁾ Not for bovine, ovine, caprine and porcine casings.

Treatment	FMD (1)	RP	RVFV	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	HPAI	NCD
Bleaching (7)													
Drying (7)													
MILK													
Heat treatment (sterilization process) to achieve a minimum F_0 value of 3	X												
Heat treatment UHT (Ultra high temperature): Minimum 132 °C for a minimum of 1 second	X						X						
Heat treatment UHT (Ultra high temperature): Minimum 135 °C for a suitable holding time	X												
Heat treatment HTST (High temperature short time pasteurisation) if milk pH is lower than 7, minimum 72 °C for a minimum of 15 seconds	X						X						
Heat treatment HTST (High temperature short time pasteurisation) if milk pH is 7 or higher, minimum 72 °C for a minimum of 15 seconds, applied twice	X				SC (8)		X						
Heat treatment HTST (High temperature short time pasteurisation) combined with a physical treatment to achieve pH value below 6 for a minimum of 1 hour or to achieve a minimum of 72 °C, combined with desiccation	X												
Pasteurisation consisting in a single heat treatment with an effect at least equivalent to that achieved by applying 72 °C for 15 seconds	X		X	X									

(7) Not for bovine, ovine, caprine and porcine casings.

(8) Safe commodity.

Treatment	HPAI	NCD
EGGS		
Heat treatment:		
— Whole egg:		
— 60,0 °C – 188 sec.		
— completely cooked		
— Whole egg blends:		
— 60 °C – 188 sec.		
— completely cooked		
— 61,1 °C – 94 sec.		
— Liquid egg white:		
— 55,6 °C – 870 sec.	X	
— 56,7 °C – 232 sec.		
— Plain or pure egg yolk:		
— 60 °C – 288 sec.		
— 10 % salted yolk:		
— 62,2 °C – 138 sec.		
— Dried egg white:		
— 67 °C – 20 hours		
— 54,4 °C – 50,4 hours		
— 51,7 °C – 73,2 hours		
Heat treatment:		
— Whole egg:		
— 55 °C – 2 521 sec.		
— 57 °C – 1 596 sec.		
— 59 °C – 674 sec.		
— completely cooked		
— Liquid egg white:		
— 55 °C – 2 278 sec.		
— 57 °C – 986 sec.		
— 59 °C – 301 sec.		
— 10 % salted egg yolk:		
— 55 °C – 176 sec.		
— Dried egg white:		
— 57 °C – 54,0 hours		X

ANNEX VIII

RISK-MITIGATING TREATMENTS FOR PRODUCTS NOT OF ANIMAL ORIGIN FROM THE PROTECTION ZONE

(as referred to in Articles 36 and 52 of this Regulation)

Treatment	FMD ⁽¹⁾	RP
Heat treatment, minimum temperature of 80 °C and for a minimum of 10 minutes, steam in a closed chamber	X	X
Storage in package or bales under shelter at premises situated not closer than 2 km to the nearest outbreak and releasing from the premises do not take place before at least three months have elapsed following the completion of cleaning and disinfection according to Article 15	X	X

⁽¹⁾ Disease abbreviations in accordance with Annex II.

ANNEX IX

MARKING OF FRESH MEAT FROM THE PROTECTION ZONE

(as referred to in Articles 33 and 49 of this Regulation)

1. The mark to be applied to fresh meat of poultry originating in the protection zone and not intended to another Member State pursuant to Article 33(1)(b) must comply with the following:

- (a) shape and content:

Where 'XY' means the relevant country code provided for in point 6 of Part B of Section I of Annex II of Regulation (EC) No 853/2004 and '1234' means the approval number of the establishment referred to in point 7 of Part B of Section I of Annex II of Regulation (EC) No 853/2004;

- (b) dimensions:

- 'XY' width of 8 mm,
- '1234' width of 11 mm,
- width outer diameter of not less than 30 mm,
- line thickness of square of 3 mm.

2. The mark to be applied to fresh meat intended for treatment in a processing plant pursuant to Article 33(2)(a) shall consist in, either:

- (a) the identification mark provided for in Regulation (EC) No 853/2004 with an additional diagonal cross consisting of two straight lines intersecting at the centre of the stamp and enabling the information thereon to remain legible; or

- (b) a single oval stamp, 6,5 cm wide by 4,5 cm high, in which the following information must appear in perfectly legible characters:

- on the upper part, the full name or ISO code of the Member State in capitals,
 - in the centre, the approval number of the slaughterhouse,
 - on the lower part, one of the following sets of initials CE, EC, EF, EG, EK, EY, EO, ES, EU, EB, WE or EZ,
 - two straight lines crossing at the centre of the stamp in such a way that the information is not obscured,
 - the letters must be at least 0,8 cm high and the figures at least 1 cm high.
-

ANNEX X

DURATION OF THE MEASURES IN THE PROTECTION ZONE

(as referred to in Article 39 of this Regulation)

Category A diseases	Minimum period of duration of measures in the protection zone (Article 39(1))	Additional period of duration of surveillance measures in the protection zone (Article 39(3))
Foot and mouth disease	15 days	15 days
Infection with rinderpest virus	21 days	9 days
Infection with Rift Valley fever virus	30 days	15 days
Infection with lumpy skin disease virus	28 days	17 days
Infection with <i>Mycoplasma mycoides subsp. mycoides</i> SC (Contagious bovine pleuropneumonia)	45 days	Not applicable
Sheep pox and goat pox	21 days	9 days
Infection with peste des petits ruminants virus	21 days	9 days
Contagious caprine pleuropneumonia	45 days	Not applicable
African horse sickness	12 months	Not applicable
Infection with <i>Burkholderia mallei</i> (Glanders)	6 months	Not applicable
Classical swine fever	15 days	15 days
African swine fever	15 days	15 days
Highly pathogenic avian influenza	21 days	9 days
Infection with Newcastle disease virus	21 days	9 days

ANNEX XI

DURATION OF THE MEASURES IN THE SURVEILLANCE ZONE

(as referred to in Articles 55 and 56 of this Regulation)

Category A diseases	Minimum period of duration of measures in the surveillance zone
Foot and mouth disease	30 days
Infection with rinderpest virus	30 days
Infection with Rift Valley fever virus	45 days
Infection with lumpy skin disease virus	45 days
Infection with <i>Mycoplasma mycoides subsp. mycoides</i> SC (Contagious bovine pleuropneumonia)	45 days
Sheep pox and goat pox	30 days
Infection with peste des petits ruminants virus	30 days
Contagious caprine pleuropneumonia	45 days
African horse sickness	12 months
Infection with <i>Burkholderia mallei</i> (Glanders)	Not applicable
Classical swine fever	30 days
African swine fever	30 days
Highly pathogenic avian influenza	30 days
Infection with Newcastle disease virus	30 days

ANNEX XII

SAMPLING PROCEDURES AND DIAGNOSTIC METHODS FOR CATEGORY A DISEASES IN AQUATIC ANIMALS

1. The following procedures apply to the clinical examination and collection of samples:

(a) the clinical examination and the sampling for laboratory examinations must include:

- (i) aquaculture animals of listed species showing clinical signs of the relevant category A disease; and
- (ii) aquaculture animals likely to have recently died from the suspected/confirmed category A disease; and
- (iii) aquaculture animals with an epidemiological link to a suspected or confirmed case of a category A disease;

(b) the minimum number of samples to be collected is:

Type of animals	Scenario			
	Report of increased mortality	Introduction of infected animals	Post-mortem or clinical signs observed	Suspicion based on other circumstances
Molluscs (the whole animal)	30	30	—	150
Crustaceans	10		10	150
Fish	—	—	10	30

(c) the following additional criteria apply to the sampling of molluscs:

- (i) animals suspected to be infected must be selected for sampling. If listed species are present in the population of animals concerned by the suspicion, those must be selected for sampling;
- (ii) if weak, gaping or freshly dead but not decomposed molluscs are present, those must be selected first. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;
- (iii) if the establishment uses more than one water source for mollusc production, molluscs representing all water sources must be included for sampling to ensure that all parts of the establishment are proportionally represented in the sample;
- (iv) when sampling from a group of mollusc farming establishments which apparently have identical epidemiological status, molluscs from a representative number of sampling points must be included in the sample.

The main factors to be considered when selecting those sampling points must be stocking density, water currents, the presence of listed species, both susceptible and vector species, bathymetry and management practices. Natural beds within or adjacent to the mollusc farming establishment(s) must be included in the sample;

(d) the following additional criteria apply when sampling crustaceans:

- (i) if weak or moribund crustaceans of listed species are present in the production units, those crustaceans must be selected first. If such animals are not present, the crustaceans selected must include crustaceans of different year classes, proportionally represented in the sample;
- (ii) if more than one water source is used for crustacean production, crustaceans of listed species representing all water sources must be included in the sample to ensure that all parts of the establishment are proportionally represented in the sample;
- (iii) when collection of samples from wild populations of listed species is required under Article 102(a) of this Regulation, the number and geographical distribution of the sampling points must be determined in a way that ensures a reasonable coverage of the area suspected to be infected.

The sampling points must be representative for the different ecosystems where the wild populations of susceptible species are located such as marine, estuary, river and lake systems;

(e) the following additional criteria apply for sampling fish:

- (i) if weak, abnormally behaving or freshly dead but not decomposed fish are present, those fish must be selected. If such animals are not present, the fish selected must include fish of listed species, belonging to different year classes, proportionally represented in the sample;
- (ii) if more than one water source is used for fish production, listed species representing all water sources must be included for sampling to ensure that all parts of the establishment are proportionally represented in the sample;
- (iii) if rainbow trout (*Onchorynchus mykiss*) or European perch (*Perca fluviatilis*) are present, only fish of those species may be selected for sampling. If neither rainbow trout nor European perch are present, the sample must be representative of all other listed species present, following the criteria in points (a) to (d);
- (iv) when collection of samples from wild populations of listed species is required under Article 102(a) of this Regulation, the number and geographical distribution of the sampling points must be determined in a way that ensures a reasonable coverage of the area suspected to be infected.

The sampling points must also be representative of the different ecosystems where the wild populations of susceptible species are located such as marine, estuary, river and lake systems;

- (f) the selection of organs to be sampled, preparation, storage and shipment of the samples to the laboratory must be carried out in compliance with recommendations from the European Union reference laboratory for the relevant disease.

2. Samples must be examined in the laboratory using the diagnostic methods and procedures approved by the European Union reference laboratory for the relevant disease.
-

ANNEX XIII

MINIMUM PERIODS OF FALLOWING OF AFFECTED AQUACULTURE ESTABLISHMENTS

Periods for the fallowing provided for in Article 81 and for the synchronous fallowing provided for in Article 96(4) and (5) of this Regulation

Category A disease	Minimum period of fallowing of the affected establishment	Minimum period of synchronised fallowing of affected establishments in the same protection zone	Supplementary requirements
Infection with <i>Mikrocytos mackini</i>	6 months	4 weeks	Must include the coldest period of the year
Infection with <i>Perkinsus marinus</i>	6 months	4 weeks	Must include the warmest period of the year
Infection with <i>Taura syndrome virus</i>	6 weeks	4 weeks	Must include the warmest period of the year
Infection with <i>Yellow head syndrome virus</i>	6 weeks	3 weeks	Must include the warmest period of the year
<i>Epizootic haematopoietic necrosis</i>	8 weeks	4 weeks	Must include the warmest period of the year

ANNEX XIV

CRITERIA FOR ESTABLISHING RESTRICTED ZONES AS REGARDS CATEGORY A DISEASES IN AQUATIC ANIMALS

1. Restricted zones as referred to in Article 85 must be defined on a case-by-case basis taking into account at least the following factors:
 - (a) the accumulated number, the accumulated percentage and the distribution of the mortalities of molluscs/crustaceans/fish in the establishment or group of farming establishments infected with category A diseases;
 - (b) relevant information regarding movements to and from the infected establishment(s);
 - (c) the distance to and density of neighbouring establishments;
 - (d) the presence of wild aquatic animals;
 - (e) any knowledge concerning mortalities, suspected cases or outbreaks in wild aquatic animals which are, or could be related to the specific category A disease;
 - (f) the proximity to processing establishments, and the species present at those establishments, especially as regards listed species;
 - (g) farming practices applied in the affected and neighbouring establishments;
 - (h) hydrodynamic conditions and other identified factors of epidemiological significance.
 2. For the geographical demarcation of the protection and surveillance zones for category A diseases affecting molluscs and crustaceans, the following minimum requirements apply:
 - (a) the protection zone must be established in the immediate vicinity of an establishment or group of farming establishments officially confirmed as infected with a category A disease and must correspond to an area determined according to appropriate hydrodynamic and epidemiological data;
 - (b) the surveillance zone must be established outside the protection zone and must correspond to an area surrounding the protection zone, determined according to appropriate hydrodynamic or epidemiological data.
 3. For the geographical demarcation of the protection and surveillance zones for category A diseases affecting fish, the following minimum requirements must apply:
 - (a) the protection zone must be established around an establishment where *Epizootic hematopoietic necrosis* (EHN) has been confirmed. This zone shall correspond:
 - (i) in coastal areas: to an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment in which EHN has been officially confirmed, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;
 - (ii) in inland areas: to the entire water catchment area of the establishment in which EHN has been officially confirmed. The competent authority may limit the extension of the zone to parts of the water catchment area, or the area of the establishment, provided this does not compromise prevention of the spread of the disease;
 - (b) the surveillance zone must be established by the competent authority outside the protection zone and must:
 - (i) in coastal areas: correspond to an area, surrounding the protection zone, of overlapping tidal excursion; or an area, surrounding the protection zone, and included in a circle of radius 10 km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;
 - (ii) in inland areas: be an extended area outside the established protection zone.
-

ANNEX XV

SURVEILLANCE SCHEME AND DURATION OF CONTROL MEASURES IN THE SURVEILLANCE ZONE FOR CATEGORY A DISEASES IN AQUACULTURE ANIMALS

(as referred to in Articles 98 and 101 of this Regulation)

1. Surveillance scheme

The establishments and groups of aquaculture establishments keeping listed species within a surveillance zone must undergo surveillance as provided for in Article 98 to check for infection with the relevant category A disease. The surveillance must include health visits, including sampling from production units. Those visits must be carried out by the competent authority in accordance with Tables 1 and 2.

The criteria set out in point 1 of Annex XII, as appropriate for the species, apply to sampling.

Table 1

Scheme for surveillance comprising health visits and samplings in establishments and groups of establishments for category A diseases in aquatic animals, except epizootic hematopoietic necrosis

Category A disease	Number of health visits per year	Number of laboratory examinations per year	Number of animals in the sample	Period of the year for sampling	Residency period of the sampled animals in the establishment
Infection with <i>Mikrocytos mackini</i>	1	1	150	When the prevalence of infection is known to be maximal or April–May, after 3–4 months period when seawater temperatures are less than 10 °C	4 months
Infection with <i>Perkinsus marinus</i>	1	1	150	When the prevalence of infection is known to be maximal or in the month of September, October or November	4 months
Infection with <i>Taura syndrome virus</i>	2	2	150	In the period of the year when water temperature is likely to reach its highest annual level	2 months
Infection with <i>Yellow head syndrome virus</i>	2	2	150	In the period of the year when water temperature is likely to reach its highest annual level	2 months

Table 2

Specific scheme for surveillance comprising health visits and samplings in establishments for epizootic haematopoietic necrosis (EHN) in aquatic animals ⁽¹⁾

Type of establishment	Number of health inspections per year (2 years)	Number of samplings per year (2 years)	Number of fish in the sample	
			Number of growing fish	Number of brood stock fish ⁽²⁾
(a) Establishments with brood-stock	2	2	150 (first and second inspection)	150 (first or second inspection)
(b) Establishments with brood-stock only	2	1	0	150 ⁽²⁾ (first or second inspection)
(c) Establishments without broodstock	2	2	150 (first and second inspection)	0

Maximum number of fish per pool: 10

⁽¹⁾ The sampling of fish for laboratory examination must be carried out whenever the water temperature is between 11 and 20 °C. The water temperature requirement must also apply to health inspections. In establishments where the water temperature does not reach 11 °C during the year, sampling and health visits must be carried out when the water temperature is at its highest level.

⁽²⁾ Samples from broodstock must not include gonadal fluids, milt or ova as there is no evidence of EHN causing reproductive tract infection.

2. Duration of the control measures in the surveillance zone

Category A disease	Minimum periods of surveillance
Infection with <i>Mikrocytos mackini</i>	3 years
Infection with <i>Perkinsus marinus</i>	3 years
Infection with <i>Taura syndrome virus</i>	2 years
Infection with <i>Yellow head syndrome virus</i>	2 years
<i>Epizootic haematopoietic necrosis</i>	2 years

When the period of surveillance has elapsed and there has been no new detection of infection with the relevant category A disease, the measures in the surveillance zone must be lifted as provided for in Article 101 of this Regulation.

COMMISSION DELEGATED REGULATION (EU) 2020/688**of 17 December 2019****supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law ⁽¹⁾'), and in particular the second subparagraph of Article 3(5), Article 125(2), Article 131(1), Article 132(2), Article 135, Article 136(2), Article 137(2), Article 140, Article 144(1), Article 146(1), Article 147, Article 149(4), Article 154(1), Article 156(1), Article 160, Article 162(3) and (4), Article 163(5)(b) and (c) and Article 164(2) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases that are transmissible to animals or humans. In Chapters 3-5 of Title I of Part IV, it lays down the animal health requirements for movements within the Union of kept and wild terrestrial animals and germinal products thereof. The Regulation also empowers the Commission to adopt rules to supplement certain non-essential elements of that Regulation by means of delegated acts. It is therefore appropriate to adopt such rules in order to ensure the smooth functioning of the new legal framework established by Regulation (EU) 2016/429.
- (2) The rules and risk mitigation measures laid down in this Regulation are required to supplement the animal health requirements laid down in Chapters 3-5 of Title I of Part IV of Regulation (EU) 2016/429 as regards the movements within the Union of kept and wild terrestrial animals and of hatching eggs, to ensure that those commodities do not pose a significant risk of spread of listed diseases referred to in Article 5(1) and Annex II of the same Regulation, as amended by Commission Delegated Regulation (EU) 2018/1629 ⁽²⁾ and categorised in accordance with Article 9(1)(d) of Regulation (EU) 2016/429 by Commission Implementing Regulation (EU) 2018/1882 ⁽³⁾. Regulation (EU) 2016/429 aims to provide a simpler and more flexible regulatory framework comparing to the one applying prior to its adoption, while at the same time ensuring a more risk-based approach to animal health requirements, and improved animal disease preparedness, prevention and control. It also aims to collect the rules on animal diseases in a single act, rather than their being scattered over a number of different acts. The rules laid down in this Regulation concerning certain germinal products, notably hatching eggs, follow the same approach. The content of the rules is substantively linked, since they are to apply to all operators moving kept or wild terrestrial animals or hatching eggs. In the interests of simplicity and transparency, as well as to facilitate the application of the rules and avoid duplication, they should be laid down in a single act rather than in a number of cross-referenced separate acts.
- (3) Article 5(1) and Annex II to Regulation (EU) 2016/429, as amended by Commission Delegated Regulation (EU) 2018/1629, provide the list of animal diseases of special relevance for Union intervention, while Commission Implementing Regulation (EU) 2018/1882 categorises them on the basis of the specific measures to apply to them, and lists the animal species to which those rules should apply. Category D diseases are considered to pose a considerable risk of spread when animals are moved between Member States.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2018/1629 of 25 July 2018 amending the list of diseases set out in Annex II to Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 272, 31.10.2018, p. 11).

⁽³⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

- (4) Eradication programmes exist for the eradication of category B or C diseases. The rules for these programmes are laid down in Commission Delegated Regulation (EU) 2020/689 ⁽⁴⁾. These eradication programmes apply to an establishment, zone or Member State, depending on the disease in question, and the measures required include certain animal health guarantees for movements of animals. The Delegated Regulation mentioned above also sets out the rules for the recognition of disease-free Member States and zones following the successful completion of the respective eradication programme. This Regulation should therefore also provide for such animal health guarantees in respect of movements of animals to other Member States or zones carrying out eradication programmes or having a recognised disease-free status.
- (5) To mitigate the risk of spread of disease between Member States, it is necessary to lay down in this Regulation supplementary animal health requirements concerning the diseases referred to in recitals (3) and (4) above, the animal species listed for the respective disease in Implementing Regulation (EU) 2018/1882 and eradication programmes and disease-free status. The relevant standards recommended in the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE) should be taken into account.
- (6) Article 125 of Regulation (EU) 2016/429 sets out the required disease prevention measures in relation to transport of animals, and empowers the Commission to lay down supplementary requirements for cleaning and disinfecting means of transport of kept terrestrial animals and biosecurity measures to mitigate the possible risks arising from animal transport operations within the Union. It is necessary, therefore, to lay down in this Regulation more detailed rules on structural requirements for means of transport and containers and more detailed biosecurity requirements for animal transport operations, and to provide for certain exemptions. Similar rules also apply to operators engaged in the transport of certain germinal products, notably hatching eggs of poultry and captive birds, and such rules should also be laid down in this Regulation on the basis of Article 157(3) of Regulation (EU) 2016/429.
- (7) Requirements for cleaning and disinfection of means of transport and biosecurity measures to mitigate the possible risks arising from certain animal transport operations were laid down in the rules that applied prior to Regulation (EU) 2016/429, in particular Council Directives 64/432/EEC ⁽⁵⁾, 91/68/EEC ⁽⁶⁾, 2009/156/EC ⁽⁷⁾ and 2009/158/EC ⁽⁸⁾ for transport operations of bovine, porcine, ovine, caprine and equine animals, poultry and hatching eggs. Those requirements have proven to be effective in preventing the risk of spread of animal diseases within the Union through transport operations. It is therefore appropriate to maintain the substance of those requirements and adapt them to transport operations of all kept terrestrial animals and hatching eggs.
- (8) Article 132(2) of Regulation (EU) 2016/429 requires that the Commission determines a maximum timeframe within which the operator of a slaughterhouse receiving kept ungulates and poultry for slaughter from another Member State should ensure that those animals are slaughtered. This Regulation should therefore provide for such a maximum timeframe within which animals should be slaughtered, to ensure that their health status would not compromise the health status of the animals at the place of destination. Regulation (EU) 2016/429 also lays down rules for the movement of consignments of ungulates susceptible to infection with Bluetongue virus (serotypes 1-24), which may have a specific risk of spread due to the vector-borne transmission of the disease. This Regulation should therefore lay down certain specific provisions on the slaughtering of those animals.

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (see page 211 of this Official Journal).

⁽⁵⁾ Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 121, 29.7.1964, p. 1977/64).

⁽⁶⁾ Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19).

⁽⁷⁾ Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae (OJ L 192, 23.7.2010, p. 1).

⁽⁸⁾ Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports of third countries of, poultry and hatching eggs (OJ L 343, 22.12.2009, p. 74).

- (9) In respect of movements to other Member States of kept ungulates and poultry, Article 131(1) of Regulation (EU) 2016/429 empowers the Commission to lay down rules concerning residency periods, the period of time necessary to limit the introduction of kept ungulates or poultry into establishments prior to movement, and supplementary animal health requirements to mitigate the risk of spread of listed diseases as referred to in Article 9(1)(d) thereof. It is therefore necessary to lay down appropriate measures in this Regulation to safeguard the health of animals and prevent the spread of disease through movements of ungulates, poultry and captive birds. These measures should take account of the rules that applied prior to the application of Regulation (EU) 2016/429. Such rules for ungulates, poultry and captive birds were laid down in Council Directives 64/432/EEC, 91/68/EEC and 2009/158/EC, 2009/156/EC and, in part, Council Directive 92/65/EEC⁽⁹⁾. Where relevant, those rules should introduce new or different requirements, in particular to take account of new scientific developments and standards or the list of diseases provided for in Article 5(1) of Regulation (EU) 2016/429 and Delegated Regulation (EU) 2018/1629 and the diseases' categorisation subject to Implementing Regulation (EU) 2018/1882.
- (10) Similarly, Articles 160(2) and 164(2) of Regulation (EU) 2016/429 empower the Commission to adopt delegated acts laying down animal health requirements for movements to other Member States of germinal products of poultry and captive birds, i.e. hatching eggs. This Regulation must also therefore provide for those rules.
- (11) As a baseline, movements of terrestrial animals to another Member State should take place from the establishment of origin directly to the place of destination in that Member State. By way of derogation, however, this movement may be interrupted, and animals may undergo assembly operations. These operations represent a specific risk for spreading animal diseases. Article 135 of Regulation (EU) 2016/429 requires the Commission to adopt delegated acts laying down rules supplementing those provided for in Articles 133 and 134 thereof for assembly operations in respect of kept ungulates and poultry, where those animals are being moved to another Member State. It is therefore necessary to lay down such requirements in this Regulation.
- (12) Under the rules applicable prior to Regulation (EU) 2016/429, set out in Directives 64/432/EEC, 91/68/EEC and 2009/156/EC, some consignments of ungulates did not move directly from an establishment of origin to an establishment of destination. Dealers, assembly centres and marshalling centres grouped animals of the same health status, which had arrived in consignments from different establishments, for dispatch to their respective destinations. The rules laid down in those Directives have proven effective in preventing the spread of transmissible animal diseases within the Union. Accordingly, the main substance of those rules should be maintained, but updated to take account of experience gained in their application and current scientific knowledge. Account should be taken of Article 133 of Regulation (EU) 2016/429, which provides that operators may subject kept ungulates and poultry to a maximum of three assembly operations during a movement from a Member State of origin to another Member State.
- (13) In addition, derogation from the rules on assembly operations should be provided under Article 140(b) of Regulation (EU) 2016/429 for ungulates participating in exhibitions and sporting, cultural and similar events, as alternative risk-mitigation measures in place reduce the risk that those operations pose in terms of spreading listed diseases. These derogations are provided for in this Regulation.
- (14) Article 136(2) of Regulation (EU) 2016/429 empowers the Commission to lay down detailed rules for the movement between Member States of certain kept terrestrial animals other than ungulates and poultry.
- (15) Prior to the application of Regulation (EU) 2016/429, Union rules for movement between Member States of certain kept terrestrial animals including primates, captive birds, honeybees and bumble bees, dogs, cats and ferrets were laid down in Directive 92/65/EEC. Those rules have proven to be effective in minimising the risk of spread of listed diseases between Member States. Accordingly, the main substance of those rules should be maintained in this Regulation, but updated to take account of the practical experience gained in their application. In addition, this Regulation should provide possibilities for derogations in cases where alternative risk-mitigation measures are put in place.
- (16) Article 3(5) of Regulation (EU) 2016/429 empowers the Commission to lay down rules to ensure that Part IV thereof is correctly applied to movements of pet animals, other than non-commercial movements. This Regulation, therefore, must provide for certain such rules.

⁽⁹⁾ Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

- (17) Implementing Regulation (EU) 2018/1882 lists the species of carnivores posing a considerable risk of spread of *Echinococcus multilocularis* and of rabies virus when they are moved between Member States. Supplementary animal health requirements should therefore be provided for other carnivores to mitigate the risk of the spread of those diseases between Member States.
- (18) Article 137(2) of Regulation (EU) 2016/429 requires the Commission to lay down detailed rules in addition to those referred to in Article 137(1) thereof for movements of kept terrestrial animals into confined establishments and for movements of kept terrestrial animals into those confined establishments, where risk-mitigation measures are in place to guarantee that such movements do not pose a significant risk to the health of kept terrestrial animals within that confined establishment and the surrounding establishments.
- (19) Prior to the application of Regulation (EU) 2016/429, Union rules for movements of terrestrial animals kept in approved bodies, institutes or centres were laid down in Directive 92/65/EEC. Articles 95 and 137 of Regulation (EU) 2016/429 establish the concept of a 'confined establishment' corresponding to an 'approved body, institute or centre' referred to in Article 2(1)(c) of Directive 92/65/EEC. Accordingly, the main substance of those former rules should be maintained, but should be updated to take account of the practical experience gained in their application. Account should also be taken of the relevant standards recommended for primates in the Terrestrial Animal Health Code of the OIE.
- (20) Article 138(3) of Regulation (EU) 2016/429 empowers the Commission to lay down rules for the granting of derogations by the competent authority of the place of destination, supplementing those referred to in Article 138(1) and 138(2) thereof, in relation to movement of kept terrestrial animals for scientific purposes. Prior to the application of Regulation (EU) 2016/429, Directive 92/65/EEC provided that dogs, cats and ferrets which are to be moved for scientific purposes to another Member State do not have to be vaccinated against rabies, and dogs do not have to have been treated against infestation with *Echinococcus multilocularis* where such animals were destined for approved bodies, institutes or centres. This Regulation should provide for a similar derogation.
- (21) Article 140(a) of Regulation (EU) 2016/429 empowers the Commission to lay down specific requirements supplementing the rules laid down in Articles 126 to 136 thereof for movements of kept terrestrial animals intended for circuses, exhibitions and sporting events.
- (22) Prior to the application of Regulation (EU) 2016/429, Union rules for movements of terrestrial animals kept in circuses and animal acts were laid down, based on Directive 92/65/EEC, in Commission Regulation (EC) No 1739/2005 ⁽¹⁰⁾ repealed by Commission Delegated Regulation (EU) 2019/2035 ⁽¹¹⁾ as from 21 April 2021. Given that those animals are currently moved to other Member States without an accompanying animal health certificate when the circus or animal act to which they belong travels, the present Regulation should maintain the possibility of such intra-Union movements. It is therefore appropriate to lay down in this Regulation the animal health requirements for movements to other Member States of terrestrial animals kept in travelling circuses or animal acts and to provide for a derogation from the animal health certification requirements as provided for in Article 143(1) of Regulation (EU) 2016/429.
- (23) Prior to the application of Regulation (EU) 2016/429, Union rules for movements of captive birds intended for exhibition in another Member State were laid down in Directive 92/65/EEC and other acts.
- (24) To prevent the risk of spread of listed diseases relevant to the movements of captive birds between Member States, it is appropriate in this Regulation to maintain Union rules for movements of captive birds intended for exhibition in another Member State. In addition, this Regulation should also lay down specific provisions for birds of prey attending flight hunting exhibitions in another Member State and for racing pigeons to be moved to sporting events in other Member States.

⁽¹⁰⁾ Commission Regulation (EC) No 1739/2005 of 21 October 2005 laying down animal health requirements for the movement for circus animals between Member States (OJ L 279, 22.10.2005, p. 47).

⁽¹¹⁾ Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115).

- (25) Article 144(1)(a) of Regulation (EU) 2016/429 empowers the Commission to grant derogations from animal health certification requirements, provided for in Article 143(1) thereof, for kept terrestrial animals moved between Member States.
- (26) Currently, in accordance with the rules laid down in Directive 2009/156/EC, registered equine animals may be moved without an accompanying animal health certificate between Member States which, on a reciprocal basis, have implemented an alternative control system providing relevant animal health guarantees equivalent to those laid down in the animal health certificate. This Regulation should provide for a similar derogation. However, special conditions should be established for movement of those animals, including the consent of the Member State of destination.
- (27) Article 144(1)(c) of Regulation (EU) 2016/429 empowers the Commission to lay down the requirements for animal health certification for movements to other Member States of kept terrestrial animals other than ungulates, poultry and animals intended for confined establishments in cases where an animal health certificate is imperative in order to ensure that the movement in question complies with the animal health requirements provided for in Articles 124 to 142 of Regulation (EU) 2016/429. This Regulation should therefore establish requirements for animal health certification which would allow movements to other Member States of consignments of captive birds, honeybees, bumble bees (except bumble bees from approved environmentally isolated bumble bee production establishments), primates, dogs, cats, ferrets and other carnivores.
- (28) Article 164(2) of Regulation (EU) 2016/429 also empowers the Commission to lay down the animal health certification and notification requirements for movements to other Member States of germinal products of kept terrestrial animals other than bovine, ovine, caprine, porcine and equine animals and germinal products of poultry. This Regulation should therefore establish requirements for animal health certification which would allow movements to other Member States of consignments of hatching eggs of captive birds.
- (29) Movements to other Member States of carnivores other than dogs, cats and ferrets should also be allowed in cases where there is no authorised anti-rabies vaccine for those carnivores in the Member State of origin and the vaccination is carried out in accordance with Article 10(1) of Directive 2001/82/EC of the European Parliament and of the Council ⁽¹²⁾ which provides for the use of medicinal products outside the terms of the marketing authorisation.
- (30) Article 146(1) of Regulation (EU) 2016/429 requires the Commission to lay down detailed rules and additional information on the content of animal health certificates for different species and categories of kept terrestrial animals and for specific types of movements. Article 162(3) of the same Regulation requires the Commission to adopt delegated acts concerning the information to be contained in the animal health certificate for movements between Member States of hatching eggs, taking into account the minimum information which must be included in that animal health certificate pursuant to Article 162(1). Therefore it is necessary to establish the content of the certificates that are to accompany consignments of kept terrestrial animals and hatching eggs when those consignments are moved to another Member State.
- (31) Article 147 of Regulation (EU) 2016/429 empowers the Commission to adopt delegated acts concerning specific measures derogating from, or supplementing, the obligation of operators to ensure that animals are accompanied by an animal health certificate for the particular types of movements of kept terrestrial animals. This Regulation should therefore lay down rules for animal health certification for movements of ungulates and poultry through establishments carrying out assembly operations provided for in Article 133 of Regulation (EU) 2016/429 prior to reaching their final place of destination.
- (32) To ensure that kept terrestrial animals certified for export to a third country and being transported through another Member State to the external border of the Union fulfil the animal health requirements for movement within the Union, operators should ensure that consignments of those animals are accompanied by animal health certificates providing attestations at least as strict as those required for the movement of kept ungulates or poultry intended for slaughter in the Member State where the exit point is located.

⁽¹²⁾ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

- (33) Article 149(4) of Regulation (EU) 2016/429 empowers the Commission to adopt delegated acts laying down rules on the documentary, identity and physical checks and examinations to be carried out by the official veterinarian in relation to different species and categories of kept terrestrial animals in order to verify compliance with the animal health requirements. Taking into account the scope of this Regulation, which extends to hatching eggs, this Regulation therefore needs to apply this provision by establishing the necessary rules for this purpose, including the timeframes for carrying out such checks and examinations and for the official veterinarian's issuing of animal health certificates prior to the movement of consignments of kept terrestrial animals and of hatching eggs, and the duration of the validity of animal health certificates, including conditions for its extension.
- (34) Articles 152, 153 and 163 of Regulation (EU) 2016/429 require operators to inform the competent authority in their Member State of origin in advance of the intended movement to another Member State of kept terrestrial animals and of hatching eggs, and to provide all the necessary information to enable that competent authority to notify the movement of kept terrestrial animals and of hatching eggs to the competent authority of the Member State of destination. Therefore, this Regulation should lay down detailed rules concerning the requirements for advance notification by operators, the information necessary to notify such movements and the emergency procedures for such notifications.
- (35) Articles 153(2) and (4), 154(1)(c) and 163(2) of Regulation (EU) 2016/429 provide for the use of the 'Traces' system for notification purposes when consignments of kept terrestrial animals and of hatching eggs are intended to be moved to other Member States. Traces is the integrated computerised veterinary system as provided for in Commission Decisions 2003/24/EC ⁽¹³⁾ and 2004/292/EC ⁽¹⁴⁾. Since Article 131 of Regulation (EU) 2017/625 of the European Parliament and of the Council ⁽¹⁵⁾ provides for the establishment of an information management system for official controls (IMSOC), which will incorporate functions of the Traces system, this Regulation should refer to IMSOC instead of Traces.
- (36) Article 155 of Regulation (EU) 2016/429 sets out the conditions for the movement of wild terrestrial animals from a habitat in one Member State to a habitat or an establishment in another Member State. This Regulation should lay down the animal health, certification and notification requirements for such movements in accordance with the powers laid down in Article 156(1) of Regulation (EU) 2016/429.
- (37) This Regulation should be applicable from 21 April 2021 in accordance with the date of application of Regulation (EU) 2016/429,

HAS ADOPTED THIS REGULATION:

PART I

GENERAL RULES

Article 1

Subject-matter

This Regulation supplements the rules for the prevention and control of animal diseases transmissible to animals or to humans laid down in Article 5(1) of Regulation (EU) 2016/429 as regards movements within the Union of kept terrestrial animals, wild terrestrial animals and hatching eggs.

⁽¹³⁾ Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system (OJ L 8, 14.1.2003, p. 44).

⁽¹⁴⁾ Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC (OJ L 94, 31.3.2004, p. 63).

⁽¹⁵⁾ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

Article 2

Scope

1. This Regulation shall apply to:
 - (a) kept and wild terrestrial animals and hatching eggs;
 - (b) establishments where those animals and hatching eggs are kept or undergo assembly operations;
 - (c) operators keeping those animals and hatching eggs;
 - (d) operators transporting terrestrial animals and hatching eggs;
 - (e) competent authorities of Member States.
2. Part II shall apply to movements of kept terrestrial animals and hatching eggs only when occurring between Member States, with the exception of Articles 4 to 6 and Article 63, which shall in addition apply to movements of kept terrestrial animals and hatching eggs within a Member State.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (1) 'means of transport' means road or rail vehicle, vessels and aircrafts;
- (2) 'container' means any crate, box, receptacle or other rigid structure used for the transport of animals or eggs which is not the means of transport;
- (3) 'environmentally isolated production establishment' means an establishment where its structures together with its strict biosecurity measures, ensure an effective isolation of the production of animals from the associated facilities and from the environment;
- (4) 'bovine animal' means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species;
- (5) 'establishment free from "disease"' means an establishment granted the disease-free status in accordance with the requirements set out in Delegated Regulation (EU) 2020/689;
- (6) 'status free from "disease"' means a disease-free status of a Member State or a zone thereof as approved by the Commission in accordance with Article 36 of Regulation (EU) 2016/429;
- (7) '"disease" has not been reported' means that no animal or group of animals of relevant species kept on the establishment has been classified as a confirmed case of that disease and any suspect case of that disease has been ruled out;
- (8) '"animals" intended for slaughter' means kept terrestrial animals to be transported, either directly or after undergoing an assembly operation, to a slaughterhouse;
- (9) 'approved quarantine establishment' means an establishment granted the approval in accordance with Article 14 of Delegated Regulation (EU) 2019/2035;
- (10) 'approved eradication programme' means a disease eradication programme implemented in a Member State or zone thereof as approved by the Commission in accordance with Article 31(3) of Regulation (EU) 2016/429;
- (11) 'ovine animal' means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species;
- (12) 'caprine animal' means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species;
- (13) 'porcine animal' means an animal of the species of ungulates belonging to the family *Suidae* listed in Annex III to Regulation (EU) 2016/429;

- (14) 'equine animal' means an animal of species of solipeds belonging to the genus *Equus* (including horses, asses, and zebras) and the offspring of crossings of those species;
- (15) 'camelid animal' means an animal of the species of ungulates belonging to the family *Camelidae* listed in Annex III to Regulation (EU) 2016/429;
- (16) 'cervid animal' means an animal of the species of ungulates belonging to the family *Cervidae* listed in Annex III to Regulation (EU) 2016/429;
- (17) 'other kept ungulates' means kept ungulates other than bovine, ovine, caprine, porcine, equine, camelid and cervid animals;
- (18) 'vector protected establishment' means part or all facilities of an establishment that are protected against attacks from *Culicoides* by appropriate physical and management means, with a status of vector protected establishment granted by the competent authority in accordance with Article 44 of Delegated Regulation (EU) 2020/689.
- (19) 'vector-free period' means in a defined area the period of inactivity of *Culicoides* determined in accordance with Section 5 of Chapter 1 of Part II of Annex V to Delegated Regulation (EU) 2020/689.
- (20) 'breeding poultry' means poultry 72 hours old or more, intended for the production of hatching eggs;
- (21) 'productive poultry' means poultry 72 hours old or more, reared for the production of meat, eggs for consumption or other products or for restocking supplies of game birds;
- (22) 'flock' means all poultry or captive birds of the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit; in housed poultry, this includes all birds sharing the same airspace;
- (23) 'day-old chicks' means all poultry less than 72 hours old;
- (24) 'specified pathogen-free eggs' means hatching eggs derived from 'chicken flocks free from specified pathogens', as described in the European Pharmacopoeia ⁽¹⁶⁾ and which are intended solely for diagnostic, research or pharmaceutical use;
- (25) 'registered equine animal' means:
 - (a) a purebred breeding animal of the species *Equus caballus* and *Equus asinus* entered or eligible for entry in the main section of a breeding book established by a breed society or breeding body recognised in accordance with Articles 4 or 34 of Regulation (EU) 2016/1012;
 - (b) a kept animal of the species *Equus caballus* registered with an international association or organisation, either directly or through its national federation or branches, which manages horses for competition or racing ('registered horse');
- (26) 'primates' means animals of the species belonging to the order Primates excluding humans;
- (27) 'honeybee' means an animal of the *Apis mellifera* species;
- (28) 'bumble bee' means an animal of the species belonging to the genus *Bombus*;
- (29) 'dog' means a kept animal of the *Canis lupus* species;
- (30) 'cat' means a kept animal of the *Felis silvestris* species;
- (31) 'ferret' means a kept animal of the *Mustela putorius furo* species;
- (32) 'other carnivores' means animals of the species belonging to the order Carnivora other than dogs, cats and ferrets;
- (33) 'travelling circus' means an exhibition or fair that includes animals or animal acts which is intended to move between Member States;
- (34) 'animal act' means any act featuring animals kept for the purpose of an exhibition or fair, and which may form part of a circus;
- (35) 'racing pigeon' means any pigeon transported or intended for transport from its pigeon house to another Member State in order to be released to fly back to the Member State of origin;

⁽¹⁶⁾ <http://www.edqm.eu> (latest edition).

PART II

MOVEMENTS WITHIN THE UNION OF KEPT TERRESTRIAL ANIMALS AND HATCHING EGGS

CHAPTER 1

General requirements for movements of kept terrestrial animals and hatching eggs within the Union

Section 1

Disease prevention measures in relation to transport within the Union in addition to those provided for in Regulation (EU) 2016/429*Article 4***General requirements regarding means of transport**

Operators, including transporters, shall ensure that the means of transport used for transporting kept terrestrial animals or hatching eggs, with the exception of the means of transport for the terrestrial animals referred to in Article 6, are:

- (a) constructed in such a way that
 - (i) animals or hatching eggs cannot escape or fall out;
 - (ii) visual inspection of the space where animals are kept is possible;
 - (iii) the escape of animal excrements, litter or feed is prevented or minimised;
 - (iv) in the case of poultry and captive birds, the escape of feathers is prevented or minimised;
- (b) cleaned and disinfected as soon as possible after every transport of animals, hatching eggs or any item representing an animal health risk, and, if necessary, cleaned and disinfected again and in any case dried or allowed to dry before any new loading of animals or hatching eggs.

*Article 5***Requirements regarding containers in which kept terrestrial animals and hatching eggs are transported**

1. Operators, including transporters, shall ensure that containers in which kept terrestrial animals and hatching eggs are transported, with the exception of the containers for the terrestrial animals referred to in Article 6:

- (a) comply with the requirements in Article 4(a);
- (b) contain only animals or hatching eggs of the same species, category and type, and of the same health status;
- (c) are:
 - (i) either unused and purpose-designed disposable containers to be destroyed after first use;or
 - (ii) cleaned and disinfected after use and dried or allowed to dry before any subsequent use.

2. In the case of poultry and hatching eggs, operators, including transporters, shall ensure that containers in which kept poultry and hatching eggs are transported in the means of transport bear the following indications:

- (a) for day-old chicks and hatching eggs:
 - (i) the name of the Member State of origin;
 - (ii) the approval or registration number of the establishment of origin;

- (iii) the species of poultry concerned;
- (iv) the number of animals or hatching eggs;
- (b) for breeding poultry and productive poultry, the approval or registration number of the establishment of origin.

3. In the case of queen honeybees transported under derogation provided for in Article 49, operators, including transporters, shall ensure that containers or the entire consignment are covered with fine mesh of not more than 2 mm in pore size immediately after the visual examination for the health certification by the official veterinarian.

4. In the case of bumble bees from environmentally isolated production establishments for bumble bees, operators, including transporters, shall ensure that they are isolated during the transport in separate epidemiological units with each colony in a closed container which was new or cleaned and disinfected before use.

Article 6

Exemptions from the requirements regarding means of transport and containers in which kept terrestrial animals and hatching eggs are transported

1. The requirements set out in Articles 4 and 5 shall not apply to the transport of:
 - (a) terrestrial animals kept in travelling circuses and animal acts;
 - (b) animals of the species listed in Part A of Annex I to Regulation (EU) 2016/429 in numbers exceeding those authorised in accordance with Article 246(1) and (2) of that Regulation, if they are transported for non-commercial purposes;
 - (c) animals of species listed in Part B of Annex I to Regulation (EU) 2016/429 transported for non-commercial purposes in numbers exceeding those set for those species where rules setting the maximum number of pet animals of the species concerned have been adopted in accordance with Article 246(3).
2. The requirements set out in Article 4(b) and in Article 5(1)(b) and (c) shall not apply to the transport of equine animals within a Member State, unless those equine animals are intended for slaughter.
3. The competent authority may decide that the requirements set out in Article 4(b) shall not apply to the transport:
 - (a) within an establishment when
 - (i) the transported animals are kept on the establishment and the transport is carried out by the operator of that establishment;and
 - (ii) the means of transport used for transporting kept terrestrial animals are cleaned and disinfected before leaving the establishment;
 - or
 - (b) between establishments within the Member State when
 - (i) the establishments belong to the same supply chain;and
 - (ii) the means of transport used for transporting kept terrestrial animals are cleaned and disinfected by the end of each day if animals have been transported in these means of transport.
4. The requirements set out in Articles 4 and 5(1) and (2) shall not apply to the transport of honeybees and bumble bees.

Section 2

Supplementary requirements for movements of terrestrial animals to other Member States in relation to vaccination*Article 7***Requirements for movements of terrestrial animals and hatching eggs to another Member State in relation to vaccination against category A diseases**

In case the Member State of origin has introduced vaccination against a category A disease, operators shall only move terrestrial animals or hatching eggs to another Member State when those animals and hatching eggs fulfil the specific conditions laid down in accordance with Article 47 of Regulation (EU) 2016/429 for the relevant category A disease and animals of listed species for that disease.

Section 3

Additional requirements for operators of slaughterhouses receiving kept terrestrial animals from other Member States*Article 8***Maximum timeframe within which kept ungulates and poultry from other Member States have to be slaughtered**

Operators of slaughterhouses shall ensure that kept ungulates and poultry received from another Member State are slaughtered at the latest within 72 hours of arrival at the slaughterhouse.

*Article 9***Supplementary risk mitigating measures for operators of slaughterhouses**

1. Operators of slaughterhouses shall ensure that animals of listed species for infection with Bluetongue virus (serotypes 1-24) are slaughtered at the latest within 24 hours of arrival at the slaughterhouse when they come from another Member State and do not fulfil at least one of the following criteria:

- (a) they fulfil at least one of the requirements for infection with Bluetongue virus (serotype 1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V Delegated Regulation (EU) 2020/689;

or

- (b) they fulfil the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689 that were agreed by the competent authority of the Member State of destination.

2. In addition to the requirements laid down in paragraph 1, when animals of the species listed for infection with Bluetongue virus (serotypes 1-24) are transported through another Member State and do not fulfil at least one of the conditions laid down in Article 32(1)(a) to (c) or in Article 32(2), operators of slaughterhouses shall ensure that such animals are slaughtered at the latest within 24 hours of arrival at the slaughterhouse.

CHAPTER 2

Supplementary animal health requirements for movements of kept ungulates to other Member States

Section 1

bovine animals

Article 10

Requirements for movements of kept bovine animals to other Member States

1. Operators shall only move kept bovine animals to another Member State when the following requirements are fulfilled:
 - (a) the animals have been continuously resident in the establishment for at least 30 days prior to departure, or since birth, if they are younger than 30 days of age, and during this period they have not been in contact with kept bovine animals of a lower health status or subject to movement restrictions for animal health reasons or with kept animals coming from an establishment which did not fulfil the requirements set out in point (b);
 - (b) any animals entering the Union from a third country or territory during the last 30 days prior to the departure of the animals referred to in point (a), and introduced into the establishment where those animals were resident, are kept separate so as to prevent direct and indirect contact with all other animals on that establishment;
 - (c) the animals come from an establishment free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination regarding bovine animals, and one of the following conditions is fulfilled:
 - (i) the establishment is situated in a Member State or zone thereof with the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* regarding the bovine population;
 - or
 - (ii) the animals have been subjected to a test for infection with *Brucella abortus*, *B. melitensis* and *B. suis* with one of the diagnostic methods provided for in Part 1 of Annex I, carried out, with negative results, on a sample taken during the last 30 days prior to departure, and in the case of post-parturient females taken at least 30 days after parturition;
 - or
 - (iii) the animals are less than 12 months old;
 - or
 - (iv) the animals are castrated;
 - (d) the animals come from an establishment free from infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), and at least one of the following conditions is fulfilled:
 - (i) the establishment is situated in a Member State or zone thereof with the status free from infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*);
 - or
 - (ii) the animals have been subjected to a test for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) with one of the diagnostic methods provided for in Part 2 of Annex I, carried out, with negative results, during the last 30 days prior to departure;
 - or
 - (iii) the animals are less than 6 weeks old;
 - (e) the animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;

- (f) the animals come from an establishment situated in an area of at least 150 km radius around that establishment in which infection with epizootic haemorrhagic disease virus has not been reported in kept animals of listed species for that disease during the last 2 years prior to departure;
 - (g) the animals come from an establishment in which anthrax in ungulates has not been reported during the last 15 days prior to departure;
 - (h) the animals come from an establishment in which surra (*Trypanosoma evansi*) has not been reported during the last 30 days prior to departure, and in case they come from an establishment in which surra (*Trypanosoma evansi*) has been reported during the last 2 years prior to departure, following the last outbreak the affected establishment has remained under movement restrictions until:
 - (i) the infected animals have been removed from the establishment;and
 - (ii) the remaining animals on the establishment have been subjected to a test for surra (*Trypanosoma evansi*) with one of the diagnostic methods provided for in Part 3 of Annex I, carried out, with negative results, on samples taken at least 6 months after the infected animals have been removed from the establishment;
 - (i) except in the case of kept bovine animals referred to in Articles 11(4), 12(4) and Article 13, the animals fulfil at least one of the requirements for infection with Bluetongue virus (serotype 1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689;
 - (j) the conditions set out in Articles 32 and 33 are fulfilled where applicable.
2. The provisions in paragraph 1 shall not apply to kept bovine animals intended for slaughter as referred to in Article 14.

Article 11

Supplementary requirements for movements of kept bovine animals to other Member States or zones thereof with disease-free status for specific diseases

1. Operators shall only move kept bovine animals to another Member State or zone thereof with the status free from enzootic bovine leukosis when the animals are in compliance with the requirements set out in Article 10 and provided that the requirements in either point (a) or point (b) are fulfilled:
- (a) the animals come from an establishment free from enzootic bovine leukosis;
- or
- (b) if the animals come from an establishment that is not free from enzootic bovine leukosis, then enzootic bovine leukosis has not been reported in that establishment during the last 24 months prior to departure, and
 - (i) if the animals are over 24 months of age, they have been subjected to a serological test for enzootic bovine leukosis with one of the diagnostic methods provided for in Part 4 of Annex I, carried out with negative results
 - either on samples taken on two occasions at an interval of at least four months while kept in isolation from the other bovine animals of the establishment;or
 - on a sample taken during the last 30 days prior to their departure, and all bovine animals over 24 months kept in the establishment have been subjected to a serological test for enzootic bovine leukosis with one of the diagnostic methods provided for in Part 4 of Annex I, carried out, with negative results, on samples taken on two occasions at an interval of not less than four months during the last 12 months prior to the departure of the animals;or
 - (ii) in case the animals are less than 24 months of age, they were born to dams, which have been subjected to a serological test for enzootic bovine leukosis with one of the diagnostic methods provided for in Part 4 of Annex I, carried out, with negative results, on samples taken on two occasions at an interval of not less than four months during the last 12 months prior to the departure of the animals.

2. Operators shall only move kept bovine animals to another Member State or zone thereof with the status free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis when the animals are in compliance with the requirements set out in Article 10, they have not been vaccinated against infectious bovine rhinotracheitis/infectious pustular vulvovaginitis and provided that the requirements in either point (a) or point (b) are fulfilled:

- (a) if the animals come from an establishment free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, either
 - (i) the establishment is situated in a Member State or zone thereof with the status free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis;or
 - (ii) the animals have been subject to quarantine for at least 30 days prior to departure and have been subjected to a serological test for the detection of antibodies against whole bovine herpes virus-1 (BoHV-1) with one of the diagnostic methods provided for in Part 5 of Annex I, with a negative result, carried out on a sample taken during the last 15 days prior to their departure;
- (b) if the animals come from an establishment not free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, they have been kept in an approved quarantine establishment for at least 30 days prior to departure and have been subjected to a serological test for the detection of antibodies against whole BoHV-1, with one of the diagnostic methods provided for in Part 5 of Annex I, with a negative result, carried out on a sample taken not less than 21 days after commencement of the quarantine.

3. Operators shall only move kept bovine animals to another Member State or zone thereof with the status free from bovine viral diarrhoea when the animals are in compliance with the requirements set out in Article 10, they have not been vaccinated against bovine viral diarrhoea and provided that the requirements in either point (a) or point (b) are fulfilled:

- (a) if the animals come from an establishment free from bovine viral diarrhoea,
 - (i) the establishment is either situated in a Member State or zone thereof with the status free from bovine viral diarrhoea or has been subject to a testing regime as referred in point 1(c) (ii) or (iii) of Section 2 of Chapter 1 of Part VI of Annex IV to Delegated Regulation (EU) 2020/689, carried out, with negative results, within the last four months prior to departure of the animals;or
 - (ii) the animals have been tested individually to exclude the presence of bovine viral diarrhoea virus prior to their departure;
- (b) if the animals come from an establishment not free from bovine viral diarrhoea, they have been subjected to a test for bovine viral diarrhoea virus antigen or genome with one of the diagnostic methods provided for in Part 6 of Annex I, carried out with negative results, and either
 - (i) the animals have been kept in an approved quarantine establishment for a period of at least 21 days prior to their departure and, in case of pregnant dams, they have been subjected to a serological test for the detection of antibodies against bovine viral diarrhoea virus with one of the diagnostic methods provided for in Part 6 of Annex I, carried out, with negative results, on samples taken not less than 21 days after commencement of the quarantine;or
 - (ii) the animals have been subjected to a serological test for the detection of antibodies against bovine viral diarrhoea virus with one of the diagnostic methods provided for in Part 6 of Annex I, with positive results, carried out on samples taken either prior to departure or, in case of pregnant dams, before insemination preceding the current gestation.

4. By way of derogation from Article 10(1)(i), the competent authority of the Member State of origin may authorise the movement of kept bovine animals which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689 to another Member State or zone thereof with the status free from infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689.

5. The provisions in paragraphs 1 to 4 shall not apply to kept bovine animals intended for slaughter as referred to in Article 14.

Article 12

Supplementary requirements for movements of kept bovine animals to other Member States or zones thereof with approved eradication programmes for specific diseases

1. Operators shall only move kept bovine animals to another Member State or zone thereof with an approved eradication programme for enzootic bovine leukosis when the animals are in compliance with the requirements set out in Article 10 and provided the requirements in either point (a) or point (b) are fulfilled:

(a) the animals come from an establishment free from enzootic bovine leukosis;

or

(b) if the animals come from an establishment that is not free from enzootic bovine leucosis, enzootic bovine leukosis has not been reported in that establishment during the last 24 months prior to departure of the animals, and

(i) in case the animals are over 24 months of age, they have been subjected to a serological test for enzootic bovine leukosis with one of the diagnostic methods provided for in Part 4 of Annex I, carried out, with negative results,

either

— on samples taken on two occasions at an interval of at least four months while kept in isolation from the other bovine animals of the establishment;

or

— on samples taken during the last 30 days prior to their departure, provided that all bovine animals over 24 months kept in the establishment have been subjected to a serological test for enzootic bovine leukosis with one of the diagnostic methods provided for in Part 4 of Annex I, carried out, with negative results, on samples taken on two occasions at an interval of at least four months during the last 12 months prior to the departure of the animals;

or

(ii) in case the animals are less than 24 months of age, they were born to dams, which have been subjected to a serological test for enzootic bovine leukosis with one of the diagnostic methods provided for in Part 4 of Annex I, carried out, with negative results, on samples taken on two occasions at an interval of not less than four months during the last 12 months prior to the departure of the animals.

2. Operators shall only move kept bovine animals to another Member State or zone thereof with an approved eradication programme for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis when the animals are in compliance with the requirements set out in Article 10 and provided that the requirements in either point (a) or point (b) are fulfilled:

(a) if the animals come from an establishment free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis,

either

(i) the establishment is situated in a Member State or zone thereof with the status free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis;

or

(ii) the establishment is situated in a Member State or zone thereof with an approved eradication programme for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis;

or

(iii) the animals have been subject to quarantine for at least 30 days prior to departure and have been subjected to a serological test for the detection of antibodies against whole BoHV-1 or, in case of animals vaccinated with a gE-deleted vaccine, antibodies against the BoHV-1 gE protein, with one of the diagnostic methods provided for in Part 5 of Annex I, with a negative result, on a sample taken during the last 15 days prior to their departure;

or

- (iv) the animals are destined for an establishment which keeps bovine animals for meat production without contact to bovine animals of other establishments, and from which they are directly moved to the slaughterhouse;

or

- (b) if the animals come from an establishment not free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, they have been kept in an approved quarantine establishment for at least 30 days prior to departure and have been subjected to a serological test for the detection of antibodies against whole BoHV-1 with one of the diagnostic methods provided for in Part 5 of Annex I, with a negative result, on a sample taken not less than 21 days after commencement of the quarantine.

3. Operators shall only move kept bovine animals to another Member State or zone thereof with an approved eradication programme for bovine viral diarrhoea when the animals are in compliance with the requirements set out in Article 10 and provided that the requirements in either point (a) or point (b) are fulfilled:

- (a) if the animals come from an establishment free from bovine viral diarrhoea,

- (i) the establishment is situated in a Member State or zone thereof with the status free from bovine viral diarrhoea;

or

- (ii) the establishment is situated in a Member State or zone thereof with an approved eradication programme for bovine viral diarrhoea;

or

- (iii) the establishment has been subject to a testing regime as referred in point 1(c) (ii) or (iii) of Section 2 of Chapter 1 of Part VI of Annex IV to Delegated Regulation (EU) 2020/689, carried out, with negative results, within the last four months prior to departure;

or

- (iv) the animals have been tested individually to exclude the presence of bovine viral diarrhoea virus prior to departure;

or

- (v) the animals are destined for an establishment which keeps bovine animals for meat production separate from bovine animals of other establishments, and from which they are directly moved to the slaughterhouse;

- (b) if the animals come from an establishment not free from bovine viral diarrhoea, they have been subjected to a test for bovine viral diarrhoea virus antigen or genome with one of the diagnostic methods provided for in Part 6 of Annex I, carried out, with negative results,

and

- (i) the animals either have been kept in an approved quarantine establishment for a period of at least 21 days prior to their departure and, in case of pregnant dams, were subjected to a serological test for the detection of antibodies against the bovine viral diarrhoea virus with one of the diagnostic methods provided for in Part 6 of Annex I, carried out, with negative results, on samples taken not less than 21 days after commencement of the quarantine;

or

- (ii) the animals were subjected to a serological test for the detection of antibodies against the bovine viral diarrhoea virus with one of the diagnostic methods provided for in Part 6 of Annex I, with positive results, carried out on samples taken either prior to departure or, in case of pregnant dams, before the insemination preceding the current gestation.

4. By way of derogation from Article 10(1)(i), the competent authority of the Member State of origin may authorise the movement of kept bovine animals which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689 to another Member State or zone thereof with an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689.

5. The provisions in paragraph 1 to 4 shall not apply to kept bovine animals intended for slaughter as referred to in Article 14.

Article 13

Derogations for movements of kept bovine animals to other Member States or zones thereof without a disease-free status and without an approved eradication programme for infection with Bluetongue virus

By way of derogation from Article 10(1)(i), the competent authority of the Member State of origin may authorise the movement of kept bovine animals which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689 to another Member State or zone thereof without a disease-free status and without an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised. If the Member State of destination sets conditions for the authorisation of such movement, those conditions must be any one of the conditions referred to in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689.

Article 14

Derogation for movements of kept bovine animals intended for slaughter to other Member States

By way of derogation from the requirements set out in Articles 10, 11 and 12, operators may move kept bovine animals intended for slaughter to another Member State when the following requirements are fulfilled:

(a) the animals

either

- (i) come from an establishment free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with or without vaccination regarding bovine animals;

or

- (ii) are castrated;

or

- (iii) are entire bovine animals older than 12 months of age and have been subjected to a test for infection with *Brucella abortus*, *B. melitensis* and *B. suis* with one of the diagnostic methods provided for in Part 1 of Annex I, carried out, with negative results, on a sample taken during the last 30 days prior to departure, and in the case of post-parturient females on a sample taken at least 30 days after parturition;

(b) the animals either

- (i) come from an establishment free from infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*);

or

- (ii) have been subjected to a test for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) with one of the diagnostic methods provided for in Part 2 of Annex I, carried out, with negative results, during the last 30 days prior to departure;

(c) the animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;

(d) the animals come from an establishment in which anthrax in ungulates has not been reported during the last 15 days prior to departure;

(e) the animals come from an establishment in which infection with Bluetongue virus (serotypes 1-24) has not been reported during the last 30 days prior to departure.

Section 2

ovine and caprine animals

Article 15

Requirements for movements of kept ovine and caprine animals to other Member States

1. Operators shall only move kept ovine and caprine animals to another Member State when the following requirements are fulfilled:

- (a) the animals have been continuously resident in the establishment for at least 30 days prior to departure, or since birth, if they are younger than 30 days of age, and during this period they have not been in contact with kept ovine or caprine animals of a lower health status or subject to movement restrictions for animal health reasons, or with kept animals coming from an establishment which did not fulfil the requirements set out in point (b);
- (b) any animals entering the Union from a third country or territory during the last 30 days prior to the departure of the animals referred to in point (a), and introduced into the establishment where those animals were resident, are kept separate so as to prevent direct and indirect contact with all other animals on that establishment;
- (c) except when they are moved in accordance with Article 16, they come from an establishment free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination regarding ovine and caprine animals, and

either

- (i) the establishment is situated in a Member State or zone thereof with the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* regarding the ovine and caprine population;

or

- (ii) the animals have been subjected to a test for infection with *Brucella abortus*, *B. melitensis* and *B. suis* with one of the diagnostic methods provided for in Part 1 of Annex I, carried out, with negative results, on a sample taken during the last 30 days prior to departure, and in the case of post-parturient females, taken at least 30 days after parturition;

or

- (iii) the animals are less than 6 months old;

or

- (iv) the animals are castrated.

- (d) the animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
- (e) the animals come from an establishment situated in an area of at least 150 km radius around that establishment in which infection with epizootic haemorrhagic disease virus has not been reported in kept animals of listed species for that disease during the last 2 years prior to departure;
- (f) the animals come from an establishment in which anthrax in ungulates has not been reported during the last 15 days prior to departure;
- (g) the animals come from an establishment in which surra (*Trypanosoma evansi*) has not been reported during the last 30 days prior to departure, and in case they come from an establishment in which surra (*Trypanosoma evansi*) has been reported during the last 2 years prior to departure, following the last outbreak the affected establishment has remained under movement restrictions until:

- (i) the infected animals have been removed from the establishment;

and

- (ii) the remaining animals on the establishment have been subjected to a test for surra (*Trypanosoma evansi*) with one of the diagnostic methods provided for in Part 3 of Annex I, carried out, with negative results, on samples taken at least 6 months after the infected animals have been removed from the establishment;

- (h) except when the animals are moved in accordance with Article 17, they fulfil at least one of the requirements for infection with Bluetongue virus (serotype 1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689;
 - (i) the conditions set out in Articles 32 and 33 are fulfilled where applicable.
2. Operators shall only move kept ovine animals to another Member State when in compliance with the requirements set out in paragraph 1 and they come from an establishment in which infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) has not been reported during the last 42 days prior to departure.
3. Operators shall only move kept caprine animals to another Member State when in compliance with the requirements set out in paragraph 1 and they come from an establishment in which surveillance for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) has been carried out on the caprine animals kept on the establishment in accordance with point 1 and point 2 of Part 1 of Annex II during at least the last 12 months prior to departure, and during this period
- (i) only caprine animals from establishments applying the measures provided for in this paragraph have been introduced in the establishment referred to in paragraph 1(a);
 - (ii) in case infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) has been reported in caprine animals kept on the establishment, measures were taken in accordance with Part 1(3) of Annex II.
4. Operators shall only move kept uncastrated male ovine animals to another Member State when in compliance with the requirements set out in paragraph 1 and 2 and provided that the following requirements are fulfilled:
- (a) the animals come from an establishment in which ovine epididymitis (*Brucella ovis*) has not been reported during the last 12 months prior to departure;
 - (b) the animals have been subjected to a serological test for ovine epididymitis (*Brucella ovis*), carried out, with negative results, on a sample taken during the last 30 days prior to departure.
5. The provisions of paragraph 1 to 4 shall not apply to kept ovine and caprine animals intended for slaughter as referred to in Article 18.

Article 16

Derogation for movements of kept ovine and caprine animals to other Member States or zones thereof without the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis*

By way of derogation from the requirements set in Article 15(1)(c), operators may move kept ovine and caprine animals to another Member State or zone thereof without the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* regarding ovine and caprine animals if they come from an establishment free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination regarding ovine and caprine animals.

Article 17

Derogations for movements of kept ovine and caprine animals to other Member States or zones thereof regarding infection with Bluetongue virus (serotype 1-24)

By way of derogation from Article 15(1)(h), the competent authority of the Member State of origin may authorise the movement of kept ovine and caprine animals which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689 to another Member State or zone thereof

- (a) with a disease-free status or with an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689;

- (b) without a disease-free status and without an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised. If the Member State of destination sets conditions for the authorisation of such movement, those conditions must be any one of the conditions referred to in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689.

Article 18

Derogation for movements of kept ovine and caprine animals intended for slaughter to other Member States

By way of derogation from the requirements set out in Article 15, operators may move kept ovine and caprine animals intended for slaughter to another Member State when the following requirements are fulfilled:

- (a) the animals are either individually identified in accordance with Article 45 of Delegated Regulation (EU) 2019/2035, or alternatively, they have been continuously resident in the establishment for at least 21 days prior to departure, or since birth, if they are younger than 21 days of age;
- (b) the animals
 - either
 - (i) come from an establishment free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with or without vaccination regarding ovine and caprine animals;
 - or
 - (ii) are older than 6 months of age and have been subjected to a test for infection with *Brucella abortus*, *B. melitensis* and *B. suis* with one of the diagnostic methods provided for in Part 1 of Annex I, carried out, with negative results, on a sample taken during the last 30 days prior to departure, and in the case of post-parturient females taken at least 30 days after parturition;
 - or
 - (iii) are castrated;
- (c) the animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
- (d) the animals come from an establishment in which anthrax in ungulates has not been reported during the last 15 days prior to departure;
- (e) the animals come from an establishment in which infection with Bluetongue virus (serotypes 1-24) has not been reported during the last 30 days prior to departure..

Section 3

porcine animals

Article 19

Requirements for movements of kept porcine animals to other Member States

1. Operators shall only move kept porcine animals to another Member State when the following requirements are fulfilled:
 - (a) the animals have been continuously resident in the establishment for at least 30 days prior to departure, or since birth, if they are younger than 30 days of age, and during this period they have not been in contact with kept porcine animals of a lower health status or subject to movement restrictions for animal health reasons, or with kept animals coming from an establishment which did not fulfil the requirements set out in point (b);
 - (b) any animals entering the Union from a third country or territory during the last 30 days prior to the departure of the animals referred to in point (a), and introduced into the establishment where those animals were resident, are kept separate so as to prevent direct and indirect contact with all other animals on that establishment;

- (c) the animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
- (d) the animals come from an establishment in which infection with Aujeszky's disease virus has not been reported during the last 30 days prior to departure;
- (e) the animals come from an establishment in which anthrax in ungulates has not been reported during the last 15 days prior to departure;
- (f) the animals come from an establishment in which infection with *Brucella abortus*, *B. melitensis* and *B. suis* in porcine animals has not been reported during the last 42 days prior to departure, and in which during at least the last 12 months prior to departure

either

- (i) biosecurity and risk mitigating measures, including housing conditions and feeding systems, have been applied as necessary to prevent transmission of infection with *Brucella abortus*, *B. melitensis* and *B. suis* from wild animals of listed species for that disease to porcine animals kept on the establishment, and only porcine animals from establishments applying equivalent biosecurity and risk mitigating measures have been introduced;

or

- (ii) surveillance for infection with *Brucella abortus*, *B. melitensis* and *B. suis* has been carried out on the porcine animals kept on the establishment in accordance with point 1 and point 2 of Annex III during at least the last 12 months prior to departure, and during this period
 - only porcine animals from establishments applying the measures provided for in point (i) or in this point have been introduced in the establishment referred to in point (a);
 - in case infection with *Brucella abortus*, *B. melitensis* and *B. suis* has been reported in porcine animals kept on the establishment, measures were taken in accordance with point 3 of Annex III.

- 2. The provisions in paragraph 1 shall not apply to kept porcine animals intended for slaughter as referred to in Article 21.

Article 20

Supplementary requirements for movements of kept porcine animals to Member States or zones thereof with disease-free status or with an approved eradication programme for infection with Aujeszky's disease virus

- 1. Operators shall only move kept porcine animals to another Member State or zone thereof with the status free from infection with Aujeszky's disease virus when in compliance with the requirements set out in Article 19, not vaccinated against infection with Aujeszky's disease virus and provided that the requirements in either point (a) or point (b) are fulfilled:

- (a) if the animals come from an establishment free from infection with Aujeszky's disease virus,

either

- (i) the establishment is situated in a Member State or zone thereof with the status free from infection with Aujeszky's disease virus;

or

- (ii) the animals have been subjected to a serological test for the detection of antibodies against whole Aujeszky's disease virus with the diagnostic method provided for in Part 7 of Annex I, with a negative result, on a sample taken during the last 15 days prior to their departure. For porcine animals less than four months old born to dams vaccinated with a gE-deleted vaccine, the diagnostic method for the detection of antibodies against Aujeszky's disease virus gE protein provided for in Part 7 of Annex I may be used. The number of porcine animals tested must allow at least for the detection of 10 % seroprevalence of the consignment with 95 % confidence;

- (b) if the animals come from an establishment not free from infection with Aujeszky's disease virus, the following requirements are fulfilled:

- (i) the animals have been kept in an approved quarantine establishment for a period of at least 30 days;

and

- (ii) the animals have been subjected to a serological test for the detection of antibodies against whole Aujeszky's disease virus with the diagnostic method provided for in Part 7 of Annex I, with a negative result, carried out on samples taken on two occasions at an interval of not less than 30 days, the last sample taken during the last 15 days prior to departure.
2. Operators shall only move kept porcine animals to another Member State or zone thereof with an approved eradication programme for infection with Aujeszky's disease virus when in compliance with the requirements set out in Article 19 and provided that the requirements in either point (a) or point (b) are fulfilled:
- (a) if the animals come from an establishment free from infection with Aujeszky's disease virus,
 - either
 - (i) the establishment is situated in a Member State or zone thereof with the status free from infection with Aujeszky's disease virus;
 - or
 - (ii) the establishment is situated in a Member State or zone thereof with an approved eradication programme for infection with Aujeszky's disease virus;
 - or
 - (iii) the animals have been subjected to a serological test for the detection of antibodies against whole Aujeszky's disease virus or antibodies against Aujeszky's disease virus-gE protein, where applicable, with one of the diagnostic methods provided for in Part 7 of Annex I, with a negative result, on a sample taken during the last 15 days prior to their departure. The number of porcine animals tested must allow at least for the detection of 10 % seroprevalence of the consignment with 95 % confidence;
 - (b) if the animals come from an establishment not free from infection with Aujeszky's disease virus the following requirements are fulfilled:
 - (i) they have been kept in an approved quarantine establishment for a period of at least 30 days;and
 - (ii) they have been subjected to a serological test for the detection of antibodies against whole Aujeszky's disease virus or antibodies against Aujeszky's disease virus gE protein, where applicable, with one of the diagnostic methods provided for in Part 7 of Annex I, with a negative result, carried out on samples taken on two occasions at an interval of not less than 30 days, the last sample taken during the last 15 days prior to departure.
3. The provisions in paragraph 1 and 2 shall not apply to kept porcine animals intended for slaughter as referred to in Article 21.

Article 21

Derogation for movements of kept porcine animals intended for slaughter to other Member States

1. By way of derogation from the requirements set out in Article 19, operators may move kept porcine animals intended for slaughter to another Member State when those animals come from an establishment
- (a) in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
 - (b) in which anthrax in ungulates has not been reported during the last 15 days prior to departure.
2. By way of derogation from the requirements set out in Article 20, operators may move kept porcine animals intended for slaughter to another Member State or zone thereof with the status free from infection with Aujeszky's disease virus or with an approved eradication programme for infection with Aujeszky's disease virus when in compliance with the requirements in paragraph 1 and the following requirements are fulfilled:
- (a) the animals come from an establishment in which infection with Aujeszky's disease virus has not been reported during the last 30 days prior to departure;

- (b) the animals are transported directly to the slaughterhouse in the Member State of destination without undergoing any assembly operations in that Member State or zone thereof, or any Member State or zone thereof of passage with the status free from infection with Aujeszky's disease virus.

Section 4

Equine animals

Article 22

Requirements for movements of equine animals to other Member States

1. Operators shall only move equine animals to another Member State when the following requirements are fulfilled:
 - (a) the animals come from an establishment in which surra (*Trypanosoma evansi*) has not been reported during the last 30 days prior to departure, or in case they come from an establishment in which surra (*Trypanosoma evansi*) has been reported during the last 2 years prior to departure, following the last outbreak the affected establishment has remained under movement restriction until:
 - (i) the infected animals have been removed from the establishment,and
 - (ii) the remaining animals in the establishment have been subjected to a test for surra (*Trypanosoma evansi*) with one of the diagnostic methods provided for in Part 3 of Annex I, carried out, with negative results, on samples taken at least 6 months after the last infected animal has been removed from the establishment;
 - (b) the animals come from an establishment in which dourine has not been reported during the last 6 months prior to departure, or in case they come from an establishment in which dourine has been reported during the last 2 years prior to departure, following the last outbreak the affected establishment has remained under movement restriction until:
 - (i) the infected animals have been killed and destroyed or slaughtered, or the infected entire male equine animals have been castrated;and
 - (ii) the remaining equine animals in the establishment, with the exception of the castrated male equine animals referred to in point (i), have been subjected to a test for dourine with the diagnostic method provided for in Part 8 of Annex I, carried out, with negative results, on samples taken at least 6 months after the measures described in point (i) have been completed;
 - (c) the animals come from an establishment in which equine infectious anaemia has not been reported during the last 90 days prior to departure, or in case they come from an establishment in which equine infectious anaemia has been reported during the last 12 months prior to departure, following the last outbreak the affected establishment has remained under movement restriction until:
 - (i) the infected animals have been killed and destroyed or slaughtered and the establishment was cleaned and disinfected;and
 - (ii) the remaining animals in the establishment have been subjected to a test for equine infectious anaemia with the diagnostic method provided for in Part 9 of Annex I, carried out, with negative results, on samples taken on two occasions with a minimum interval of 3 months after the measures described in point (i) have been completed;
 - (d) the animals come from an establishment in which Venezuelan equine encephalomyelitis has not been reported during the last 6 months prior to departure, or in case they come from an establishment situated in a Member State or zone thereof in which Venezuelan equine encephalomyelitis has been reported during the last 2 years, they comply with the conditions in point (i) and the conditions in either point (ii) or point (iii):
 - (i) during the period of at least 21 days prior to departure they have remained clinically healthy and any animal referred to in point (ii) or point (iii) which showed a rise in body temperature above physiological range, taken daily, have been subjected to a diagnostic test for Venezuelan equine encephalomyelitis with the diagnostic method provided for in point (a) of Part 10(1) of Annex I, with negative results;and

- (ii) the animals were kept in quarantine for a period of at least 21 days protected from attacks by insect vector, and either
 - have been vaccinated against Venezuelan equine encephalomyelitis with a complete primary course and revaccinated according to manufacturer's recommendations not less than 60 days and not more than 12 months prior to the date of dispatch;
 - or
 - have been subjected to a test for Venezuelan equine encephalomyelitis with the diagnostic method provided for in point (b) of Part 10(1) of Annex I, carried out, with negative results, on a sample taken not less than 14 days after the date of entry into quarantine;
- (iii) the animals have been subjected to
 - a test for Venezuelan equine encephalomyelitis with the diagnostic method provided for in point (b) of Part 10(1) of Annex I, without an increase in antibody titre, carried out on paired samples taken on two occasions with an interval of 21 days, the second of which was taken during a period of 10 days prior to the date of departure;and
 - a test for the detection of Venezuelan equine encephalomyelitis virus genome with the diagnostic method provided for in Part 10(2) of Annex I, with negative result, carried out on a sample taken within 48 hours prior to departure, and the animals have been protected from attacks by insect vectors after sampling until departure;
- (e) the animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
- (f) the animals come from an establishment in which anthrax in ungulates has not been reported during the last 15 days prior to departure;
- (g) the animals have not been in contact with kept animals of listed species for the diseases referred to in points (a) to (f) which did not comply with the requirements in points (a) to (e) during the last 30 days prior to departure, and with the requirement in point (f) during the last 15 days prior to departure.

2. By way of derogation from paragraph 1(a), (b) and (c), the movement restrictions referred to in paragraph 1(a), (b) and (c) shall apply for at least 30 days after the last animal on the establishment of listed species for the respective disease referred to in paragraph 1(a), (b) and (c) was either killed and destroyed or slaughtered, and the premises were cleaned and disinfected.

3. On request by the competent authority, the operator requesting the animal health certificate referred to in Article 76 shall provide the address details of any establishment keeping equine animals on which the equine animals to be moved were kept during the 30 days preceding the intended movement to another Member State.

Section 5

Camelid animals

Article 23

Requirements for movement of kept camelid animals to other Member States

1. Operators shall only move kept camelid animals to another Member State when the following requirements are fulfilled:
 - (a) the animals have been continuously resident in the establishment for at least 30 days prior to departure, or since birth, if they are younger than 30 days of age, and during this period they have not been in contact with kept camelid animals of a lower health status or subject to movement restrictions for animal health reasons, or with kept animals coming from an establishment which did not fulfil the requirements set out in point (b);
 - (b) any animals entering the Union from a third country or territory during the last 30 days prior to the departure of the animals referred to in point (a), and introduced into the establishment where those animals were resident, are kept separate so as to prevent direct and indirect contact with all other animals on that establishment;

- (c) the animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
- (d) the animals come from an establishment in which infection with *Brucella abortus*, *B. melitensis* and *B. suis* in camelid animals has not been reported during the last 42 days prior to departure, and they have been subjected to a test for infection with *Brucella abortus*, *B. melitensis* and *B. suis* with one of the diagnostic methods provided for in Part 1 of Annex I, carried out, with negative results, on a sample taken during the last 30 days prior to departure, and in the case of post-parturient females taken at least 30 days after parturition;
- (e) the animals come from an establishment in which surveillance for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) has been carried out on the camelid animals kept on the establishment in accordance with point (1) and point (2) of Part 2 of Annex II during at least the last 12 months prior to departure, and during this period
 - (i) only camelid animals from establishments applying the measures provided for in this point have been introduced in the establishment referred to in point (a);
 - (ii) in case infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) has been reported in camelid animals kept on the establishment, measures were taken in accordance with point 3 of Part 2 of Annex II.
- (f) in case the animals are moved to a Member State or zone thereof with disease-free status or with an approved eradication programme for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis in bovine animals, they come from an establishment in which infectious bovine rhinotracheitis/infectious pustular vulvovaginitis in camelid animals has not been reported during the last 30 days prior to departure;
- (g) the animals come from an establishment situated in an area of at least 150 km radius around that establishment in which infection with epizootic haemorrhagic disease virus has not been reported in any establishment during the last 2 years prior to departure;
- (h) the animals come from an establishment in which anthrax in ungulates has not been reported during the last 15 days prior to departure;
- (i) the animals come from an establishment in which surra (*Trypanosoma evansi*) has not been reported during the last 30 days prior to departure, and in case they come from an establishment on which surra (*Trypanosoma evansi*) has been reported during the last 2 years prior to departure, following the last outbreak the affected establishment has remained under movement restriction until:
 - (i) the infected animals have been removed from the establishment;and
 - (ii) the remaining animals on the establishment have been subjected to a test for surra (*Trypanosoma evansi*) with one of the diagnostic methods provided for in Part 3 of Annex I, carried out, with negative results, on samples taken at least 6 months after the infected animals have been removed from the establishment;
- (j) except when the animals are moved in accordance with Article 24, they fulfil at least one of the requirements for infection with Bluetongue virus (serotype 1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689;
- (k) the conditions set out in Articles 32 and 33 are fulfilled where applicable.

2. The provisions of paragraph 1 shall not apply to kept camelid animals intended for slaughter as referred to in Article 25.

Article 24

Derogations for movements of kept camelid animals to other Member States or zones thereof regarding infection with Bluetongue virus (serotype 1-24)

By way of derogation from Article 23(1)(j), the competent authority of the Member State of origin may authorise the movement of kept camelid animals which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689 to another Member State or zone thereof

- (a) with a disease-free status or with an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689;

- (b) without a disease-free status and without an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised. If the Member State of destination sets conditions for the authorisation of such movement, those conditions must be any one of the conditions referred to in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689.

Article 25

Derogation for movements of kept camelid animals intended for slaughter to other Member States

By way of derogation from the requirements set out in Article 23, operators may move kept camelid animals intended for slaughter to another Member State or zone thereof when those animals come from an establishment

- (a) in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
- (b) in which anthrax in ungulates has not been reported during the last 15 days prior to departure.
- (c) in which infection with Bluetongue virus (serotypes 1-24) has not been reported during the last 30 days prior to departure.

Section 6

Cervid animals

Article 26

Requirements for movement of kept cervid animals to other Member States

1. Operators shall only move kept cervid animals to another Member State when the following requirements are fulfilled:
 - (a) the animals have been continuously resident in the establishment for at least 30 days prior to departure, or since birth, if they are younger than 30 days of age, and during this period they have not been in contact with kept cervid animals of a lower health status or subject to movement restrictions for animal health reasons, or with kept animals coming from an establishment which did not fulfil the requirements set out in point (b);
 - (b) any animals entering the Union from a third country or territory during the last 30 days prior to the departure of the animals referred to in point (a), and introduced into the establishment where those animals were resident, are kept separate so as to prevent direct and indirect contact with all other animals on that establishment;
 - (c) the animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
 - (d) the animals come from an establishment in which infection with *Brucella abortus*, *B. melitensis* and *B. suis* in cervid animals has not been reported during the last 42 days prior to departure;
 - (e) the animals come from an establishment in which surveillance for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) has been carried out on the cervid animals kept on the establishment in accordance with point (1) and point (2) of Part 3 of Annex II during at least the last 12 months prior to departure, and during this period
 - (i) only cervid animals from establishments applying the measures provided for in this point have been introduced in the establishment referred to in point (a);
 - (ii) in case infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) has been reported in cervid animals kept on the establishment, measures were taken in accordance with point (3) of Part 3 of Annex II;
 - (f) in case the animals are moved to a Member State or zone thereof with disease-free status or with an approved eradication programme for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis in bovine animals, they come from an establishment in which infectious bovine rhinotracheitis/infectious pustular vulvovaginitis in cervid animals has not been reported during the last 30 days prior to departure;
 - (g) the animals come from an establishment situated in an area of at least 150 km radius around that establishment in which infection with epizootic haemorrhagic disease virus has not been reported in any establishment during the last 2 years prior to departure;

- (h) the animals come from an establishment in which anthrax in ungulates has not been reported during the last 15 days prior to departure;
 - (i) the animals come from an establishment in which surra (*Trypanosoma evansi*) has not been reported during the last 30 days prior to departure, and in case they come from an establishment on which surra (*Trypanosoma evansi*) has been reported during the last 2 years prior to departure, following the last outbreak the affected establishment has remained under movement restriction until:
 - (i) the infected animals have been removed from the establishment;
- and
- (ii) the remaining animals on the establishment have been subjected to a test for surra (*Trypanosoma evansi*) with one of the diagnostic methods provided for in Part 3 of Annex I, carried out, with negative results, on samples taken at least 6 months after the infected animals have been removed from the establishment;
 - (j) except when they are moved in accordance with Article 27, they comply with at least one of the requirements for infection with Bluetongue virus (serotype 1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689;
 - (k) the conditions set out in Articles 32 and 33 are fulfilled where applicable.

2. The provisions of paragraph 1 shall not apply to kept cervid animals intended for slaughter as referred to in Article 28.

Article 27

Derogations for movements of kept cervid animals to other Member States or zones thereof regarding infection with Bluetongue virus (serotype 1-24)

By way of derogation from Article 26(1)(j), the competent authority of the Member State of origin may authorise the movement of kept cervid animals which do not comply with at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689 to another Member State or zone thereof

- (a) with a disease-free status or with an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689;
- (b) without a disease-free status and without an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised. If the Member State of destination sets conditions for the authorisation of such movement, those conditions must be any one of the conditions referred to in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689.

Article 28

Derogation for movements of kept cervid animals intended for slaughter to other Member States

By way of derogation from the requirements set out in Articles 26, operators may move kept cervid animals intended for slaughter to another Member State or zone thereof where those animals come from an establishment

- (a) in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
- (b) in which anthrax in ungulates has not been reported during the last 15 days prior to departure;
- (c) in which no infection with Bluetongue virus (serotypes 1-24) has been reported during the last 30 days prior to departure.

Section 7

Other ungulates

Article 29

Requirements for movement of other kept ungulates to other Member States

1. Operators shall only move other kept ungulates to another Member State when the following requirements are fulfilled:
 - (a) the animals have been continuously resident in the establishment for at least 30 days prior to departure, or since birth, if they are younger than 30 days of age, and during this period they have not been in contact with other kept ungulates of a lower health status or subject to movement restrictions for animal health reasons, or with kept animals coming from an establishment which did not fulfil the requirements set out in point (b);
 - (b) any animals entering the Union from a third country or territory during the last 30 days prior to the departure of the animals referred to in point (a), and introduced into the establishment where those animals were resident, are kept separate so as to prevent direct and indirect contact with all other animals on that establishment;
 - (c) in the case of other kept ungulates of listed species for infection with rabies virus, the animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
 - (d) in the case of other kept ungulates of listed species for infection with *Brucella abortus*, *B. melitensis* and *B. suis*, they come from an establishment in which infection with *Brucella abortus*, *B. melitensis* and *B. suis* in other kept ungulates of listed species for this disease has not been reported during the last 42 days prior to departure;
 - (e) in the case of other kept ungulates of listed species for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), they come from an establishment in which infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in kept animals of listed species for this disease has not been reported during the last 42 days prior to departure;
 - (f) in the case of other kept ungulates of listed species for infection with epizootic haemorrhagic disease virus, the animals come from an establishment situated in an area of at least 150 km radius around that establishment in which infection with epizootic haemorrhagic disease virus has not been reported in any establishment during the last 2 years prior to departure;
 - (g) the animals come from an establishment in which anthrax in ungulates has not been reported during the last 15 days prior to departure;
 - (h) in the case of other kept ungulates of listed species for surra (*Trypanosoma evansi*), they come from an establishment in which surra (*Trypanosoma evansi*) has not been reported during the last 30 days prior to departure, and in case they come from an establishment on which surra (*Trypanosoma evansi*) has been reported during the last 2 years prior to departure, following the last outbreak the affected establishment has remained under movement restriction until:
 - (i) the infected animals have been removed from the establishment;and
 - (ii) the remaining animals on the establishment have been tested with one of the diagnostic methods provided for in Part 3 of Annex I for surra (*Trypanosoma evansi*), carried out, with negative results, on samples taken at least 6 months after the infected animals have been removed from the establishment;
 - (i) in the case of other kept ungulates of listed species for infection with Bluetongue virus (serotype 1-24), they fulfil at least one of the requirements for infection with Bluetongue virus (serotype 1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689. This point shall not apply to other kept ungulates referred to in Article 30.
 - (j) the conditions set out in Articles 32 and 33 are fulfilled where applicable.
2. The provisions of paragraph 1 shall not apply to other kept ungulates intended for slaughter as referred to in Article 31.

*Article 30***Derogation for movements of other kept ungulates to other Member States or zones thereof regarding infection with Bluetongue virus (serotype 1-24)**

By way of derogation from Article 29(1)(i), the competent authority of the Member State of origin may authorise the movement of other kept ungulates of listed species for infection with Bluetongue virus (serotype 1-24) which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689 to another Member State or zone thereof

- (a) with a disease-free status or with an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689;
- (b) without a disease-free status and without an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised. If the Member State of destination sets conditions for the authorisation of such movement, those conditions must be any one of the conditions referred to in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689.

*Article 31***Derogation for movements of other kept ungulates intended for slaughter to other Member States**

By way of derogation from the requirements set out in Article 29, operators may move other kept ungulates intended for slaughter to another Member State or zone thereof

- (a) when those animals come from an establishment in which anthrax in ungulates has not been reported during the last 15 days prior to departure;
- (b) in the case of other kept ungulates of listed species for infection with rabies, when those animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure;
- (c) in the case of other kept ungulates of listed species for infection with Bluetongue virus (serotypes 1-24), when those animals come from an establishment in which infection with Bluetongue virus (serotypes 1-24) has not been reported during the last 30 days prior to departure.

*Section 8***Supplementary animal health requirements regarding infection with Bluetongue virus (serotypes 1-24)***Article 32***Biosecurity and risk-mitigating measures for transport operations to another Member State or zone thereof with the status free from, or with an approved eradication programme for infection with Bluetongue virus (serotypes 1-24)**

1. Operators shall only move kept animals of listed species for infection with Bluetongue virus (serotypes 1-24) to another Member State or zone thereof with the status free from, or with an approved eradication programme for that disease, where at least one of the following requirements are fulfilled:

- (a) the transport takes place in a Member State or zone thereof with the status free from infection with Bluetongue virus (serotypes 1-24);
- (b) the animals are protected from attacks by vectors;

and

- (i) the planned journey does not include the unloading of the animals for a period longer than one day;

or

- (ii) the animals are unloaded in a vector protected establishment;
 - or
 - (iii) the animals are unloaded in a Member State or a zone thereof during the vector-free period;
- (c) the animals
- (i) have been vaccinated against all the serotypes of Bluetongue virus (serotypes 1-24) reported during the last two years in the Member State or zone thereof of passage and they are still within the immunity period of time guaranteed in the specifications of the vaccine;
 - or
 - (ii) were subjected with positive results to a serological test able to detect specific antibodies against all serotypes of Bluetongue virus (serotypes 1-24) reported in the Member State or zone thereof of passage during the last two years prior to departure;
- (d) the animals are intended for slaughter.

2. By way of derogation from paragraph 1, the competent authority of the Member State of origin may authorise the movement of kept animals if the competent authority of the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689 and one of the following conditions is fulfilled

- (a) the animals fulfil the specific animal health requirements defined by the competent authority of destination to ensure the animals, prior to departure, have sufficient immunological protection as regards all serotypes of Bluetongue virus (serotypes 1-24) reported in the Member State or zone thereof of passage during the last two years prior to departure;
- or
- (b) the animals fulfil the requirements laid down in point (a) of this paragraph or in point (c) of paragraph 1 in order to ensure they are protected against the serotypes of Bluetongue virus reported in the Member State or zone thereof of passage during the last two years prior to departure and not reported in the Member State or zone of destination during the same period.

Article 33

Biosecurity and risk-mitigating measures for transport operations through another Member State or zone thereof with the status free from, or with an approved eradication programme for infection with Bluetongue virus (serotypes 1-24)

1. Operators shall only move animals of listed species for infection with Bluetongue virus (serotypes 1-24) through another Member State or zone thereof of passage with the status free from, or with an approved eradication programme for that disease, where at least one of the following requirements are fulfilled:

- (a) the animals fulfil at least one of the requirements set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689;
- or
- (b) the means of transport where the animals are loaded have been protected from attacks by vectors during transport;
- and
- (i) the planned journey does not include the unloading of the animals for a period longer than one day;
- or
- (ii) the animals are unloaded in a vector protected establishment or during the vector-free period.

2. By way of derogation from paragraph 1, the competent authority of the Member State of origin may authorise the movements of animals of listed species for infection with Bluetongue virus (serotypes 1-24) through another Member State or zone thereof of passage with the status free from, or with an approved eradication programme for that disease, if the Member State of passage has informed the Commission and the other Member States that such movements are authorised under the conditions laid down in Article 43(2)(a), (c) and (d) of Delegated Regulation (EU) 2020/689.

CHAPTER 3

Supplementary animal health requirements for movements of poultry and hatching eggs to other Member States

Section 1

Poultry

Article 34

Requirements for movements of breeding poultry and productive poultry

1. Operators shall only move breeding poultry and productive poultry to another Member State when the following requirements are fulfilled:

- (a) the animals have been continuously resident in one or more approved establishments keeping poultry:
 - (i) since hatching;
 - or
 - (ii) for at least:
 - 42 days prior to departure, in the case of breeding poultry and productive poultry for the production of meat or eggs for consumption;
 - or
 - 21 days prior to departure, in the case of productive poultry for restocking supplies of game birds;
- (b) the animals come from a flock in which infection with *Salmonella Pullorum*, *S. Gallinarum* and *S. arizonae* has not been reported and those animals come from establishments which, in case of confirmation of infection with *Salmonella Pullorum*, *S. Gallinarum* and *S. arizonae* during the last 12 months prior to departure have applied the following measures:
 - (i) the infected flock has been slaughtered or it has been killed and destroyed;
 - (ii) following the slaughter or killing of the infected flock referred to in point (i), the establishment has been cleaned and disinfected;
 - (iii) following the cleaning and disinfection referred to in point (ii), all flocks on the establishment tested negative for infection with *Salmonella Pullorum*, *S. Gallinarum* and *S. arizonae* in two tests performed with an interval of at least 21 days in accordance with the surveillance programme referred to in Article 8(b) of Delegated Regulation (EU) 2019/2035;
- (c) the animals come from a flock in which avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) has not been reported and those animals come from establishments which in case of confirmation of avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) during the last 12 months prior to departure have applied the following measures:
 - either
 - (i) the infected flock tested negative for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in two tests performed in accordance with the surveillance programme referred to in Article 8(b) of Delegated Regulation (EU) 2019/2035 on the entire flock with an interval of at least 60 days;
 - or
 - (ii) the infected flock has been slaughtered or it has been killed and destroyed, the establishment has been cleaned and disinfected and following the cleaning and disinfection all flocks on the establishment tested negative for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in two tests performed with an interval of at least 21 days in accordance with the surveillance programme referred to in Article 8(b) of Delegated Regulation (EU) 2019/2035;
- (d) the animals come from flocks which show no clinical signs or suspicion of listed diseases relevant for the species;

- (e) the surveillance provided for in Article 3(1)(a) and (b)(ii) of Delegated Regulation (EU) 2020/689 has not detected any confirmed case of infection with low pathogenic avian influenza viruses in the flock of origin of the animals during the last 21 days prior to departure;
 - (f) in the case of productive poultry for restocking supplies of game birds, the animals have had no contact with birds of lower health status during the last 21 days prior to departure;
 - (g) in the case of ducks and geese, the animals have been subjected to a test for highly pathogenic avian influenza according to Annex IV, with negative results;
 - (h) the relevant requirements related to vaccination as provided for in Article 41 and 42 for the specific category of poultry.
2. The provisions of paragraph 1 shall not apply to the movement of less than 20 heads of poultry other than ratites moved in accordance with Article 37.

Article 35

Requirements for movements of poultry intended for slaughter

1. Operators shall only move poultry intended for slaughter to another Member State when the following requirements are fulfilled:
- (a) the animals have been continuously resident in a registered or approved establishment keeping poultry:
 - (i) since hatching;
 - or
 - (ii) for at least the last 21 days prior to departure;
 - (b) the animals come from flocks which show no clinical signs or suspicion of listed diseases relevant for the species;
 - (c) the relevant requirements related to vaccination as provided for in Article 41 and 42 for the specific category of poultry.
2. The provisions of paragraph 1 shall not apply to the movement of less than 20 heads of poultry other than ratites moved in accordance with Article 37.

Article 36

Requirements for movements of day-old chicks

1. Operators shall only move day-old chicks to another Member State when the following requirements are fulfilled:
- (a) the animals come from an approved hatchery;
 - (b) the animals have been hatched from hatching eggs which:
 - (i) fulfil the requirements of Article 38 and originate from flocks which have been subjected to checks in accordance with Article 91(1)(f) and Article 91(2)(f);
 - or
 - (ii) have entered into the Union from a third country or territory or zone thereof;
 - (c) the relevant requirements related to vaccination as provided for in Article 41 and 42 for the specific category of poultry.
2. In the case of day-old chicks hatched from hatching eggs which have entered into the Union from a third country or territory or zone thereof, the competent authority of the Member State of origin of those day-old chicks shall inform the competent authority of the Member State of intended destination that the hatching eggs had entered the Union from a third country.
3. The provisions of paragraphs 1 and 2 shall not apply to the movement of less than 20 heads of poultry other than ratites moved in accordance with Article 37.

Article 37

Derogation for movements of less than 20 heads of poultry other than ratites

By way of derogation from the requirements set out in Articles 34, 35 and 36, operators may move less than 20 heads of poultry other than ratites to another Member State when the following requirements are fulfilled:

- (a) the animals come from flocks which have been continuously resident in a single registered establishment since hatching or for at least 21 days prior to departure;
- (b) the animals come from flocks which show no clinical signs or suspicion of listed diseases relevant for the species;
- (c) the surveillance provided for in Article 3(1)(a) and (b)(ii) of Delegated Regulation (EU) 2020/689 has not detected any confirmed case of infection with low pathogenic avian influenza viruses in the flock of origin of the animals during the last 21 days prior to departure;
- (d) the animals have had no contact with newly-arrived poultry or with birds of lower health status during the last 21 days prior to departure;
- (e) in the case of ducks and geese, except those intended for slaughter, the animals have been subjected to a test for highly pathogenic avian influenza according to Annex IV, with negative results;
- (f) the animals have been subjected to tests for infection with *Salmonella* Pullorum, *S. Gallinarum* and *S. arizonae* and for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in accordance with Annex V, with negative results;
- (g) the relevant requirements related to vaccination as provided for in Article 41 and 42 for the specific category of poultry.

Section 2

Hatching eggs of poultry

Article 38

Requirements for movements of hatching eggs of poultry

Operators shall only move hatching eggs of poultry to another Member State when those eggs fulfil the following requirements:

- (a) they come from an approved establishment;
- (b) they come from flocks which have been continuously resident in one or more approved establishments keeping poultry since hatching or for at least the last 42 days prior to the collection of the eggs;
- (c) they come from animals which fulfil the requirements in Article 34(1)(b), (c) and (d);
- (d) they are individually marked with the approval number of the establishment of the flock of origin referred to in Article 21(a) of Delegated Regulation (EU) 2019/2035;
- (e) they have been disinfected;
- (f) the relevant requirements related to vaccination as provided for in Articles 41 and 42.

Article 39

Derogation for movements of less than 20 hatching eggs of poultry other than ratites

By way of derogation from the requirements set out in Article 38, operators may move less than 20 hatching eggs of poultry other than ratites to another Member State when those eggs fulfil the following requirements:

- (a) they come from a registered establishment;
- (b) they come from flocks which:
 - (i) have been continuously resident in a registered establishment since hatching, or for at least 21 days prior to the collection of the eggs;
 - (ii) show no clinical signs or suspicion of listed diseases relevant for the species;
 - (iii) have been subjected to tests for infection with *Salmonella* Pullorum, *S. Gallinarum* and *S. arizonae* and for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in accordance with Annex V, with negative results;
- (c) the relevant requirements related to vaccination as provided for in Article 41 and 42.

*Article 40***Derogation for movements of specified pathogen-free eggs**

By way of derogation from the requirements set out in Article 38, operators shall only move specified pathogen-free eggs to another Member State when those eggs fulfil the following requirements:

- (a) they come from an approved establishment keeping poultry;
- (b) they come from flocks which are free from specified pathogens as described in the European Pharmacopoeia and the results of all tests and clinical examinations required for this specific status have been favourable;
- (c) they are marked individually with the approval number of the establishment of origin referred to in Article 21(a) of Delegated Regulation (EU) 2019/2035.

*Section 3***Requirements as regards vaccination***Article 41***Requirements in relation to vaccination against infection with Newcastle disease virus**

In the case where poultry, hatching eggs of poultry or the flocks of origin of hatching eggs or day-old chicks have been vaccinated against infection with Newcastle disease virus with other than inactivated vaccines, the vaccines administered shall satisfy the criteria of Annex VI.

*Section 4***Specific conditions as regards movements to Member States or zones thereof with the status free from infection with Newcastle disease virus without vaccination***Article 42***Additional requirements for movements of poultry and hatching eggs of poultry to a Member State or zone thereof with the status free from infection with Newcastle disease virus without vaccination**

Operators shall only move poultry and hatching eggs of poultry from a Member State or zone thereof which does not have the status free from infection with Newcastle disease virus without vaccination to a Member State or zone thereof which has the status free from infection with Newcastle disease virus without vaccination when those animals and hatching eggs, in addition to the requirements of Sections 1 to 3 for the specific commodity, fulfil the following requirements as regards infection with Newcastle disease virus:

- (a) in the case of breeding poultry and productive poultry, they:
 - (i) are not vaccinated against infection with Newcastle disease virus;
 - (ii) have been isolated for 14 days prior to departure, at either the establishment of origin under the supervision of an official veterinarian or in an approved quarantine establishment, where:
 - no poultry has been vaccinated against infection with Newcastle disease virus during the last 21 days prior to departure;
 - no other birds were introduced during the last 21 days prior departure;
 - no vaccination has been carried out in the quarantine establishment;
 - (iii) have tested negative, during the last 14 days prior to departure, in serological tests to detect antibodies against Newcastle disease virus, performed on blood samples at a level which gives 95 % confidence of detecting infection at 5 % prevalence;

- (b) in the case of poultry intended for slaughter, those animals come from flocks which either:
 - (i) are not vaccinated against infection with Newcastle disease virus and have tested negative, during the last 14 days prior to departure, in serological tests to detect antibodies against Newcastle disease virus performed on blood samples at a level which gives 95 % confidence of detecting infection at 5 % prevalence;
 - or
 - (ii) are vaccinated against infection with Newcastle disease virus and have tested negative, during the last 14 days prior to departure, in a test to detect the presence of Newcastle disease virus, performed at a level which gives 95 % confidence of detecting infection at 5 % prevalence;
- (c) in the case of day-old chicks, they:
 - (i) are not vaccinated against infection with Newcastle disease virus;
 - (ii) come from hatching eggs satisfying the conditions in point (d);
 - (iii) come from a hatchery where working practice ensures that such hatching eggs are incubated at completely separate times and locations from hatching eggs not satisfying the conditions in point (d);
- (d) in the case of hatching eggs of poultry, they:
 - (i) are not vaccinated against infection with Newcastle disease virus;
 - (ii) come from flocks which are:
 - either
 - not vaccinated against infection with Newcastle disease virus;
 - or
 - vaccinated against infection with Newcastle disease virus using inactivated vaccines;
 - or
 - vaccinated against infection with Newcastle disease virus using live vaccines that satisfy the criteria in Annex VI and vaccination has taken place at least 30 days before the collection of the hatching eggs.

CHAPTER 4

Assembly operations in respect of kept ungulates and poultry

Article 43

Specific rules for assembly operations of kept ungulates and poultry

1. During the movement of kept ungulates and poultry from the establishment of origin to an establishment in the Member State of destination, operators shall ensure that the animals are not subjected to more than three assembly operations and that those assembly operations are carried out on establishments approved for assembly operations or on means of transport in accordance with Article 44 under the following conditions:
 - (a) each of the kept ungulates and poultry subjected to those assembly operations is moved to their final place of destination in another Member State at the latest within 20 days after the date of leaving the establishment of origin;
 - (b) the period of time between the date of departure of each of the kept ungulates and poultry from its establishment of origin and the date of its departure from the establishment approved for assembly operations in the Member State of origin to another Member State shall be no longer than 14 days.
2. On request by the competent authority, the operator requesting the animal health certificate in order to comply with Article 143(1) of Regulation (EU) 2016/429 shall provide a movement history, including all assembly operations, of the animals forming the consignment since their departure from the establishment of origin.
3. By way of derogation from paragraph 1(a), in the case of transport by waterway/sea of animals, the period of 20 days laid down in paragraph 1(a), may be extended by the duration of the journey by waterway/sea.

*Article 44***Specific rules for assembly operations taking place on means of transport**

Operators of the establishments keeping ungulates or poultry intended to be assembled on the means of transport before being moved to another Member State shall ensure that the loading is carried out on the establishment without the means of transport entering the premises in which animals are kept.

*Article 45***Detailed rules for biosecurity measures for assembly operations**

1. Operators of establishments approved for assembly operations shall ensure that
 - (a) the establishment or epidemiologically separate animal accommodation areas within the establishment are emptied of animals and cleaned and disinfected at regular intervals not exceeding 14 days of uninterrupted occupation;
 - (b) the tyres of the means of transport, from which animals are unloaded or onto which animals are loaded, are disinfected before leaving the establishment.
2. Operators carrying out assembly operations of kept ungulates or poultry on means of transport shall ensure that the tyres of the means of transport are disinfected before leaving the establishment of origin.

*Article 46***Derogations for movements of ungulates for exhibitions and sporting, cultural and similar events**

1. The conditions laid down in Articles 126(2) and 134(b) of Regulation (EU) 2016/429 and in Articles 43, 44 and 45 of this Regulation shall not apply to the movement of kept ungulates to another Member State for the purpose of participating in exhibitions and sporting, cultural and similar events.
2. The permission by the Member State referred to in the second subparagraph of Article 133(2) of Regulation (EU) 2016/429 shall not be required when individually certified registered equine animals share a means of transport in order to be transported to another Member State to participate in any of the activities referred to in paragraph 1.

*CHAPTER 5****Requirements for movements of kept terrestrial animals other than kept ungulates and poultry, and for movements of hatching eggs of captive birds to other Member States****Section 1***Primates***Article 47***Requirements for movements of primates to other Member States**

Operators shall only move primates to another Member State when the animals

either

1. have been kept in a confined establishment and are transported to a confined establishment in the Member State of destination in accordance with the requirements in Article 64(1);
- or
2. come from an establishment other than a confined establishment and are transported to a confined establishment in the Member State of destination in accordance with the requirements of Article 63(2)(b).

Section 2

Honeybees and Bumble bees

Article 48

Requirements regarding the movement of honeybees to other Member States

Operators shall only move honeybees in any stage of their lifecycle, including honeybee brood, to other Member States when the following requirements are fulfilled:

- (a) the animals and the hives of origin do not show signs of American foulbrood, infestation with *Aethina tumida* (Small hive beetle) or infestation with *Tropilaelaps* spp.;
- (b) they come from an apiary situated in the centre of a circle of at least:
 - (i) 3 km radius, where American foulbrood has not been reported during the last 30 days prior to departure and which is not restricted due to an outbreak of American foulbrood;
 - (ii) 100 km radius, where infestation with *Aethina tumida* (Small hive beetle) has not been reported and which is not restricted due to a suspected case or the confirmed occurrence of infestation with *Aethina tumida* (Small hive beetle) unless a derogation is provided for in Article 49;
 - (iii) 100 km radius, where infestation with *Tropilaelaps* spp. has not been reported and which is not restricted due to a suspected case or confirmed occurrence of infestation with *Tropilaelaps* spp..

Article 49

Derogation for the movement of queen honeybees to other Member States

By way of derogation from Article 48(b)(ii), operators may move queen honeybees where those animals fulfil the requirements of Article 48(a), (b)(i) and (iii) and the following requirements:

- (a) in the apiary of origin infestation with *Aethina tumida* (Small hive beetle) has not been reported and that apiary is situated at a distance of at least 30 km from the limits of a protection zone of at least 20 km in radius established by the competent authority around a confirmed occurrence of infestation with *Aethina tumida* (Small hive beetle);
- (b) the apiary of origin is not located in a zone restricted by protective measures established by the Union due to the confirmed occurrence of infestation with *Aethina tumida* (Small hive beetle);
- (c) the apiary of origin is situated in an area where annual surveillance for the detection of infestation with *Aethina tumida* (Small hive beetle) by the competent authority is ongoing to provide a confidence level of at least 95 % of detecting infestation with *Aethina tumida* (Small hive beetle) if at least 2 % of the apiaries were infested;
- (d) the apiary of origin is inspected every month during the production season by the competent authority with negative results to provide a confidence level of at least 95 % of detecting infestation with *Aethina tumida* (Small hive beetle) if at least 2 % of the hives were infested;
- (e) they are caged individually with a maximum of 20 accompanying attendants.

Article 50

Additional requirements as regards infestation with *Varroa* spp. for the movement of honeybees to other Member States

Operators shall only move honeybees in any stage of their lifecycle, including honeybee brood, to another Member State or zone thereof with the status free from infestation with *Varroa* spp. when in compliance with the requirements set out in Article 48 and provided that the following requirements are fulfilled:

- (a) they come from a Member State or zone thereof with the status free from infestation with *Varroa* spp.;
- (b) they are protected from infestation with *Varroa* spp. during transport.

Article 51

Requirements for the movement of bumble bees to other Member States

Operators shall only move bumble bees to other Member States when the following requirements are fulfilled:

- (a) they do not show signs of infestation with *Aethina tumida* (Small hive beetle);
- (b) they come from an establishment situated in the centre of a circle around the establishment of at least 100 km radius, where infestation with *Aethina tumida* (Small hive beetle) has not been reported and which is not restricted due to a suspected case or confirmed occurrence of infestation with *Aethina tumida* (Small hive beetle). These requirements shall not apply to bumble bees from environmentally isolated production establishments moved in accordance with Article 52.

Article 52

Derogation for the movement of bumble bees from environmentally isolated production establishments for bumble bees to other Member States

By way of derogation from Article 51(b), operators may move bumble bees from environmentally isolated production establishments for bumble bees to other Member States when in compliance with Article 51(a) and provided the following requirements are fulfilled:

- (a) they have been bred isolated in separate epidemiological units with each colony in a closed container which was new or cleaned and disinfected before use;
- (b) regular surveys on the epidemiological unit carried out in accordance with written standard operating procedures has not detected the infestation with *Aethina tumida* (Small hive beetle) within the epidemiological unit.

Section 3

Dogs, cats and ferrets

Article 53

Requirements for the movement of dogs, cats and ferrets to other Member States

Operators shall only move dogs, cats and ferrets to another Member State when the following requirements are fulfilled:

- (a) the animals are individually identified:
 - either
 - (i) in accordance with Article 70 of Delegated Regulation (EU) 2019/2035;
 - or
 - (ii) by a clearly readable tattoo applied before 3 July 2011;
- (b) the animals are accompanied by an individual identification document as provided for in Article 71 of Delegated Regulation (EU) 2019/2035 which documents that
 - (i) the identified animal comes from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure, and has received a complete primary course of anti-rabies vaccination at least 21 days prior to movement, or has been re-vaccinated against rabies in accordance with the validity requirements set out in Part 1 of Annex VII. This requirement shall not apply to dogs, cats and ferrets moved in accordance with Article 54(1) and (2);
 - (ii) in case of dogs, they have been subjected to the risk-mitigation measures for infestation with *Echinococcus multilocularis* in accordance with Part 2(1) of Annex VII and, where applicable, in case of dogs, cats or ferrets for other diseases in accordance with Part 2(3) of Annex VII within the required period set out therein prior to entering a Member State or zone thereof eligible to require the application of those measures. This requirement shall not apply to dogs, cats and ferrets moved in accordance with Article 54(2).

Article 54

Derogation from the requirements regarding anti-rabies vaccination and treatment against infestation with *Echinococcus multilocularis*

1. By way of derogation from Article 53(b)(i), operators may move dogs, cats and ferrets less than 12 weeks old and which have not received an anti-rabies vaccination, or between 12 and 16 weeks old which have received an anti-rabies vaccination, but do not yet meet the validity requirements set out in Part 1 of Annex VII to another Member State provided that:

- (a) the Member State of destination has authorised such movements in general and has informed the public on a dedicated website that such movements are authorised; and
- (b) one of the following conditions is fulfilled:
 - (i) the animal health certificate referred to in Article 86 is complemented by a declaration of the operator which states that from birth until the time of departure the animals have had no contact with kept terrestrial animals under suspicion of infection with rabies virus or wild animals of listed species for infection with rabies virus;

or

- (ii) it can be established from the identification document of the mother, on whom the animals referred to in this paragraph still depend, that, before their birth, the mother received an anti-rabies vaccination which complied with the validity requirements set out in Part 1 of Annex VII.

2. By way of derogation from Article 53(b)(i) and (ii), operators may move dogs, cats and ferrets not vaccinated against rabies, and dogs not treated against infestation with *Echinococcus multilocularis* by direct transport to a confined establishment.

Article 55

Pet keeper's obligation for movements of dogs, cats and ferrets other than non-commercial movements

When a non-commercial movement of dogs, cats or ferrets kept as pet animals in households cannot be carried out in accordance with the conditions laid down in Article 245(2) or Article 246(1) and (2) of Regulation (EU) 2016/429, pet keepers shall only move dogs, cats and ferrets kept as pet animals in households to another Member State when the following requirements are fulfilled:

- (a) the animals are individually identified:

either

- (i) in accordance with Article 70 of Delegated Regulation (EU) 2019/2035;

or

- (ii) by a clearly readable tattoo applied before 3 July 2011;

- (b) the animals are accompanied by an individual identification document as provided for in Article 71 of Delegated Regulation (EU) 2019/2035 which documents that

- (i) the identified animal has received a complete primary course of anti-rabies vaccination at least 21 days prior to departure, or has been re-vaccinated against rabies in accordance with the validity requirements set out in Part 1 of Annex VII. This provision shall not apply to dogs, cats and ferrets moved in accordance with the conditions in Article 56.
 - (ii) in case of dogs, they have been subjected to the risk-mitigation measures for infestation with *Echinococcus multilocularis* in accordance with Part 2(1) of Annex VII and where applicable, in case of dogs, cats or ferrets for other diseases in accordance with Part 2(3) of Annex VII within the required period set out therein prior to entering a Member State or zone thereof eligible to require the application of those measures.

*Article 56***Derogation from the anti-rabies vaccination requirement for movements of dogs, cats and ferrets other than non-commercial movements**

By way of derogation from Article 55(b)(i), pet keepers may move dogs, cats and ferrets less than 12 weeks old which have not received an anti-rabies vaccination, or dogs, cats and ferrets between 12 and 16 weeks old which have received an anti-rabies vaccination, but do not yet meet the validity requirements set out in Part 1 of Annex VII, kept as pet animals in households to another Member State, provided that

- (a) the Member State of destination has authorised such movements in general and has informed the public on a dedicated website that such movements are authorised; and
 - (b) one of the following conditions is fulfilled:
 - (i) the animal health certificate referred to in Article 86 is complemented by a declaration of the pet keeper which states that from birth until the time of departure the animals have had no contact with kept terrestrial animals under suspicion of infection with rabies virus or wild animals of listed species for infection with rabies virus;
- or
- (ii) it can be established from the identification document of the mother, on whom the animals referred to in this paragraph still depend, that, before their birth, the mother received an anti-rabies vaccination which complied with the validity requirements set out in Part 1 of Annex VII.

*Article 57***Information obligation of competent authorities as regards derogation from anti-rabies vaccination requirements for dogs, cats and ferrets**

Member States shall make available to the public information on the acceptance in general of dogs, cats and ferrets less than 12 weeks old which have not received an anti-rabies vaccination, or dogs, cats and ferrets between 12 and 16 weeks old which have received an anti-rabies vaccination, but do not yet meet the validity requirements set out in Part 1 of Annex VII referred to in Article 54(1)(a) and in Article 56(a) coming from other Member States.

*Section 4***Other carnivores***Article 58***Requirements for the movement of other carnivores to other Member States**

1. Operators shall only move other carnivores to another Member State when those other carnivores fulfil the following requirements:
 - (a) the animals are either individually identified or identified as a group of animals of the same species kept together during the movement to destination;
 - (b) the animals come from an establishment in which infection with rabies virus in kept terrestrial animals has not been reported during the last 30 days prior to departure,
 - (c) the animals have received a complete primary course of anti-rabies vaccination at least 21 days prior to departure, or have been re-vaccinated against rabies in accordance with the validity requirements set out in Part 1 of Annex VII;
 - (d) in case of canidae, the animals have been subjected to the risk-mitigation measures for infestation with *Echinococcus multilocularis* in accordance with Part 2(2) of Annex VII within the required period set out therein prior to entering a Member State or zone thereof eligible to require the application of those measures;
 - (e) insofar as measures were adopted pursuant to Regulation (EU) 2016/429 for an infection other than rabies listed for carnivores or certain carnivore species, the animals of the species included in those measures have been subjected to the risk-mitigation measures in accordance with of Part 2(3) of Annex VII for those carnivore species within the required period set out therein prior to entering a Member State or zone thereof eligible to require the application of those measures to animals belonging to those carnivore species.

2. By way of derogation from paragraph 1(c) and (d), operators may move other carnivores not vaccinated against rabies and canidae not treated against infestation with *Echinococcus multilocularis* when the animals are transported directly to

(a) a confined establishment;

or

(b) an establishment where these animals are kept as fur animals as defined in point (1) of Annex I to Commission Regulation (EU) No 142/2011 ⁽¹⁷⁾.

Section 5

Captive birds and hatching eggs of captive birds

Article 59

Requirements for movements of captive birds

1. Operators shall only move captive birds other than psittacidae to another Member State when the following requirements are fulfilled:

- (a) the animals have been continuously resident in a registered or a confined establishment since hatching or for at least 21 days prior to departure;
- (b) the animals come from flocks which show no clinical sign or suspicion of listed diseases relevant for the species;
- (c) the animals show no clinical signs or suspicion of listed diseases relevant for the species;
- (d) in case the animals have entered the Union from a third country or territory or zone thereof, they have been quarantined in accordance with the requirements for entry into the Union in the approved quarantine establishment of destination in the Union;
- (e) in the case of pigeons, the animals are vaccinated against infection with Newcastle disease virus and come from an establishment where vaccination against infection with Newcastle disease virus is carried out;
- (f) the relevant requirements related to vaccination as provided for in Articles 61 and 62.

2. Operators shall only move psittacidae to another Member State when the following requirements are fulfilled:

- (a) the conditions provided for in paragraph 1 are fulfilled;
- (b) the animals come from an establishment on which avian chlamydiosis has not been confirmed during the last 60 days prior to departure and which in case avian chlamydiosis has been confirmed during the last 6 months prior to departure has applied the following measures:
 - (i) infected birds and birds likely to be infected have received treatment;
 - (ii) following the completion of the treatment, they have been found negative to laboratory testing for avian chlamydiosis;
 - (iii) after the completion of the treatment, the establishment has been cleaned and disinfected;
 - (iv) at least 60 days have elapsed from the completion of the cleaning and disinfection referred to in point (iii);
- (c) in case the animals have been in contact with captive birds from establishments on which avian chlamydiosis has been diagnosed during the last 60 days prior to departure, they are found negative to laboratory testing for avian chlamydiosis performed at least 14 days after contact;
- (d) the animals are identified in accordance with Article 76 of Delegated Regulation (EU) 2019/2035.

⁽¹⁷⁾ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

*Article 60***Requirements for movements of hatching eggs of captive birds**

Operators shall only move hatching eggs of captive birds to another Member State when those eggs fulfil the following requirements:

- (a) they come from a registered or confined establishment;
- (b) they come from flocks which have been kept in a registered or confined establishment;
- (c) they come from flocks which show no clinical signs or suspicion of listed diseases relevant for the species;
- (d) they fulfil the relevant requirements related to vaccination as provided for in Articles 61 and 62.

*Article 61***Requirements in relation to vaccination against infection with Newcastle disease virus**

In the case where captive birds, hatching eggs of captive birds or the flocks of origin of the hatching eggs have been vaccinated against infection with Newcastle disease virus with other than inactivated vaccines, the vaccines administered shall satisfy the criteria of Annex VI.

*Article 62***Requirements for movements of captive birds and hatching eggs of captive birds to a Member State or zone thereof with the status free from infection with Newcastle disease virus without vaccination**

Operators shall only move captive birds of galliformes species and hatching eggs of captive birds of galliformes species from a Member State or zone thereof which does not have the status free from infection with Newcastle disease virus without vaccination to a Member State or zone thereof which has the status free from infection with Newcastle disease virus without vaccination when the requirements of Articles 59 to 61 for the specific commodity are fulfilled and those animals and hatching eggs fulfil the following requirements as regards infection with Newcastle disease virus:

- (a) in the case of captive birds:
 - (i) the animals are not vaccinated against infection with Newcastle disease virus;
 - (ii) the animals have been isolated for 14 days prior to departure, at either the establishment of origin under the supervision of an official veterinarian or in an approved quarantine establishment, where:
 - no captive birds have been vaccinated against infection with Newcastle disease virus during the last 21 days prior to departure;
 - no other birds were introduced during the last 21 days prior to departure;
 - no vaccination has been carried out in the quarantine establishment;
 - (iii) the animals have tested negative, during the last 14 days prior to departure, to serological tests to detect antibodies against Newcastle disease virus, performed on blood samples at a level which gives 95 % confidence of detecting infection at 5 % prevalence;
- (b) in the case of hatching eggs of captive birds, they:
 - (i) are not vaccinated against infection with Newcastle disease virus;
 - (ii) come from flocks which are:
 - either
 - not vaccinated against infection with Newcastle disease virus;
 - or

- vaccinated against infection with Newcastle disease virus using inactivated vaccines;
- or
- vaccinated against infection with Newcastle disease virus using live vaccines that satisfy the criteria in Annex VI and vaccination has taken place at least 30 days before the collection of the hatching eggs.

CHAPTER 6

Requirements for movements of kept terrestrial animals into confined establishments

Article 63

Requirements for movements of kept terrestrial animals from establishments other than confined establishments into a confined establishment

1. Operators shall only move kept terrestrial animals other than primates coming from establishments other than a confined establishment into a confined establishment in compliance with the following requirements:

- (a) the animals are subjected to quarantine for a period appropriate for the diseases listed for the species to be moved and in any case of at least 30 days and during this period they are kept:

either

- (i) prior to their movement, in an approved quarantine establishment or in quarantine facilities of another confined establishment;

or

- (ii) after their movement, in a quarantine facility of the confined establishment of final destination;

- (b) the animals show no clinical signs or suspicion of diseases listed for the species at the time of movement;
- (c) the animals fulfil the requirements for identification laid down in Delegated Regulation (EU) 2019/2035 relevant for the species;
- (d) the animals fulfil the requirements for vaccination, treatment or testing laid down in this Regulation applicable for the movement of the animals.

2. Operators shall only move kept primates to a confined establishment in compliance with rules that are at least as strict as those referred to in the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), Edition 2018, in Articles 5.9.1 to 5.9.5 with regard to quarantine measures applicable to primates and in Article 6.12.4 with regard to quarantine requirements for primates from an uncontrolled environment, and such movement has been authorised

- (a) in the case of movement within a Member State, by the competent authority of that Member State,

or

- (b) in the case of movement to another Member State, by an agreement of the competent authority of Member State of origin and the competent authority of Member State of destination.

Article 64

Requirements for movements of kept terrestrial animals from confined establishments into confined establishments in other Member States

1. Operators shall only move kept terrestrial animals from a confined establishment to a confined establishment in another Member State if those animals do not pose a significant risk to the spread of diseases for which they are listed, based on the results of the surveillance plan covering those animals.

2. Operators shall only move kept animals belonging to the families of *Antilocapridae*, *Bovidae*, *Camelidae*, *Cervidae*, *Giraffidae*, *Moschidae* or *Tragulidae* to another Member State or zone thereof in compliance with at least one of the requirements for infection with Bluetongue virus (serotype 1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689.

3. By way of derogation from paragraph 2, the competent authority of the Member State of origin may authorise the movement of such animals which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689 to another Member State or zone thereof

- (a) with a disease-free status or with an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689;

or

- (b) without a disease-free status and without an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised. If the Member State of destination sets conditions for the authorisation of such movement, those conditions must be any one of the conditions referred to in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689.

CHAPTER 7

Special rules and exemptions

Article 65

Special rules for movement of travelling circuses and animal acts to other Member States

1. Operators of travelling circuses and animal acts shall only move their circuses and animal acts to another Member State when the following requirements are fulfilled:

- (a) they provide the competent authority in the Member State where the travelling circus or animal act is situated with an itinerary of their intended movement to another Member State at least 10 working days before departure;
- (b) the movement document referred to in Article 77 of Delegated Regulation (EU) 2019/2035 accompanying all animals to be moved is duly updated,

and

- (i) the individual identification document for each dog, cat and ferret to be moved, referred to in Article 71 of Delegated Regulation (EU) 2019/2035, is duly completed with the information referred to in Article 53(b)(i) and (ii);
 - (ii) the identification document for the group of kept birds to be moved, referred to in Article 79 of Delegated Regulation (EU) 2019/2035, is duly updated.
- (c) during the last 12 months prior to departure:
 - (i) bovine, ovine, caprine, camelid and cervid animals have been subjected to a test for infection with *Brucella abortus*, *B. melitensis* and *B. suis* with one of the diagnostic methods provided for in Part 1 of Annex I, with negative results;
 - (ii) bovine, caprine and cervid animals have been subjected to a test for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) with one of the diagnostic methods provided for in Part 1 of Annex I, with negative results;
 - (iii) pigeons have been vaccinated against infection with the Newcastle disease virus;
- (d) all the animals of travelling circuses and animal acts were inspected by the official veterinarian during the period of 10 working days prior to departure of the travelling circus and animal act and were found clinically healthy for the listed diseases as applied to listed species or to categories of animals.

2. Operators of travelling circuses and animal acts shall only move kept animals belonging to the families of *Antilocapridae*, *Bovidae*, *Camelidae*, *Cervidae*, *Giraffidae*, *Moschidae* or *Tragulidae* to another Member State or zone thereof in compliance with at least one of the requirements for infection with Bluetongue virus (serotype 1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689.

3. By way of derogation from paragraph 2, the competent authority of the Member State of origin may authorise the movement of such animals which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689 to another Member State or zone thereof

- (a) with a disease-free status or with an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689;

or

- (b) without a disease-free status and without an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised. If the Member State of destination sets conditions for the authorisation of such movement, those conditions must be any one of the conditions referred to in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689.

Article 66

Obligation of the competent authority in relation to movement of travelling circuses and animal acts to other Member States

The competent authority of the Member State of origin shall sign and stamp the itinerary referred to in Article 65(1)(a) provided that:

- (a) the travelling circus or animal act is not subject to any animal health restriction relating to a disease listed for the species of an animal kept in the travelling circus and animal act;
- (b) the animal health requirements set out in Article 65 are complied with;
- (c) all the identification documents accompanying the animals during the movement of the travelling circus and animal act are duly updated and the animals fulfil the requirements for vaccination, treatment or testing laid down in this Regulation applicable for the movement of the relevant species.

Article 67

Requirements for movements of captive birds intended for exhibitions

1. Operators shall only move captive birds to an exhibition in another Member State when those animals fulfil the conditions set out in Article 59.

2. The operator of the exhibition, excluding flight hunting exhibitions for birds of prey, shall ensure that:

- (a) the entry into the exhibition of animals is limited to captive birds registered in advance for the participation in the exhibition;
- (b) the entry into the exhibition of birds originating from establishments situated in the Member State where the exhibition takes place does not jeopardise the health status of birds participating in the exhibition by

either

- (i) requiring the same health status for all captive birds participating in the exhibition;

or

- (ii) keep the captive birds originating from the Member State where the exhibition takes place on separate premises or enclosures apart from captive birds originating from other Member States;

- (c) a veterinarian

- (i) carries out identity checks on captive birds participating in the exhibition prior to their entry in the exhibition;
- (ii) monitors the clinical conditions of the birds upon entry into and during the exhibition.

3. Operators shall ensure that captive birds moved to an exhibition in accordance with paragraphs 1 and 2 are only moved from such exhibitions to another Member State when they fulfil one of the following requirements:

(a) the animals are accompanied by an animal health certificate in accordance with Article 81;

or

(b) in the case of captive birds others than birds of prey which have taken part in a flight hunting exhibition, the animals are accompanied by a declaration issued by the veterinarian referred to in paragraph 2(c) stating that the health status of the birds as attested in the original animal health certificate in accordance with Article 81 has not been compromised during the exhibition, as well as by the valid original animal health certificate in accordance with Article 81 issued by the competent authority of the Member State of origin for the movement of the captive birds to the exhibition annexed to that declaration;

or

(c) in the case of birds of prey which have taken part in a flight hunting exhibition, the animals are accompanied by the valid original animal health certificate in accordance with Article 81 issued by the competent authority of the Member State of origin for the movement of the birds of prey to the flight hunting exhibition, provided they are moved back to the Member State of origin.

4. The veterinarian referred to in paragraph 2(c) shall only issue the declaration referred to in paragraph 3(b) provided:

(a) the animals are moved back to the Member State of origin;

(b) arrangements have been made that the intended movement of the captive birds to the Member State of origin will be completed within the period of validity of the original animal health certificate in accordance with Article 81 issued by the competent authority of the Member State of origin for the movement of the captive birds to the exhibition;

(c) the conditions in paragraph 2(b) have been fulfilled.

Article 68

Specific requirements for movements of racing pigeons to sporting events in another Member State

Operators shall only move racing pigeons to sporting events in another Member State when those animals fulfil the conditions in Article 59.

CHAPTER 8

Animal health certificates and movement notification

Section 1

Requirements for animal health certification

Article 69

Derogation for movements of kept equine animals to other Member States

The animal health certification requirements provided for in Article 143(1) of Regulation (EU) 2016/429 shall not apply to the movement of registered equine animals to another Member State, provided:

(a) the competent authority of the Member State of origin has authorised the derogation;

(b) the competent authority of the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in point (c) and point (d);

(c) equine animals kept and moved on the respective territories of the Member State of origin and of the Member State of destination fulfil at least the animal health requirements for movement of kept equine animals to other Member States, and in particular with the additional animal health requirements laid down in Article 22;

(d) the competent authority of the Member State of origin and the competent authority of the Member State of destination have systems in place to ensure traceability of kept equine animals moved under the conditions of this Article.

*Article 70***Derogation for movements of terrestrial animals of travelling circuses and animal acts to other Member States**

The animal health certification requirements provided for in Article 143(1) to Regulation (EU) 2016/429 shall not apply to the movement of terrestrial animals of travelling circuses and animal acts to another Member State.

*Article 71***Animal health certificate for certain kept terrestrial animals**

1. Operators shall only move captive birds, honeybees, bumble bees except bumble bees from approved environmentally isolated production establishments, primates, dogs, cats, ferrets or other carnivores to another Member State if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin.
2. By way of derogation from paragraph 1, operators may move captive birds from exhibitions back to the Member State of origin of the birds in accordance with Article 67(3).
3. By way of derogation from paragraph 1, the animal health certificate issued by the competent authority of the Member State of origin for the movement of birds of prey from the establishment in the Member State of origin to a flight hunting exhibition in another Member State may accompany these birds of prey during their return from that exhibition to the Member State of origin, provided the movement takes place within the period of validity of that certificate.

*Article 72***Animal health certificate for hatching eggs of captive birds**

Operators shall only move hatching eggs of captive birds to another Member State if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin.

Section 2**Content of animal health certificates for kept terrestrial animals and hatching eggs***Article 73***Details on content of animal health certificate for kept bovine animals**

1. The animal health certificate for kept bovine animals, except those kept bovine animals referred to in paragraph 2, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 10, and for those in Articles 11, 12 and 13 where applicable.
2. The animal health certificate for kept bovine animals being moved either directly or after undergoing an assembly operation to a slaughterhouse in another Member State for immediate slaughter, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 14.

*Article 74***Details on content of animal health certificate for kept ovine and caprine animals**

1. The animal health certificate for kept ovine and caprine animals, except those kept ovine and caprine animals referred to in paragraph 2 and 3, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for:
 - (a) in case of ovine animals except uncastrated male ovine animals, in Article 15(1) and (2);

- (b) in case of caprine animals, in Article 15(1) and (3);
- (c) in case of uncastrated male ovine animals, in Article 15(1), (2) and (4);
- (d) in Article 17 where applicable.

2. The animal health certificate for kept ovine and caprine animals moved to another Member State or zone thereof with an approved eradication programme for infection with *Brucella abortus*, *B. melitensis* and *B. suis*, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for:

- (a) in Article 15(1)(a), (b) and (d) to (h);
- (b) in either Article 15(1)(c) or Article 16;
- (c) in Article 17 where applicable.

3. The animal health certificate for kept ovine and caprine animals being moved either directly or after undergoing an assembly operation to a slaughterhouse in another Member State for immediate slaughter, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 18.

Article 75

Details on content of animal health certificate for kept porcine animals

1. The animal health certificate for kept porcine animals, except those kept porcine animals referred to in paragraph 2, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 19, and for those in Article 20 where applicable.

2. The animal health certificate for kept porcine animals being moved either directly or after undergoing an assembly operation to a slaughterhouse in another Member State for immediate slaughter, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 21.

Article 76

Details on content of animal health certificate for kept equine animals

1. The animal health certificate for kept equine animals, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 22.

2. The animal health certificate referred to in paragraph 1

- (a) shall be issued for an individual equine animal;

or

- (b) may be issued for a consignment of equine animals

- (i) dispatched directly to another Member State without undergoing assembly operations;

or

- (ii) transported either directly or after undergoing an assembly operation to a slaughterhouse for immediate slaughter in another Member State.

*Article 77***Details on content of animal health certificate for kept camelid animals**

1. The animal health certificate for kept camelid animals, except those kept camelid animals referred to in paragraph 2, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 23, and for those in Article 24 where applicable.
2. The animal health certificate for kept camelid animals being moved either directly or after undergoing an assembly operation to a slaughterhouse in another Member State for immediate slaughter, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 25.

*Article 78***Details on content of animal health certificate for kept cervid animals**

1. The animal health certificate for kept cervid animals, except those kept cervid animals referred to in paragraph 2, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 26, and for those in Article 27 where applicable.
2. The animal health certificate for kept cervid animals being moved either directly or after undergoing an assembly operation to a slaughterhouse in another Member State for immediate slaughter, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 28.

*Article 79***Details on content of animal health certificate for other kept ungulates**

1. The animal health certificate for other kept ungulates, except those other kept ungulates referred to in paragraph 2, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 29, and for those in Article 30 where applicable.
2. The animal health certificate for other kept ungulates being moved either directly or after undergoing an assembly operation to a slaughterhouse in another Member State for immediate slaughter, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 31.

*Article 80***Details on content of animal health certificate for poultry**

The animal health certificate for poultry, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for:

- (a) in the case of breeding poultry and productive poultry, in Article 34 and in Articles 41 and 42 where applicable for the specific category of poultry;
- (b) in the case of poultry for slaughter, in Article 35 and in Articles 41 and 42 where applicable for the specific category of poultry;

- (c) in the case of day-old chicks, in Article 36 and in Articles 41 and 42 where applicable for the specific category of poultry;
- (d) in the case of less than 20 heads of poultry other than ratites, in Article 37 and in Articles 41 and 42 where applicable for the specific category of poultry.

Article 81

Details on content of animal health certificate for captive birds

1. The animal health certificate for captive birds, except those referred to in paragraphs 2 and 3, that is issued by the competent authority of the Member State of origin in accordance with Article 71(1), shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 59, and for those in Articles 61 and 62 where applicable for the specific category of birds.
2. The animal health certificate for captive birds intended for exhibitions, that is issued by the competent authority of the Member State of origin in accordance with Article 71(1), shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 67(1).
3. The animal health certificate for racing pigeons, that is issued by the competent authority of the Member State of origin in accordance with Article 71(1), shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 68.

Article 82

Details on content of animal health certificate for hatching eggs of poultry

The animal health certificate for hatching eggs of poultry, that is issued by the competent authority of the Member State of origin in accordance with Article 161(1) of Regulation (EU) 2016/429, shall contain the general information provided for in point 2 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for:

- (a) in case of hatching eggs of poultry, except those referred to in points (b) and (c), in Article 38, and in Articles 41 and 42 where applicable for the specific category of eggs;
- (b) in case of less than 20 hatching eggs of poultry other than ratites, in Article 39 and in Articles 41 and 42 where applicable for the specific category of eggs;
- (c) in case of specified pathogen-free eggs of poultry, in Article 40.

Article 83

Details on content of animal health certificate for hatching eggs of captive birds

The animal health certificate for hatching eggs of captive birds, that is issued by the competent authority of the Member State of origin in accordance with Article 72, shall contain the general information provided for in point 2 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 60 and in Articles 61 and 62 where applicable for the specific category of eggs.

Article 84

Details on content of animal health certificate for honeybees and bumble bees

1. The animal health certificate for honeybees, that is issued by the competent authority of the Member State of origin in accordance with Article 71(1), shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 48, and in Articles 49 and 50 where applicable.
2. The animal health certificate for bumble bees, except bumble bees from approved environmentally isolated production establishments, that is issued by the competent authority of the Member State of origin in accordance with Article 71(1), shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 51.

*Article 85***Details on content of animal health certificate for primates**

The animal health certificate for primates, that is issued by the competent authority of the Member State of origin in accordance with Article 71(1), shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 47.

*Article 86***Details on content of animal health certificate for dogs, cats and ferrets**

1. The animal health certificate for dogs, cats and ferrets, except those dogs, cats and ferrets referred to in paragraph 2, that is issued by the competent authority of the Member State of origin in accordance with Article 71(1), shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 53, and in Article 54 where applicable.

2. The animal health certificate for dogs, cats and ferrets kept as pet animals, that is issued by the competent authority of the Member State of origin in accordance with Article 71(1), shall contain the general information provided for in point 1 of Part 1 of Annex VIII, an attestation of compliance with the requirements provided for in Article 55, and in Article 56 where applicable, and a link to the identification document referred to in Article 71 of Delegated Regulation (EU) 2019/2035.

*Article 87***Details on content of animal health certificate for other carnivores**

The animal health certificate for other carnivores, that is issued by the competent authority of the Member State of origin in accordance with Article 71(1), shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 58.

*Article 88***Details on content of animal health certificate for terrestrial animals moved from a confined establishment to a confined establishment in another Member State**

The animal health certificate for terrestrial animals moved from a confined establishment to a confined establishment in another Member State, that is issued by the competent authority of the Member State of origin in accordance with Article 143(1) of Regulation (EU) 2016/429 or in Article 71(1) of this Regulation, shall contain the general information provided for in point 1 of Part 1 of Annex VIII and an attestation of compliance with the requirements provided for in Article 64.

*Section 3***animal health certification requirements for specific types of movements of kept terrestrial animals***Article 89***Animal health certification for movement of ungulates and poultry through establishments carrying out assembly operations**

The competent authority shall issue the animal health certificate referred to in Articles 73 to 80 for the movement to another Member State of ungulates and poultry subject to assembly operations as follows:

- (a) the documentary, identity and physical checks and examinations referred to in Article 91(1) are carried out before issuing the first animal health certificate referred to in Articles 73 to 80

either

- (i) in the establishment of origin, where the animals are destined for

— direct movement to an establishment approved for assembly operations in the Member State of passage;

or

- an assembly operation on a means of transport in the Member State of origin in order to be moved directly to another Member State;
 - or
 - (ii) in an establishment approved for assembly operations, where the animals have been assembled in the Member State of origin for dispatch to another Member State;
 - or
 - (iii) in an establishment approved for assembly operations in a Member State of passage, in case the animals have been subjected to an assembly operation in such a Member State;
- (b) the animal health certificate referred to in Articles 73 to 80 is completed based on official information:
- (i) available to the certifying official veterinarian who carried out the checks and examinations referred to in point (a)(i) and (ii) in the Member State of origin;
 - or
 - (ii) provided in the first or second animal health certificate referred to in Articles 73 to 80 available to the certifying official veterinarian who carried out the checks and examinations referred to in point (a)(iii) in the Member State of passage, where one is visited.

Article 90

Animal health certification for kept ungulates and poultry intended for export to third countries during their movement from the Member State of origin through the territory of other Member States to the external border of the Union

Operators shall ensure that kept ungulates or poultry intended for export to a third country that are being transported to the external border of the Union through another Member State are accompanied by health certificates in which it is attested that:

- (i) the animals comply at least with the requirements in accordance with this Chapter for the movement of kept ungulates or poultry intended for slaughter in the Member State where the exit point is located;
- and
- (ii) in case of animals of the species listed for infection with Bluetongue virus (serotypes 1-24), the animals comply at least with Article 33 when the exit point is located in a Member State or zone thereof with a disease-free status or with an approved eradication programme for infection with Bluetongue virus (serotype 1-24).

Section 4

Rules on the responsibility of the competent authority for animal health certification

Article 91

Responsibility of the competent authority for animal health certification

1. Before signing an animal health certificate, the official veterinarian shall carry out the following types of documentary, identity and physical checks and examinations in order to verify compliance with the requirements:
 - (a) in relation to kept ungulates, an identity check and a clinical examination of the animals of the consignment for the purpose of detection of clinical signs or suspicion of listed diseases relevant for the species;
 - (b) in relation to breeding poultry, productive poultry and less than 20 heads of poultry other than ratites, a documentary check of the health and production records kept at the establishment, an identity check of the animals of the consignment and a clinical inspection of the flock of origin and of the animals of the consignment for the purpose of detection of clinical signs or suspicion of listed diseases relevant for the species;
 - (c) in relation to poultry intended for slaughter, a documentary check of the health and production records kept at the establishment, an identity check of the animals of the consignment and a clinical inspection of the flock of origin for the purpose of detection of clinical signs or suspicion of listed diseases relevant for the species;

- (d) in relation to day-old chicks, a documentary check of the health and production records kept at the establishment of the flock of origin for the purpose of detection of clinical signs or suspicion of listed diseases relevant for the species;
 - (e) in relation to captive birds:
 - (i) an identity check of the animals of the consignment;
 - (ii) a documentary check of the health and production records kept at the establishment and a clinical inspection of the flock of origin and of the animals of the consignment for the purpose of detection of clinical signs or suspicion of listed diseases relevant for the species;
 - (f) in relation to hatching eggs of poultry, a documentary check of the health and production records kept at the establishment of the flock of origin and where applicable the records kept at the hatchery of dispatch, an identity check of the hatching eggs and
either
 - (i) a clinical inspection of the flock of origin for the purpose of detection of clinical signs or suspicion of listed diseases relevant for the species;or
 - (ii) monthly health inspection visits of the health status of the flock of origin and an evaluation of its current health status as assessed by up-to-date information supplied by the operator;
 - (g) in relation to hatching eggs of captive birds, a documentary check of the health and production records kept at the establishment, an identity check of the hatching eggs and a clinical inspection of the flock of origin for the purpose of detection of clinical signs or suspicion of listed diseases relevant for the species;
 - (h) in relation to honeybees and bumble bees an identity check and
either
 - (i) a visual examination of the animals, their packaging and any accompanying feed or other material for the purpose of detection of occurrence of American foulbrood, *Aethina tumida* (Small hive beetle) and *Tropilaelaps spp.* for honeybees or *Aethina tumida* (Small hive beetle) for bumble bees;or
 - (ii) in relation to queen honeybees to be certified under derogation provided for in Article 49, a documentary check of the records of the monthly health inspection during the production season, a visual examination of their individual cages for the purpose of verification of the maximum number of attendants per cage and a visual examination of the animals, their packaging and any accompanying feed or other material for the purpose of detection of occurrence of American foulbrood, *Aethina tumida* (Small hive beetle) and *Tropilaelaps spp.*;
 - (i) in relation to primates, a documentary check of the health records, an identity check and a clinical examination, and where this is not possible, a clinical inspection, of the animal(s) of the consignment for the purpose of detection of clinical signs or suspicion of listed diseases relevant for the species;
 - (j) in relation to dogs, cats, ferrets and other carnivores, an identity check and a clinical examination, and where this is not possible, a clinical inspection, of the animals of the consignment for the purpose of detection of clinical signs or suspicion of listed diseases relevant for the species;
 - (k) in relation to terrestrial animals from a confined establishment moving to a confined establishment in another Member State, a documentary check of the health records, an identity check and a clinical examination, and where this is not possible, a clinical inspection, of the animals of the consignment for the purpose of detection of clinical signs or suspicion of listed diseases relevant for the species.
2. The official veterinarian shall carry out the documentary, identity and physical checks and examinations as provided for in paragraph 1 and issue the animal health certificate:
- (a) within the last 24 hours before departure from the establishment of origin, or where applicable the establishment approved for assembly operations, in relation to kept ungulates except equine animals;
 - (b) within the last 48 hours before departure from the establishment of origin in relation to equine animals, or, in the case of equine animals referred to in Article 92(2), on the last working day before departure;

- (c) within the last 48 hours before departure from the establishment of origin, in relation to breeding poultry, productive poultry, less than 20 heads of poultry other than ratites and captive birds;
- (d) within the last 5 days before departure from the establishment of origin, in relation to poultry intended for slaughter;
- (e) within the last 24 hours before departure from the establishment of origin in relation to day-old chicks;
- (f) in relation to hatching eggs of poultry:
 - (i) within the last 72 hours before departure of the hatching eggs from the establishment of origin, in the case of the documentary checks, the identity checks, the clinical inspection of the flock of origin and the evaluation of its current health status as assessed by up-to-date information supplied by the operator;
 - (ii) within the last 31 days before departure of the hatching eggs from the establishment of origin, in the case of monthly health inspection visits of the flock of origin;
- (g) within the last 48 hours before departure from the establishment of origin, in relation to hatching eggs of captive birds;
- (h) within the last 48 hours before departure from the establishment of origin, in relation to honeybees and bumble bees and within the last 24 hours before departure from the establishment of origin, in relation to queen honeybees to be certified under derogation;
- (i) within the last 48 hours before departure from the establishment of origin, in relation to primates;
- (j) within the last 48 hours before departure from the establishment of origin, in relation to dogs, cats, ferrets and other carnivores;
- (k) within the last 48 hours before departure from the establishment of origin, in relation to terrestrial animals from a confined establishment to a confined establishment in another Member State.

3. The animal health certificate shall be valid for 10 days from the date of issuing, without prejudice to the derogations established under Article 92.

Article 92

Derogation from the duration of validity of the animal health certificate

1. By way of derogation from Article 91(3), in the case of transport by waterway/sea of animals, the period of 10 days for the validity of the animal health certificate may be extended by the duration of the journey by waterway/sea.

2. Also by way of derogation from Article 91(3), the certificate for equine animals referred to in Article 76(2)(a) shall be valid for 30 days provided:

- (a) the equine animal to be moved is accompanied by its single lifetime identification document as provided for in Article 114(1)(c) of Regulation (EU) 2016/429 which includes a validation mark issued by the competent authority, or the body to which this activity was delegated, for a period not exceeding 4 years, to document that the animal is habitually resident in an establishment recognised by the competent authority as an establishment of low health risk due to frequent animal health visits, additional identity checks and health testing and the absence of natural breeding on the establishment, except in dedicated and separated premises;

or

- (b) the registered equine animal to be moved is accompanied by its single lifetime identification document as provided for in Article 114(1)(c) of Regulation (EU) 2016/429 which includes a license issued for a period not exceeding 4 years either for the participation in equestrian competitions by the national federation of the Fédération Equestre Internationale or for the participation in races by the competent racing authority, and which documents at least two visits per year by a veterinarian, including those necessary to carry out regular equine influenza vaccinations and examinations required for movements to other Member States or third countries.

3. During the period of validity, the certificate referred to in paragraph 2 shall be sufficient for

- (a) multiple entries into other Member States;
- (b) the return to the establishment of departure indicated therein.

Section 5

Detailed rules on notification of movements of kept terrestrial animals and hatching eggs to other Member States*Article 93***Advance notification by operators of movement of bumble bees from approved environmentally isolated production establishments between Member States**

In the case of bumble bees from approved environmentally isolated production establishments being moved to another Member State, the operator of the establishment of origin shall notify the competent authority of the Member State of origin in advance of the departure of those bumble bees.

*Article 94***Advance notification by operators of travelling circuses and animal acts when they intend to move kept terrestrial animals between Member States**

In the case of travelling circuses and animal acts being moved to another Member State, the operator of the travelling circuses and animal acts shall notify the competent authority of the Member State of origin at least 10 days before the departure of those travelling circuses and animal acts.

*Article 95***Advance notification by operators of movements of hatching eggs of captive birds between Member States**

In the case of hatching eggs of captive birds being moved to another Member State, the operator of the establishment of origin shall notify the competent authority of the Member State of origin in advance of the intended movement of those germinal products.

*Article 96***Information obligation of operators concerning the notification of movements of kept terrestrial animals to other Member States**

The operators notifying the competent authority in their Member State of origin as provided for in Article 152 of Regulation (EU) 2016/429, shall provide the competent authority with the information concerning each consignment of kept terrestrial animals to be moved to another Member State provided for in:

- (a) points 1(a) to (d) in Part 1 of Annex VIII concerning kept terrestrial animals except bumble bees from approved environmentally isolated production establishments to be moved to another Member State;
- (b) part 2 of Annex VIII concerning bumble bees from approved environmentally isolated production establishments.

*Article 97***Information obligation of the competent authority concerning the notification of movements of kept terrestrial animals to other Member States**

The competent authority of the Member State of origin notifying the competent authority of the Member State of destination in accordance with Article 153(1) of Regulation (EU) 2016/429, shall provide the information concerning each consignment of kept terrestrial animals to be moved to another Member State provided for in:

- (a) points 1(a) to (d) in Part 1 of Annex VIII concerning kept terrestrial animals except bumble bees from approved environmentally isolated production establishments to be moved to another Member State;
- (b) part 2 of Annex VIII concerning bumble bees from approved environmentally isolated production establishments.

*Article 98***Notification of movements of hatching eggs to other Member States**

The operators notifying the competent authority in their Member State of origin in accordance with Article 163 of Regulation (EU) 2016/429 and Article 95 of this Regulation, shall provide the competent authority with the information provided for in points 2(a) to (e) in Part 1 of Annex VIII concerning each consignment of hatching eggs to be moved to another Member State.

*Article 99***Emergency procedures**

In the event of power cuts and other disturbances of IMSOC, the competent authority of the place of origin of the kept terrestrial animals or hatching eggs to be moved to another Member State shall comply with the contingency arrangements established pursuant to Article 134(d) of Regulation (EU) 2017/625.

*Article 100***Designation of regions for the management of notifications of movements**

When designating regions for the management of notifications of movements provided for in Article 97 and 98, Member States shall ensure that:

- (a) all parts of their territory is covered by at least one region;
- (b) each designated region falls within the responsibility of a competent authority designated for animal health certification in that region;
- (c) the competent authority responsible for the designated region has access to IMSOC;
- (d) the personnel of the competent authority responsible for the designated region possess the appropriate ability and knowledge, and have received specific training, or have equivalent practical experiences in the use of IMSOC for production, handling and transmission of the information provided for in Articles 97 and 98.

PART III

MOVEMENTS OF WILD TERRESTRIAL ANIMALS*Article 101***Requirements for movement of wild terrestrial animals to other Member States**

1. Operators shall only move wild terrestrial animals from their habitat of origin by loading them directly onto a means of transport to be taken to a habitat or an establishment in another Member State without the animals entering any establishment in the Member State of origin.
2. Operators and transporters shall ensure that the means of transport used for transporting wild terrestrial animals, except honeybees and bumble bees, are:
 - (a) constructed in such a way that
 - (i) animals cannot escape or fall out;
 - (ii) visual inspection of the animals on the means of transport is possible;
 - (iii) the escape of animal excrements, litter or feed is prevented or minimised;
 - (iv) in the case of birds, the escape of feathers is prevented or minimised;
 - (v) where necessary, the animals can be restrained or transported sedated;
 - (b) cleaned and disinfected immediately after every transport of animals, or any item representing an animal health risk, and, if necessary, disinfected again and in any case dried or allowed to dry before any new loading of animals.

3. Operators and transporters shall ensure that containers in which wild terrestrial animals, except honeybees and bumble bees, are transported:

- (a) comply with the conditions in point 2(a);
- (b) contain only wild animals of the same species coming from the same habitat;
- (c) are marked to detail species and number of animals;
- (d) are either unused purpose-designed disposable containers to be destroyed after first use or cleaned and disinfected after use and dried or allowed to dry before any subsequent use.

4. Operators shall only move wild terrestrial animals from their habitat of origin to a habitat or an establishment in another Member State when the following additional requirements are fulfilled:

- (a) the majority of the animals of the consignment have been resident in the habitat of origin for at least 30 days prior to departure, or since birth, if they are younger than 30 days of age, and during this period they have not been in contact with kept animals of a lower health status or subject to movement restrictions for animal health reasons or with kept animals coming from an establishment which did not fulfil the requirements set out in point (b);
- (b) any animals entering the Union from a third country or territory during the last 30 days prior to the departure of the animals referred to in paragraph 1, and introduced into an establishment situated in the habitat where those animals were resident, are kept separate so as to prevent direct and indirect contact with all other animals on that establishment and in the habitat;
- (c) those animals come from a habitat in which the following diseases and infections have not been reported during the stipulated timeframes:
 - (i) infection with rabies virus during the last 30 days prior to departure;
 - (ii) infection with *Brucella abortus*, *B. melitensis* and *B. suis* in wild terrestrial animals of listed species for that disease during the last 42 days prior to departure;
 - (iii) infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in wild terrestrial animals of listed species for that disease during the last 42 days prior to departure;
 - (iv) infection with epizootic haemorrhagic disease virus within a radius of 150 km in wild terrestrial animals of listed species for that disease during the last 2 years prior to departure;
 - (v) anthrax in ungulates during the last 15 days prior to departure;
 - (vi) surra (*Trypanosoma evansi*) during the last 30 days prior to departure;
- (d) when those animals belong to the families of *Antilocapridae*, *Bovidae*, *Camelidae*, *Cervidae*, *Giraffidae*, *Moschidae* or *Tragulidae*, the habitat of origin shall be in compliance with at least one of the requirements for infection with Bluetongue virus (serotype 1-24) set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689;
- (e) those animals are not known to have been in contact with wild terrestrial animals which did not fulfil the requirements set out in point (c) during the last 30 days prior to departure.

5. By way of derogation from paragraph 4(d), the competent authority of the Member State of origin may authorise the movement of wild terrestrial animals which do not fulfil at least one of the requirements laid down in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V to Delegated Regulation (EU) 2020/689 to another Member State or zone thereof:

- (a) with a disease-free status or with an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised under the conditions referred to in Article 43(2) of Delegated Regulation (EU) 2020/689;

or

- (b) without a disease-free status and an approved eradication programme for infection with Bluetongue virus (serotype 1-24), if the Member State of destination has informed the Commission and the other Member States that such movements are authorised. If the Member State of destination sets conditions for the authorisation of such movement, those conditions must be any one of the conditions referred to in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V of Delegated Regulation (EU) 2020/689.

Article 102

Details on content of animal health certificate for wild terrestrial animals

The animal health certificate for wild terrestrial animals, that is issued by the competent authority of the Member State of origin in accordance with Article 155(1)(c) of Regulation (EU) 2016/429, shall contain the general information provided for in point 3 of Annex VIII and an attestation of compliance with the requirements provided for in Article 101(4), and those in Article 101(5) of this Regulation where applicable.

Article 103

Rules concerning the responsibility of the competent authority for animal health certification for movements of wild terrestrial animals to other Member States

1. Before signing the animal health certificate provided for in Article 102 for the movement of wild terrestrial animals, the official veterinarian shall carry out the following types of identity check and examinations:
 - (a) an examination of available information demonstrating that the requirements provided for in Article 101(4) are fulfilled;
 - (b) an identity check;
 - (c) a clinical examination, and where this is not possible, a clinical inspection of the animals of the consignment for the purpose of detection of clinical signs or suspicion of listed or emerging diseases relevant for the species.
2. The official veterinarian shall carry out the documentary, identity and physical checks and examinations as provided for in paragraph 1 and issue the animal health certificate within the last 24 hours before departure of the consignment from the habitat.
3. The animal health certificate shall be valid for 10 days from the date of issuing.
4. By way of derogation from paragraph 3, in the case of transport by waterway/sea of wild terrestrial animals, the period of 10 days for the validity of the animal health certificate may be extended by the duration of the journey by waterway/sea.

Article 104

Requirements for advance notification by operators of movements of wild terrestrial animals to other Member States

Operators other than transporters moving wild terrestrial animals to another Member State shall notify the competent authority of the Member State of origin at least 24 hours before the departure of the consignment.

Article 105

Obligation of operators concerning the notification of movements of wild terrestrial animals to other Member States

For the purposes of the notification referred to in Article 155(1)(d) of Regulation (EU) 2016/429, operators other than transporters moving wild terrestrial animals to another Member State shall provide the competent authority in the Member State of origin with the information provided for in Article 145(1) of Regulation (EU) 2016/429 and in points 3(a) to (d) in Part 1 of Annex VIII concerning each consignment of those animals to be moved to another Member State.

*Article 106***Responsibility of the competent authority concerning the notification of movements of wild terrestrial animals to other Member States**

The competent authority of the Member State of origin notifying the competent authority of the Member State of destination in accordance with Article 155(1)(d) of Regulation (EU) 2016/429, shall provide the information provided for in points 3(a) to (d) in Part 1 of Annex VIII concerning each consignment of wild terrestrial animals to be moved to another Member State.

*Article 107***Emergency procedures**

In the event of power cuts and other disturbances of IMSOC, the competent authority of place of origin of wild terrestrial animals shall comply with the contingency arrangements established pursuant to Article 134(d) of Regulation (EU) 2017/625.

PART IV

FINAL PROVISIONS*Article 108*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply as of 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 December 2019.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

DIAGNOSTIC METHODS

Part 1

Infection with *Brucella abortus*, *B. melitensis* and *B. suis*

1. Serological tests for bovine, ovine, caprine and camelid animals:
 - (a) buffered *Brucella* antigen tests;
 - (b) complement fixation test (CFT);
 - (c) indirect enzyme-linked immunosorbent assay (I-ELISA);
 - (d) fluorescence polarisation assay (FPA);
 - (e) competitive enzyme-linked immunosorbent assay (C-ELISA).
2. Serological tests for porcine animals:
 - (a) buffered *Brucella* antigen tests;
 - (b) complement fixation test (CFT);
 - (c) indirect enzyme-linked immunosorbent assay (I-ELISA);
 - (d) fluorescence polarisation assay (FPA);
 - (e) competitive enzyme-linked immunosorbent assay (C-ELISA).
3. Brucellin skin test (BST) for ovine, caprine and porcine animals

Part 2

Infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*)

1. Tuberculin skin tests:
 - (a) the single intradermal tuberculin test (SITT);
 - (b) the comparative intradermal tuberculin test (CITT).
2. Test available for blood samples:
 - (a) gamma-interferon assay.

Part 3

Surra (*Trypanosoma evansi*)

Serological tests:

- (a) enzyme-linked immunosorbent assay (ELISA) for trypanosomiasis;
- (b) card agglutination test for trypanosomiasis (CATT) at a serum dilution of 1:4.

Part 4

Enzootic bovine leukosis

Serological tests:

- (a) tests for blood samples:
 - (i) agar gel immuno-diffusion test (AGID);

- (ii) blocking enzyme-linked immunosorbent assay (B-ELISA);
 - (iii) indirect enzyme-linked immunosorbent assay (I-ELISA).
- (b) test for milk samples:
- (i) indirect enzyme-linked immunosorbent assay (I-ELISA).

Part 5

Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

	Methods:
Non-vaccinated bovine animals	BoHV-1 I-ELISA ^(a)
	gB B-ELISA ^(b)
Bovine animals vaccinated with a gE-deleted vaccine	gE B-ELISA ^(c)

^(a) enzyme-linked immunosorbent assay (ELISA) for the detection of antibodies against BoHV-1 whole virus.

^(b) ELISA for the detection of antibodies against BoHV-1-gB protein. When referred to tests for the detection of antibodies against whole BoHV-1, this method may also be used.

^(c) ELISA for the detection of antibodies against BoHV-1-gE protein.

Part 6

Bovine viral diarrhoea

1. Direct methods:
 - (a) real-time reverse transcription-polymerase chain reaction (real-time RT-PCR);
 - (b) bovine viral diarrhoea virus (BVDV) antigen detection enzyme-linked immunosorbent assay (ELISA).
2. Serological tests:
 - (a) indirect enzyme-linked immunosorbent assay (I-ELISA);
 - (b) blocking enzyme-linked immunosorbent assay (B-ELISA).

Part 7

Infection with Aujeszky's disease virus

	Methods:
Porcine animals	Aujeszky's disease virus (ADV) ELISA ^(a)
Porcine animals less than 4 months old born to dams vaccinated with a gE-deleted vaccine	gE ELISA ^(b)

^(a) ELISA for the detection of antibodies against whole ADV, ADV-gB protein or ADV-gD protein. For batch control of ADV-gB kits and ADV-gD kits or whole ADV kits, Community reference serum ADV 1, or sub-standards, must be scored positive at a dilution of 1:2.

^(b) ELISA for the detection of antibodies against ADV-gE protein. For batch control, Community reference serum ADV 1, or sub-standards, must be scored positive at a dilution of 1:8.

Part 8

Dourine

Complement fixation test for dourine, at a serum dilution of 1:5.

Part 9

Equine infectious anaemia

Serological tests:

- (a) agar gel immuno-diffusion test (AGID);
- (b) enzyme-linked immunosorbent assay (ELISA) for equine infectious anaemia.

Part 10

Venezuelan equine encephalomyelitis

1. Serological tests:

- (a) virus isolation test for Venezuelan equine encephalomyelitis;
- (b) haemagglutination inhibition test for Venezuelan equine encephalomyelitis;

2. Direct method:

reverse transcription-polymerase chain reaction (RT-PCR) for the detection of Venezuelan equine encephalomyelitis virus genome.

ANNEX II

MINIMUM PRE-MOVEMENT REQUIREMENTS AS REGARDS INFECTION WITH MYCOBACTERIUM TUBERCULOSIS COMPLEX (*M. BOVIS*, *M. CAPRAE* AND *M. TUBERCULOSIS*) IN CAPRINE, CAMELID AND CERVID ANIMALS

Part 1

Minimum requirements for a pre-movement programme as regards infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in caprine animals

1. The pre-movement surveillance programme to detect infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in an establishment for the purpose of movement to another Member State of kept caprine animals as referred to in Article 15(3) must at least include the following elements:
 - (a) post-mortem inspection of all slaughtered caprine animals from the establishment;
 - (b) post-mortem examination of fallen stock of all caprine animals older than 9 months, unless impossible for logistical reasons or not necessary for scientific reasons;
 - (c) an annual animal health visit carried out by a veterinarian;
 - (d) annual testing of all caprine animals kept on the establishment for breeding purposes, with negative results.
2. By way of derogation from paragraph 1, the annual testing provided for in point 1(d) does not have to be required if the competent authority, based on a risk assessment, considers the risk of infection as negligible in the Member State or zone, and the following conditions are fulfilled:
 - (a) the pre-movement surveillance programme referred to in paragraph 1 has been carried out on the establishment for at least 24 months, and infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in caprine animals kept on the establishment has not been reported during this period;
 - (b) the establishment is situated in a Member State or zone thereof free from infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in its bovine animal population.
3. If infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in caprine animals kept on the establishment has been reported, such animals may be moved to another Member State only when all caprine animals older than 6 weeks kept on the establishment have been tested, with negative results. These tests must be carried out on samples collected no earlier than 42 days after the removal of the last confirmed case and of the last animal which tested positive using a diagnostic method.

Part 2

Minimum requirements for a pre-movement programme as regards infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in camelid animals

1. The pre-movement surveillance programme to detect infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in an establishment for the purpose of movement to another Member State of kept camelid animals as referred to in Article 23(1)(e) must at least include the following elements:
 - (a) post-mortem inspection of all slaughtered camelid animals from the establishment;
 - (b) post-mortem examination of fallen stock of camelid animals older than 9 months, unless impossible for logistical reasons or not necessary for scientific reasons;
 - (c) an annual animal health visit carried out by a veterinarian;
 - (d) annual testing of all camelid animals kept on the establishment for breeding purposes, with negative results.
2. By way of derogation from paragraph 1, the annual testing provided for in point 1(d) does not have to be required if the competent authority, based on a risk assessment, considers the risk of infection as negligible in the Member State or zone, and the following conditions are fulfilled:

- (a) the pre-movement surveillance programme referred to in paragraph 1 has been carried out on the establishment for at least 24 months and infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in camelid animals kept on the establishment has not been reported during this period;
 - (b) the establishment is situated in a Member State or zone thereof free from infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in its bovine animal population;
3. If infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in camelid animals kept on the establishment has been reported, such animals may be moved to another Member State only when all camelid animals older than 6 weeks kept on the establishment have been tested, with negative results. These tests must be carried out on blood samples collected no earlier than 42 days after the removal of the last confirmed case and of the last animal which tested positive using a diagnostic method.

Part 3

Minimum requirements for a pre-movement programme as regards infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in cervid animals

1. The pre-movement surveillance programme to detect infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in an establishment for the purpose of movement to another Member State of kept cervid animals as referred to in Article 26(1)(e) must at least include the following elements:
- (a) post-mortem inspection of all slaughtered cervid animals from the establishment;
 - (b) post-mortem examination of fallen stock of cervid animals older than 9 months, unless impossible for logistical reasons or not necessary for scientific reasons;
 - (c) an annual animal health visit carried out by a veterinarian;
 - (d) annual testing of cervid animals kept on the establishment for breeding purposes, with negative results.
2. By way of derogation from paragraph 1, the annual testing provided for in point 1(d) does not have to be required if the competent authority, based on a risk assessment, considers the risk of infection as negligible in the Member State or zone, and the following conditions are fulfilled:
- (a) the pre-movement surveillance programme referred to in paragraph 1 has been carried out on the establishment for at least 24 months, and infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in cervid animals kept on the establishment has not been reported during this period;
 - (b) the establishment is situated in a Member State or zone thereof free from infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in its bovine animal population;
3. If infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*) in cervid animals kept on the establishment has been reported, such animals may be moved to another Member State only when all cervid animals older than 6 weeks kept on the establishment have been tested on two occasions, with a minimum interval of 6 months, for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), with negative results. The first test must be performed on cervid animals or samples collected from cervid animals no earlier than 6 months after the removal of the last confirmed case and of the last animal which tested positive using a diagnostic method.
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ANNEX III

**MINIMUM PRE-MOVEMENT REQUIREMENTS AS REGARDS INFECTION WITH *BRUCELLA ABORTUS*,
B. MELITENSIS AND *B. SUIIS* IN PORCINE ANIMALS**

1. The pre-movement surveillance programme to detect infection with *Brucella abortus*, *B. melitensis* and *B. suis* in an establishment for the purpose of movement to another Member State of kept porcine animals, as referred to in Article 19(1)(f)(ii), must at least include the following elements:
 - (a) an annual animal health visit carried out by a veterinarian;
 - (b) if porcine animals are kept on the establishment for breeding, an annual immunological survey carried out in the porcine population of that establishment, using one of the diagnostic methods listed in Part 1(2) of Annex I, with at least a capacity to demonstrate with a 95 % level of confidence the absence of infection with *Brucella abortus*, *B. melitensis* and *B. suis* with a target prevalence of 10 %.
 2. By way of derogation from point 1, the animal health visit referred to in point 1(a) and the survey provided for in point 1(b) does not have to be required if the competent authority, based on a risk assessment, considers the risk of infection with *Brucella abortus*, *B. melitensis* and *B. suis* as negligible in the Member State or zone thereof, and the following conditions are fulfilled:
 - (a) infection with *Brucella abortus*, *B. melitensis* and *B. suis* has not been reported in the kept porcine population for the last five years;
 - (b) infection with *Brucella abortus*, *B. melitensis* and *B. suis* has not been reported in the population of wild animals of listed species for the past 5 years, and during that period of time, wild boars have been included in the targeted animal population for surveillance as provided for in Article 4 of Delegated Regulation (EU) 2020/689;
 - (c) the Member State or zone thereof is free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* in its bovine, ovine and caprine populations.
 3. If infection with *Brucella abortus*, *B. melitensis* and *B. suis* in porcine animals kept on the establishment has been reported, such animals may be moved to another Member State only when all porcine animals kept on the establishment have been subjected to a test on two occasions, with negative results. The first test must be carried out on samples collected no earlier than 3 months after the removal of the infected animals and the animals which tested positive using one of the diagnostic methods provided for in Part 1(2) of Annex I. The second test must be carried out on samples collected no earlier than 6 months and no later than 12 months after the first test.
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ANNEX IV

TESTING OF DUCKS AND GEESE FOR HIGHLY PATHOGENIC AVIAN INFLUENZA

During the week prior to the time of loading for dispatch, ducks and geese must have tested negative in a virological examination for highly pathogenic avian influenza, either by virus isolation or by molecular testing at a level which gives 95 % confidence of detecting infection at 5 % prevalence.

ANNEX V

REQUIREMENTS FOR TESTING CONSIGNMENTS OF LESS THAN 20 HEADS OF POULTRY OTHER THAN RATITES OR LESS THAN 20 HATCHING EGGS OF POULTRY OTHER THAN RATITES

1. Consignments of less than 20 heads of poultry other than ratites or less than 20 hatching eggs of poultry other than ratites must have tested negative in accordance with point 2 for the following disease agents for the relevant listed species:
 - (a) infection with *Salmonella* Pullorum, *S. Gallinarum* and *S. arizonae*;
 - (b) avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*).
 2. Testing:
 - (a) for breeding poultry, productive poultry and poultry intended for slaughter, the animals must have tested negative in serological and/or bacteriological tests for the diseases under point 1 within 21 days preceding the time of loading for dispatch;
 - (b) for hatching eggs and day-old chicks, the flock of origin must have tested negative in serological tests and/or bacteriological tests for the diseases under point 1 within 21 days preceding the time of loading for dispatch at a level which gives 95 % confidence of detecting infection at 5 % prevalence;
 - (c) if the animals have been vaccinated against infection with any serotype of *Salmonella* or *Mycoplasma*, only bacteriological testing must be used. The confirmation method must be capable of differentiating between live vaccinal strains and field strains.
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ANNEX VI

CRITERIA FOR VACCINES AGAINST INFECTION WITH NEWCASTLE DISEASE VIRUS

Live attenuated vaccines against infection with Newcastle disease virus must be prepared from a Newcastle disease virus strain for which the master seed has been tested and shown to have an intracerebral pathogenicity index (ICPI) of:

- (a) less than 0,4 if not less than 10^7 EID₅₀ (50 % Embryo Infectious Dose) are administered to each bird in the ICPI test;
or
 - (b) less than 0,5 if not less than 10^8 EID₅₀ are administered to each bird in the ICPI test.
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ANNEX VII

VALIDITY OF ANTI-RABIES VACCINATION AND RISK-MITIGATING MEASURES FOR DISEASES OTHER THAN RABIES

Part 1

Validity of anti-rabies vaccinations for dogs, cats, ferrets and other carnivores

The validity requirements for vaccination against infection with rabies virus referred to in Articles 53(b)(i), 55(b)(i) and 58(1)(c) are those set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council ⁽¹⁾.

Where no anti-rabies vaccine is authorised in a Member State for carnivores other than dogs, cats and ferrets, anti-rabies vaccination carried out in accordance with Article 10(1) of Directive 2001/82/EC must be deemed valid.

Part 2

Risk-mitigating measures for diseases other than rabies

1. The risk-mitigating measures for infestation with *Echinococcus multilocularis* referred to in Articles 53(b)(ii) and 55(b)(ii) are those laid down in Commission Delegated Regulation (EU) 2018/772 ⁽²⁾ in combination with Commission Implementing Regulation (EU) 2018/878 ⁽³⁾.
2. By way of derogation from paragraph 1, the treatment referred to in Article 58(1)(d) of canidae other than dogs against infestation with *Echinococcus multilocularis* must be carried out and documented no earlier than 48 hours prior to entry into a Member State or zone thereof listed in the Annex to Implementing Regulation (EU) 2018/878.
3. The risk-mitigating measures for diseases other than infection with rabies virus and infestation with *Echinococcus multilocularis* referred to in Articles 53(b)(ii) and 55(b)(ii) are the preventive health measures applicable to the relevant species of carnivores adopted in accordance with Article 19(1) of Regulation (EU) No 576/2013.

⁽¹⁾ Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

⁽²⁾ Commission Delegated Regulation (EU) 2018/772 of 21 November 2017 supplementing Regulation (EU) No 576/2013 of the European Parliament and of the Council with regard to preventive health measures for the control of *Echinococcus multilocularis* infection in dogs and repealing Delegated Regulation (EU) No 1152/2011 (OJ L 130, 28.5.2018, p. 1).

⁽³⁾ Commission Implementing Regulation (EU) 2018/878 of 18 June 2018 adopting the list of Member States, or parts of the territory of Member States, that comply with the rules for categorisation laid down in Article 2(2) and (3) of Delegated Regulation (EU) 2018/772 concerning the application of preventive health measures for the control of *Echinococcus multilocularis* infection in dogs (OJ L 155, 19.6.2018, p. 1).

ANNEX VIII

INFORMATION TO BE CONTAINED IN ANIMAL HEALTH CERTIFICATES AND NOTIFICATIONS

Part 1

Information to be contained in the animal health certificate for terrestrial animals and hatching eggs moved to another Member State

1. The animal health certificate for the kept terrestrial animals referred to in Article 143(1) of Regulation (EU) 2016/429 and in Article 71(1) of this Regulation moved to another Member State must contain at least the following information:
 - (a) the name and address of the consignor and the consignee;
 - (b) the name and address of the establishment of dispatch, and
 - (i) where the establishment of dispatch is an approved establishment, the unique approval number of that establishment; or
 - (ii) where the establishment of dispatch is a registered establishment, the unique registration number of that establishment;
 - (c) the name and address of the establishment of destination, and
 - (i) where the establishment of destination is an approved establishment, the unique approval number of that establishment; or
 - (ii) where the establishment of destination a registered establishment, the unique registration number of that establishment;
 - (d) the species and category of animals and identification, where required;
 - (e) information on the animal health situation and additional guarantees in relation to:
 - (i) the Member State or zone of origin;
 - (ii) the establishment and flock of origin of the animals, including test results where applicable;
 - (iii) the animals to be dispatched, including test results or vaccinations where applicable;
 - (f) the date and place of issue and period of validity of the animal health certificate, the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.
2. The animal health certificate for hatching eggs referred to in Article 161(1) of Regulation (EU) 2016/429 and in Article 72 of this Regulation moved to another Member State must contain at least the following information:
 - (a) the name and address of the consignor and the consignee;
 - (b) the name and address of the establishment of dispatch, and
 - (i) where the establishment of dispatch is an approved establishment, the unique approval number of that establishment; or
 - (ii) where the establishment of dispatch is a registered establishment, the unique registration number of that establishment;
 - (c) the name and address of the establishment of destination, and,
 - (i) where the establishment of destination is an approved establishment, the unique approval number of that establishment; or
 - (ii) where the establishment of destination a registered establishment, the unique registration number of that establishment;
 - (d) the category of hatching eggs;

- (e) information allowing identification of hatching eggs:
 - (i) the species and identification, where required, of the animals from which they originate;
 - (ii) the marking applied on the hatching eggs, where required;
 - (iii) the place and date of their collection;
 - (f) information on the animal health situation and additional guarantees in relation to:
 - (i) the Member State or zone thereof of origin;
 - (ii) the establishment and flock of origin, including test results where applicable;
 - (iii) the animals from which hatching eggs were collected, including test results where applicable;
 - (iv) the hatching eggs to be dispatched;
 - (g) the date and place of issue and the period of validity of the animal health certificate and the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.
3. The animal health certificate for wild terrestrial animals referred to in Article 155(1)(c) of Regulation (EU) 2016/429 moved to another Member State must contain at least the following information:
- (a) the name and address of the consignor and the consignee;
 - (b) the place where animals were captured and loaded for dispatch;
 - (c) the place of destination, and
 - (i) where the place of destination is the habitat, the place where animals are intended to be unloaded; or
 - (ii) where the establishment of destination is a registered establishment, the unique registration number of that establishment;
 - (d) the species and category of animals;
 - (e) the date and place of issue and period of validity of the animal health certificate, the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.

Part 2

Information in the notification of movements for certain terrestrial animals for which animal health certificate is not required

The notification for moving bumble bees from approved environmentally isolated production establishments to another Member State must contain at least the following information:

- (a) the name and address of the consignor and the consignee;
 - (b) the name, address and unique approval number of the establishment of dispatch;
 - (c) the name and address of the establishment of destination, and
 - (i) where the establishment of destination is an approved establishment, the unique approval number of that establishment; or
 - (ii) where the establishment of destination is a registered establishment, the unique registration number of that establishment;
 - (d) the species, category and quantity and size of colonies;
 - (e) the date of dispatch.
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COMMISSION DELEGATED REGULATION (EU) 2020/689**of 17 December 2019****supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law ⁽¹⁾'), and in particular Article 29, Article 31(5), 32(2), 37(5), Article 39, Article 41(3), Article 42(6) and Article 280(4) thereof,

Whereas:

- (1) The Animal Health Law lays down rules for the prevention and control of animal diseases transmissible to animals or to humans. The rules laid down in this Regulation are required to supplement those laid down in Chapters 2, 3 and 4 of Part II of the Animal Health Law on surveillance, eradication programmes and disease-free status, as well as those in Part IX on transitional arrangements concerning existing surveillance or eradication programmes and existing disease-free status.
- (2) These rules are substantially linked with many intended to be applied together. In the interest of simplicity and transparency, as well as to facilitate their application and avoid a multiplication of rules, they should therefore be laid down in a single act rather than in a number of separate acts with many cross-references and the risk of duplication.
- (3) Indeed, surveillance represents an intrinsic part of any eradication programme and disease-free status is in most cases an outcome of a successful surveillance and eradication process. Moreover, surveillance is needed, besides other measures, as a key tool for maintaining the disease-free status after its achievement. The rules on surveillance, eradication programmes and disease-free status, including transitional rules, often serve common purposes and refer to complementary activities of operators, veterinarians and competent authorities. Therefore it is appropriate to group together these rules in a single delegated regulation.
- (4) Surveillance is a key element of an efficient and effective disease prevention and control policy. It should be implemented jointly by operators and the competent authority. It should also be designed to meet the objectives of early detection of outbreaks of any listed and emerging disease and to demonstrate compliance with the criteria for the granting, maintaining, suspension or withdrawal of disease-free status.
- (5) The competent authority should put in place a basic general surveillance system for listed and emerging diseases of terrestrial animals based on notification and investigations of disease events in targeted animal population.
- (6) These general surveillance requirements for terrestrial animals should be complemented by more specific requirements depending on the expected output of surveillance. They should be designed to serve different specific purposes such as Union surveillance programmes, compulsory and optional eradication programmes, demonstration of disease-free status, disease control measures, in the context of the approval of certain establishments and the movements of animals and animal products.
- (7) The approach to designing general surveillance requirements for aquatic animals is similar to that for terrestrial animals, although not identical. All aquaculture establishments need to implement a basic surveillance system based on notification and investigation of disease events in a targeted animal population. In addition, surveillance for listed and emerging diseases of aquatic animal needs to incorporate certain disease control measures, when it is necessary to take such measures in aquaculture establishments.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

- (8) In addition to the general surveillance requirements, which apply to all aquaculture establishments, specific surveillance requirements apply to certain approved aquaculture establishments. These specific measures include implementing a risk-based surveillance scheme based on assessment of the risk that an establishment has of contracting and spreading an aquatic disease, be it listed or non-listed.
- (9) The specific surveillance requirements also relate to the implementation of eradication programmes for certain listed diseases in order to obtain disease-free status from that disease and to maintain that status once achieved.
- (10) In addition, Member States should be given the possibility to implement surveillance, in the form of 'surveillance programmes' for Category C diseases of aquatic animals at establishment level, without opting for a disease eradication programme. Surveillance programmes differ from eradication programmes in that they are based on a system of targeted surveillance which is comprehensive but which does not encompass all the elements of an eradication programme. Unlike eradication programmes, surveillance programmes do not offer the possibility to achieve official disease-free status.
- (11) The specific eradication and surveillance programmes set out in this Regulation serve to substantiate health requirements for certain movements of animals and products of animal origin within the Union and in certain cases, of animals and products of animal origin entering the Union.
- (12) The Animal Health Law requires rules for listed diseases to apply to listed species. Surveillance may not be relevant for all categories of animals of listed species, in particular as regards wild animals or certain categories of kept animals. Therefore this Regulation should provide rules to specify the relevant targeted animal population for the purpose of surveillance. It should also be possible to expand the targeted animal population to non-listed kept species to ensure early detection of emerging diseases.
- (13) Derogations should also make possible to further limit targeted terrestrial animal populations to specific surveillance purposes, namely: (i) Union surveillance programmes; (ii) compulsory or optional eradication programmes; and (iii) surveillance-based animal health requirements for movements within the Union or for entry into the Union.
- (14) Diagnostic methods, together with the subsequent collection of samples to perform them, techniques, validation and interpretation are of a very technical nature and are subject to frequent modifications due to developments in scientific standards. Therefore to ensure that they are up to date, the rules on diagnostic methods should indicate in a flexible manner which methods should be used and how. In the area of animal diseases, there are different possible sources of scientific standards for diagnostic methods. It is therefore important to indicate the hierarchical order in which the methods should be considered, taking into account the general principles of sampling, analyses, tests and diagnoses laid down in Regulation (EU) 2017/625 of the European Parliament and of the Council ⁽²⁾.
- (15) To ensure optimal use of all resources and to avoid unnecessary administrative burdens and costs for operators and the competent authorities, the detection of listed and emerging diseases should draw on sources of information gathered during official controls and other official activities not primarily intended for the surveillance of those diseases.
- (16) The confirmation of a disease according to its case definition is the responsibility of the competent authority; it should be supported by appropriate investigations to confirm or rule out the presence of a suspected disease. Such investigations are relevant where the confirmation of the disease triggers disease control measures, as well as in certain other circumstances depending on the consequences of the confirmation of the disease. It is therefore important that this Regulation should lay down the additional circumstances where the confirmation of the disease is necessary.

⁽²⁾ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

- (17) The definitions of a suspected case and confirmed case of a listed disease and, where relevant, an emerging disease are of key importance. These enable operators, veterinarians and other stakeholders involved in surveillance to identify circumstances where it is necessary to notify the competent authority and for the competent authority to apply disease control measures. Therefore it is necessary to provide general criteria for the definitions of a suspected case and a confirmed case and to provide, where needed, disease-specific definitions, depending on the specific characteristics of certain diseases.
- (18) A Union surveillance programme is a surveillance programme relevant for the Union as a whole. This is necessary in order to achieve greater harmonisation of surveillance of a specific disease across the Union due to its specific public or animal health concerns. Therefore it is necessary to lay down the criteria that diseases eligible for Union surveillance programme should meet.
- (19) Commission Decision 2010/367/EU ⁽³⁾ lays down minimal requirements for surveillance programmes for avian influenza in poultry and in wild birds and sets out technical guidelines in its annexes. This Regulation should provide for similar technical guidelines in an annex. However, the level of detail in this Regulation is lower to ensure a good capacity to adapt to changes in the situation as regards surveillance of avian influenza. Therefore the technical requirements for the Union surveillance programme for avian influenza focus exclusively on the objectives, the scope and the methodological principles to follow.
- (20) The Animal Health Law sets out rules for the application of compulsory and optional eradication programmes for category B and category C diseases in Member States. These diseases, or groups of them, have their own characteristics. Their eradication should be based on a disease control strategy specific for the disease in question. This should include at least: (i) the surveillance that needs to be performed in order to achieve disease-free status as the ultimate goal; (ii) the timeframe; (iii) a definition of the animal population that is subject to the eradication programme; (iv) the territory in which this eradication programme will apply; and (v) specific disease prevention and control measures that will apply to the disease during the eradication phase.
- (21) If the territory in which an eradication programme will be implemented includes the external border of the Member State, the competent authority should make efforts to address the risk of introduction of the disease from outside its borders.
- (22) The purpose of an eradication programme is to achieve disease-free status on the territory covered by the programme. Ideally, for terrestrial animals it should cover the whole territory of the Member State where the disease is present. If this is not possible, the minimum area that is acceptable should be defined. The minimum surface of the area should take into account the experience gained through previous eradication programmes and allow for flexibility depending on the specific characteristics of the disease.
- (23) The programme's qualitative or quantitative targets should be set by the competent authority. Final targets should be based on the criteria for granting disease-free status, while intermediate targets may also comprise other activities or steps important for achieving the disease-free status, reflecting the evolution of the programme.
- (24) The competent authority should determine the period of application of the eradication programmes. In the case of optional eradication programmes for category C diseases, a maximum period of application of the programme is laid down in order to prevent disproportionate and long lasting disruption of movements within the Union. Nevertheless, the competent authority may start the eradication programme before its approval by the Commission but should not implement restrictions to the movements within the Union at that stage. A possibility should also be provided for Member States to request that the Commission extend this period where justified circumstances exist.
- (25) The eradication strategy of certain diseases might be based on granting disease-free status at establishment level. The disease-specific measures for such diseases should be grouped and spell out obligations for the operators and for the competent authorities.
- (26) The targeted animal population to be included in the disease eradication programme should be set out on a disease-specific basis. The possibility for the competent authority to include in the programme certain additional animal populations should also be set out on a disease-specific basis.

⁽³⁾ Commission Decision 2010/367/EU of 25 June 2010 on the implementation by Member States of surveillance programmes for avian influenza in poultry and wild birds (OJ L 166, 1.7.2010, p. 22).

- (27) The primary responsibility for obtaining and maintaining the establishment's disease-free status lies with the operator as it is the primary recipient of the benefits linked to the disease-free status. Therefore the operator should comply with certain obligations in order to be granted and maintain disease-free status.
- (28) Once the general and disease specific criteria for achieving disease-free status have been met by the operator, it is for the competent authority to grant that status. When these specific criteria are no longer met, it is also for the competent authority to either suspend or withdraw the status.
- (29) Moreover, the obligations for operators and competent authorities in the context of eradication programmes should, where necessary, be detailed considering the specific disease profile. The disease-specific requirements are of a technical nature and are set out for each specific disease in annexes to this Regulation.
- (30) Commission Implementing Regulation (EU) 2018/1882 ⁽⁴⁾ lists infection with *Brucella abortus*, *B. melitensis* and *B. suis* and infection with *Mycobacterium tuberculosis* complex for compulsory eradication programmes and lists enzootic bovine leukosis, infection with Aujeszky's disease virus, infectious bovine rhinotracheitis/infectious pustular vulvovaginitis and bovine viral diarrhoea for optional eradication programmes. For these diseases, eradication programmes should be based on the granting of establishment disease-free status.
- (31) Eradication programmes based on granting disease-free status at establishment level should include all establishments keeping animals from the targeted animal population. However, the competent authority should have the possibility to exclude certain specific types of establishments and slaughterhouses from the eradication programme provided appropriate risk mitigating measures are implemented.
- (32) In the case of eradication programmes based on granting disease-free status at establishment level, the competent authority should have the possibility to attribute different health status to different epidemiological units.
- (33) In the case of terrestrial animals, the requirements to demonstrate disease-free status at establishment level are based on the absence of infection supported by the testing and surveillance regime, by the conditions for introducing animals and germinal products into the establishments and, if necessary, by restrictions on the use of vaccination. When the conditions for maintaining the disease-free status are no longer satisfied, specific requirements apply to suspend, withdraw and restore this status. Due to their technical nature, the disease-specific detailed requirements and the list of diagnostic methods to be used for granting and maintenance of the status are laid down in annexes.
- (34) Conditions for granting, maintaining, suspending and withdrawing disease-free status at establishment level were set out in the following Union rules in place before the date of application of this Regulation: Council Directive 64/432/EEC ⁽⁵⁾ for bovine brucellosis and bovine tuberculosis and Council Directive 91/68/EEC ⁽⁶⁾ for brucellosis in sheep and goats. The Animal Health Law repealed those provisions. Also, Commission Delegated Regulation (EU) 2018/1629 ⁽⁷⁾ has aligned the scope of disease agents involved in brucellosis and bovine tuberculosis with the Terrestrial Animal Health Code of the World Organisation for Animal Health ⁽⁸⁾ (OIE) ('the Terrestrial Code'). They are now infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis* and infection with *Mycobacterium tuberculosis* complex. It is therefore appropriate to revise the technical requirements related to the status of these diseases, so as to seek alignment with the Terrestrial Code while taking into account the experience gained in previous eradication programmes for these diseases.

⁽⁴⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

⁽⁵⁾ Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 121, 29.7.1964, p. 1977/64).

⁽⁶⁾ Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19).

⁽⁷⁾ Commission Delegated Regulation (EU) 2018/1629 of 25 July 2018 amending the list of diseases set out in Annex II to Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 272, 31.10.2018, p. 11).

⁽⁸⁾ Terrestrial Animal Health Code, World Organisation for Animal Health, 2018.

- (35) In the case of disease eradication programmes for terrestrial animals based on granting disease-free status at establishment level, if a disease is suspected or confirmed, the competent authority should implement measures to prevent its spread. These measures are to be implemented primarily in the establishment where the suspected case is kept but the competent authority should have the possibility to expand the measures to other animals or establishments when there is a risk of spreading the disease.
- (36) When applying the disease control measures in response to a suspected or confirmed case, the competent authority should introduce certain prohibitions on movements of animals. However, the competent authority should also have the possibility to allow the movement of certain animals from the establishment where a suspected or confirmed case is kept, to take account of animal welfare conditions and to facilitate the sustainability of the disease control measures.
- (37) Following the confirmation of a case, at least all animals recognised as confirmed cases should be removed. When these animals are put to death, the competent authority should have the possibility to decide whether this is done by slaughtering, meaning that their meat is intended to enter the food chain, or by killing, meaning that the meat is not intended for that purpose.
- (38) For certain diseases that can be spread by infected products of animal origin or fomites, or which may have a potential public health impact, the competent authority should introduce measures in infected establishments to prevent the spread of those diseases through these products or fomites. The measures to mitigate such risks should therefore be set out in this Regulation.
- (39) In the case of terrestrial animals, once disease-free status has been achieved at establishment level, for the sake of programme efficiency, it should be possible to carry out a stepwise reduction in the level of surveillance activities after a certain period of continuous disease-free status in the establishment.
- (40) Enzootic bovine leukosis (EBL) was subject to compulsory eradication under the Union rules in place before the date of application of this Regulation. This disease is now categorised for optional eradication in accordance with Implementing Regulation (EU) 2018/1882.
- (41) Union rules in place before the date of application of this Regulation contained well-established and effective principles and criteria for the recognition, maintenance, suspension and restoring of officially EBL-free status. Many Member States successfully applied these rules during the implementation of past EBL eradication programmes. The rules have been reviewed against the Terrestrial Code and included in this Regulation.
- (42) Member States or zones which have been free from EBL for several years and have therefore reached a steady animal health situation free of EBL, should continue to demonstrate the absence of infection. Risk-based surveillance is an appropriate means of ensuring early detection if the disease is reintroduced and of substantiating freedom from EBL. Member States should therefore establish a suitable surveillance system from the date of application of this Regulation.
- (43) Additional guarantees for intra-Union trade of pigs in relation to infection with Aujeszky's disease virus (ADV) were part of Union rules in place before the date of application of this Regulation. A number of Member States have successfully applied those rules and eradicated infection with ADV in the pig population kept in their territory. The strategy for the eradication of infection with ADV in this Regulation takes account of the Terrestrial Code and of criteria that have proven successful in eradicating the infection with ADV.
- (44) The rules in this Regulation on infectious bovine rhinotracheitis/Infectious pustular vulvovaginitis (IBR/IPV) are based on Commission Decision 2004/558/EC ⁽⁹⁾ with provisions on additional guarantees for intra-Community trade of bovine animals. These include requirements to obtain, maintain and restore freedom at establishment level from bovine herpesvirus 1 (BoHV-1). The rules have been developed taking into consideration the standards of the Terrestrial Code and the EFSA scientific opinion ⁽¹⁰⁾.

⁽⁹⁾ Commission Decision 2004/558/EC of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (OJ L 249, 23.7.2004, p. 20).

⁽¹⁰⁾ The EFSA Journal (2006) 311, Opinion on the 'Definition of a BoHV-1-free animal and a BoHV-1-free holding, and the procedures to verify and maintain this status'.

- (45) Union rules in place before the date of application of this Regulation do not contain provisions for bovine viral diarrhoea (BVD) with the exception of provisions related to the trade of germinal products. In Implementing Regulation (EU) 2018/1882, BVD is now listed as a 'category C disease' for optional eradication. Therefore provisions on eradication programmes and the granting and maintenance of disease-free status with regard to BVD are laid down in this Regulation.
- (46) The Terrestrial Code lacks a chapter on BVD and criteria for BVD freedom and related animal movements. However, a chapter on BVD is available in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the OIE. These diagnostic standards have been considered for the provisions related to BVD in this Regulation.
- (47) Implementing Regulation (EU) 2018/1882 lists infection with the rabies virus as a category B disease. Therefore this Regulation includes provisions on compulsory eradication programmes and the granting and maintenance of disease-free status with regard to infection with the rabies virus.
- (48) Wild foxes constitute the main reservoir of infection with the rabies virus in the EU. It is therefore appropriate that the measures in eradication programmes are primarily focused on the wild fox population. However, all other mammal species are susceptible and many other animal species are listed in Implementing Regulation (EU) 2018/1882 for this disease. The competent authorities should address other animal populations in the eradication programmes when there is a risk to human or animal health.
- (49) For infection with rabies eradication programmes, the disease control strategy is primarily based on vaccination of the relevant targeted animal population, supported by other important activities such as surveillance, implementation of disease control measures, the control of pet movements and monitoring of the effectiveness of the vaccination. As the vaccination provisions are of a very technical nature, they are laid down in an annex.
- (50) Implementing Regulation (EU) 2018/1882 lists infection with bluetongue virus (serotypes 1-24) (infection with BTV) as a category C disease for optional eradication programme. This implies a change in the policy against this disease as Council Directive 2000/75/EC ⁽¹¹⁾, applicable prior to this Regulation, provided for its immediate eradication. New provisions are laid down in this Regulation to address the new status of the disease.
- (51) For infection with BTV, the disease control strategy is primarily based on vaccination of the relevant targeted animal population supported by other activities such as surveillance, implementation of disease control measures, control of the movements of animals and germinal products, and minimising exposure to vectors.
- (52) In its opinion ⁽¹²⁾ on the control, surveillance and movement of animals in the case of infection with BTV, EFSA indicates that for eradication to succeed, vaccination coverage should be at least 95 % of susceptible bovine and ovine animals for a minimum period of 5 years. It is therefore expected that the eradication programmes for infection with BTV include a vaccination campaign, although flexibility should be provided for in this Regulation to take into account the specific circumstances of each case.
- (53) A Member State or zone thereof free from infection with BTV or under an eradication programme for infection with BTV should be protected from the introduction of any BTV serotypes by the movement of kept animals or germinal products. Therefore requirements for the introduction of kept animals or germinal products into Member States or zones thereof free from infection with BTV or under an eradication programme for infection with BTV should be part of the provisions on eradication programmes. This should also be reflected in the criteria for the maintenance of the disease-free status. The same principles should apply to movements of animals through the Member States or zones thereof free from infection with BTV or under an eradication programme for infection with BTV.
- (54) In addition, because of the diversity of the local situations that may prevail, the competent authority should have the possibility to allow the introduction of animals or germinal products based on ad hoc requirements, provided that such introduction does not jeopardise the health status at the destination. It is therefore appropriate that this Regulation provides for the requirements and conditions under which such introduction may be authorised. Such requirements should be based on the status of animals or germinal products, independently of the Member State or zone of origin.

⁽¹¹⁾ Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue (OJ L 327, 22.12.2000, p. 74).

⁽¹²⁾ EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2017. Scientific opinion on bluetongue: control, surveillance and safe movement of animals. EFSA Journal 2017; 15(3):4698, 126.

- (55) An eradication programme for a category B or category C disease of aquatic animals should take account of the type of surveillance requirements required to obtain and maintain disease-free status, of details of the territory and the animal population to be covered by the programme; and of the programme's intermediate and final targets. The eradication programme should include the control measures to be implemented in infected establishments of aquatic animals.
- (56) The eradication programme for aquatic animal diseases should include intermediate and final targets which will be used to assess progress towards achieving disease-free status. Where relevant, these targets should take account of the risk wild animals pose to the success of the eradication programme. In particular, any possibility of deviation from the proposed period of application of 6 years should be taken in to account when devising the programme's intermediate and final targets.
- (57) In the case of aquatic animals, the population which is to be included in the eradication programme consists of those species which are listed in Implementing Regulation (EU) 2018/1882. However, the competent authority should have the possibility to exclude from the programme the species listed as a vector in Implementing Regulation (EU) 2018/1882 if it has carried out a risk assessment which has resulted in the risk posed by those animals being deemed negligible.
- (58) The competent authority should have the possibility to include additional aquatic animal populations when such animals pose a significant risk to the health status. It also should be able to exclude certain low-risk establishments from the eradication programme if their exclusion does not jeopardise its successful completion.
- (59) When a Member State has decided to participate in an eradication programme for a category C disease, operators are obliged to comply with conditions for introductions of animals of listed species, to notify suspicion of listed diseases, to comply with disease control measures when a disease is suspected or confirmed and to take any other measures that may be required by the competent authority, including vaccination.
- (60) When the presence of a listed disease of aquatic animals is suspected or confirmed in a disease-free Member State, zone or compartment, or in one which is subject to a eradication programme, the competent authority should take appropriate measures to control the disease. These rules should therefore be laid down in this Regulation. These include establishing a restricted zone when the presence of a listed disease has been confirmed in an establishment participating in the eradication programme or in an establishment which has been declared disease-free. This also includes the minimum requirements applying to geographical demarcation of a restricted zone and the factors affecting it.
- (61) Following the confirmation of a listed aquatic disease in a disease-free Member State, zone or compartment, or in one which is subject to a eradication programme, the competent authority carries out strict controls in infected establishments and in other establishments located in the restricted zone. The nature of the controls and the level of flexibility the competent authority applies to movements are set out in this Regulation. Where flexibility is applied, it is limited to circumstances where the health status of aquatic animals at the establishment of destination or enroute to that destination is not jeopardised.
- (62) Once an aquatic disease outbreak has occurred in an establishment and that establishment remains or commences an eradication programme, it is important to remove aquatic animals that are dead, moribund or showing clinical signs within a period set by the competent authority and in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽¹³⁾. In this way, the disease can be successfully controlled.
- (63) The Animal Health Law requires the Commission to develop detailed rules for the granting of disease-free status to Member States, zones and compartments. These rules should include disease-specific criteria to demonstrate the absence of the disease in the targeted animal population and the general criteria that support effective control of the health status of that targeted animal population.
- (64) The general criteria comprise the territorial scope, surveillance, biosecurity, disease control measures and consistent implementation of other operational rules set out in the Animal Health Law as regards the registration and approval of establishments, traceability of animals and movement requirements.

⁽¹³⁾ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

- (65) This Regulation lays down disease-specific criteria based on the absence of listed species or based on the disease agent or vector's incapacity to survive. These criteria should be drawn up in a flexible way to allow the competent authority to justify the case for obtaining disease-free status based on the specific situation. Therefore general requirements are laid down in this Regulation to indicate on what basis Member States may request the granting of disease-free status for their entire territory or a zone thereof or, in the case of aquaculture animals, for compartments.
- (66) This Regulation lays down disease-specific criteria based on the outcome of eradication programme and on historical and surveillance data. These criteria are based on results of the surveillance, the implementation of measures to prevent introduction of the disease and conditions for the use of vaccines.
- (67) Because of their technical nature these criteria are laid down in annexes and grouped by disease with the criteria for maintaining the disease-free statuses.
- (68) It is appropriate that this Regulation lay down modernised requirements for the granting and maintenance of disease-free status taking account of the Union rules in place before the date of application of this Regulation, the Terrestrial Code, the Aquatic Animal Health Code of the OIE and, in the absence of existing provisions, the best available scientific evidence.
- (69) Implementing Regulation (EU) 2018/1882 lists infestation with *Varroa* spp. as a category C disease for optional eradication. This Regulation lays down provisions for achieving and maintaining infestation with *Varroa* spp.-free status.
- (70) Implementing Regulation (EU) 2018/1882 lists infection with Newcastle disease virus as a category A disease for immediate eradication measures. Therefore this Regulation does not contain provisions for an eradication programme for infection with Newcastle disease virus. However, it should be possible for the competent authority to grant the status free from infection with Newcastle disease virus without vaccination on the basis of historical and surveillance data.
- (71) Two different types of compartments are possible in the case of aquatic animals. Independent compartments operate under strictly defined conditions which ensure they operate independently of the health status of the surrounding waters. Dependent compartments on the other hand, are influenced by the health status of the surrounding waters and operate therefore, under more flexible conditions. Dependent compartments are however, only established once the competent authority has assessed a number of epidemiological factors and put in place whatever risk mitigating measures are necessary to prevent the introduction of disease into the compartment.
- (72) In the case of aquatic animals, and given the lower level of risk associated with individual establishments which are independent of the surrounding waters, special provisions are laid down in this Regulation for independent compartments when they commence aquaculture activities for the first time or when they recommence aquaculture activities after a break in production. In such cases, disease-free status should be declared immediately provided certain conditions are met. Provisions are also laid down for independent compartments where a disease outbreak has occurred. To ensure that such outbreaks have been successfully dealt with by the cleaning, disinfection and fallowing which have been carried out after de-population, a sample of the animals used to repopulate the compartment should be tested before disease-free status can be declared.
- (73) When conditions to maintain disease-free status are no longer fulfilled because of suspicion or confirmation of the disease, the competent authority should apply disease control measures. These measures should apply during the different steps of disease control from when an outbreak of the disease is suspected to when the event is resolved and the disease-free status restored.
- (74) If the competent authority detects a breach of the conditions required to maintain disease-free status in the Member State, zone or compartment, measures should be implemented to remedy the situation. The competent authority should have the option to suspend the disease-free status when it is still possible to satisfactorily resolve the breach and therefore not to have the disease-free status withdrawn by the Commission.
- (75) When a Member State wishes to obtain disease-free status for a listed aquatic disease for its entire territory or for a zone thereof accounting for more than 75 % of its territory, or which is shared with another Member State or third country, it will apply to the Commission for approval. In all other cases, a system of self-declaration is followed.

- (76) Self-declaration of freedom from aquatic animal diseases for zones and compartments other than those which are Commission-approved follows a system which is designed to give transparency to the process and which will make it easier and potentially quicker for Member States to declare disease-free status. The entire process will be completed electronically unless another Member State or the Commission indicate concerns which cannot be resolved satisfactorily. If there are concerns that cannot be resolved satisfactorily, the declaration is brought to the Standing Committee on Plants, Animals, Food and Feed.
- (77) This Regulation contains provisions on the approval of disease-free status of Member States or zones thereof. These rules may differ from the rules in force before the date of application of this Regulation. Appropriate transitional rules are needed to ensure a smooth transition from the existing regime on the approval of disease-free status to the new requirements.
- (78) With a view to the uniform application of Union legislation on surveillance, eradication programmes and disease-free status and to ensure that it is clear and transparent, Commission Decision 2000/428/EC ⁽¹⁴⁾, Commission Decision 2002/106/EC ⁽¹⁵⁾; Commission Decision 2003/422/EC ⁽¹⁶⁾, Commission Decision 2006/437/EC ⁽¹⁷⁾, Commission Regulation (EC) No 1266/2007 ⁽¹⁸⁾, Commission Decision 2008/896/EC ⁽¹⁹⁾ and Commission Implementing Decision (EU) 2015/1554 ⁽²⁰⁾ should be repealed by this Regulation.
- (79) The Animal Health Law applies from 21 April 2021. Accordingly, the rules laid down in this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

PART I

GENERAL PROVISIONS

Article 1

Subject-matter and scope

1. This Regulation supplements the rules on surveillance, eradication programmes and disease-free status for certain listed and emerging diseases of terrestrial, aquatic and other animals as provided for in Regulation (EU) 2016/429.
2. Chapter 1 of Part II of this Regulation lays down the rules for surveillance of the diseases referred to in Article 9(1) of Regulation (EU) 2016/429 and the emerging diseases as defined in Article 6(2) of that Regulation in relation to:
 - (a) the design of the surveillance including the targeted animal population and the diagnostic methods;
 - (b) the disease confirmation and the case definition;
 - (c) Union surveillance programmes.

⁽¹⁴⁾ Commission Decision 2000/428/EC of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease (OJ L 167, 7.7.2000, p. 22).

⁽¹⁵⁾ Commission Decision 2002/106/EC of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever (OJ L 39, 9.2.2002, p. 71).

⁽¹⁶⁾ Commission Decision 2003/422/EC of 26 May 2003 approving an African swine fever diagnostic manual (OJ L 143, 11.6.2003, p. 35).

⁽¹⁷⁾ Commission Decision 2006/437/EC of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC (OJ L 237, 31.8.2006, p. 1).

⁽¹⁸⁾ Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue (OJ L 238, 27.10.2007, p. 37).

⁽¹⁹⁾ Commission Decision 2008/896/EC of 20 November 2008 on guidelines for the purpose of the risk based animal health surveillance scheme provided for in Council Directive 2006/88/EC (OJ L 322, 2.12.2008, p. 30).

⁽²⁰⁾ Commission Implementing Decision (EU) 2015/1554 of 11 September 2015 laying down rules for the application of Directive 2006/88/EC as regards requirements for surveillance and diagnostic methods (OJ L 247, 23.9.2015, p. 1).

3. Chapter 2 of Part II of this Regulation lays down the rules for eradication programmes for the diseases of terrestrial animals referred to in points (b) and (c) of Article 9(1) of Regulation (EU) 2016/429 in relation to:

- (a) the disease control strategy, the territory, the animal populations, the targets and the period of application;
- (b) the obligations of operators and competent authorities;
- (c) the disease control measures in the event of suspicion and of confirmation.

4. Chapter 3 of Part II of this Regulation lays down the rules for eradication programmes for the diseases of aquatic animals referred to in points (b) and (c) of Article 9(1) of Regulation (EU) 2016/429 in relation to:

- (a) the disease control strategy, the territory, the animal populations, the targets and the period of application;
- (b) the obligations of operators and competent authorities;
- (c) the disease control measures in the event of suspicion and of confirmation.

5. Chapter 4 of Part II of this Regulation lays down the rules for disease-free status with regard to certain diseases of terrestrial and aquatic animals referred to in Article 9(1) of Regulation (EU) 2016/429 in relation to:

- (a) the criteria for the approval of the disease-free status of Member States and zones;
- (b) the criteria for the approval of the disease-free status for compartments keeping aquaculture animals;
- (c) the criteria for the maintenance of the disease-free status;
- (d) the suspension, the withdrawal and the restoration of disease-free status.

6. Part III of this Regulation lays down transitional and final provisions in relation to:

- (a) the approval of the disease-free status of Member States, zones and compartments which are recognised disease-free under the legislation in force before the date of application of this Regulation;
- (b) the approval of eradication programmes of Member States, zones and compartments which have an approved eradication or surveillance programme under the legislation in force before the date of application of this Regulation.

Article 2

Definitions

For the purpose of this Regulation, the following definitions shall apply:

- (1) 'category E disease': means a listed disease for which there is a need for surveillance within the Union, as referred to in point (e) of Article 9(1) of Regulation (EU) 2016/429;
- (2) 'targeted animal population' means the population of animals of listed species defined by species and, as appropriate, by categories, relevant for the surveillance activities, the eradication programmes or the disease-free status of a specific disease;
- (3) 'additional animal population' means the population of kept or wild animals of listed species subjected to optional prevention, surveillance and disease control measures necessary to achieve or maintain the disease-free status of a targeted animal population;
- (4) 'category A disease': means a listed disease that does not normally occur in the Union and for which immediate eradication measures must be taken as soon as it is detected, as referred to in point (a) of Article 9(1) of Regulation (EU) 2016/429;
- (5) 'category B disease': means a listed disease which must be controlled in all Member States with the goal of eradicating it throughout the Union, as referred to in point (b) of Article 9(1) of Regulation (EU) 2016/429;

- (6) 'category C disease': means a listed disease which is of relevance to some Member States and for which measures are needed to prevent it from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease concerned, as referred to in point (c) of Article 9(1) of Regulation (EU) 2016/429;
- (7) 'bovine animal' or 'animal of the bovine species' means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species;
- (8) 'ovine animal' or 'animal of the ovine species' means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species;
- (9) 'caprine animal' or 'animal of the caprine species' means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species;
- (10) 'travelling circus' means an exhibition or fair that includes animals or animal acts which is intended to move between Member States;
- (11) 'animal acts' means any act featuring animals kept for the purpose of an exhibition or fair, and which may form part of a circus;
- (12) 'porcine animal' or 'animal of the porcine species' means an animal of the species of ungulates of family *Suidae* listed in Annex III to Regulation (EU) 2016/429;
- (13) 'means of transport' means road or rail vehicles, vessels and aircrafts;
- (14) 'dog' means a kept animal of the *Canis lupus* species;
- (15) 'cat' means a kept animal of the *Felis silvestris* species;
- (16) 'ferret' means a kept animal of the *Mustela putorius furo* species;
- (17) 'seasonally BTV-free area' means the whole territory of a Member State or a zone thereof where the competent authority has established a temporary status of freedom from infection with bluetongue virus (serotype 1-24) ('infection with BTV') in accordance with Article 40(3) on the basis of a vector-free period and the demonstration of absence of the disease in listed animal species;
- (18) 'vector protected establishment' means part or all facilities of an establishment that are protected against attacks from *Culicoides* by appropriate physical and management means, with a status of vector protected establishment being granted by the competent authority in accordance with Article 44;
- (19) 'well-boat' means a vessel used by the aquaculture industry which has a well or tank for the storage and transport of live fish in water;
- (20) 'fallowing' means, for disease management purposes, an operation where an establishment is emptied of aquaculture animals from listed species, and where feasible, of water;
- (21) 'eligibility period' means the period of time before the competent authority submits the application for disease-free status or, when relevant, before the provisional declaration referred to in point (a) of Article 83(1) is published electronically;
- (22) 'non-listed species', means an animal species or group of animal species not listed in the Annex to Commission Implementing Regulation (EU) 2018/1882 for a particular disease;
- (23) 'flock' means all poultry or captive birds of the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit; in housed poultry includes all birds sharing the same airspace;
- (24) 'DIVA (differentiating infected from vaccinated animals) vaccination' means a vaccination using vaccines that enable in conjunction with appropriate serological diagnostic methods, the detection of infected animals in a vaccinated population;
- (25) 'DIVA vaccinated animals' means animals that have been vaccinated in the framework of a DIVA vaccination;
- (26) 'approved germinal product establishment' means a semen collection centre, an embryo collection team, an embryo production team, a germinal product processing establishment or a germinal product storage centre, approved in accordance with Article 97(1) of Regulation (EU) 2016/429;

- (27) 'semen' means the ejaculate of an animal or animals, either in the unaltered state or prepared or diluted;
- (28) 'oocytes' means the haploid stages of the ootidogenesis including secondary oocytes and ova;
- (29) 'embryo' means the initial stage of development of an animal while it is capable of being transferred to a recipient dam;
- (30) 'vector-free period' means in a defined area the period of inactivity of *Culicoides* determined in accordance with Section 5 of Chapter 1 of Part II of Annex V;
- (31) 'honeybees' means animals of the *Apis mellifera* species;
- (32) 'breeding poultry' means poultry 72 hours old or more, intended for the production of hatching eggs;
- (33) 'random annual surveillance' means a surveillance consisting of at least one survey of a targeted animal population organised during the year for which probability-based sampling methods are used to select units to examine.

PART II

SURVEILLANCE, ERADICATION PROGRAMMES, DISEASE-FREE STATUS

CHAPTER 1

Surveillance

Section 1

Design of surveillance, Targeted animal population and diagnostic methods

Article 3

Design of surveillance

1. The competent authority shall design the surveillance for listed and emerging diseases of terrestrial animals and other animals taking into account:
 - (a) general surveillance requirements based on:
 - (i) notification as provided for in Article 18(1) of Regulation (EU) 2016/429;
 - (ii) appropriate veterinary investigation of increased mortalities and other signs of serious diseases or significantly decreased production rates with an undetermined cause;
 - (iii) investigation by the competent authority in the event of the suspicion of a category E disease or, if relevant, of an emerging disease;
 - (iv) targeted animal population for surveillance as provided for in Article 4;
 - (v) the contribution of official controls and other official activities as provided for in Article 7;
 - (b) specific surveillance requirements:
 - (i) in Union surveillance programme;
 - (ii) as a part of compulsory or optional eradication programmes;
 - (iii) for demonstrating and maintaining disease-free status;
 - (iv) as a part of disease control measures;
 - (v) in the context of approval of certain establishments;
 - (vi) for the movements of terrestrial animals within the Union or their entry into the Union.

2. The competent authority shall design the surveillance for listed and emerging diseases of aquatic animals taking into account:

(a) general surveillance requirements based on:

- (i) notification as provided for in Article 18(1) of Regulation (EU) 2016/429;
- (ii) appropriate veterinary investigation of increased mortalities and other signs of serious diseases or significantly decreased production rates with an undetermined cause;
- (iii) investigation by the competent authority in the event of the suspicion of a category E disease or, if relevant, of an emerging disease;
- (iv) targeted animal population for surveillance as provided for in Article 4;
- (v) the contribution of official controls and other official activities as provided for in Article 7;
- (vi) disease control measures;

(b) specific surveillance requirements:

- (i) as a part of the risk-based surveillance scheme set out in Chapter 1 of Part I of Annex VI, involving a risk ranking and regular animal health visits as provided for in Chapters 2 and 3 of Part I of Annex VI;
- (ii) as a part of the eradication programmes provided for in Chapters 1 to 6 of Part II of Annex VI;
- (iii) for demonstrating and maintaining disease-free status;
- (iv) for demonstrating, in accordance with the surveillance programmes provided for in Chapters 1 to 6 of Part III of Annex VI, that establishments which are not participating in the eradication programme referred to in point (ii) or which have not obtained the disease-free status referred to in point (iii) are not infected;
- (v) for the movements of aquatic animals within the Union or their entry into the Union.

Article 4

Targeted animal population

1. The competent authority shall specify the targeted animal population relevant to the surveillance referred to in Article 3 for each listed disease and, when relevant, for each emerging disease and shall include:

- (a) kept animals of listed species;
- (b) wild animals of listed species if:
 - (i) they are subject to a Union surveillance programme, or to a compulsory or an optional eradication programme or to the surveillance necessary for the granting or maintenance of a disease-free status;
 - (ii) the competent authority considers that they constitute a risk that may impair the health status of other species in a Member State, zone or compartment; or
 - (iii) surveillance is necessary to assess animal health requirements for entry into the Union or movements within the Union.

2. To ensure the early detection of an emerging disease in species other than those referred to in point (a) of paragraph 1, the competent authority shall include, in the targeted animal population, kept animals of species that are not listed for the purpose of the relevant listed disease if the following criteria apply:

- (a) they are moved to establishments in another Member State, zone or compartment; and
- (b) due to the number of animals or the frequency of the movements, the competent authority considers the animals to constitute a risk that might impair the health status of other kept animals in another Member State, zone or compartment, should a disease emerge in that species.

Article 5

Exclusion of certain kept terrestrial animals from the targeted animal population

1. By way of derogation from point (a) of Article 4(1), the competent authority may limit the targeted animal population for the surveillance of a disease other than a category A disease to the categories of kept animals of listed species that are subject, for that disease, to:

- (a) Union surveillance programmes;
- (b) compulsory or optional eradication programmes or surveillance necessary for the granting or maintenance of a disease-free status; or
- (c) surveillance-based animal health requirements for the movements within the Union or the entry into the Union.

2. The categories of kept animals referred to in paragraph 1 may be based on the animals' age, their sex, the location and type of production.

Article 6

Diagnostic methods

1. The competent authority shall ensure that the collection of samples, the techniques, validation and interpretation of the diagnostic methods for the purposes of surveillance shall comply:

- (a) with the specific legislation adopted in accordance with Regulation (EU) 2016/429 and the relevant details and guidance made available on the websites of the European Union Reference Laboratories (EURL) and of the Commission;
- (b) when not covered by the legislation, details and guidance referred to in point (a), with the collection of samples, the techniques, validation and interpretation of the diagnostic methods laid down in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) ('the Terrestrial Manual' ⁽²¹⁾) as amended or the Manual of Diagnostic Tests for Aquatic Animals of the OIE ('the Aquatic Manual' ⁽²²⁾) as amended;
- (c) when not covered by points (a) and (b) of this paragraph, with the methods laid down in point (b) of Article 34(2) and Article 34(3) of Regulation (EU) 2017/625.

2. The diagnostic methods for granting and maintaining disease-free status are laid down in:

- (a) Section 1 of Annex III for infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
- (b) Section 2 of Annex III for infection with *Mycobacterium tuberculosis* complex (*Mycobacterium bovis*, *M. caprae* and *M. tuberculosis*) (MTBC);
- (c) Section 3 of Annex III for enzootic bovine leukosis (EBL);
- (d) Section 4 of Annex III for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV);
- (e) Section 5 of Annex III for infection with Aujeszky's disease virus (ADV);
- (f) Section 6 of Annex III for bovine viral diarrhoea (BVD);
- (g) point 2 of Section 5 of Chapter 1 of Part II of Annex VI for viral haemorrhagic septicaemia (VHS);
- (h) point 2 of Section 5 of Chapter 1 of Part II of Annex VI for infectious haematopoietic necrosis (IHN);
- (i) point 2 of Section 5 of Chapter 2 of Part II of Annex VI for infection with highly polymorphic region deleted infectious salmon anaemia virus (HPR-deleted ISAV);
- (j) point 2 of Section 5 of Chapter 3 of Part II of Annex VI for infection with *Marteilia refringens*;

⁽²¹⁾ <http://www.oie.int/en/standard-setting/terrestrial-manual/access-online/>

⁽²²⁾ <http://www.oie.int/en/standard-setting/aquatic-manual/access-online/>

- (k) point 2 of Section 5 of Chapter 4 of Part II of Annex VI for infection with *Bonamia exitiosa*;
- (l) point 2 of Section 5 of Chapter 5 of Part II of Annex VI for infection with *Bonamia ostreae*;
- (m) point 2 of Section 5 of Chapter 6 of Part II of Annex VI for infection with white spot syndrome virus (WSSV).

Article 7

Contribution of official controls and other official activities to animal health surveillance

1. The competent authority shall, if relevant, include in the design of the surveillance referred to in Article 3 of this Regulation the outcome of the official controls and other official activities defined in Article 2 of Regulation (EU) 2017/625. These official controls and other official activities include:

- (a) ante-mortem and post-mortem inspections;
- (b) inspections at border control posts;
- (c) official controls and other official activities at markets and assembly operations;
- (d) official controls and other official activities during transport of live animals;
- (e) public health related inspections and sampling in establishments;
- (f) any other official controls during which establishments, animals or samples are inspected or examined.

2. When the competent authority suspects a listed disease or an emerging disease in the context of official controls or other official activities referred to in paragraph 1, it shall ensure that all relevant authorities are informed. This shall be done:

- (a) immediately in case of a category A disease or of an emerging disease;
- (b) without delay for other diseases.

Section 2

Disease confirmation and case definitions

Article 8

Criteria for official confirmation of listed diseases, other than category A diseases, and certain emerging diseases and subsequent confirmation of outbreaks

1. The competent authority shall, on suspicion of listed diseases, other than category A disease, or of an emerging disease, conduct an investigation to confirm or to rule out the presence of that disease when:

- (a) there is a need to determine the health status of the Member State, zone or compartment thereof; or
- (b) there is a need to collect necessary information on the occurrence of the disease for any of the following purposes:
 - (i) to implement measures to protect animal or human health;
 - (ii) to implement animal health requirements for movements of animals or products; or
 - (iii) to comply with the requirements laid down in a Union surveillance programme.

2. The competent authority shall confirm an outbreak of any of the diseases referred to in paragraph 1 when it has classified an animal or a group of animals as a confirmed case of these diseases in accordance with Article 9(2).

*Article 9***Case definitions**

1. The competent authority shall classify an animal or a group of animals as a suspected case of a listed disease or of an emerging disease when:
 - (a) clinical, post-mortem or laboratory examinations conclude that clinical sign(s), post-mortem lesion(s) or histological findings are indicative of that disease;
 - (b) result(s) from a diagnostic method are indicating the likely presence of the disease in a sample from an animal or from a group of animals; or
 - (c) an epidemiological link with a confirmed case has been established.
2. The competent authority shall classify an animal or a group of animals, as a confirmed case of a listed disease or of an emerging disease when:
 - (a) the disease agent, excluding vaccine strains, has been isolated in a sample from an animal or from a group of animals;
 - (b) an antigen or nucleic acid specific to the disease agent that is not a consequence of vaccination has been identified in a sample from an animal or from a group of animals showing clinical signs consistent with the disease or an epidemiological link with a suspected or confirmed case; or
 - (c) a positive result from an indirect diagnostic method that is not a consequence of vaccination has been obtained in a sample from an animal or from a group of animals showing clinical signs consistent with the disease or an epidemiological link with a suspected or confirmed case.
3. Disease specific definitions of a suspected case and a confirmed case of listed diseases are laid down for terrestrial animals in Annex I and for aquatic animals in point 3 of Section 5 of Chapters 1 to 6 of Part II of Annex VI.
4. In the absence of disease specific definitions as provided for in paragraph 3, the criteria laid down in paragraphs 1 and 2 shall apply to definitions of a suspected case and a confirmed case of listed diseases and, if relevant, emerging diseases.

Section 3**Union surveillance programme***Article 10***Criteria for and contents of Union surveillance programmes**

1. A category E disease shall be subject to a Union surveillance programme in accordance with Article 28 of Regulation (EU) 2016/429 if it meets all of the following criteria:
 - (a) it poses a particular threat to animal and possibly human health on the whole Union territory with possible serious economic consequences for the farming community and the wider economy;
 - (b) it is susceptible to an evolution of the disease profile, in particular with regard to the risk for human health and animal health;
 - (c) infected wild animals pose a particular threat for the introduction of the disease into a part or the whole of the Union territory;
 - (d) it is fundamental to obtain, through surveillance, regularly updated information on the evolution of its circulation and on the characterisation of the disease agent, to assess those risks and adapt risk mitigating measures accordingly.
2. The competent authority shall implement Union surveillance programmes for the relevant disease in accordance with the contents set out in Annex II.

*Article 11***Information to be included in the submission of and reporting on Union surveillance programmes**

1. The competent authority shall, when submitting a Union surveillance programme, include in that submission at least the following information:
 - (a) description of the epidemiological situation of the disease before the date of the beginning of the implementation of the programme and data on the epidemiological evolution of the disease;
 - (b) targeted animal population, epidemiological units and zones of the programme;
 - (c) organisation of the competent authority, supervision of the implementation of the programme, official controls to be applied during the implementation of the programme and the role of all relevant operators, animal health professionals, veterinarians, animal health laboratories and other natural or legal persons concerned;
 - (d) description and demarcation of the geographical and administrative areas in which the programme is to be implemented;
 - (e) indicators to measure the progress of the programme;
 - (f) diagnostic methods used, number of samples tested, frequency of testing and sampling patterns;
 - (g) risk factors to be considered for the design of a risk-based targeted surveillance.
2. The competent authority shall, when reporting on a Union surveillance programme, include in that report at least the following information:
 - (a) the description of the measures implemented and the results obtained based on the information referred to in point (b) and points (d) to (f) of paragraph 1; and
 - (b) the results of the follow-up of the epidemiological evolution of the disease in case of a suspected or confirmed case.

*CHAPTER 2****Eradication programmes for category B and C diseases of terrestrial animals****Section 1***General provisions***Article 12***Disease control strategy for the eradication of category B and C diseases of terrestrial animals**

1. The competent authority shall, when establishing a compulsory eradication programme for a category B disease or an optional eradication programme for a category C disease of terrestrial animals, base those programmes on a disease control strategy that includes for each disease:
 - (a) the territory and animal population covered by the eradication programme as provided for in Article 13(1);
 - (b) the duration of the eradication programme as provided for in Article 15, including its final and intermediate targets as provided for in Article 14; and
 - (c) the disease specific requirements laid down:
 - (i) in Articles 16 to 31 for infection with *Brucella abortus*, *B. melitensis* and *B. suis*, infection with MTBC, EBL, IBR/IPV, infection with ADV and BVD;
 - (ii) in Articles 32 to 36 for infection with rabies virus (RABV);
 - (iii) in Articles 37 to 45 for infection with BTV.

2. The competent authority may include in the eradication programme coordinated measures at its common land or coastal border with other Member States or third countries to ensure that the objectives of the programme are achieved and that the results will last.

Where such coordination has not been established, the competent authority shall include in the eradication programme, if feasible, effective risk mitigating measures, including intensified surveillance.

Article 13

Territorial scope and animal populations

1. The competent authority shall determine the scope of the eradication programme, including:
 - (a) the territory covered; and
 - (b) the targeted animal population and, as necessary, additional animal populations.
2. The territory covered by the eradication programme referred to in point (a) of paragraph 1 shall be:
 - (a) the entire territory of the Member State; or
 - (b) one or several zones, provided that each zone corresponds to administrative unit(s) of at least 2 000 km² and includes at least one of the regions established in accordance with Article 21 of Regulation (EU) 2016/429.
3. By way of derogation from paragraph 2, the competent authority may define zones smaller than 2 000 km² taking into account:
 - (a) a minimum surface not significantly lower than 2 000 km²; or
 - (b) the existence of natural barriers relevant to the disease profile.

Article 14

Final and intermediate targets

1. The competent authority shall include in the eradication programme qualitative and quantitative final targets that are covering all the disease specific requirements laid down in Article 72 for granting disease-free status.
2. The competent authority shall include in the eradication programme qualitative and quantitative intermediate annual or multiannual targets to reflect progress made towards the final targets. These intermediate targets shall include:
 - (a) all of the disease specific requirements referred to in paragraph 1; and
 - (b) if necessary, additional requirements that are not included in the criteria for granting disease-free status to assess progress towards eradication.

Article 15

Period of application

1. The competent authority shall include in the eradication programme the period of application taking into account the initial situation and the intermediate targets indicated in Article 14(2).
2. For category C diseases, the period of application of the eradication programme shall not exceed 6 years from the date of its initial approval by the Commission in accordance with Article 31(3) of Regulation (EU) 2016/429. In duly justified cases, the Commission may, upon request of Member States, extend the period of application of the eradication programme for an additional 6-year period.

Section 2

Requirements for eradication programmes based on granting disease-free status at the level of establishments

Article 16

Disease control strategy based on the disease-free status at establishment level

1. The competent authority shall design the disease control strategy of an eradication programme with respect to the targeted animal population kept in establishments for the following diseases of terrestrial animals:
 - (a) infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
 - (b) infection with MTBC;
 - (c) EBL;
 - (d) IBR/IPV;
 - (e) infection with ADV;
 - (f) BVD.
2. Disease control strategies of eradication programmes referred to in paragraph 1 shall be based on:
 - (a) the implementation of disease specific measures laid down in Articles 18 to 31 until all relevant establishments reach disease-free status;
 - (b) the granting, suspension and withdrawal by the competent authority of the disease-free status of all relevant establishments;
 - (c) the implementation of biosecurity and other risk mitigating measures;
 - (d) the optional implementation of vaccination programmes.

Article 17

Targeted and additional animal populations for eradication programmes for certain diseases

1. The competent authority shall apply a compulsory eradication programme to the following targeted animal populations:
 - (a) for infection with *Brucella abortus*, *B. melitensis* and *B. suis*, kept bovine animals, kept ovine animals and kept caprine animals;
 - (b) for infection with MTBC, kept bovine animals.
2. The competent authority shall apply the optional eradication programme to the following targeted animal populations:
 - (a) for EBL, kept bovine animals;
 - (b) for IBR/IPV, kept bovine animals;
 - (c) for infection with ADV, kept porcine animals;
 - (d) for BVD, kept bovine animals.
3. The competent authority shall include additional animal populations where it considers that such animals pose a significant risk to the health status of animals referred to in paragraphs 1 or 2.

Article 18

Obligations of operators with respect to eradication programmes for certain diseases

1. The operators of establishments where animals from the targeted animal populations referred to in Article 17 are kept, other than slaughterhouses, shall comply with the following general and disease specific requirements to obtain and maintain the disease-free status of the establishments:

- (a) general requirements:
 - (i) surveillance of the targeted and additional animal populations for the relevant disease as ordered by the competent authority pursuant to Article 3(1);
 - (ii) in the case of movement of animals from the targeted animal populations, ensuring that the health status of the establishments is not jeopardised due to transport or introduction into the establishments of animals of the targeted or additional animal populations or products thereof;
 - (iii) vaccination of the kept animals of targeted animal populations against the relevant disease;
 - (iv) disease control measures in the event the disease is suspected or confirmed;
 - (v) any additional measures considered necessary by the competent authority that may include, if relevant, separation of animals according to their health status by physical protection measures and management measures;
- (b) disease specific requirements laid down in:
 - (i) Chapters 1 and 2 of Part I of Annex IV for infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
 - (ii) Chapter 1 of Part II of Annex IV for infection with MTBC;
 - (iii) Chapter 1 of Part III of Annex IV for EBL;
 - (iv) Chapter 1 of Part IV of Annex IV for IBR/IPV;
 - (v) Chapter 1 of Part V of Annex IV for infection with ADV;
 - (vi) Chapter 1 of Part VI of Annex IV for BVD.

2. The operators of slaughterhouses, where animals from the targeted animal populations referred to in Article 17 are kept and slaughtered shall comply with the general requirements laid down in points (a)(i), (iv) and (v) of paragraph 1.

Article 19

Derogation with regard to granting disease-free status to establishments

By way of derogation from Article 18 and provided that the relevant targeted animal populations comply with the general requirements laid down in point (a) of Article 18(1), the competent authority may decide that the obligations of operators to obtain and maintain disease-free status laid down in Article 18(1) do not apply to operators of the following establishments:

- (a) confined establishments;
- (b) establishments where animals are only kept for assembly operations;
- (c) establishments where animals are only kept for the purpose of animal acts;
- (d) travelling circuses.

Article 20

Obligation of the competent authority to grant, suspend and withdraw disease-free status

1. The competent authority shall grant disease-free status at establishment level according to the compliance of the establishments' operators with the requirements laid down in Article 18.

2. The competent authority shall suspend or withdraw disease-free status at establishment level when the conditions for suspension or withdrawal have been met. Those conditions are laid down in:

- (a) Sections 3 and 4 of Chapters 1 and 2 of Part I of Annex IV for infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
- (b) Sections 3 and 4 of Chapter 1 of Part II of Annex IV for infection with MTBC;
- (c) Sections 3 and 4 of Chapter 1 of Part III of Annex IV for EBL;
- (d) Sections 3 and 4 of Chapter 1 of Part IV of Annex IV for IBR/IPV;
- (e) Sections 3 and 4 of Chapter 1 of Part V of Annex IV for infection with ADV;
- (f) Sections 3 and 4 of Chapter 1 of Part VI of Annex IV for BVD.

3. The competent authority shall specify:

- (a) the details of the testing regime, including as necessary, the disease specific requirements referred to in point (b) of Article 18(1) when the disease-free status is suspended or withdrawn; and
- (b) the maximum period of time during which disease-free status may be suspended where there is a breach of the conditions referred to in paragraph 2.

4. The competent authority may attribute distinct health status to different epidemiological units of the same establishment provided that its operator:

- (a) has submitted for the consideration of the competent authority the information about the different epidemiological units established within the establishment to be granted distinct health status prior to any suspicion or confirmation of the disease in accordance with Articles 21 and 24;
- (b) has set up a system, to which the competent authority has access upon request, to trace the movements of animals and germinal products to, from and between the epidemiological units; and
- (c) has separated the epidemiological units by physical and management means and complies with any risk mitigating measures requested by the competent authority for that purpose.

Article 21

Disease control measures in the event of suspicion of certain diseases

1. The competent authority shall, when it suspects a case of the relevant disease, conduct investigations, initiate an epidemiological enquiry and suspend the disease-free status of the establishment where the suspected case occurred until the investigations and the epidemiological enquiry are concluded.

2. Pending the outcome of the investigations and the epidemiological enquiry referred to in paragraph 1, the competent authority:

- (a) shall prohibit movement of animals from the relevant targeted animal population out of the establishment unless it has authorised their immediate slaughter in a designated slaughterhouse;
- (b) shall, when it considers it necessary for the control of the risk of spreading the disease:
 - (i) where technically possible, order the isolation of the suspected cases in the establishment;
 - (ii) restrict the introduction of animals from the relevant targeted animal population into the establishment;
 - (iii) restrict the movement of products from the relevant targeted animal population from or to the establishment.

3. The competent authority shall maintain the measures referred to in paragraphs 1 and 2 until the presence of the disease has been ruled out or confirmed.

*Article 22***Extension of disease control measures in the event of suspicion of certain diseases**

1. The competent authority shall, when it considers it necessary, extend the measures laid down in Article 21 to:
 - (a) relevant additional animal populations kept in the establishment;
 - (b) any establishment which has an epidemiological link with the establishment where the suspected case occurred.
2. If the presence of the disease is suspected in wild animals, the competent authority shall, when it considers it necessary, extend to the establishments that are at risk of infection the measures laid down in Article 21.

*Article 23***Derogations from disease control measures in the event of suspicion of certain diseases**

1. By way of derogation from Article 21(1), based on duly justified grounds, the competent authority may decide not to suspend the disease-free status of the whole establishment when there are different epidemiological units as referred to in Article 20(4).
2. By way of derogation from point (a) of Article 21(2), the competent authority may authorise movement of animals from the relevant targeted animal population to an establishment under its official supervision provided that the following requirements are complied with:
 - (a) the animals shall only be moved by direct transport;
 - (b) in the establishment of destination, the animals shall be kept in closed facilities, with no contact with kept animals of a higher health status or with wild animals of listed species for the relevant disease.
3. By way of derogation from point (a) of Article 21(2), in the case of a category C disease, the competent authority may authorise movement of animals from the relevant targeted animal population provided that they are moved, if necessary by direct transport, to an establishment located in an area that is neither disease-free nor covered by an optional eradication programme.
4. When making use of the derogation laid down in paragraph 2, the competent authority shall:
 - (a) suspend the disease-free status of the establishment of destination of the animals that are subject to the derogations, until the end of the investigations referred to in Article 21(1);
 - (b) prohibit, until the end of the investigations referred to in Article 21(1), the movement of animals from that establishment, unless it has authorised their direct transport to a designated slaughterhouse for immediate slaughter;
 - (c) in case of suspicion of infection with *Brucella abortus*, *B. melitensis* and *B. suis* or with MTBC, maintain the prohibition laid down in point (b) after the end of the investigation until all the animals that moved in the establishment following the derogation laid down in paragraph 2 have been slaughtered.
5. The competent authority may use the derogations provided for in paragraphs 1 to 3 only if operators of establishments of origin and of destination and transporters of the animals that are subject to the derogations:
 - (a) apply appropriate biosecurity and other risk mitigating measures necessary to prevent the spread of the disease; and
 - (b) provide the competent authority with guarantees that all the necessary biosecurity and other risk mitigating measures have been taken.

*Article 24***Official confirmation of certain diseases and disease control measures**

1. If a case is confirmed, the competent authority shall:
 - (a) withdraw the disease-free status of the infected establishment(s);

- (b) adopt the measures laid down in Articles 25 to 31 in the infected establishment(s).
2. By way of derogation from point (a) of paragraph 1, the competent authority may limit the withdrawal of the disease-free status to the epidemiological units where a case was confirmed.
3. If the disease is confirmed in wild animals, the competent authority shall conduct, if necessary, an epidemiological enquiry and investigations as provided for in Article 25. If it considers it necessary in order to prevent the spread of the disease, it shall:
- (a) order relevant disease control measures as provided for in Articles 21 to 25 and in Article 30 in establishments keeping the targeted animal population and the additional animal populations;
 - (b) conduct or order other proportionate and necessary prevention, surveillance and disease control measures with respect to the relevant wild animal population or in its habitat.

Article 25

Epidemiological enquiry and investigations in case of confirmation of certain diseases

1. When the disease is confirmed, the competent authority shall:
- (a) conduct an epidemiological enquiry;
 - (b) conduct investigations and apply the measures laid down in Article 21 in all epidemiologically linked establishments; and
 - (c) adapt the surveillance to the identified risk factors, taking into account the conclusions of the epidemiological enquiry.
2. The competent authority shall consider the need to conduct an investigation on wild animals from additional animal populations where the epidemiological enquiry reveals epidemiological links between kept and wild animals.
3. The competent authority shall as soon as possible inform about the situation:
- (a) operators and relevant authorities from the Member States concerned by the epidemiological links with the confirmed case; and
 - (b) the competent authorities from other Member States or third countries that may be concerned by the epidemiological links with the infected establishment(s).

Article 26

Movement of animals to or from infected establishments

1. The competent authority shall prohibit movements of animals from targeted animal population out of the infected establishment unless it has authorised their immediate slaughter in a designated slaughterhouse.
2. When the competent authority considers it necessary in order to prevent the spread of the disease, it shall:
- (a) order the isolation of the suspected and confirmed cases in the establishment where technically possible;
 - (b) restrict the movements of animals from targeted animal population within the establishment;
 - (c) restrict the introduction of animals from targeted animal population in the establishment;
 - (d) restrict the movement of products of animals from targeted animal population from and to the infected establishment.
3. The competent authority shall, when it considers it necessary, extend the measures in paragraphs 1 and 2 to animals and products from additional animal populations to prevent the spread of the disease.

Article 27

Testing and removal of animals from infected establishments

1. Following confirmation of the disease, the competent authority shall order that in infected establishments the following testing is conducted within a maximum period of time to be determined by it:
 - (a) testing of those animals whose testing is considered necessary to complete the epidemiological enquiry;
 - (b) testing to restore the disease-free status as laid down in:
 - (i) Section 4 of Chapters 1 and 2 of Part I of Annex IV for infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
 - (ii) Section 4 of Chapter 1 of Part II of Annex IV for infection with MTBC;
 - (iii) Section 4 of Chapter 1 of Part III of Annex IV for EBL;
 - (iv) Section 4 of Chapter 1 of Part IV of Annex IV for IBR/IPV;
 - (v) Section 4 of Chapter 1 of Part V of Annex IV for infection with ADV;
 - (vi) Section 4 of Chapter 1 of Part VI of Annex IV for BVD; and
 - (c) any additional testing it considers necessary to ensure the swift detection of infected animals that may contribute to the spreading of the disease.
2. By way of derogation from point (b) of paragraph 1, testing shall not be ordered when disease-free status is restored in accordance with:
 - (i) point 2 of Section 1 of Chapters 1 and 2 of Part I of Annex IV for infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
 - (ii) point 2 of Section 1 of Chapter 1 of Part II of Annex IV for infection with MTBC;
 - (iii) point 2 of Section 1 of Chapter 1 of Part III of Annex IV for EBL;
 - (iv) point 2 of Section 1 of Chapter 1 of Part IV of Annex IV for IBR/IPV;
 - (v) point 2 of Section 1 of Chapter 1 of Part V of Annex IV for infection with ADV;
 - (vi) point 2 of Section 1 of Chapter 1 of Part VI of Annex IV for BVD.
3. The competent authority shall order that in infected establishments all animals recognised as confirmed cases and, if necessary, as suspected cases are slaughtered within a maximum period of time it determines.
4. The slaughtering of the animals referred to in paragraph 3 shall be carried out under official supervision in a designated slaughterhouse.
5. The competent authority may order the killing and destruction of some or all of the animals referred to in paragraph 3 instead of their slaughtering.
6. The competent authority shall extend the measures laid down in this Article to animals from additional animal populations when this is necessary to eradicate the disease in the infected establishments.

Article 28

Management of products from infected establishments

1. The competent authority shall in all establishments infected with *Brucella abortus*, *B. melitensis* and *B. suis* or with MTBC, order that:
 - (a) milk from confirmed cases shall either be fed only to animals in the same establishment after it has been processed to ensure the inactivation of the disease agent, or it shall be disposed of;

(b) manure, straw, feed or any other matter and substance which has come into contact with a confirmed case or with contaminated material shall be either collected and disposed of as soon as possible or, following an appropriate risk assessment, stored and processed to reduce to an acceptable level the risk of spreading of the disease.

2. In the event of infection with *Brucella abortus*, *B. melitensis* and *B. suis*, the competent authority shall order that in all infected establishments foetuses, still-born animals, animals which have died from the disease after birth and placentae shall be collected and disposed of.

3. In the event of infection with a category C disease, the competent authority shall when it considers it necessary, order any appropriate measures provided for paragraphs 1 and 2.

4. The competent authority shall, when it considers it necessary, order the trace-back, the processing or the disposal of any products from infected establishments that may constitute a risk of spreading the disease or affect human health.

Article 29

Derogations from the restriction of movement of animals from infected establishments

1. By way of derogation from Article 26(1), the competent authority may authorise movement of clinically healthy animals, other than confirmed cases, to an establishment under its official supervision provided that the following requirements are complied with:

- (a) the movement does not jeopardise the health status of animals at the establishment of destination or enroute to that destination;
- (b) the animals shall only be moved by direct transport; and
- (c) in the establishment of destination, the animals shall be kept, in closed facilities, with no contact with kept animals of a higher health status or with wild animals of listed species for the relevant disease.

2. By way of derogation from Article 26(1) in the case of a category C disease, the competent authority may authorise movement of clinically healthy animals from the relevant targeted animal population, other than confirmed cases, provided that:

- (a) they are moved, if necessary by direct transport, to an establishment located in an area that is neither disease-free nor covered by an optional eradication programme; and
- (b) the movement does not jeopardise the health status of targeted or additional animal populations at the establishment of destination or enroute to that destination.

3. When making use of the derogation laid down in paragraph 1, the competent authority shall withdraw the disease-free status of the establishment of destination of the animals that are subject to the derogation and shall:

- (a) order the movement of the animals by direct transport, within a maximum period of time it determines, from the establishment of destination to a designated slaughterhouse for immediate slaughter; or
- (b) in case of a category C disease order the disease control measures laid down in Articles 26 to 30 until the disease-free status of the establishment is regained.

4. The competent authority may use the derogations provided for in paragraphs 1 and 2 only if operators of establishments of origin and of destination and transporters of the animals that are subject to the derogations:

- (a) apply appropriate biosecurity and other risk mitigating measures necessary to prevent the spread of the disease; and
- (b) provide the competent authority with the guarantees that all the necessary biosecurity and other risk mitigating measures have been taken.

*Article 30***Cleaning and disinfection and other measures to prevent the spread of infection**

1. The competent authority shall order the operators of all infected establishments and those receiving animals from infected establishments the cleaning and disinfection or, where relevant, the safe disposal of:
 - (a) all parts of the establishments that may have been contaminated after the removal of the confirmed and suspected cases and before repopulation;
 - (b) any feed, materials, substances, husbandry related equipment, medicinal equipment and production related equipment that may have been contaminated;
 - (c) any protective clothing or safety equipment used by operators and visitors;
 - (d) all means of transport, containers and equipment after the transport of animals or products from infected establishments;
 - (e) loading areas for animals after each use.
2. The competent authority shall approve the protocol for the cleaning and disinfection.
3. The competent authority shall supervise the cleaning and disinfection, or where relevant, the safe disposal and shall not restore or grant again disease-free status to the establishment until it considers that the cleaning and disinfection, or where relevant, the safe disposal, has been completed.
4. The competent authority may, based on a risk assessment, regard a pasture as contaminated and prohibit its use for kept animals of higher health status than that of the targeted animal population or, if epidemiologically relevant, additional animal populations, for a period of time sufficient to consider the risk of persistence of the disease agent to be negligible.

*Article 31***Risk mitigating measures to prevent reinfection**

Before or upon lifting of the disease control measures, the competent authority shall order proportionate risk mitigating measures to prevent the reinfection of the establishment taking into account relevant risk factors as indicated by the results of the epidemiological enquiry. These measures shall at least take account of:

- (a) persistence of the disease agent in the environment or in wild animals; and
- (b) biosecurity measures that are adapted to the specificities of the establishment.

*Section 3***Provisions for eradication programmes for infection with RABV***Article 32***Disease control strategy of eradication programmes for infection with RABV**

1. The competent authority shall, when establishing an eradication programme for infection with RABV, base it on a disease control strategy that includes:
 - (a) vaccination of the animals from the targeted animal population that it considers relevant;
 - (b) implementation of measures to reduce the risk of contact with infected animals;
 - (c) control of the risk of spread and introduction of the disease in the territory of its Member State.
2. The competent authority shall implement the eradication programme taking into account that it shall be:
 - (a) based on a risk assessment, updated, as necessary, according to the evolution of the epidemiological situation;
 - (b) supported by public information campaigns involving all relevant stakeholders;

- (c) coordinated, if necessary, with relevant authorities in charge of public health, wild animal populations or hunting;
- (d) scaled according to a territorial risk-based approach.

3. The competent authority may be involved in the implementation of eradication programmes for infection with RABV in a third country or territory, to prevent the risk of spread and introduction of RABV in the territory of its Member State.

Article 33

Targeted animal population for eradication programmes for infection with RABV

1. The competent authority shall apply the eradication programme for infection with RABV to the following targeted animal population: kept and wild animals of species of the following families: Carnivora, Bovidae, Suidae, Equidae, Cervidae and Camelidae.
2. The competent authority shall address the measures in the eradication programme primarily to wild foxes, being the main reservoir of RABV.
3. The competent authority shall subject other targeted animal populations than wild foxes to the measures of the eradication programme when it considers that such animals pose a significant risk.
4. The competent authority may include wild animals of species of the order Chiroptera in the targeted animal population relevant to surveillance referred to in Article 4.

Article 34

Obligations of the competent authority in the context of eradication programmes for infection with RABV

1. The competent authority shall:
 - (a) conduct surveillance of infection with RABV for the purposes of:
 - (i) early detection of the infection; and
 - (ii) follow up of the trend in the number of infected animals, which shall include, according to a risk-based approach, the collection and testing of wild foxes and other wild carnivores found dead;
 - (b) carry out disease control measures in the event of suspicion or confirmation of infection with RABV as laid down in Articles 35 and 36;
 - (c) apply, if necessary, risk mitigating measures to prevent the spread of RABV by movements of dogs, cats and ferrets.
2. The competent authority shall, when it considers it necessary, order:
 - (a) vaccination, and the monitoring of the effectiveness of vaccination, in accordance with Section 2 of Chapter 1 of Part I of Annex V of wild foxes and, if relevant, of other animals referred to in Article 33(3);
 - (b) the identification and registration of dogs, cats and ferrets;
 - (c) movement restrictions of relevant kept animals of species referred to in Article 33(3) that are not vaccinated against infection with RABV in accordance with Section 1 of Chapter 1 of Part I of Annex V;
 - (d) the measures provided for in Article 35 when an animal of a listed species wounded a person or an animal without an understandable reason and in contradiction with its normal behaviour or presented an unexplained change in behaviour followed by death within 10 days.

*Article 35***Disease control measures in the event of suspicion of infection with RABV**

When infection with RABV is suspected, the competent authority shall:

- (a) conduct further investigations to confirm or rule out the presence of the disease;
- (b) order relevant movement restrictions or killing of suspected cases to protect humans and animals against the risk of being infected pending the results of the investigations;
- (c) order any risk mitigating measures justified to reduce the risk of further transmission of RABV to humans or to animals.

*Article 36***Disease control measures in the event of confirmation of infection with RABV**

When infection with RABV is confirmed, the competent authority shall take measures to prevent further transmission of the disease to animals and to humans, for which:

- (a) it shall conduct an epidemiological enquiry, which shall include the identification of the RABV strain involved, to identify the likely source of the infection and epidemiological links;
- (b) it shall, unless it considers further investigations are necessary, rule out an infection with RABV in animals with an epidemiological link when:
 - (i) a minimum period of 3 months has lapsed since the epidemiological link with the confirmed case occurred; and
 - (ii) no clinical signs have been detected in those animals;
- (c) it shall, when it considers it necessary, take one or more of the measures laid down in Articles 34 and 35;
- (d) it shall ensure that carcasses of confirmed cases of infected wild animals are disposed of or processed in accordance with the rules laid down in Article 12 of Regulation (EC) No 1069/2009.

*Section 4***Provisions for eradication programmes for infection with BTV***Article 37***Disease control strategy of eradication programmes for infection with BTV**

1. The competent authority shall, when establishing an optional eradication programme for infection with BTV, base the programme on a disease control strategy that includes:

- (a) surveillance of infection with BTV in accordance with the requirements set out in Chapter 1 of Part II of Annex V;
- (b) vaccination of the relevant targeted animal population for eradicating the disease by means of regular vaccination campaigns to be implemented, as relevant, in accordance with a long-term strategy;
- (c) movement restrictions of the targeted animal population in accordance with the requirements laid down in Articles 43 and 45;
- (d) risk mitigating measures to minimise transmission of infection with BTV through vectors.

2. The competent authority shall implement the eradication programme taking into account that:

- (a) it shall detect and eradicate all the serotypes 1-24 present in the territory covered by the eradication programme;
- (b) the territory covered by the eradication programme shall be:
 - (i) the whole territory of the Member State; or
 - (ii) a zone or zones that include a territory within at least a 150-km radius of each infected establishment.

3. By way of derogation from point (b)(ii) of paragraph 2, the competent authority may adapt the zone(s) covered by the eradication programme in accordance with:

- (a) the geographical situation of the infected establishment(s) and the boundaries of the corresponding administrative units;
- (b) the ecological and meteorological conditions;
- (c) the abundance, activity and distribution of the vectors present in the zone(s);
- (d) the BTV serotype involved;
- (e) the results of the epidemiological enquiry provided for in Article 42;
- (f) the results of the surveillance activities.

Article 38

Targeted and additional animal populations for eradication programmes for infection with BTV

1. The competent authority shall apply the eradication programme for infection with BTV to the following targeted animal population: kept animals from species of families of Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Moschidae and Tragulidae.

2. The competent authority shall, when it considers it is necessary, apply the eradication programme to the following additional animal populations: wild animals from species of families of Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Moschidae and Tragulidae.

Article 39

Obligations of operators in the context of eradication programmes for infection with BTV

1. The operators of establishments, other than slaughterhouses, where animals from the targeted animal population referred to in Article 38(1) are kept shall:

- (a) comply with the requirements ordered by the competent authority as regards the surveillance of animals from the targeted animal population;
- (b) comply with the requirements ordered by the competent authority as regards the entomological surveillance;
- (c) have animals from the targeted animal population vaccinated following the orders of the competent authority;
- (d) implement disease control measures in the event the disease is suspected or confirmed following the orders of the competent authority;
- (e) comply with movement requirements following the orders of the competent authority;
- (f) implement any additional measures considered necessary by the competent authority which may include, if relevant, protection of kept animals from attacks by vectors in accordance with the animals' health status.

2. The operators of slaughterhouses, where animals from the targeted animal population referred to in Article 38(1) are kept and slaughtered, shall:

- (a) comply with the requirements ordered by the competent authority as regards the surveillance of animals from the targeted animal population;
- (b) implement disease control measures in the event the disease is suspected or confirmed following the orders of the competent authority;
- (c) implement any additional measures considered necessary by the competent authority which may include, if relevant, protection of kept animals from attacks by vectors in accordance with the animals' health status.

*Article 40***Obligations of the competent authority in the context of eradication programmes for infection with BTV**

1. The competent authority shall in the territory covered by an eradication programme for infection with BTV referred to in point (b) of Article 37(2):
 - (a) map the territory covered in a set of geographical units in accordance with point 1 of Section 4 of Chapter 1 of Part II of Annex V;
 - (b) conduct surveillance of infection with BTV in each geographical unit, as relevant with regard to the epidemiological situation, according to the requirements laid down in Chapter 1 of Part II of Annex V;
 - (c) apply the disease control measures laid down in Articles 41 and 42 in the event of suspicion or confirmation of the disease;
 - (d) order operators of establishments of bovine, ovine or caprine animals and, if necessary, other targeted animal populations to have their animals vaccinated; and
 - (e) apply the requirements laid down in Articles 43 and 45 to the movements of animals from the targeted animal population.
2. By way of derogation from point (d) of paragraph 1, the competent authority may decide not to order operators to have their animals vaccinated if following a risk assessment, it duly justifies that the implementation of other measures is sufficient to eradicate the disease.
3. The competent authority shall, when it considers it necessary and if possible, establish a seasonally BTV-free area as provided for in Chapter 5 of Part II of Annex V. In that event, the competent authority shall make available to the Commission and to the other Member States:
 - (a) information demonstrating the fulfilment of the specific criteria for determining the seasonally BTV-free period;
 - (b) the start and end dates of the period;
 - (c) information demonstrating the cessation of the transmission of BTV in the area; and
 - (d) the delimitation of the area which complies with the minimum requirements laid down in Article 13.

*Article 41***Disease control measures in the event of suspicion of infection with BTV**

1. In the event of suspicion of infection with BTV, the competent authority shall conduct an investigation to confirm or rule out the disease.
2. Pending the outcome of the investigation referred to in paragraph 1, the competent authority shall:
 - (a) restrict movement of animals and germinal products from the targeted animal population from the establishment where they are kept unless authorised for the purpose of immediate slaughter;
 - (b) order relevant risk mitigating measures, when necessary and technically feasible, to prevent or reduce exposure of animals from the targeted animal population to attacks by vectors.
3. The competent authority shall, when it considers it necessary, extend the measures provided for in paragraphs 1 and 2 to establishments where animals from the targeted animal population had a similar exposure to infectious vectors to that of the suspected cases.
4. The measures provided for in this Article may be withdrawn when the competent authority considers that they are no longer necessary to limit the risk of spreading the disease.

*Article 42***Disease control measures in the event of confirmation of infection with BTV**

1. In the event of confirmation of infection with BTV, the competent authority shall:
 - (a) confirm the outbreak and, if necessary, establish or extend the zone under eradication programme;
 - (b) conduct an epidemiological enquiry, if necessary;
 - (c) restrict movement of animals of the targeted animal population from the establishment where they are kept unless authorised for the purpose of immediate slaughter;
 - (d) restrict movement of germinal products of animals from the targeted animal population from the establishment where they are kept;
 - (e) order relevant risk mitigating measures, when it considers it necessary and technically feasible, to prevent or reduce exposure of animals from the targeted animal population to attacks by vectors;
 - (f) apply the disease control measures provided for in Article 41 to all establishments having an epidemiological link with the confirmed case, including those keeping animals from the targeted animal population having a similar exposure to infectious vectors to that of the confirmed case.
2. In addition to measures laid down in paragraph 1 and in order to prevent the disease from spreading, the competent authority shall, when it considers it necessary:
 - (a) order operators of establishments of bovine, ovine or caprine animals and, if necessary, other targeted animal populations to have their animals vaccinated against the infection with the relevant BTV serotype(s) as provided for in point (d) of Article 40(1);
 - (b) investigate and monitor the health status of the targeted animal population in the proximity of the establishment where the confirmed case is kept.
3. The measures provided for in this Article may be withdrawn when the competent authority considers that they are no longer necessary to limit the risk of spreading the disease.

*Article 43***Movement of kept animals and germinal products from the targeted animal population to Member States or zones covered by eradication programmes for infection with BTV**

1. The competent authority shall only authorise the introduction of animals from the targeted animal population in the territory covered by an eradication programme for infection with BTV referred to in point (b) of in Article 37(2) if they comply with at least one of the requirements set out in points 1 to 4 of Section 1 of Chapter 2 of Part II of Annex V.
2. By way of derogation from paragraph 1, the competent authority may also authorise the introduction of animals from the targeted animal population in the territory covered by the eradication programme for infection with BTV if:
 - (a) it has assessed the risk that the introduction poses to the health status of the place of destination as regards infection with BTV, taking into account possible risk mitigating measures it may adopt at the place of destination;
 - (b) it prohibits the movement of these animals to another Member State:
 - (i) for a period of 60 days after the introduction; or
 - (ii) until a negative polymerase chain reaction (PCR) test for BTV serotypes 1-24 was carried out on samples collected not earlier than 14 days after the introduction;
 - (c) it adapts, if necessary, the surveillance in accordance with point 6 of Section 4 of Chapter 1 of Part II of Annex V; and
 - (d) the animals comply with any one of the requirements set out in points 5 to 8 of Section 1 of Chapter 2 of Part II of Annex V.

3. The competent authority shall only authorise the introduction of germinal products from the targeted animal population in the territory covered by an eradication programme for infection with BTV referred to in point (b) of Article 37(2) if they comply with at least one of the requirements set out in points 1 to 3 of Section 2 of Chapter 2 of Part II of Annex V.
4. By way of derogation from paragraph 3, the competent authority may also authorise the introduction of germinal products from the targeted animal population in the territory covered by an eradication programme for infection with BTV if:
- (a) it has assessed the risk that the introduction poses to the health status of the place of destination as regards infection with BTV, taking into account possible risk mitigating measures it may adopt at the place of destination;
 - (b) it prohibits the movement of these germinal products to another Member State; and
 - (c) the germinal products comply with the requirements set out in point 4 of Section 2 of Chapter 2 of Part II of Annex V.
5. When the competent authority receiving the animals or the germinal products uses the derogations provided for in paragraphs 2 or 4, it shall:
- (a) inform the Commission thereof as soon as possible;
 - (b) accept animals or germinal products from the targeted animal population that comply with the requirements for the relevant derogation regardless of the Member State or zone of origin of the animal or germinal products.
6. When the competent authority receiving the animals or the germinal products no longer uses the derogations provided for in paragraphs 2 or 4, it shall inform the Commission as soon as possible.

Article 44

Vector protected establishment

1. The competent authority may, upon request by the operator, grant the status 'vector protected establishment' to establishments or facilities complying with the criteria laid down in Chapter 3 of Part II of Annex V.
2. The competent authority shall verify at the appropriate frequency, but at least at the beginning, during and at the end of the required protection period, the effectiveness of the measures carried out by means of a vector trap inside the establishment.
3. The competent authority shall immediately withdraw the status vector protected establishment when the conditions referred to in paragraph 1 are no longer complied with.

Article 45

Movement of animals through Member States or zones covered by eradication programmes for infection with BTV

1. The competent authority shall only authorise movement of animals from the targeted animal population through the territory covered by an eradication programme for infection with BTV referred to in point (b) of Article 37(2) if:
- (a) the animals from the targeted animal population comply with at least one of the requirements set out in points 1 to 3 of Section 1 of Chapter 2 of Part II of Annex V; or
 - (b) the means of transport onto which the animals are loaded have been protected from attacks by vectors and the journey does not include the unloading of the animals for a period longer than 1 day, or the animals are unloaded for a period longer than 1 day in a vector protected establishment or during the vector-free period.
2. By way of derogation from paragraph 1, the competent authority may also authorise the movement of animals from targeted animal population through the territory covered by an eradication programme for infection with BTV if the requirements laid down in points (a), (c) and (d) of Article 43(2) are complied with.

CHAPTER 3

Eradication programmes for category B and C diseases of aquatic animals

Section 1

General provisions*Article 46***Disease control strategy for the eradication of category B and C diseases of aquatic animals**

1. The competent authority shall, when establishing a compulsory eradication programme for a category B disease or an optional eradication programme for a category C disease of aquatic animals, base those programmes on a disease control strategy that includes for each disease:

- (a) the type of surveillance requirements necessary to achieve the conditions for granting and maintaining disease-free status taking into account point (b)(ii) of Article 3(2);
- (b) the territory and animal population covered by the eradication programme as provided for in Articles 47 and 51;
- (c) the duration of the eradication programme provided for in Article 49 including its final and intermediate targets as provided for in Article 48;
- (d) the disease specific preventive and control measures laid down in Articles 55 to 65.

2. The competent authority may include in the eradication programme coordinated measures at its common land or coastal border with other Member States or third countries to ensure that the objective of the programmes are achieved and will last.

Where such coordination has not been established, the competent authority shall include in the eradication programme, if feasible, effective risk mitigating measures including intensified surveillance.

*Article 47***Territorial scope and animal population**

1. The competent authority shall determine the scope of the eradication programme including:

- (a) the territory covered; and
- (b) the targeted animal population and, if necessary, additional animal populations.

2. The territory covered by the eradication programme referred to in point (a) of paragraph 1 may be:

- (a) the entire territory of the Member State;
- (b) one or several zones; or
- (c) the geographical location of the establishments of which the compartment or compartments are comprised.

3. All establishments located within the Member State, zone or compartment covered by the eradication programme shall be included in the eradication programme.

4. By way of derogation from paragraph 3 the competent authority may exclude from the eradication programme, aquaculture establishments which do not pose a significant risk to the success of that programme and which are exempted from the obligation to apply for approval.

*Article 48***Final and intermediate targets**

1. The competent authority shall include in the eradication programme qualitative and quantitative final targets that cover all the disease specific requirements laid down in Article 72 for granting disease-free status.

2. Where this is technically possible, the competent authority implementing an eradication programme shall also include in that programme qualitative and quantitative final targets based on the health status of wild animal populations that constitute a threat to the achievement of disease-free status.

3. The competent authority shall include in the eradication programme qualitative and quantitative intermediate annual or multiannual targets to reflect progress made towards the final targets. These intermediate targets shall include:

- (a) all of the disease specific requirements referred to in paragraph 1 and the targets provided for in paragraph 2; and
- (b) if necessary, additional requirements that are not included in the requirements for granting disease-free status to assess progress towards eradication.

Article 49

Period of application

1. The period of application of eradication programmes for listed aquatic animal diseases are laid down in Part II of Annex VI, specifically Sections 2 and 3 of:

- (a) Chapter 1 for VHS and IHN;
- (b) Chapter 2 for infection with HPR-deleted ISAV;
- (c) Chapter 3 for infection with *Marteilia refringens*;
- (d) Chapter 4 for infection with *Bonamia exitiosa*;
- (e) Chapter 5 for infection with *Bonamia ostreae*;
- (f) Chapter 6 for infection with WSSV.

2. For category C diseases, the period of application of an eradication programme shall not exceed 6 years from the date of its initial approval by the Commission in accordance with Article 31(3) of Regulation (EU) 2016/429. In duly justified cases, the Commission may, upon request of Member States, extend the period of application of the eradication programme for an additional 6-year period.

Section 2

Requirements for Eradication programmes

Article 50

Minimum requirements for an eradication programme

The competent authority shall base the eradication programme for a specific category B or C disease in a Member State, zone, or compartment on:

- (a) the determination of the health status of the Member State, zone or compartment by ascertaining the health status of all establishments where animals from the listed species are kept;
- (b) the implementation of disease control measures in all establishments where suspected and confirmed cases are detected;
- (c) the implementation of biosecurity and other risk mitigating measures to reduce the risk of the listed species in an establishment becoming infected;
- (d) in certain cases, vaccination, as part of the eradication programme.

Article 51

Animal population to be included in eradication programmes for category B and C diseases

1. The competent authority shall apply the eradication programme to listed species kept in establishments within the territory of the Member State, the zone or compartment.

2. By way of derogation from paragraph 1, the competent authority may decide to exclude from the eradication programme, based on a risk assessment, establishments keeping only vector species referred to in the table set out in the Annex to Implementing Regulation (EU) 2018/1882.

3. Where technically feasible, the competent authority shall include in the eradication programme additional animal populations when such animals:

- (a) pose a significant risk to the health status of animals referred to in paragraph 1;
- (b) are included due to the small number of aquaculture establishments in the eradication programme and when their inclusion is necessary to obtain a satisfactory epidemiological coverage of the Member State, zone or compartment.

Article 52

Measures to be taken in Member States, zones or compartments covered by eradication programmes

1. In order to monitor the progress of eradication programmes, the competent authority shall classify the health status of all establishments where animals from the listed species are kept according to:

- (a) the health status of each establishment as known at the time the eradication programme commences;
- (b) the compliance with conditions for the introduction of animals from listed species into the establishment;
- (c) the compliance by the operator with the obligation to notify the competent authority of any suspicion or detection of the disease;
- (d) the fulfilment of disease control measures to be applied if the disease is suspected or confirmed;
- (e) the vaccination regimes that may apply to animals from listed species kept in the establishment;
- (f) any additional measures considered necessary by the competent authority.

2. The competent authority shall:

- (a) commence, maintain, or withdraw the eradication programme according to the compliance or non-compliance of establishments with the requirements laid down in paragraph 1;
- (b) inform the operators of the relevant establishments about the evolution of the health status and the necessary measures for granting disease-free status.

3. Operators shall comply with the requirements set out in points (b) to (f) of paragraph 1 so that the eradication programme can be implemented until such time as it has been successfully completed or is withdrawn.

Article 53

Derogation from classification of the health status of confined establishments

By way of derogation from Article 52(1), the competent authority may decide not to classify the health status of confined establishments, if the animal population kept in these confined establishments is subjected to appropriate risk mitigating measures and disease control measures to ensure that it does not constitute a risk of spreading the disease.

Article 54

Vaccination

The competent authority may, include in eradication programmes under its official supervision:

- (a) vaccination of listed species;
- (b) vaccination of an additional animal population of kept animals;
- (c) vaccination of an additional animal population of wild animals.

*Article 55***Disease control measures in the event of suspicion of certain diseases**

1. The competent authority shall, when it suspects a case of the relevant disease in an establishment, conduct the necessary investigation.
2. Pending the outcome of the investigation referred to in paragraph 1, the competent authority shall:
 - (a) prohibit the introduction of animals or products of animal origin into the establishment;
 - (b) where technically possible, order the isolation of units in the establishment where suspected animals are kept;
 - (c) prohibit the movement of animals and products of animal origin out of the establishment unless authorised by the competent authority for the purpose of immediate slaughter or processing in a disease control aquatic food establishment, or for direct human consumption in the case of molluscs or crustacea which are sold live for that purpose;
 - (d) prohibit the movement of equipment, feed and animal by-products from the establishment unless authorised by the competent authority.
3. The competent authority shall maintain the measures referred to in paragraphs 1 and 2 until the presence of the disease has been ruled out or confirmed.

*Article 56***Extension of disease control measures in the event of suspicion of certain diseases**

1. The competent authority shall, when it considers it necessary, extend the measures laid down in Article 55 to:
 - (a) any establishment which due to hydrodynamic conditions, has an increased risk of contracting the disease from the suspected establishment;
 - (b) any establishment which has a direct epidemiological link with the suspected establishment.
2. If the presence of the disease is suspected in wild aquatic animals, the competent authority shall, when it considers it necessary, extend the measures laid down in Article 55 to the concerned establishments.

*Article 57***Derogation from disease control measures in the event of suspicion of disease**

1. By way of derogation from point (c) of Article 55(2) the competent authority may authorise the movement of aquaculture animals to an establishment under its official supervision provided that the following requirements are complied with:
 - (a) only animals showing no symptoms of disease are moved;
 - (b) the health status of aquaculture animals at the establishment of destination or aquatic animals enroute to that establishment is not jeopardised by the movement;
 - (c) in the establishment of destination they have no contact with aquaculture animals of a higher health status with respect to the relevant disease; and
 - (d) the animals are kept in the establishment of destination for a maximum period of time to be determined by the competent authority.
2. When making use of the derogation laid down in paragraph 1, the competent authority shall:
 - (a) re-classify the health status of the establishment of destination, if relevant, in accordance with the criteria laid down in Article 52(1), until the end of the investigation referred to in Article 55(1);
 - (b) prohibit the movement of animals from the establishment of destination until the end of the investigation, unless it has authorised their transport to a disease control aquatic food establishment for immediate slaughter or processing or for direct human consumption, in the case of molluscs or crustacea which are sold live for that purpose.

3. The competent authority may use the derogation provided for in paragraph 1 only if operators of establishments of origin and of destination and transporters of the animals that are subject to the derogation:

- (a) apply appropriate biosecurity and other risk mitigating measures necessary to prevent the spread of the disease;
- (b) provide the competent authority with guarantees that all the necessary biosecurity and other risk mitigating measures have been taken; and
- (c) provide the competent authority with guarantees that animal by-products as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009 from the aquatic animals referred to in paragraph 1(c) of this Article are processed or disposed of as Category 1 or Category 2 material in accordance with Articles 12 or 13 of that Regulation.

Article 58

Official confirmation of certain diseases and disease control measures

1. If a case is confirmed, the competent authority shall:

- (a) declare the establishment(s) infected;
- (b) reclassify the health status of the infected establishment(s);
- (c) establish a restricted zone which is of an appropriate size;
- (d) adopt the measures laid down in Articles 59 to 65 in the infected establishment(s).

2. The minimum requirements that shall apply with regard to the establishment(s) of the restricted zone are set out in Part II of Annex VI, specifically in:

- (a) point 1(a) of Section 3 of Chapter 1 for VHS and IHN;
- (b) point 1(a) of Section 3 of Chapter 2 for infection with HPR-deleted ISAV;
- (c) point 1(a) of Section 3 of Chapter 3 for infection with *Marteilia refringens*;
- (d) point 1(a) of Section 3 of Chapter 4 for infection with *Bonamia exitiosa*;
- (e) point 1(a) of Section 3 of Chapter 5 for infection with *Bonamia ostreae*;
- (f) point 1(a) of Section 3 of Chapter 6 for infection with WSSV.

3. By way of derogation from point (c) of paragraph 1, the competent authority may decide not to establish a restricted zone:

- (a) when an infected establishment does not discharge untreated effluent into surrounding waters; and
- (b) where the biosecurity measures which exist at the establishment are of a standard which ensures that infection is fully contained within it.

4. The competent authority may take risk mitigating measures relating to the following activities in the restricted zone:

- (a) the movement of well-boats through the restricted zone;
- (b) fishing activities;
- (c) other activities that may pose a risk of disease spread.

5. If the disease is confirmed in wild aquatic animals, the competent authority may:

- (a) develop and implement the prevention, surveillance and disease control measures that are necessary to prevent the spread of the disease to kept animals of listed species or to additional animal populations;
- (b) apply intensified surveillance of wild aquatic animal populations and in establishments having a direct epidemiological link with the confirmed case;
- (c) take measures to eradicate the disease from the relevant wild aquatic animal population, where feasible.

*Article 59***Epidemiological enquiry and investigations in case of confirmation of certain diseases**

1. When the disease is confirmed, the competent authority shall:
 - (a) conduct an epidemiological enquiry;
 - (b) conduct investigations and apply the measures laid down in Article 55(2) in all epidemiologically linked establishments;
 - (c) adapt the surveillance to the identified risk factors, taking into account the conclusions of the epidemiological enquiry.
2. The competent authority shall consider the need to conduct an investigation on wild animals where the epidemiological enquiry reveals epidemiological links between kept and wild animals.
3. The competent authority shall as soon as possible inform:
 - (a) operators and relevant authorities from the Member State concerned by the epidemiological links with the confirmed case; and
 - (b) the competent authorities from other Member States or third countries that may be concerned by the epidemiological links with the infected establishment(s).

*Article 60***Movements to or from an infected establishment and any other establishment located in the restricted zone**

1. The competent authority shall in all infected establishment(s) and any other establishment(s) located in the restricted zone:
 - (a) where technically possible, order the isolation of suspected and confirmed cases;
 - (b) prohibit the movement of animals or products of animal origin from the listed species for the relevant disease out of the establishment(s) unless authorised by the competent authority for immediate slaughter or processing in a disease control aquatic food establishment or for direct human consumption in the case of molluscs or crustacea which are sold live for that purpose;
 - (c) prohibit the introduction of animals from the listed species for the relevant disease to the establishment(s) unless authorised by the competent authority on duly justified grounds;
 - (d) prohibit the movement of equipment, feed and animal by-products from the establishment(s) unless authorised by the competent authority.
2. The competent authority shall extend the measures in points (a) to (c) of paragraph 1 to kept animals from additional animal populations if they present a risk of spreading the disease.

*Article 61***Derogations from the restriction of movement of animals and products of animal origin from infected establishments**

1. By way of derogation from point (b) Article 60(1), the competent authority may authorise the movement of aquaculture animals to an establishment under its official supervision located within the same restricted zone provided that:
 - (a) only animals showing no symptoms of disease are moved;
 - (b) the health status of aquaculture animals at the establishment of destination or aquatic animals enroute to that establishment is not jeopardised by the movement;
 - (c) in the establishment of destination they have no contact with aquaculture animals of a higher health status with respect to the relevant disease;
 - (d) the animals are kept in the establishment of destination for a maximum period of time to be determined by the competent authority.

2. When making use of the derogation laid down in paragraph 1, the competent authority shall:
 - (a) re-classify the health status of the establishment of destination, if relevant, in accordance with the criteria laid down in Article 52(1);
 - (b) prohibit the movement of animals from the establishment of destination, unless it has authorised their transport to a disease control aquatic food establishment for immediate slaughter or processing or for direct human consumption, in the case of molluscs or crustacea which are sold live for that purpose. In all cases, animal by-products as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009 shall be processed or disposed of as Category 1 or Category 2 material in accordance with Articles 12 or 13 of that Regulation.
 - (c) keep the establishment of destination under its official supervision until the completion of cleaning, disinfection and appropriate fallowing of the establishment.
3. By way of derogation from point (b) Article 60(1), the competent authority may authorise the movement of aquaculture animals to other infected establishments which are not implementing an eradication programme for that specific disease provided that:
 - (a) only animals showing no symptoms of disease are moved;
 - (b) the health status of aquaculture animals at the establishment of destination or aquatic animals enroute to that establishment is not jeopardised by the movement; and
 - (c) the movement complies with the certification requirements set out in Article 208(2) of Regulation (EU) 2016/429.
4. By way of derogation from point (b) of Article 60(1), the competent authority may authorise the movement of aquaculture animals and products of animal origin to slaughtering and processing facilities other than disease control aquatic food establishments provided that:
 - (a) only animals showing no symptoms of disease are moved;
 - (b) the slaughtering and processing facility is not located in a Member State, zone or compartment which is implementing an eradication programme for that specific disease or which has been declared disease-free;
 - (c) the health status of aquatic animals enroute for the slaughtering and processing facility or in its vicinity is not jeopardised by the movement;
 - (d) the movement complies with the certification requirements set out in Article 208(2) of Regulation (EU) 2016/429.
5. By way of derogation from point (b) of Article 60(1), the competent authority may authorise the movement of animals and products of animal origin from additional animal populations from the infected establishment(s) to other establishments without further restrictions provided that:
 - (a) a risk assessment has been completed;
 - (b) risk mitigating measures are implemented, where necessary, to ensure that the health status of the aquatic animals at the establishment of destination or enroute to that destination is not jeopardised; and
 - (c) the movement complies with the certification requirements set out in Article 208(2) of Regulation (EU) 2016/429.

Article 62

Removal of infected animals

1. Following confirmation of the disease, the competent authority shall in all infected establishments order, within a maximum period of time to be determined by the competent authority, the following measures in relation to aquatic animals from listed species for the relevant disease:
 - (a) removal of all dead animals;
 - (b) removal and killing of all moribund animals;
 - (c) removal and killing of all animals showing symptoms of disease;
 - (d) slaughtering for human consumption, or in the case of molluscs or crustacea which are sold live, removal from the water of the animals that remain at the establishment(s) after the measures in points (a) to (c) have been completed.

2. The competent authority may order, based on duly justified grounds, the slaughtering for human consumption, or in the case of molluscs or crustacea which are sold live, removal from the water of:
 - (a) all animals from listed species for the relevant disease in the infected establishment(s), without testing these animals;
 - (b) suspected animals which have an epidemiological link with a confirmed case.
3. Slaughtering for human consumption or removal from the water of the animals referred to in paragraph 1 shall be carried out under official supervision either in the infected establishment(s) with subsequent processing in a disease control aquatic food establishment, or in a disease control aquatic food establishment, as appropriate.
4. The competent authority shall extend the measures laid down in this Article to aquaculture animals of additional animal populations when it is necessary to control the disease.
5. The competent authority may order the killing and destruction of some or all the animals referred to in paragraph 1 and animals of non-listed species in the infected establishment(s) instead of their slaughter for human consumption.
6. All animal by-products from animals that are slaughtered or killed in compliance with this Article shall be processed or disposed of as Category 1 or Category 2 material in accordance with Articles 12 or 13 of Regulation (EC) No 1069/2009.

Article 63

Cleaning and disinfection

1. The competent authority shall for all infected establishments order the cleaning and disinfection of the following structures and items prior to repopulation:
 - (a) the establishments, in so far as this is technically possible, after the removal of the animals referred to in Article 62(1) and of all feed that may have been contaminated;
 - (b) any husbandry related equipment including but not limited to feeding, grading, treatment and vaccination equipment, and workboats;
 - (c) any production related equipment including but not limited to cages, netting, trestles, bags and longlines;
 - (d) any protective clothing or safety equipment used by operators and visitors;
 - (e) all means of transport including tanks and other equipment used to move infected animals or personnel who have been in contact with infected animals.
2. The competent authority shall approve the protocol for the cleaning and disinfection.
3. The competent authority shall supervise the cleaning and disinfection and shall not restore or grant again disease-free status to the establishments until it considers that the cleaning and disinfection has been completed.

Article 64

Fallowing

1. The competent authority shall order the fallowing of all infected establishments. The fallowing shall be carried out following completion of the cleaning and disinfection process laid down in Article 63.
2. The duration of the fallowing shall be appropriate to the relevant pathogen and to the type of production system used in the infected establishments. Certain fallowing periods are laid down in Part II of Annex VI, specifically in:
 - (a) point 1(c) of Section 3 of Chapter 1 for VHS and IHN;
 - (b) point 1(c) of Section 3 of Chapter 2 for infection with HPR-deleted ISAV;
 - (c) point 1(c) of Section 3 of Chapter 3 for infection with *Marteilia refringens*;

- (d) point 1(c) of Section 3 of Chapter 4 for infection with *Bonamia exitiosa*;
- (e) point 1(c) of Section 3 of Chapter 5 for infection with *Bonamia ostreae*;
- (f) point 1(c) of Section 3 of Chapter 6 for infection with WSSV.

3. The competent authority shall order synchronous following of the infected establishments within the protection zone or where no protection zone has been established, within the restricted zone. Synchronous following may also be extended to other establishments based on risk assessment. The duration of the synchronous following and the extent of the area within which such following shall take place are laid down in Part II of Annex VI, specifically in:

- (a) point 1 of Section 3 of Chapter 1 for VHS and IHN;
- (b) point 1 of Section 3 of Chapter 2 for infection with HPR-deleted ISAV;
- (c) point 1 of Section 3 of Chapter 3 for infection with *Marteilia refringens*;
- (d) point 1 of Section 3 of Chapter 4 for infection with *Bonamia exitiosa*;
- (e) point 1 of Section 3 of Chapter 5 for infection with *Bonamia ostreae*;
- (f) point 1 of Section 3 of Chapter 6 for infection with WSSV.

Article 65

Risk mitigating measures to prevent reinfection

Before or upon removal of the disease control measures, the competent authority shall order proportionate risk mitigating measures to prevent the reinfection of the establishment taking into account relevant risk factors as indicated by the results of the epidemiological enquiry. These measures shall at least take account of:

- (a) persistence of the disease agent in the environment or in wild animals;
- (b) biosecurity measures that are adapted to the specificities of the establishment.

CHAPTER 4

Disease-free status

Section 1

Approval of disease-free status of Member States and zones

Article 66

Criteria for the granting of disease-free status

Disease-free status may only be granted to Member States or zones thereof when the following general and specific criteria are complied with:

- (a) general criteria:
 - (i) the territorial scope complies with the requirements laid down in Articles 13 or 47 as relevant;
 - (ii) the surveillance for the disease complies with the requirements laid down in paragraph 1 or 2 of Article 3 as relevant;
 - (iii) operators comply with obligations as regards biosecurity measures as laid down in Article 10 of Regulation (EU) 2016/429;
 - (iv) the disease control measures relevant to the disease in the event of a suspicion or confirmation of the disease comply with the requirements laid down for:
 - infection with *Brucella abortus*, *B. melitensis* and *B. suis*, infection with MTBC, EBL, IBR/IPV, infection with ADV and BVD in Articles 21 to 31;

- infection with RABV in Articles 35 and 36;
 - infection with BTV in Articles 41 and 42;
 - VHS, IHN, infection with HPR-deleted ISAV, infection with *Marteilia refringens*, infection with *Bonamia exitiosa*, infection with *Bonamia ostreae* and infection with WSSV in Articles 55 to 65;
- (v) the establishments were registered or approved, as relevant to the type of establishment;
- (vi) identification of animals from the targeted animal population and traceability of germinal products were ensured, as relevant for the type of animal;
- (vii) when moved, the animals from the targeted animal population or products thereof complied with the animal health requirements for the movement within the Union and entry into the Union of those animals and products thereof;
- (b) specific criteria for granting disease-free status based on Articles 67 to 71.

Article 67

Disease-free status based on the absence of listed species

1. The criteria to recognise the disease-free status of a Member State or of a zone because of the absence of the listed species for that disease are as follows:
- (a) the general criteria laid down in point (a)(i) and (a)(ii) of Article 66 have been fulfilled for an eligibility period of at least 5 years and the disease was not detected; and
 - (b) the listed species relevant to the disease in question are absent from kept and wild animal populations.
2. The Member State shall provide documentary evidence to substantiate the fulfilment of the criteria in paragraph 1. The documentary evidence shall demonstrate the sustainability of disease-free status considering that:
- (a) the likelihood of the presence of animals from listed species in the Member State's territory or a zone thereof was assessed and was found to be negligible; and
 - (b) the likelihood of introduction of animals from listed species into the Member State's territory or a zone thereof was found to be negligible.

Article 68

Disease-free status based on the disease agent's incapacity to survive

1. The criteria to recognise the disease-free status of a Member State or of a zone because of the disease agent's incapacity to survive are as follows:
- (a) the general criteria laid down in points (a)(i) and (a)(ii) of Article 66 have been fulfilled for an eligibility period of at least 5 years and the disease was not detected;
 - (b) the disease has never been reported or, if reported, it has been demonstrated that the disease agent did not survive;
 - (c) the value of at least one critical environmental parameter that is not compatible with the survival of the disease agent is reached;
 - (d) the disease agent is exposed to that critical environmental parameter for a period of time that is sufficient to destroy it.
2. The Member State shall provide the following evidence to substantiate the fulfilment of the criteria in paragraph 1:
- (a) with respect to the fulfilment of the criteria set out in points (a) and (b) of paragraph 1, documentary evidence;
 - (b) with respect to the fulfilment of the criteria set out in points (c) and (d) of paragraph 1, scientific evidence.

*Article 69***Disease-free status of terrestrial animals based on the incapacity to survive of listed vectors for listed diseases of terrestrial animals**

1. The criteria to recognise the disease-free status of a Member State or of a zone because of the incapacity to survive of listed vectors for that listed disease are as follows:
 - (a) the general criteria laid down in points (a)(i) and (a)(ii) of Article 66 have been fulfilled for an eligibility period of at least 5 years and the disease was not detected;
 - (b) the disease has never been reported, or, if reported, it has been demonstrated that the disease agent has not been transmitted;
 - (c) the transmission of the disease agent is entirely dependent on the presence of listed vectors and no other mode of natural transmission is known to occur;
 - (d) the listed vectors are not naturally present in the Member State or zones thereof;
 - (e) the accidental or intentional introduction of listed vectors is unlikely to have occurred in the past or to occur in the future;
 - (f) the value of at least one critical environmental parameter that is not compatible with the survival of the listed vectors is reached;
 - (g) the listed vectors are exposed to that critical environmental parameter for a period of time that is sufficient to destroy it.
2. The Member State shall provide the following evidence to substantiate the fulfilment of the criteria in paragraph 1:
 - (a) with respect to the fulfilment of the criteria set out in points (a) and (b) of paragraph 1, documentary evidence;
 - (b) with respect to the fulfilment of the criteria set out in points (c) to (g) of paragraph 1, scientific evidence.

If the disease has occurred, the Member State shall provide documentary evidence that surveillance has demonstrated with a 95 % level of confidence that the prevalence rate of the disease was lower than 1 %.

*Article 70***Disease-free status based on historical and surveillance data**

1. The criteria to recognise the disease-free status of a Member State or a zone thereof based on historical and surveillance data are as follows:
 - (a) the disease has never been reported in the Member State or in the zone thereof or it has been eradicated in the Member State or the zone thereof and not reported for at least 25 years;
 - (b) the disease has been reported in the past 25 years, it has been eradicated from the Member State or zone thereof and the disease specific requirements referred to in Article 72 are complied with.
2. A Member State wishing to obtain the approval of disease-free status for its entire territory or for a zone thereof on the basis of the provisions set out in point (a) of paragraph 1 shall have implemented the following measures for an eligibility period of at least 10 years:
 - (a) disease surveillance of kept animals of listed species;
 - (b) prevention to control the introduction of the disease agent;
 - (c) ban on vaccination against the disease unless it is compliant with the disease specific requirements referred to in Article 72;
 - (d) disease surveillance substantiating the fact that the disease is not known to be established in wild animals from listed species within the Member State or zone.

3. By way of derogation from point (b) of paragraph 1 the Commission may, for a period of two years following the entry of application of this Regulation, grant disease-free status to Member States or zones as regards:

- (a) infection with RABV, if it was notifiable in accordance with Article 8 of Directive 64/432/EEC and, when necessary monitoring was implemented in accordance with Article 4 of Directive 2003/99/EC ⁽²³⁾ of the European Parliament and of the Council, and no case was reported in listed animals species for the past two years;
- (b) infection with BTV, if all restricted zones have been lifted in accordance with Article 6 of Regulation (EC) No 1266/2007 before the date of application of this Regulation.

4. The criteria provided for in paragraph 1 to obtain disease-free status shall only apply:

- (a) in a new Member State, during a maximum period of two years following its accession to the Union; or
- (b) for a maximum period of two years following the date of application of the implementing acts adopted in accordance with Article 9(2) of Regulation (EU) 2016/429 that categorise for the first time the relevant disease as a category B or C disease.

5. By way of derogation from paragraph 4, the granting of disease-free status based on historical and surveillance data shall not be subject to the maximum two-year period for the following statuses:

- (a) status free from infestation with *Varroa* spp.;
- (b) status free from infection with Newcastle disease virus without vaccination.

6. By way of derogation from point (b) of paragraph 4, the granting of disease-free status based on historical and surveillance data shall not apply to the following diseases:

- (a) infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
- (b) infection with MTBC;
- (c) EBL;
- (d) IBR/IPV;
- (e) infection with ADV;
- (f) VHS;
- (g) IHN;
- (h) infection with HPR-deleted ISAV;
- (i) infection with *Bonamia ostreae*;
- (j) infection with *Marteilia refringens*.

Article 71

Disease-free status based on eradication programmes

1. The criteria to recognise the disease-free status of a Member State or a zone based on eradication programmes are as follows:

- (a) the competent authority has been running an approved eradication programme as referred to in Articles 12 or 46; and
- (b) the competent authority has completed the eradication programme and submitted to the Commission an application for recognition of disease-free status that demonstrates that the disease specific requirements laid down in Article 72 are complied with.

2. By way of derogation from paragraph 1, in the case of aquatic animals where a zone covers less than 75 % of the territory of a Member State and is not shared with another Member State or third country, disease-free status may be achieved in accordance with Article 83.

⁽²³⁾ Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).

Article 72

Disease specific requirements for disease-free status

Disease specific requirements for the granting of disease-free status to a Member State or to a zone are provided in:

- (a) Section 1 of Chapter 3 of Part I of Annex IV for status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* in kept bovine animals and Section 1 of Chapter 4 of Part I of Annex IV for status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* in kept ovine and caprine animals;
- (b) Section 1 of Chapter 2 of Part II of Annex IV for status free from infection with MTBC;
- (c) Section 1 of Chapter 2 of Part III of Annex IV for status free from EBL;
- (d) Section 1 of Chapter 2 of Part IV of Annex IV for status free from IBR/IPV;
- (e) Section 1 of Chapter 2 of Part V of Annex IV for status free from infection with ADV;
- (f) Section 1 of Chapter 2 of Part VI of Annex IV for status free from BVD;
- (g) Section 1 of Chapter 2 of Part I of Annex V for status free from infection with RABV;
- (h) Section 1 of Chapter 4 of Part II of Annex V for status free from infection with BTV;
- (i) Section 1 of Part III of Annex V for status free from infestation with *Varroa* spp.;
- (j) Section 1 of part IV of Annex V for status free from infection with Newcastle disease virus without vaccination;
- (k) Section 2 of Chapter 1 of Part II of Annex VI for status free from VHS;
- (l) Section 2 of Chapter 1 of Part II of Annex VI for status free from IHN;
- (m) Section 2 of Chapter 2 of Part II of Annex VI for status free from infection with HPR-deleted ISAV;
- (n) Section 2 of Chapter 3 of Part II of Annex VI for status free from infection with *Marteilia refringens*;
- (o) Section 2 of Chapter 4 of Part II of Annex VI for status free from infection with *Bonamia exitiosa*;
- (p) Section 2 of Chapter 5 of Part II of Annex VI for status free from infection with *Bonamia ostreae*;
- (q) Section 2 of Chapter 6 of Part II of Annex VI for status free from infection with WSSV.

Section 2

Approval of disease-free status for compartments keeping aquaculture animals

Article 73

Criteria for the granting of disease-free status to compartments keeping aquaculture animals

1. Disease-free status may only be granted to a compartment keeping aquaculture animals when the following general and specific criteria are complied with:

- (a) general criteria:
 - (i) the territorial scope complies with point (c) of Article 47(2);
 - (ii) the surveillance for the disease complies with the requirements laid down in Articles 3(2), 4 and 6 to 9;
 - (iii) operators comply with obligations as regards biosecurity measures as laid down in Article 10 of Regulation (EU) 2016/429;
 - (iv) compliance with the disease control measures relevant to the disease in the event of a suspicion or confirmation;
 - (v) the establishments of which the compartment is comprised are approved;

- (vi) traceability of the animals from the targeted animal population was ensured;
 - (vii) when moved, the animals from the targeted animal population or products thereof complied with the animal health requirements for movement within the Union or for entry into the Union of those animals and products thereof;
- (b) specific criteria for granting disease-free status based on the provisions of Articles 74 to 77.
2. The disease-free status referred to in paragraph 1 may be granted to:
- (a) compartments which are independent of the health status of the surrounding natural waters; and
 - (b) compartments which are dependent on the health status of the surrounding natural waters but where conditions exist which create an effective disease specific separation between the compartment and other aquatic animal populations which may be infected.
3. In the case of the dependent compartments referred to in point (b) of paragraph 2, the competent authority shall:
- (a) assess at least the following epidemiological factors:
 - (i) geographical location of each establishment in the compartment and the nature of the water supply;
 - (ii) health status of other aquaculture establishments in the water system;
 - (iii) the location of the establishments referred to in point (ii) and their distance from the dependent compartment;
 - (iv) production volume of the establishments referred to in point (ii) as well as their method of production and the source of their animals;
 - (v) presence and abundance of wild aquatic animals from relevant listed species in the water system and their health status;
 - (vi) details of whether the species referred to in point (v) are sedentary or migratory;
 - (vii) possibility of the wild aquatic animals referred to in point (v) entering the compartment;
 - (viii) general biosecurity measures in the compartment;
 - (ix) general hydrological conditions in the water system;
 - (b) classify all establishments in the compartment as high risk, in compliance with Chapter 1 of Part I of Annex VI;
 - (c) impose whatever measures are found to be necessary to prevent the introduction of disease.
4. When a disease-free declaration for a dependent compartment is made to the Commission in accordance with Article 83, the competent authority shall provide the assessment referred to in point (a) of paragraph 3 and details of any measure which were put in place to prevent the introduction of the disease into the compartment.

The competent authority shall communicate to the Commission without delay any subsequent changes to the epidemiological factors set out in point (a) of paragraph 3 and measures taken to mitigate their impact.

Article 74

Disease-free status based on the absence of listed species

1. The criteria to recognise the disease-free status of a compartment keeping aquaculture animals because of the absence of the listed species for that disease are as follows:
- (a) the general criteria laid down in points (a)(i) and (a)(ii) of Article 73(1) have been fulfilled for an eligibility period of at least 5 years and the disease was not detected; and
 - (b) the listed species relevant to the disease in question are absent from kept and wild animal populations.

2. The Member State shall provide documentary evidence to substantiate the fulfilment of the criteria in paragraph 1. The documentary evidence shall demonstrate the sustainability of the disease-free status considering that:

- (a) the likelihood of the presence of animals from listed species in the compartment was assessed and found to be negligible; and
- (b) the likelihood of introduction of animals from listed species into the compartment was found to be negligible.

Article 75

Disease-free status based on the disease agent's incapacity to survive

1. The criteria to recognise the disease-free status of a compartment keeping aquaculture animals because of the disease agent's incapacity to survive are as follows:

- (a) the general criteria laid down in points (a)(i) and (a)(ii) of Article 73(1) have been fulfilled for an eligibility period of at least 5 years and the disease was not detected;
- (b) the disease has never been reported or if reported, it has been demonstrated that the disease agent did not survive;
- (c) the value of at least one critical environmental parameter that is not compatible with the survival of the disease agent is reached;
- (d) the disease agent is exposed to that critical parameter during a sufficient period of time to destroy it.

2. The Member State shall provide the following evidence to substantiate the fulfilment of the criteria in paragraph 1:

- (a) with respect to the fulfilment of the criteria set out in points (a) and (b) of paragraph 1, documentary evidence;
- (b) with respect to the fulfilment of the criteria set out in points (c) and (d) of paragraph 1, scientific evidence.

Article 76

Disease-free status based on historical and surveillance data

1. The criteria to recognise the disease-free status of a compartment keeping aquaculture animals based on historical and surveillance data are as follows:

- (a) the disease has never been reported in the compartment or it has been eradicated in the compartment and not reported for at least 25 years;
- (b) the disease has been reported in the past 25 years, it has been eradicated from the compartment and the disease specific requirements referred to in Article 78 are complied with.

2. A Member State wishing to obtain the approval of disease-free status for the compartment on the basis of the provisions set out in point (a) of paragraph 1 shall have implemented the following measures for an eligibility period of at least 10 years:

- (a) disease surveillance of kept animals of listed species;
- (b) prevention to control the introduction of the disease agent;
- (c) ban on vaccination against the disease unless it is compliant with the disease specific requirements referred to in Article 78;
- (d) disease surveillance substantiating the fact that the disease is not known to be established in wild animals from listed species within the compartment.

3. The criteria provided for in paragraph 1 shall only apply:

- (a) in a new Member State, during a maximum period of two years following its accession to the Union; or
- (b) for a maximum period of two years following the date of application of the implementing acts adopted in accordance with Article 9(2) of Regulation (EU) 2016/429 that categorise for the first time the relevant disease as a category B or C disease.

4. By way of derogation from point (b) of paragraph 3, the granting of disease-free status based on historical and surveillance data shall not apply to the following diseases:

- (a) VHS;
- (b) IHN;
- (c) infection with HPR-deleted ISAV;
- (d) infection with *Bonamia ostreae*;
- (e) infection with *Marteilia refringens*.

Article 77

Disease-free status based on eradication programmes

1. The criteria to recognise the disease-free status of a compartment keeping aquaculture animals based on eradication programmes are:

- (a) the competent authority has been running an approved eradication programme as referred to in Article 46; and
- (b) the competent authority has completed the eradication programme and submitted to the Commission the final report that demonstrates that the disease specific requirements laid down in Article 78 are complied with.

2. By way of derogation from paragraph 1, where a compartment covers less than 75 % of the territory of a Member State and the water catchment supplying the compartment is not shared with another Member State or third country, disease-free status may be achieved in accordance with Article 83.

Article 78

Disease specific requirements for disease-free status

Disease-specific requirements for the granting of disease-free status to a compartment keeping aquaculture animals are provided in:

- (a) Section 2 of Chapter 1 of Part II of Annex VI for status free from VHS;
- (b) Section 2 of Chapter 1 of Part II of Annex VI for status free from IHN;
- (c) Section 2 of Chapter 2 of Part II of Annex VI for status free from infection with HPR-deleted ISAV;
- (d) Section 2 of Chapter 3 of Part II of Annex VI for status free from infection with *Marteilia refringens*;
- (e) Section 2 of Chapter 4 of Part II of Annex VI for status free from infection with *Bonamia exitiosa*;
- (f) Section 2 of Chapter 5 of Part II of Annex VI for status free from infection with *Bonamia ostreae*;
- (g) Section 2 of Chapter 6 of Part II of Annex VI for status free from infection with WSSV.

Article 79

Specific requirements for compartments which are independent of the health status of the surrounding natural waters

1. In addition to the general criteria for granting disease-free status to compartments keeping aquaculture animals as set out in Article 73(1), a compartment which comprises one or more individual establishments where the health status regarding a specific disease is independent of the health status of the surrounding natural waters, may obtain disease-free status if it complies with paragraphs 2 to 6.

2. An independent compartment may comprise:

- (a) an individual establishment which is considered a single epidemiological unit, as it is not influenced by the animal health status of the surrounding natural waters; or

- (b) more than one establishment where each establishment in the compartment complies with the criteria laid down in point (a) of this paragraph and paragraphs 3 to 6 but due to extensive movements of animals between establishments, they are considered as a single epidemiological unit, provided that all establishments operate a common biosecurity system.
3. An independent compartment shall be supplied with water:
- (a) through a water treatment plant which inactivates the relevant disease agent; or
 - (b) directly from a well, a borehole or a spring.

Where such water supply originates from a source outside the establishment, the water shall be supplied directly to the establishment, and be channelled to the establishment by means which afford appropriate protection from infection.

4. There shall be natural or artificial barriers that prevent aquatic animals from entering each establishment in the compartment from the surrounding natural waters.
5. The compartment shall, where appropriate, be protected against flooding and infiltration of water from the surrounding natural waters.
6. The compartment shall comply with the disease-specific requirements referred to in Article 78.

Article 80

Special provisions for compartments which comprise individual establishments which commence or recommence aquaculture activities and where the health status regarding a specific disease is independent of the health status of the surrounding natural waters

1. A new establishment which is to commence aquaculture activities is considered to be disease-free when:
- (a) it complies with point (a) of paragraph 2 and paragraphs 3 to 5 of Article 79; and
 - (b) it commences aquaculture activities with aquaculture animals from a disease-free Member State, zone or compartment.
2. An establishment which recommences aquaculture activities after a break and complies with paragraph 1 is considered to be disease-free without the surveillance referred to in point (a)(ii) of Article 73(1) provided:
- (a) the health history of the establishment is known to the competent authority and there has been no confirmation in the establishment of a category B or category C disease;
 - (b) the establishment is cleaned, disinfected and fallowed, if necessary, prior to repopulation.
3. An establishment which recommences its activities after the confirmation of a category B or category C disease is considered to be disease-free from the confirmed disease, provided:
- (a) a representative sample of the animals which have been repopulated into the establishment from a disease-free Member State, zone or compartment following cleaning, disinfection and fallowing is tested for the relevant disease no sooner than 3 months and no later than 12 months after they have been exposed to conditions including water temperature, which are conducive to clinical expression of the disease;
 - (b) the sampling and diagnostic tests set out in the relevant Chapter of Part II of Annex VI are used and samples are taken from the number of animals that will ensure the detection of the relevant disease with a 95 % confidence if the targeted prevalence is 2 %;
 - (c) results of the testing described in point (b) are negative.

Section 3

Maintenance, suspension and withdrawal of disease-free status

Article 81

Specific criteria on surveillance and biosecurity measures for the maintenance of disease-free status

1. The Member States, zones or compartments thereof may maintain disease-free status only if, in addition to the criteria laid down in points (a) and (c) of Article 41(1) of Regulation (EU) 2016/429, they comply with:

- (a) the undertaking of sufficient surveillance activities to enable the early detection of the disease and the demonstration of disease-free status;
- (b) the biosecurity measures ordered by the competent authority based on the risks identified to prevent the introduction of the disease;
- (c) the operational rules as referred to in points (a)(v), a(vi) and a(vii) of Article 66 or points (a)(v), a(vi) and a(vii) of Article 73(1).

2. In the case of aquatic animals, when a Member State is declared free from one or more of the listed diseases, it may discontinue targeted surveillance as referred to in points (k) to (q) of paragraph 3 and maintain its disease-free status provided that the risk of introduction of the relevant disease has been assessed and conditions conducive to clinical expression of the disease in question exist.

In disease-free zones or compartments in Member States which are not declared disease-free, or in all cases where conditions conducive to clinical expression of the disease in question do not exist, targeted surveillance shall be continued as referred to in points (k) to (q) of paragraph 3.

3. The disease specific requirements as regards surveillance and biosecurity measures are provided in:

- (a) Section 2 of Chapter 3 of Part I of Annex IV for status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals or Section 2 of Chapter 4 of Part I of Annex IV for status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept ovine and caprine animals;
- (b) Section 2 of Chapter 2 of Part II of Annex IV for status free from infection with MTBC;
- (c) Section 2 of Chapter 2 of Part III of Annex IV for status free from EBL;
- (d) Section 2 of Chapter 2 of Part IV of Annex IV for status free from IBR/IPV;
- (e) Section 2 of Chapter 2 of Part V of Annex IV for status free from infection with ADV;
- (f) Section 2 of Chapter 2 of Part VI of Annex IV for status free from BVD;
- (g) Section 2 of Chapter 2 of Part I of Annex V for status free from infection with RABV;
- (h) Section 2 of Chapter 4 of Part II of Annex V for status free from infection with BTV;
- (i) Section 2 of Part III of Annex V for status free from infestation with *Varroa* spp;
- (j) Section 2 of Part IV of Annex V for status free from infection with Newcastle disease virus without vaccination;
- (k) Section 4 of Chapter 1 of Part II of Annex VI for status free from VHS;
- (l) Section 4 of Chapter 1 of Part II of Annex VI for status free from IHN;
- (m) Section 4 of Chapter 2 of Part II of Annex VI for status free from infection with HPR-deleted ISAV;
- (n) Section 4 of Chapter 3 of Part II of Annex VI for status free from infection with *Marteilia refringens*;

- (o) Section 4 of Chapter 4 of Part II of Annex VI for status free from infection with *Bonamia exitiosa*;
- (p) Section 4 of Chapter 5 of Part II of Annex VI for status free from infection with *Bonamia ostreae*;
- (q) Section 4 of Chapter 6 of Part II of Annex VI for status free from infection with WSSV.

Article 82

Suspension, withdrawal and restoration of disease-free status

1. If the disease has been confirmed and therefore the conditions for maintaining the disease-free status of a Member State, a zone or compartment thereof are not fulfilled, the competent authority shall:
 - (a) apply without delay the relevant disease control measures;
 - (b) conduct specific surveillance to assess the extent of the outbreak;
 - (c) order any necessary risk mitigating measures.
2. If the disease has not been confirmed, but there has been a breach of one of the conditions for maintaining the disease-free status of a Member State, a zone or compartment thereof, the competent authority shall take the appropriate corrective measures and assess the risk that the health situation has changed.
3. The competent authority may where necessary, as a transitional measure, suspend the disease-free status of the Member State, a zone or compartment thereof rather than the Commission withdrawing the disease-free status. During that suspension, the competent authority shall:
 - (a) adopt all necessary prevention, surveillance and control measures to manage the situation;
 - (b) inform without delay the Commission and the other Member States about the measures adopted; and
 - (c) inform regularly the Commission and the other Member States about the evolution of the situation, of its position as regards the restoration of the disease-free status, the prolongation of its suspension or its withdrawal by the Commission.
4. Subject to compliance with the provisions of paragraph 3 the competent authority may restore the disease-free status of the Member State, zone or compartment thereof by lifting the suspension.

Section 4

Derogations from approval by the Commission

Article 83

Derogations from approval by the Commission for certain disease-free statuses for aquatic animal diseases

1. By way of derogation from the requirements to obtain approval by the Commission for disease-free status, laid down in Articles 36(4) and 37(4) of Regulation (EU) 2016/429, for aquatic animal diseases of zones or compartments, such approval for zones or compartments which cover less than 75 % of the territory of a Member State, and where the water catchment supplying the zone or compartment is not shared with another Member State or third country, shall be gained in accordance with the following procedure:
 - (a) a Member State makes a provisional declaration of freedom for the zone or compartment which fulfils the requirements for disease-free status as set out in this Regulation;
 - (b) this provisional declaration is published electronically by the Member State and the Commission and Member States are alerted to the publication;
 - (c) 60 days after publication, the provisional declaration shall take effect and the zone or compartment referred to in this paragraph shall achieve the disease-free status.

2. Within the 60-day period referred to in point (c) of paragraph 1, the Commission or Member States may seek clarification or additional information in relation to the supporting evidence provided by the Member State making the provisional declaration.

3. Where written comments are made by at least one Member State, or the Commission, within the period referred to in point (c) of paragraph 1 indicating concerns relating to the evidence which supports the declaration, the Commission, the Member State which made the declaration and where relevant, the Member State which has sought clarification or additional information, shall together examine the submitted evidence in order to resolve the concerns.

In such cases, the period referred to in point (c) of paragraph 1 is prolonged automatically for 60 days from the date on which the first concerns were raised. There shall be no further prolongation of this period

4. Where the process referred to in paragraph 3 fails, the provisions laid down in Articles 36(4) and 37(4) of Regulation (EU) 2016/429 shall apply.

PART III

TRANSITIONAL AND FINAL PROVISIONS

Article 84

Transitional provisions concerning existing disease-free status

1. The Member States and zones thereof with an approved disease-free status before the date of application of this Regulation shall be deemed to have an approved disease-free status in accordance with this Regulation for the following statuses:

- (a) free from infection with *Brucella abortus*, *B. melitensis*, *B. suis*:
 - (i) in bovine animal populations when the brucellosis-free status was granted in accordance with Directive 64/432/EEC;
 - (ii) in ovine and caprine animal populations, when the brucellosis-free (*B. melitensis*-free) status was granted in accordance with Directive 91/68/EEC;
- (b) free from infection with MTBC, when the tuberculosis-free status was granted in accordance with Directive 64/432/EEC;
- (c) free from EBL, when EBL-free status was granted in accordance with Directive 64/432/EEC;
- (d) free from IBR/IPV, when IBR-free status was granted in accordance with Directive 64/432/EEC;
- (e) free from infection with ADV, when Aujeszky's disease-free-status was granted in accordance with Directive 64/432/EEC;
- (f) free from infestation with *Varroa* spp., when varroasis-free status was granted in accordance with Council Directive 92/65/EEC ⁽²⁴⁾;
- (g) free from infection with Newcastle disease virus without vaccination when Newcastle disease non-vaccination status was granted in accordance with Directive 2009/158/EC;
- (h) free from VHS, when VHS-free status was granted in accordance with Council Directive 2006/88/EC ⁽²⁵⁾;
- (i) free from IHN, when IHN-free status was granted in accordance with Directive 2006/88/EC;
- (j) free from infection with HPR-deleted ISAV, when infection with HPR-deleted ISAV-free status was granted in accordance with Directive 2006/88/EC;

⁽²⁴⁾ Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

⁽²⁵⁾ Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

- (k) free from infection with *Bonamia ostreae*, when infection with *Bonamia ostreae*-free status was granted in accordance with Directive 2006/88/EC;
 - (l) free from infection with *Marteilia refringens*, when infection with *Marteilia refringens*-free status was granted in accordance with Directive 2006/88/EC;
 - (m) free from infection with WSSV, when white spot disease--free status was granted in accordance with Directive 2006/88/EC.
2. The compartments in Member States with an approved disease-free status before the date of application of this Regulation shall be deemed to have an approved disease-free status in accordance with this Regulation for the following statuses:
- (a) free from highly pathogenic avian influenza, when the compartment has been approved with respect to avian influenza in accordance with Commission Regulation (EC) No 616/2009 ⁽²⁶⁾;
 - (b) free from VHS, when VHS-free status was granted in accordance with Directive 2006/88/EC;
 - (c) free from IHN, when IHN-free status was granted in accordance with Directive 2006/88/EC;
 - (d) free from infection with HPR-deleted ISAV, when infection with HPR-deleted ISAV-free status was granted in accordance with Directive 2006/88/EC;
 - (e) free from infection with *Bonamia ostreae*, when infection with *Bonamia ostreae*-free status was granted in accordance with Directive 2006/88/EC;
 - (f) free from infection with *Marteilia refringens*, when infection with *Marteilia refringens*-free status was granted in accordance with Directive 2006/88/EC;
 - (g) free from infection with WSSV, when white spot disease--free status was granted in accordance with Directive 2006/88/EC.
3. The Member States deemed to have an approved disease-free status in accordance with paragraph 1 or 2 shall ensure that the conditions of maintenance of the status conform with those laid down in this Regulation.

Article 85

Transitional provisions concerning existing eradication or surveillance programmes

1. The Member States and zones thereof with an approved eradication programme or an approved surveillance programme before the date of application of this Regulation shall be deemed to have an approved eradication programme in accordance with this Regulation for the following diseases for a period of six years from the date of application of this Regulation:
- (a) IBR/IPV, when the IBR/IPV eradication programme was approved in accordance with Directive 64/432/EEC;
 - (b) infection with ADV, when the Aujeszky's disease eradication programme was approved in accordance with Directive 64/432/EEC;
 - (c) VHS, when the VHS surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;
 - (d) IHN, when the IHN surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;
 - (e) infection with HPR-deleted ISAV, when the infection with HPR-deleted ISAV surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;
 - (f) infection with *Bonamia ostreae*, when the infection with *Bonamia ostreae* surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;
 - (g) infection with *Marteilia refringens*, when the infection with *Marteilia refringens* surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;

⁽²⁶⁾ Commission Regulation (EC) No 616/2009 of 13 July 2009 implementing Council Directive 2005/94/EC as regards the approval of poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments (OJ L 181, 14.7.2009, p. 16).

- (h) infection with WSSV, when the white spot disease eradication programme was approved in accordance with Directive 2006/88/EC.
2. The compartments in Member States with an approved eradication programme or an approved surveillance programme before the date of application of this Regulation shall be deemed to have an approved eradication programme in accordance with this Regulation for the following diseases for a period of six years from the date of application of this Regulation:
- (a) VHS, when the VHS surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;
 - (b) IHN, when the IHN surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;
 - (c) infection with HPR-deleted ISAV, when the infection with HPR-deleted ISAV surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;
 - (d) infection with *Bonamia ostreae*, when the infection with *Bonamia ostreae* surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;
 - (e) infection with *Marteilia refringens*, when the infection with *Marteilia refringens* surveillance or eradication programme was approved in accordance with Directive 2006/88/EC;
 - (f) infection with WSSV, when the white spot disease surveillance or eradication programme was approved in accordance with Directive 2006/88/EC.
3. The Member States deemed to have an approved eradication programme in accordance with paragraphs 1 or 2 shall ensure that the measures in the programme conform with those laid down for eradication programmes in this Regulation.

Article 86

Repeal

The following acts are repealed as from 21 April 2021:

- Decision 2000/428/EC;
- Decision 2002/106/EC;
- Decision 2003/422/EC;
- Decision 2006/437/EC;
- Regulation (EC) No 1266/2007;
- Decision 2008/896/EC;
- Implementing Decision (EU) 2015/1554.

References to those repealed acts shall be construed as references to this Regulation.

Article 87

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 December 2019.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

SPECIFIC CASE DEFINITION OF DISEASE OF TERRESTRIAL ANIMALS

Section 1

Highly pathogenic avian influenza (HPAI)

1. An animal or a group of animals must be considered, by the competent authority, as a suspected case of HPAI when it meets the criteria laid down in Article 9(1).
2. An animal or a group of animals must be considered, by the competent authority, as a confirmed case of HPAI when:
 - (a) the disease agent responsible for HPAI, excluding vaccine strains, has been isolated in a sample from an animal or from a group of animals;
 - (b) nucleic acid specific to the disease agent for HPAI, that is not a consequence of vaccination, has been identified in a sample from an animal or from a group of animals; or
 - (c) positive result to an indirect diagnostic method, that is not a consequence of vaccination, has been obtained in a sample from a kept animal or from a group of kept animals showing clinical signs consistent with the disease or epidemiologically linked to a suspected or confirmed case.
3. For the purposes of this case definition, the disease agent responsible for HPAI must be either
 - (a) an influenza A virus of H5 and H7 subtypes or any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1,2; or
 - (b) an influenza A virus of H5 and H7 subtypes with a sequence of multiple basic amino acids present at the cleavage site of the haemagglutinin molecule (HA0) that is similar to that observed for other HPAI isolates.

Section 2

Infection with low pathogenic avian influenza viruses (LPAIV)

1. An animal or a group of animals must be considered, by the competent authority, as a suspected case of infection with LPAIV when it meets the criteria laid down in Article 9(1).
2. An animal or a group of animals must be considered, by the competent authority, as a confirmed case of infection with LPAIV when:
 - (a) the disease agent responsible for infection with LPAIV, excluding vaccine strains, has been isolated in a sample from an animal or from a group of animals;
 - (b) nucleic acid specific to the disease agent for infection with LPAIV, that is not a consequence of vaccination, has been identified in a sample from an animal or from a group of animals; or
 - (c) positive result to an indirect diagnostic method, that is not a consequence of vaccination, has been obtained in a sample from a kept animal or from a group of kept animals showing clinical signs consistent with the disease or epidemiologically linked to a suspected or confirmed case.
3. For the purposes of this case definition, the disease agent of infection with LPAIV must be any influenza A virus of H5 and H7 subtypes that are not HPAI viruses.

Section 3

Infection with Newcastle disease virus (NDV)

1. An animal or a group of animals must be considered, by the competent authority, as a suspected case of infection with NDV when it meets the criteria laid down in Article 9(1).

2. An animal or a group of animals must be considered, by the competent authority, as a confirmed case of infection with NDV when:
 - (a) the disease agent responsible for infection with NDV, excluding vaccine strains, has been isolated in a sample from an animal or from a group of animals;
 - (b) nucleic acid specific to the disease agent for infection with NDV, that is not a consequence of vaccination, has been identified in a sample from an animal or from a group of animals; or
 - (c) positive result to an indirect diagnostic method, that is not a consequence of vaccination, has been obtained in a sample from a kept animal or from a group of kept animals showing clinical signs consistent with the disease or epidemiologically linked to a suspected or confirmed case.
 3. For the purposes of this case definition, the disease agent responsible for infection with NDV must be any avian paramyxovirus type 1 (APMV-1) (avian *Avulavirus* type 1) that either:
 - (a) has an intracerebral pathogenicity index (ICPI) of 0,7 or greater; or
 - (b) presents multiple basic amino acids at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test. In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene (113–116 corresponds to residues –4 to –1 from the cleavage site).
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ANNEX II

UNION SURVEILLANCE PROGRAMME

PART I

AVIAN INFLUENZA SURVEILLANCE IN POULTRY AND WILD BIRDS

Section 1

General approach and requirements

1. TERRITORIAL SCOPE

Surveillance in poultry and wild birds must be implemented in all Member States.

2. PERIOD OF APPLICATION

Until revoked.

3. GENERAL APPROACH

The surveillance system must address the objectives provided for in Section 2 and must be built on a comprehensive approach including different components of surveillance activities complementing each other in poultry and wild bird populations:

- Early detection systems as provided for in Sections 3 and 4;
- Risk-based surveillance as provided for in Sections 5 and 6.

Section 2

Objectives for surveillance in poultry and wild birds

1. Early detection of highly pathogenic avian influenza (HPAI) in poultry.
2. Early detection of HPAI in wild birds providing for:
 - (a) an early warning for possible HPAI introduction into poultry, in particular when viruses enter the Union through migratory movements of wild birds;
 - (b) information for the assessment of risks for virus spread following findings of HPAI in wild birds.
3. Detection of HPAI in poultry species which generally do not show significant clinical signs.
4. Detection of circulating low pathogenic avian influenza viruses (LPAIV) that may easily spread between poultry flocks in particular in areas with a high density of poultry establishments in view of their potential to mutate to HPAI in order to:
 - (a) identify clusters of infection with LPAIV; and
 - (b) monitor the risk of spread of LPAIV by movements of poultry and by fomites in certain production systems at risk.
5. Contribution to increased knowledge on HPAI and LPAIV posing a potential zoonotic risk.

Section 3

Early detection of HPAI in poultry

1. The early detection systems for of HPAI in poultry must be part of the general surveillance requirements as provided for in point (a) of Article 3(1) and must be implemented throughout the poultry sector.

2. The surveillance referred to in point 1 must at least include the early detection and investigation in establishments located in an area identified as being at heightened risk for HPAI introduction and spread, of:
 - (a) any change in normal production and health parameters such as mortality rate, feed and water intake and egg production; and
 - (b) any clinical sign or post-mortem lesion suggesting HPAI.
3. Regular testing of samples collected from dead and sick poultry in establishments located in an area identified as being at heightened risk for HPAI introduction and spread may also be relevant when an increased risk has been identified at national, EU or regional level due to outbreaks of HPAI in poultry and/or wild birds.

Section 4

Early detection of HPAI in wild birds

1. The early detection of HPAI in wild birds must be based on sampling and testing of birds that have been:
 - (a) found dead;
 - (b) found injured or sick;
 - (c) hunted with clinical signs.

This surveillance may need to be increased, when HPAI has been detected in wild birds, by monitoring systems using organised patrols for detecting and collecting dead and sick birds.

2. The design of this surveillance must be risk-based, taking into account at least relevant information on ornithology, virology, epidemiology and environmental matters.
3. The surveillance must apply to birds from targeted wild bird species, as provided for in Section 8. However, all suspected episodes of mortality in wild birds must be investigated to exclude HPAI.

In addition to targeted wild bird species, additional wild bird species may also be included when their specific epidemiological relevance on the Member State's territory has been assessed.

4. In addition, the surveillance may include, at priority locations and key sites in particular those where birds of targeted wild birds species are entering the Union during their migratory movements, at least from North-East and Eastern routes, the sampling and testing of:
 - (a) birds trapped;
 - (b) hunted healthy birds;
 - (c) sentinel birds.
5. Additional sources of information obtained from investigations of wild birds in the context of HPAI outbreaks in kept birds must be included in the results of the surveillance of HPAI in wild birds.

Section 5

Risk-based complementary surveillance for HPAI in poultry species which generally do not show significant clinical signs

1. The risk-based surveillance for infection with HPAI in poultry establishments keeping ducks, geese, poultry belonging to the species of *Anseriformes* for supplies of game or quails to be released into the wild must take into account at least the following risk factors:
 - (a) the historical and current epidemiological situation of the disease and its evolution over time in poultry and wild birds;
 - (b) the proximity of establishments to water bodies and other places where migratory birds, in particular water birds, may gather in higher numbers or have their stop-over places during their movements into and through the Union;

- (c) the period of increased movements of migratory wild birds of targeted species into and through the Union;
 - (d) the structure of poultry farming including the broader sector involved in the different production systems;
 - (e) the geographical location of the establishments in an area with a high density of poultry;
 - (f) the biosecurity practices on the establishments;
 - (g) the type and frequency of movements of poultry, products and vehicles transporting poultry and trade patterns; and
 - (h) the risk assessments and scientific advice in relation to the relevance of the spread of HPAI by wild birds.
2. Based on scientific justifications, additional risk factors than those listed in points (a) to (h) of point 1 may be included and factors that are not relevant for the specific situation of the Member State may be omitted.

Section 6

Risk-based surveillance in order to identify clusters of establishments infected with lpaiv and with continuous spread of LPAIV

1. The risk-based surveillance for the detection of circulating low pathogenic avian influenza viruses (LPAIV) that may easily spread between poultry flocks in particular in areas with a high density of poultry establishments, as referred to in point 4 of Section 2, must apply to poultry establishments for which the competent authority has assessed that clusters of infection with LPAIV have repeatedly occurred in the past or are deemed more likely to occur.
2. Such clusters are characterised by infection with LPAIV of groups of establishments related in time and geographical proximity.
3. The assessment for the selection of establishments for targeted surveillance must take into account the risk for lateral transmission of the virus due to the structure and complexity of the production system and functional connections between establishments, in particular when operating in areas with a high density of establishments.
4. In addition to the selection criteria for targeted surveillance of establishments referred to in point 3, the following risk factors must be taken into account at the establishment level:
 - (a) the kept species;
 - (b) the cycle and duration of production;
 - (c) presence of several poultry species;
 - (d) presence of multi-age poultry flocks;
 - (e) presence of long-lived poultry;
 - (f) practice of all-in all-out principle;
 - (g) length of waiting period between batches; and
 - (h) biosecurity practices and housing conditions.

Section 7

Targeted poultry populations

1. Early detection systems for infection with HPAI referred to in Section 3 must apply to all poultry populations.
2. Complementary surveillance for infection with HPAI referred to in Section 5 in poultry species that do generally not display significant signs when infected with HPAI must apply to:
 - (a) breeding ducks
 - (b) breeding geese;
 - (c) fattening ducks;
 - (d) fattening geese;

- (e) quails;
 - (f) poultry of species belonging to *Anseriformes* for supplies of game to be released into the wild.
3. In addition to the species and categories listed under point 2 the targeting of sampling and testing for infection with LPAIV referred to in Section 6 may apply to the following poultry species and production categories:
- (a) laying hens including those kept in free-range;
 - (b) breeding turkeys;
 - (c) fattening turkeys;
 - (d) the poultry of species belonging to *Galliformes* for supplies of game to be released into the wild.

Section 8

Targeted Wild bird populations

Targeted wild birds species, in particular migratory water birds have shown to be at higher risk of becoming infected with, and transmitting HPAI.

The list of 'wild bird targeted species' compiled and updated in the light of the most recent knowledge is available on the website of the EURL.

Section 9

Sampling and laboratory testing methods

1. The number of poultry establishments to be sampled and the number of poultry to be tested per establishment and, as appropriate, by epidemiological unit (e.g. poultry flock, shed, etc.) on the concerned establishment must be based on a statistically valid sampling method. This method may be that used for representative sampling; i.e. an estimated prevalence to be detected according to a pre-defined level of confidence determined by the competent authority.
2. Frequency and period for testing:
 - (a) the frequency for sampling and testing of poultry establishments must be determined based on the outcome of a risk assessment by the competent authority;
 - (b) the time period for sampling must coincide with seasonal production for each production category, but must not compromise the risk-based surveillance approach;
 - (c) when relevant, the time period for sampling must take into account the period of heightened risk as referred to in point 3 of Section 3. Samples must be subjected to laboratory testing by virological methods, when taken for:
 - (i) early detection of HPAI in poultry referred to in Section 3;
 - (ii) early detection of HPAI in wild birds referred to in Section 4;
 - (iii) complementary surveillance for HPAI in poultry species which generally do not show significant clinical signs of HPAI referred to in Section 5;
 - (iv) follow-up of sero-positive findings referred to in point 4(b).

For virological testing the prevalence and time window for detection of active infection must be taken into account.

3. Samples must be subjected to laboratory testing by serological methods, when taken for:
 - (a) complementary surveillance for HPAI in poultry species which generally do not show significant clinical signs of HPAI referred to in Section 5 supplementing virological testing, as appropriate;
 - (b) detection of clusters of LPAIV infected establishments referred to in Section 6. When for technical reasons or other duly justified reasons sampling for serology is not appropriate, virological testing must be performed.

ANNEX III

DIAGNOSTIC METHODS FOR THE GRANTING AND MAINTENANCE OF DISEASE-FREE STATUS FOR CERTAIN DISEASES OF TERRESTRIAL ANIMALS

Section 1

Infection with *Brucella abortus*, *B. melitensis* and *B. suis*

1. Serological tests
 - (a) tests for blood samples
 - (i) buffered *Brucella* antigen tests;
 - (ii) complement fixation test (CFT)
 - (iii) indirect enzyme-linked immunosorbent assay (I-ELISA)
 - (iv) fluorescence polarisation assay (FPA)
 - (v) competitive enzyme-linked immunosorbent assay (C-ELISA)
 - (b) tests for milk samples
 - (i) ring test (MRT)
 - (ii) I-ELISA

2. Brucellin skin test (BST)

For the testing as referred to in section 1 and 2 of Chapter 1 of Part I of Annex IV, Brucellin skin test (BST) shall only be used in ovine and caprine animals.

Section 2

Infection with *Mycobacterium tuberculosis* complex

1. Tuberculin skin tests
 - (a) the single intradermal tuberculin test (SITT)
 - (b) the comparative intradermal tuberculin test (CITT)
2. Gamma-interferon assay

Section 3

Enzootic bovine leukosis

1. Serological tests
 - (a) tests for blood samples
 - (i) agar gel immuno-diffusion test (AGID)
 - (ii) blocking enzyme-linked immunosorbent assay (B-ELISA)
 - (iii) I-ELISA
 - (b) tests for milk samples
 - (i) I-ELISA

Section 4

Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV)

	Methods:	Matrix:
non-vaccinated bovine animals	BoHV-1 I-ELISA ^(a)	individual serum samples ^(d)
		milk samples
	gB B-ELISA ^(b)	individual serum samples ^(d)
		individual meat juice samples
DIVA vaccinated bovine animals with a gE-deleted vaccine	gE B-ELISA ^(c)	individual serum samples
		individual meat juice samples

^(a) I-ELISA for the detection of antibodies against BoHV-1 whole virus. Pools of up to 50 milk samples (individual or bulk milk) may be used in tests for granting and up to 100 milk samples (individual or bulk milk) may be used in tests for the maintenance of the status free from IBR/IPV.

^(b) B-ELISA for the detection of antibodies against BoHV-1-gB protein. When referred to tests for the detection of antibodies against whole BoHV-1 in Part IV of Annex IV this method may also be used.

^(c) B-ELISA for the detection of antibodies against BoHV-1-gE protein. Individual milk samples may be used when testing to proof the maintenance of the status free from IBR/IPV. The samples may be pooled whereat the number of samples per pool may be chosen based on documented evidence that the test is under all circumstances of day to day laboratory work sensitive enough to detect one single positive sample in the pool.

^(d) When testing is carried out to proof the maintenance of the status free from IBR/IPV individually collected samples may be pooled. The number of samples per pool may be modulated based on documented evidence that the test system is under all circumstances of day to day laboratory work sensitive enough to detect one weak positive sample in the pool of the modulated size.

Section 5

Infection with Aujeszky's disease virus (ADV)

	Methods:	Matrix:
non-vaccinated porcine animals	ADV ELISA ^(a)	individual or up to 5 pooled serum (or plasma) samples
		individual or up to 5 pooled filter paper samples
		individual meat juice samples
DIVA vaccinated porcine animals with a gE-deleted vaccine	gE ELISA ^(b)	individual serum samples

^(a) ELISA for the detection of antibodies against whole ADV, ADV-gB protein or ADV-gD protein. For batch control of ADV-gB kits and ADV-gD kits or whole ADV kits, Community reference serum ADV 1, or sub-standards, must be scored positive at the dilution of 1:2. When referred to tests for the detection of whole ADV in Part V of Annex IV either of these tests may be used.

^(b) ELISA for the detection of antibodies against ADV-gE protein. For batch control, Community reference serum ADV 1, or sub-standards, must be scored positive at the dilution 1:8.

Section 6

Bovine viral diarrhoea (BVD)

1. Direct methods:
 - (a) Real-time reverse transcription PCR
 - (b) BVDV antigen detection ELISA
2. Serological tests:
 - (a) I-ELISA
 - (b) B-ELISA

ANNEX IV

DISEASE-SPECIFIC REQUIREMENTS FOR THE GRANTING, MAINTENANCE, SUSPENSION AND WITHDRAWAL OF THE DISEASE-FREE STATUS AT THE LEVEL OF ESTABLISHMENTS AND DISEASE-SPECIFIC REQUIREMENTS FOR THE GRANTING AND MAINTENANCE OF THE DISEASE-FREE STATUS AT THE LEVEL OF MEMBER STATES OR ZONES

PART I

INFECTION WITH *BRUCELLA ABORTUS*, *B. MELITENSIS* AND *B. SUIIS*

CHAPTER 1

Establishment free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination

Section 1

Granting of the status

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination may only be granted to an establishment keeping bovine, ovine or caprine animals if:
 - (a) during the past 12 months there has been no confirmed case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in bovine, ovine or caprine animals kept in the establishment;
 - (b) during the past 3 years none of the bovine, ovine or caprine animals in the establishment has been vaccinated against infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
 - (c) the entire bovine animals over 12 months of age and the entire ovine or caprine animals over 6 months of age present in the establishment at the time of sampling have tested negative to serological test, on two occasions as follows:
 - (i) the first test must be carried out on samples taken not earlier than 3 months after the removal of the last confirmed case and of the last animal that tested positive in an immunological test;
 - (ii) the second test must be carried out on samples taken not earlier than 6 months and not later than 12 months following the date of sampling referred to in point (i);
 - (d) animals showing clinical signs consistent with infection with *Brucella abortus*, *B. melitensis* and *B. suis*, such as abortions, have been subjected to investigations with negative results;
 - (e) since the beginning of the sampling referred to in point (c)(i) all bovine, ovine or caprine animals introduced into the establishment originate from establishments free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination, or free with vaccination and have not been vaccinated against infection with *Brucella abortus*, *B. melitensis* and *B. suis* during the past 3 years, and
 - (i) originate from a Member State or a zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* for the relevant animal population;
 - (ii) are entire bovine animals over 12 months of age or entire ovine or caprine animals over 6 months of age and must have tested negative in a serological test carried out on a sample taken:
 - during the 30 days prior to their introduction into the establishment; or
 - during the 30 days following their introduction provided they have been kept isolated during this period; or
 - (iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and
 - (f) since the beginning of the sampling referred to in point (c)(i), all germinal products of bovine, ovine or caprine origin introduced into or used in the establishment originate from:
 - (i) establishments free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination; or
 - (ii) approved germinal product establishments.

2. By way of derogation from point 1, the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination may be granted to an establishment if all bovine, ovine or caprine animals originate from establishments free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination, or free with vaccination and have not been vaccinated during the past 3 years, and:
 - (a) originate from a Member State or a zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* for the relevant animal population;
 - (b) are entire bovine animals over 12 months of age or entire ovine or caprine animals over 6 months of age and have tested negative in a serological test carried out on a sample taken:
 - during the 30 days prior to their introduction into the establishment; or
 - during the 30 days following their introduction into the establishment provided they have been kept isolated during this period; or
 - (c) are post-parturient females kept in isolation since their introduction into the establishment until they tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition.
3. By way of derogation from point 1, the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination may be granted to an establishment with the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination if:
 - (a) the requirements set out in points (a), (b), (d), (e) and (f) of point 1 are fulfilled; and
 - (b) the requirement set out in point (b)(i) of Section 2 is fulfilled.

Section 2

Maintenance of the status

The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination of an establishment keeping bovine, ovine or caprine animals may only be maintained if:

- (a) the requirements set out in points (a), (b), (d), (e) and (f) of point 1 of Section 1 continue to be fulfilled; and
- (b) serological testing is carried out with negative results on samples taken from:
 - (i) all entire bovine animals over 12 months of age and all entire ovine or caprine animals over 6 months of age at appropriate intervals of not more than 12 months determined by the competent authority, taking into account the type of production, the situation of the disease and the identified risk factors; or
 - (ii) entire bovine animals over 12 months of age and entire ovine or caprine animals over 6 months of age kept in establishments located in a Member State or in a zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis*, in accordance with a testing regime set up by the competent authority, taking into account the type of production and the identified risk factors.

Section 3

Suspension and restoring of the status

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination of an establishment keeping bovine, ovine or caprine animals must be suspended if:
 - (a) one or more of the requirements set out in Section 2 are not fulfilled; or
 - (b) a case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* is suspected in a bovine, ovine or caprine animal kept in the establishment.
2. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination may only be restored if:
 - (a) the requirements set out in points (b), (d), (e) and (f) of point 1 of Section 1 and in point (b) of Section 2 are fulfilled;
 - (b) the results of further investigations substantiate absence of infection with *Brucella abortus*, *B. melitensis* and *B. suis* and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination of an establishment keeping bovine, ovine or caprine animals must be withdrawn if:
 - (a) one or more of the requirements set out in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;
 - (b) the infection with *Brucella abortus*, *B. melitensis* and *B. suis* cannot be ruled out in accordance with point 2(b) of Section 3;
 - (c) a case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* has been confirmed in a bovine, ovine or caprine animal kept in the establishment; or
 - (d) it is justified by other needs to control infection with *Brucella abortus*, *B. melitensis*, *B. suis*.
2. If the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in Section 2 are fulfilled.
3. If the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination has been withdrawn in accordance with point 1(b), 1(c) or 1(d), it may only be regained if all confirmed cases and all animals that have tested non-negative have been removed and the remaining bovine, ovine or caprine animals fulfil the requirements set out in point 1(c) of Section 1.
4. By way of derogation from point 3, where the infection with *B. suis* biovar 2 was confirmed in a single bovine, ovine or caprine animal kept in the establishment, the status may be regained after negative testing was obtained on samples taken in accordance with the requirements set out in point 1(c)(i) of Section 1.

CHAPTER 2

Establishment free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination

Section 1

Granting of the status

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination may only be granted to an establishment keeping bovine, ovine or caprine animals if:
 - (a) the requirements set out in points (a), (c) and (d) of point 1 of Section 1 of Chapter 1 are fulfilled;
 - (b) since the beginning of the sampling referred to in point (c)(i) of point 1 of Section 1 of Chapter 1, all bovine, ovine, or caprine animals introduced into the establishment originate from establishments free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination or free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination and:
 - (i) originate from a Member State or a zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* for the relevant animal population;
 - (ii) are entire bovine animals over 12 months of age or entire ovine or caprine animals over 6 months of age and have tested negative in a serological test on a sample taken
 - during the 30 days prior to their introduction into the establishment; or
 - during the 30 days following their introduction into the establishment provided they have been kept isolated during this period; or
 - (iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and

- (c) since the beginning of the sampling referred to in point (c)(i) of point 1 of Section 1 of Chapter 1, all germinal products of bovine, ovine or caprine origin introduced into or used in the establishment originate from:
 - (i) establishments free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination or free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination; or
 - (ii) approved germinal product establishments.
- 2. By way of derogation from point 1, the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination may be granted to an establishment if all bovine, ovine or caprine animals originate from establishments free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination, or free with vaccination, and:
 - (a) originate from a Member State or a zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* for the relevant animal population;
 - (b) are entire bovine animals over 12 months of age or entire ovine or caprine animals over 6 months of age and have tested negative in a serological test carried out on a sample taken:
 - (i) during the 30 days prior to their introduction into the establishment; or
 - (ii) during the 30 days following their introduction into the establishment provided they have been kept isolated during this period; or
 - (c) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition.

Section 2

Maintenance of the status

The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination of an establishment keeping bovine, ovine or caprine animals may only be maintained if:

- (a) the requirements set out in points (b) and (c) of point 1 of Section 1 of this Chapter and in points (a) and (d) of point 1 of Section 1 of Chapter 1 continue to be fulfilled; and
- (b) serological testing is carried out with negative results on samples taken from all entire bovine animals over 12 months of age and all entire ovine or caprine animals over 6 months of age at appropriate intervals of not more than 12 months determined by the competent authority taking into account the type of production, the situation of the disease and the identified risk factors.

Section 3

Suspension and restoring of the status

- 1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination of an establishment keeping bovine, ovine or caprine animals must be suspended if:
 - (a) one or more of the requirements set out in Section 2 are not fulfilled; or
 - (b) a case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* is suspected in a bovine, ovine or caprine animal kept in the establishment.
- 2. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination may only be restored if:
 - (a) the requirements set out in point 1(d) of Section 1 of Chapter 1 and points (b) and (c) of point 1 of Section 1 and point (b) of Section 2 are fulfilled;
 - (b) the results of further investigations substantiate absence of infection with *Brucella abortus*, *B. melitensis* and *B. suis* and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination of an establishment keeping bovine, ovine or caprine animals must be withdrawn if:
 - (a) one or more of the requirements set out in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;
 - (b) the infection with *Brucella abortus*, *B. melitensis* and *B. suis* cannot be ruled out in accordance with point 2(b) of Section 3;
 - (c) a case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* has been confirmed in a bovine, ovine or caprine animal kept in the establishment; or
 - (d) it is justified by other needs to control infection with *Brucella abortus*, *B. melitensis*, *B. suis*.
2. If the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in Section 2 are fulfilled.
3. If the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination has been withdrawn in accordance with point 1(b), 1(c) or 1(d), it may only be regained if all confirmed cases and all animals that have tested non-negative have been removed and the remaining bovine, ovine or caprine animals fulfil the requirements set out in point 1(c) of Section 1 of Chapter 1.
4. By way of derogation from point 3, where the infection with *Brucella suis* biovar 2 was confirmed in a single bovine, ovine or caprine animal kept in the establishment, the status may be regained after negative testing was obtained on samples taken in accordance with the requirements set out in point 1(c)(i) of Section 1 of Chapter 1.

CHAPTER 3

Member State or zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals

Section 1

Granting of the status as regards kept bovine animals

The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals may only be granted to a Member State or a zone if:

- (a) for at least the past 3 years there has been no confirmed case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in kept bovine animals;
- (b) general surveillance requirements have been carried out for the past 3 years in accordance with point (a) of Article 3(1) for the early detection of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in kept bovine animals, which included at least:
 - (i) the regular submission of samples from abortion cases for laboratory testing;
 - (ii) the timely investigation of abortion cases that may have been caused by infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
- (c) during the past 3 years, at least 99,8 % of the establishments keeping bovine animals, representing at least 99,9 % of the bovine population, have maintained their status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination;
- (d) vaccination of bovine animals against *Brucella abortus*, *B. melitensis* and *B. suis* has not taken place at least for the past 3 years and no bovine animal introduced into the Member State or zone has been vaccinated during the past 3 years prior to its introduction.

Section 2

Maintenance of the status as regards kept bovine animals

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals of a Member State or a zone may only be maintained if:
 - (a) the requirements set out in points (a), (b) and (d) of Section 1 continue to be fulfilled; and
 - (b) for the first 2 consecutive years following granting of the status, annual surveillance based on a representative sample of all establishments keeping bovine animals has been carried out that must allow at least for the detection, with a 95 % level of confidence, of infection with *Brucella abortus*, *B. melitensis* and *B. suis*, at a target prevalence rate of 0,2 % of the establishments keeping bovine animals or a target prevalence rate of 0,1 % of the bovine population;
 - (c) if no case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* has been confirmed in kept bovine animals for 2 consecutive years following granting of the status, surveillance must be based on:
 - (i) random annual surveillance that must allow at least for the detection, with a 95 % level of confidence, of infection with *Brucella abortus*, *B. melitensis* and *B. suis*, at a target prevalence rate of 0,2 % of the establishments keeping bovine animals or a target prevalence rate of 0,1 % of the bovine population; or
 - (ii) risk-based annual surveillance to detect infection with *Brucella abortus*, *B. melitensis* and *B. suis* taking into account the systems of production and the risk factors identified, including spread of infection from other animals than kept bovine animals.
2. The status of a Member State or a zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals is not affected by the confirmation of infection of *Brucella abortus*, *B. melitensis* and *B. suis* in an animal population other than kept bovine animals provided that effective measures have been implemented, and are periodically assessed, to prevent transmission of infection with *Brucella abortus*, *B. melitensis* and *B. suis* to kept bovine animals.
3. By way of derogation from point 1(a), the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals of a Member State or a zone may be maintained in the event of the confirmation of a case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* if:
 - (a) the establishment in which the infection with *Brucella abortus*, *B. melitensis* and *B. suis* was detected in kept bovine animals has been immediately subjected to the relevant disease control measures laid down in Article 24;
 - (b) within 60 days after the first confirmation of the infection, the competent authority has conducted an epidemiological enquiry and investigations, as laid down in Article 25, to identify the likely source and the distribution of the infection and established conclusions on the likely source of infection and only a limited number of establishments were infected and those establishments are epidemiologically linked to the first detected outbreak;
 - (c) the relevant disease control measures laid down in Article 21 or Article 24 have been immediately implemented in each establishment identified with suspected or confirmed cases following implementation of the measures provided for in point (b) until their disease-free status is restored or regained;
 - (d) the surveillance referred to in point 1 has been adapted and has demonstrated that the incident has been resolved.

CHAPTER 4

Member State or zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept ovine and caprine animals

Section 1

Granting of the status as regards kept ovine and caprine animals

The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept ovine and caprine animals may only be granted to a Member State or a zone if:

- (a) for at least the past 3 years there has been no confirmed case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in kept ovine and caprine animals;

- (b) general surveillance requirements have been carried out for the past 3 years in accordance with point (a) of Article 3(1) for the early detection of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in kept ovine and caprine animals, which included at least:
 - (i) the regular submission of samples from abortion cases for laboratory testing;
 - (ii) the timely investigation of abortion cases that may have been caused by infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
- (c) during the past 3 years, surveillance has been carried out on the ovine and caprine population and at least 99,8 % of the establishments keeping ovine or caprine animals, representing at least 99,9 % of the ovine and caprine population, have maintained their status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination; and
- (d) vaccination of ovine and caprine animals against *Brucella abortus*, *B. melitensis* and *B. suis* has not taken place for at least the past 3 years and no ovine or caprine animal introduced into the Member State or zone has been vaccinated during the past 3 years prior to introduction.

Section 2

Maintenance of the status as regards kept ovine and caprine animals

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept ovine and caprine animals of a Member State or a zone may only be maintained if:
 - (a) the requirements defined in points (a), (b) and (d) of Section 1 continue to be fulfilled; and
 - (b) for the first 2 consecutive years following granting of the status, annual surveillance based on a representative sample of all establishments where ovine or caprine animals are kept shall be carried out that must allow at least for the detection, with a 95 % level of confidence, of infection with *Brucella abortus*, *B. melitensis* and *B. suis* at a target prevalence rate of 0,2 % of the establishments keeping ovine or caprine animals or a target prevalence rate of 0,1 % of the ovine and caprine population;
 - (c) if no case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* has been confirmed in kept ovine and caprine animals for 2 consecutive years following granting of the status, surveillance must be based on:
 - (i) random annual surveillance that must allow at least for the detection, with a 95 % level of confidence, of infection with *Brucella abortus*, *B. melitensis* and *B. suis* at a target prevalence rate of 0,2 % of the establishments keeping ovine or caprine animals or a target prevalence rate of 0,1 % of the ovine and caprine population; or
 - (ii) risk-based annual surveillance to detect infection with *Brucella abortus*, *B. melitensis* and *B. suis*, which takes into account the systems of production and the risk factors identified, including spread of infection from other animals than kept ovine and caprine animals.
2. The status of a Member State or a zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept ovine and caprine animals is not affected by the confirmation of infection of *Brucella abortus*, *B. melitensis* and *B. suis* in an animal population other than kept ovine and caprine animals provided that effective measures have been implemented, and are periodically assessed, to prevent transmission of infection with *Brucella abortus*, *B. melitensis* and *B. suis* to kept ovine and caprine animals.
3. By way of derogation from point 1(a), the status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept ovine and caprine animals of a Member State or a zone may be maintained in the event of the confirmation of a case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* if:
 - (a) the establishment in which the infection with *Brucella abortus*, *B. melitensis* and *B. suis* was detected in kept ovine and caprine animals has been immediately subjected to the relevant disease control measures laid down in Article 24;
 - (b) within 60 days after the first confirmation of the infection, the competent authority has conducted an epidemiological enquiry and investigations, as laid down in Article 25, to identify the likely source and the distribution of the infection and established conclusions on the likely source of infection and only a limited number of establishments were infected and those establishments are epidemiologically linked to the first detected outbreak;

- (c) the relevant disease control measures laid down in Article 21 or Article 24 have been immediately implemented in each establishment identified with suspected or confirmed cases following implementation of the measures provided for in point (b) until their disease-free status is restored or regained; and
- (d) the surveillance referred to in point 1 has been adapted and has demonstrated that the incident has been resolved.

PART II

INFECTION WITH MYCOBACTERIUM TUBERCULOSIS COMPLEX

CHAPTER 1

Establishment free from infection with *Mycobacterium tuberculosis* complex

Section 1

Granting of the status

1. The status free from infection with *Mycobacterium tuberculosis* complex (*Mycobacterium bovis*, *Mycobacterium tuberculosis*, *Mycobacterium caprae*) (MTBC) may only be granted to an establishment keeping bovine animals if:
 - (a) during the past 12 months there has been no confirmed case of infection with MTBC in bovine animals kept in the establishment;
 - (b) the bovine animals over 6 weeks of age present in the establishment at the time of testing or sampling have tested negative to immunological test on two occasions as follows:
 - (i) the first test must be carried out on bovine animals or samples taken from bovine animals not earlier than 6 months after the removal of the last confirmed case and of the last animal that tested positive in an immunological test;
 - (ii) the second test must be carried out on bovine animals or on samples taken from bovine animals not earlier than 6 months and not later than 12 months following the date of testing of the bovine animal or taking of the samples referred to in point (i);
 - (c) since the beginning of the testing or sampling referred to in point (b)(i), all bovine animals introduced into the establishment originate from establishments free from infection with MTBC and:
 - (i) originate from a Member State or a zone free from infection with MTBC;
 - (ii) are bovine animals over 6 weeks of age and have tested negative in an immunological test:
 - during the 30 days prior to their introduction into the establishment; or
 - during the 30 days after their introduction provided they have been kept isolated during this period; and
 - (d) since the beginning of the testing or sampling referred to in point (b)(i), all germinal products of bovine origin introduced into or used in the establishment originate from:
 - (i) establishments free from infection with MTBC; or
 - (ii) approved germinal product establishments.
2. By way of derogation from point 1, the status free from infection with MTBC may be granted to an establishment if all bovine animals originate from establishments free from infection with MTBC and:
 - (a) originate from a Member State or a zone free from infection with MTBC;
 - (b) if they are bovine animals over 6 weeks of age, they have tested negative to an immunological test:
 - (i) during the 30 days prior to their introduction into the establishment; or
 - (ii) during the 30 days after their introduction provided they have been kept in isolation during this period.

3. By way of derogation from points 1(c) and 2(b), the competent authority may not require the test if:
- (a) the bovine animals introduced into the establishment:
 - (i) have tested negative in an immunological test carried out during the past 6 months; and
 - (ii) originate from establishments where the bovine animals have tested negative to a testing regime as provided for in points 1(c) or 2 of Section 2 carried out during the past 6 months; or
 - (b) the bovine animals introduced into the establishment:
 - (i) have tested negative in an immunological test carried out during the past 12 months; and
 - (ii) originate from establishments where the bovine animals have tested negative to a testing regime as provided for in point 2(b) or 2 (c) of Section 2 carried out during the past 12 months.

Section 2

Maintenance of the status

1. The status free from infection with MTBC of an establishment keeping bovine animals may only be maintained if:
- (a) the requirements set out in points (a), (c) and (d) of point 1 of Section 1 continue to be fulfilled;
 - (b) any suspected case of infection with MTBC in a bovine animal kept on that establishment or introduced from that establishment into a slaughterhouse is notified to the competent authority and investigated; and
 - (c) an immunological test has been carried out, with negative results, on all bovine animals over 6 weeks of age, at intervals of not more than 12 months.
2. By way of derogation from point 1(c), the competent authority may modify the testing regime as follows:
- (a) in a Member State or in a zone where the annual percentage, calculated on 31 December of each year, of establishments infected with MTBC is not more than 1 % during the last 24 months, the interval between tests may be extended to 24 months;
 - (b) in a Member State or in a zone where the annual percentage, calculated on 31 December of each year, of establishments infected with MTBC is not more than 0,2 % for the last 48 months, the interval between tests may be extended to 36 months;
 - (c) in a Member State or in a zone where the annual percentage, calculated on 31 December of each year, of establishments infected with MTBC is not more than 0,1 % for the last 72 months, the interval between tests may be extended to 48 months;
 - (d) in a Member State or a zone free from infection with MTBC, if the risk of transmission of MTBC from wild animals to bovine animals has been assessed by appropriate surveillance, the interval between tests may be based on the type of production and the risk factors identified, taking into account at least the following risks:
 - (i) a location associated with suspected or confirmed infection with MTBC in wild animals;
 - (ii) a history of infection with MTBC within the last 5 years;
 - (iii) an epidemiological link with establishments in any of points (i) or (ii).

Section 3

Suspension and restoring of the status

1. The status free from infection with MTBC of an establishment keeping bovine animals must be suspended if:
- (a) one or more of the requirements laid down in Section 2 are not fulfilled; or
 - (b) a case of infection with MTBC is suspected in a bovine animal kept in the establishment.

2. The status free from infection with MTBC may only be restored, if:
 - (a) the requirements laid down in points 1(c) and 1(d) of point 1 of Section 1, 1(b), of Section 2 and, as relevant, in point 1(c) or in point 2 of Section 2 are fulfilled;
 - (b) the results of further investigations substantiate absence of infection with MTBC and the status of all suspected cases has been determined. In case, suspected bovine animals are slaughtered in that context, investigations must include examination of samples with direct diagnostic methods.

Section 4

Withdrawal and regaining of the status

1. The status free from infection with MTBC of an establishment keeping bovine animals must be withdrawn if:
 - (a) one or more of the requirements laid down in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;
 - (b) the infection with MTBC cannot be ruled out in accordance with point 2(b) of Section 3;
 - (c) a case of infection with MTBC has been confirmed in a bovine animal kept in the establishment; or
 - (d) it is justified by other needs to control infection with MTBC.
2. If the status free from infection with MTBC has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in Section 2 are fulfilled.
3. If the status free from infection with MTBC has been withdrawn in accordance with point 1(b), 1(c) or 1(d), it may only be regained if:
 - (a) all confirmed cases and all animals that have tested non negative in a immunological test have been removed; and
 - (b) the remaining bovine animals fulfil the requirements set out in point 1(b) of Section 1.
4. By way of derogation from point 3(b), the status may be regained if:
 - (a) all bovine animals over 6 weeks of age present in the establishment at the time of testing have tested negative in two immunological tests as follows:
 - (i) the first test must be carried out on bovine animals or samples taken from bovine animals not earlier than 2 months after the removal of the last confirmed case and of the last animal that tested positive in an immunological test;
 - (ii) the second test must be carried out on bovine animals or on samples taken from bovine animals not earlier than 2 months and not later than 12 months following the date of testing or sampling of the bovine animal as referred to in point (i); and
 - (b) at least one of the following conditions apply:
 - (i) the conclusion of the epidemiological enquiry indicates that the infection is due to the introduction of one or more infected animals into the establishment during the past 12 months prior to the detection of the infection with MTBC; or
 - (ii) only a single case was confirmed or only a single bovine animal tested positive in an immunological test for MTBC since the detection of the infection with MTBC, and the status of the establishment has not been withdrawn during the past 3 years; or
 - (iii) bovine animals in the establishment have tested negative in an immunological test carried out less than 12 months prior to the detection of the infection with MTBC in accordance with point 1(c) or 2 of Section 2.

CHAPTER 2

Member State or zone free from infection with MTBC

Section 1

Granting of the status as regards kept bovine animals

The status free from infection with MTBC as regards kept bovine animals may only be granted to a Member State or a zone if:

- (a) during the past 3 years at least 99,8 % of the establishments keeping bovine animals, representing at least 99,9 % of the bovine population, have maintained their status free from infection with MTBC and the incidence rate of establishments confirmed infected during the year did not exceed 0,1 %; and
- (b) general surveillance requirements have been carried out for the past 3 years in accordance with point (a) of Article 3(1) for the detection of infection with MTBC in kept bovine animals and included at least:
 - (i) the systematic research of lesions of infection with MTBC in all bovine animals slaughtered through ante- and post-mortem surveillance;
 - (ii) the investigations of lesions that could be due to infection with MTBC.

Section 2

Maintenance of the status

1. The status free from infection with MTBC as regards kept bovine animals of a Member State or a zone may only be maintained if:
 - (a) the requirements in point (b) of Section 1 continue to be fulfilled; and
 - (b) for the first 2 consecutive years following granting of the status random annual surveillance based on a representative sampling of all establishments where bovine animals are kept must be carried out to demonstrate with a 95 % level of confidence, that:
 - (i) at least 99,8 % of the establishments, representing at least 99,9 % of the bovine population are free from infection with MTBC;
 - (ii) the incidence rate of establishment confirmed infected during the year does not exceed 0,1 %;
 - (c) if the conditions in point (b) were fulfilled for 2 consecutive years, surveillance is based on:
 - (i) random annual surveillance to demonstrate at least with a confidence level of 95 %, that the incidence rate of establishments confirmed infected during the year does not exceed 0,1 %; or
 - (ii) risk-based annual surveillance carried out to detect infection with MTBC, taking into account the systems of production, the risk factors identified, including the spread of infection from other animals than kept bovine animals and increased surveillance in establishments associated with at least one of the specific risks referred to in point 2(d) of Section 2 of Chapter 1.
2. The status of a Member State or a zone free from infection with MTBC is not affected by the confirmation of infection with MTBC in the animal population other than kept bovine animals, provided that effective measures have been implemented, and are periodically assessed, to prevent transmission of infection with MTBC to kept bovine animals.

PART III

ENZOOTIC BOVINE LEUKOSIS

CHAPTER 1

Establishment free from enzootic bovine leukosis

Section 1

Granting of the status

1. The status free from enzootic bovine leukosis (EBL) may only be granted to an establishment keeping bovine animals if:
 - (a) during the past 24 months there has been no confirmed case of EBL in bovine animals kept in the establishment;
 - (b) during the past 12 months, bovine animals older than 24 months of age kept in the establishment have tested negative to a serological test, on at least two occasions at an interval of not less than 4 months;
 - (c) since the beginning of the sampling referred to in point (b), all bovine animals introduced into the establishment:
 - (i) originate from establishments free from EBL; or
 - (ii) originate from establishments where there has been no evidence of EBL either clinical, post-mortem, or as a result of a diagnostic test for EBL within the 24 months prior to their dispatch; and
 - if over 24 months of age,
they have been subjected to serological tests, with negative results, on two occasions at an interval of not less than 4 months while kept in isolation from other bovine animals of the establishment; or
they have been subjected to a serological test, with a negative result, within 30 days prior to their introduction provided all bovine animals have been tested in accordance with point (b);
 - if less than 24 months of age,
they were born to dams, that have been subjected to a serological test for EBL, with negative results, carried out on samples taken during the past 12 months on two occasions at an interval of not less than 4 months; and
 - (d) since the beginning of the sampling referred to in point (b), all germinal products of bovine animals introduced into the establishment originate from:
 - (i) establishments free from EBL; or
 - (ii) approved germinal product establishments.
2. By way of derogation from point 1, the status free from EBL may be granted to an establishment if all bovine animals originate from establishments free from EBL located either in a Member State or zone free from EBL or in a Member State or zone covered by an approved eradication programme.

Section 2

Maintenance of the status

The status free from EBL of an establishment keeping bovine animals may only be maintained if:

- (a) the requirements laid down in points (a), (c) and (d) of point 1 of Section 1 continue to be fulfilled; and
- (b) serological testing for EBL is carried out, with negative results, on samples taken
 - (i) at intervals of not more than 36 months from all bovine animals over 24 months of age; or
 - (ii) in accordance with point (b) or (c) of Section 2 of Chapter 2, as relevant, if the establishment is located in a Member State or zone free from EBL.

Section 3

Suspension and restoring of the status

1. The status free from EBL of an establishment keeping bovine animals must be suspended if:
 - (a) one or more of the requirements laid down in Section 2 are not fulfilled;
 - (b) a case of EBL in a bovine animal that is kept on the establishment is suspected.
2. The status free from EBL may only be restored if:
 - (a) the requirements laid down in points (c) and (d) of point 1 of Section 1 and point (b) of Section 2 are fulfilled;
 - (b) the results of further investigations substantiate absence of EBL and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from EBL of an establishment keeping bovine animals must be withdrawn if:
 - (a) one or more of the requirements laid down in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended; or
 - (b) a case of EBL has been confirmed in a bovine animal kept in the establishment.
2. If the status free from EBL has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in points (c) and (d) of point 1 of Section 1 and point (b) of Section 2 are fulfilled.
3. If the status free from EBL has been withdrawn in accordance with point 1(b), it may only be regained if:
 - (a) any bovine animal presenting a positive test result for EBL and all of their offspring younger than 24 months of age have been removed;
 - (b) all bovine animals over 12 months of age have been tested negative in a serological test, on two occasions at an interval of not less than 4 months, where the first test must be carried out on samples not taken earlier than 4 months after the removal of the last confirmed case.
4. By way of derogation from point (3)(a), the offspring of dams that have been tested positive in a serological test for EBL or which have shown lesions of EBL may be kept in the establishment if:
 - (a) they have been separated from the dam immediately after calving and tested negative in a PCR test, on two occasions, where the first sample must be taken within the period of 3 to 5 weeks and the second within 8 to 10 weeks postpartum; and
 - (b) they remain in the establishment until they are 24 months of age and are tested negative in a serological test, or they are sent before that test directly to the slaughterhouse in accordance with the requirements laid down in Article 27(4).

CHAPTER 2

Member State or zone free from EBL

Section 1

Granting of the status

The status free from EBL as regards kept bovine animals may only be granted to a Member State or a zone if:

- (a) at least 99,8 % of the bovine establishments are free from EBL; and

- (b) all bovine animals over 24 months of age slaughtered within this Member State or zone are subjected to an official post-mortem examination with samples from all animals with tumours that could be caused by EBL being subjected to laboratory examination to confirm or rule out the presence of EBL.

Section 2

Maintenance of the status

The status free from EBL as regards kept bovine animals of a Member State or a zone may only be maintained if:

- (a) the requirements set out in Section 1 continue to be fulfilled; and
- (b) during the first 5 years after the granting of the status free from EBL, surveillance is carried out based on:
 - (i) annual random sampling to detect at least, with a 95 % level of confidence, establishments infected with EBL at a target prevalence rate of 0,2 %; or
 - (ii) serological testing of all bovine animals over 24 months of age on at least one occasion;
- (c) following the first 5 years after the granting of the status free from EBL, surveillance is carried out to demonstrate the absence of infection, taking into account the systems of production and the risk factors identified.

PART IV

INFECTIOUS BOVINE RHINOTRACHEITIS/INFECTIOUS PUSTULAR VULVOVAGINITIS

CHAPTER 1

Establishment free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

Section 1

Granting of the status

1. The status free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV) may only be granted to an establishment keeping bovine animals if:
 - (a) during the past 12 months there has been no confirmed case of IBR/IPV in bovine animals kept in the establishment;
 - (b) during the past 2 years none of the bovine animals kept in the establishment has been vaccinated against IBR/IPV;
 - (c) the bovine animals kept in the establishment have been subjected to at least one of the following testing regimes taking into account previous DIVA vaccinations, where serological tests for the detection of antibodies against whole BoHV-1 or, if necessary, antibodies against BoHV-1-gE have been carried out on:
 - (i) a blood, milk or meat juice sample taken from each bovine animal over a period of not more than 12 months; or
 - (ii) blood, milk or meat juice samples taken on at least two occasions at an interval of not less than 2 months and not more than 12 months from
 - all female bovine animals over 12 months of age, and
 - all male bovine animals used or intended for breeding over 12 months of age, and
 - a random sample of male animals not intended for breeding over 12 months of age. The number of animals tested must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %; or
 - (iii) in the case of an establishment in which at least 30 % of the bovine animals are lactating,
 - bulk milk samples taken on at least three occasions at intervals of not less than 3 months from lactating female bovine animals representing all epidemiological units of the establishment, and

- blood samples taken from all non-lactating female bovine animals over 12 months of age, and from all male bovine animals used or intended for breeding over 12 months of age, and
 - a random blood or meat juice sample taken from male bovine animals not intended for breeding older than 12 months of age. The number of animals tested must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %; or
- (iv) in the case of an establishment in which less than 5 % of the kept bovine animals are male and at least 95 % of the female animals over 24 months are intended or used for milk production, bulk milk samples taken on at least six occasions at intervals of not less than 2 months from lactating female bovine animals representing all epidemiological units of the establishment;
- (d) since the beginning of the sampling referred to in point (c) all bovine animals introduced into the establishment:
- (i) originate from establishments free from IBR/IPV and, in case the establishments of origin are located in a Member State or zone that is neither free from IBR/IPV nor covered by an approved eradication programme, have tested negative in a serological test for the detection of antibodies against whole BoHV-1 or, if necessary, antibodies against BoHV-1-gE on a sample taken after their introduction and before the granting of the status free from IBR/IPV; or
 - (ii) have been subjected to quarantine prior to their introduction and have tested negative in serological test for the detection of antibodies against whole BoHV-1 on a sample taken not earlier than 21 days after the beginning of the quarantine; and
- (e) since the beginning of the sampling referred to in point (c) all germinal products of bovine animals introduced into the establishment originate from:
- (i) establishments free from IBR/IPV; or
 - (ii) approved germinal product establishments.
2. By way of derogation from point 1, the status free from IBR/IPV may be granted to an establishment if all bovine animals originate from establishments free from IBR/IPV located either in a Member State or zone free from IBR/IPV or in a Member State or zone under an approved eradication programme, provided they fulfil the requirements set out in points (c) and (d) of Section 2, as relevant.

Section 2

Maintenance of the status

The status free from IBR/IPV may only be maintained in an establishment keeping bovine animals if:

- (a) the requirements laid down in points (a), (b) and (e) of point 1 of Section 1 continue to be fulfilled;
- (b) serological testing for the detection of antibodies against whole BoHV-1 or, if necessary, antibodies against BoHV-1-gE is carried out taking into account previous vaccinations with a DIVA vaccine, with negative results,
 - (i) on blood, milk or meat juice samples taken annually from all bovine animals older than 24 months of age; or
 - (ii) in the case of an establishment, in which at least 30 % of the bovine animals are lactating, at least annually on:
 - bulk milk samples taken on at least three occasions at intervals of not less than 3 months from lactating female bovine animals representing all epidemiological units of the establishment, and
 - blood samples taken from all breeding male bovine animals older than 24 months of age; or,
 - (iii) in the case of an establishment, in which less than 5 % of the kept bovine animals are male and at least 95 % of the female animals over 24 months are intended or used for milk production, at least annually on bulk milk samples taken on at least six occasions at intervals of not less than 2 months from lactating female bovine animals representing all epidemiological units of the establishment; or
 - (iv) provided the status free from IBR/IPV has been maintained for the past 3 consecutive years, annually on blood or milk samples taken from a number of bovine animals that must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %; or

- (v) if the establishment is located in a Member State or zone free from IBR/IPV, on samples taken in accordance with point 1(b) of Section 2 of Chapter 2 or point 3 of Section 2 of Chapter 2, if relevant.
- (c) only bovine animals that have not been vaccinated against infection with IBR/IPV are introduced into the establishment if it is located in a Member State or zone:
 - (i) free from IBR/IPV; or
 - (ii) where a vaccination ban is in place as part of the eradication strategy under an approved eradication programme.
- (d) all bovine animals that are introduced fulfil the requirements laid down in point 1(d)(ii) of Section 1 or originate from establishments free from IBR/IPV and have tested negative in a serological test for the detection of antibodies against whole BoHV-1 or, if necessary, antibodies against BoHV-1-gE on a sample taken in the establishments of origin within 15 days prior to their dispatch, in cases where:
 - (i) the establishment is located in a Member State or zone free from IBR/IPV and the establishments of origin are not located in a Member State or zone free from IBR/IPV; or
 - (ii) the establishment is located in a Member State or zone covered by an approved eradication programme and the establishments of origin are located in a Member State or zone that is neither free from IBR/IPV nor covered by an approved eradication programme.

Section 3

Suspension and restoring of the status

1. The status free from IBR/IPV of an establishment keeping bovine animals must be suspended if:
 - (a) one or more of the requirements laid down in Section 2 are not fulfilled;
 - (b) a case of IBR/IPV is suspected in a bovine animal kept in the establishment.
2. The status free from IBR/IPV may only be restored if:
 - (a) the requirements laid down in points 1(b) and (e) of Section 1 and points (b), (c) and (d) of Section 2 are fulfilled;
 - (b) the results of further investigations substantiate absence of IBR/IPV and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from IBR/IPV of an establishment keeping bovine animals must be withdrawn if:
 - (a) one or more of the requirements laid down in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;
 - (b) a case of IBR/IPV has been confirmed in a bovine animal kept in the establishment.
2. If the status free from IBR/IPV has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in points (b) and (e) of point 1 of Section 1 and points (b), (c) and (d) of Section 2 are fulfilled.
3. If the status free from IBR/IPV has been withdrawn in accordance with point 1(b), it may only be regained if:
 - (a) all confirmed cases have been removed;
 - (b) at least one of the testing regimes laid down in point 1(c) of Section 1 has been carried out with negative results on samples that have been taken not earlier than 30 days after the removal of the last confirmed case.

CHAPTER 2

Member State or zone free from IBR/IPV

Section 1

Granting of the status

The status free from IBR/IPV as regards kept bovine animals may only be granted to a Member State or a zone if

- (a) vaccination against IBR/IPV has been prohibited for kept bovine animals; and
- (b) at least 99,8 % of the establishments representing at least 99,9 % of the corresponding bovine population are free from IBR/IPV.

Section 2

Maintenance of the status

- 1. The status free from IBR/IPV as regards kept bovine animals of a Member State or a zone may only be maintained if:
 - (a) the requirements laid down in Section 1 continue to be fulfilled; and
 - (b) surveillance is carried out annually based on random sampling that must allow at least for the detection, with a 95 % level of confidence, of the infection of establishments with BoHV-1 at a target prevalence rate of 0,2 % of the establishments or of BoHV-1 infected bovine animals with a target prevalence rate of 0,1 % of the bovine population.
- 2. By way of derogation from point 1(a), the use of DIVA vaccination may be authorised by the competent authority in the event of an outbreak, if:
 - (a) the result of the epidemiological enquiry and investigations according to Article 25 has demonstrated that only a limited number of establishments were involved in the outbreak;
 - (b) its use is limited to controlling this outbreak as deemed necessary by the competent authority;
 - (c) the bovine animals are DIVA vaccinated under the supervision of the competent authority and the use of DIVA vaccines is documented for each animal;
 - (d) the DIVA vaccinated bovine animals are only moved directly to a slaughterhouse or to an establishment in another zone or Member State where no vaccination ban is in place.
- 3. By way of derogation from point 1(b), surveillance may be carried out to demonstrate yearly the absence of infection with BoHV-1 taking into account the systems of production and the risk factors identified, provided no outbreaks have been detected for 5 consecutive years following the granting of the status free from IBR/IPV in this Member State or zone.

PART V

INFECTION WITH AUJESZKY'S DISEASE VIRUS

CHAPTER 1

Establishment free from infection with Aujeszky's disease virus

Section 1

Granting of the status

- 1. The status free from infection with Aujeszky's disease virus (ADV) may only be granted to an establishment keeping porcine animals if:
 - (a) during the past 12 months there has been no confirmed case of infection with ADV in porcine animals kept in the establishment;

- (b) during the past 12 months none of the porcine animals kept in the establishment has been vaccinated against AD;
 - (c) during the past 12 months, the porcine animals kept in the establishment have been subjected to one of the following testing regimes taking into account previous DIVA vaccinations where serological tests for the detection of antibodies against ADV or, if necessary, antibodies against ADV-gE have been carried out, with negative results, on:
 - (i) a blood or meat juice sample taken from each porcine animal; or
 - (ii) blood or meat juice samples taken on two occasions at an interval of 2 to 3 months from a number of animals that must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %.
 - (d) since the beginning of the sampling referred to in point (c), all porcine animals introduced into the establishment:
 - (i) originate from establishments free from infection with ADV and, in case the establishments of origin are located in a Member State or zone that is neither free from infection with ADV nor covered by an approved eradication programme, have tested negative in a serological test for the detection of antibodies against whole ADV or, if necessary, antibodies against ADV-gE after their introduction and before the granting of the status free from infection with ADV; or
 - (ii) have been subjected to quarantine for a period of at least 30 days prior to their introduction and have tested negative in a serological test for the detection of antibodies against whole ADV on two occasions at an interval of not less than 30 days between collection of each sample. The sample for the last test must be taken within 15 days prior to dispatch.
 - (e) since the beginning of the sampling referred to in point (c) all germinal products from porcine animals introduced into the establishment originate from:
 - (i) establishments free from infection with ADV; or
 - (ii) approved germinal product establishments.
2. By way of derogation from point 1, the status free from infection with ADV may be granted to an establishment if all porcine animals originate from establishments free from infection with ADV located either in a Member State or zone free from infection with ADV or in a Member State or zone covered by an approved eradication programme, provided they fulfil the requirements set out in point (d) of Section 2.

Section 2

Maintenance of the status

The status free from infection with ADV of an establishment keeping porcine animals may only be maintained if:

- (a) the requirements laid down in points (a), (b) and (e) of point 1 of Section 1 continue to be fulfilled;
- (b) serological testing is carried out, with negative results, on a representative number of blood or meat juice samples taken from the porcine animals kept in the establishment, to verify the absence of infection with ADV based on a testing regime that takes into account the production cycle and the risk of introduction of ADV:
 - (i) at least once a year, in case all kept porcine animals are not vaccinated against AD, with tests for the detection of antibodies against whole ADV; or
 - (ii) at least twice a year, with tests for the detection of antibodies against whole ADV and tests for the detection of antibodies against ADV-gE, if necessary;
- (c) provided the establishment is located in a Member State or zone free from infection with ADV, the serological testing referred to in point (b) is carried out, as required, in accordance with the surveillance provided for in point 1(b) of Section 2 of Chapter 2 or point 4 of Section 2 of Chapter 2, if relevant;
- (d) all porcine animals, that are introduced:
 - (i) fulfil the requirements set out in point 1(d)(ii) of Section 1; or

- (ii) originate from establishments free from infection with ADV and have been subjected to a serological test for antibodies against whole ADV, with a negative result, on a sample collected in the establishments of origin within 15 days prior to their dispatch, in cases where:

- the establishment is located in a Member State or zone free from infection with ADV and the establishments of origin are not located in a Member State or zone free from infection with ADV; or
- the establishment is located in a Member State or zone covered by an approved eradication programme and the establishments of origin are located in a Member State or zone that is neither free from infection with ADV nor covered by an approved eradication programme.

The number of porcine animals tested must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %.

By way of derogation from the first subparagraph, for porcine animals less than 4 months old born to DIVA-vaccinated dams the serological test for the detection of antibodies against ADV-gE may be used.

Section 3

Suspension and restoring of the status

1. The status free from infection with ADV of an establishment keeping porcine animals must be suspended if:
 - (a) one or more of the requirements laid down in Section 2 are no longer fulfilled;
 - (b) a case of infection with ADV is suspected in a porcine animal kept in the establishment.
2. The status free from infection with ADV may only be restored if:
 - (a) the requirements laid down in points (b) and (e) of point 1 of Section 1 and point (b) or (c), if relevant, and (d) of Section 2 are fulfilled;
 - (b) the results of further investigations substantiate absence of infection with ADV and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from infection with ADV of an establishment keeping porcine animals must be withdrawn if:
 - (a) one or more of the requirements laid down in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;
 - (b) a case of infection with ADV has been confirmed in a porcine animal kept in the establishment.
2. If the status free from infection with ADV has been withdrawn in accordance with point 1(a), it may only be regained if the requirements set out in points (b) and (e) of point 1 of Section 1 and point (b) or (c), if relevant, and (d) of Section 2 are fulfilled.
3. If the status free from infection with ADV has been withdrawn in accordance with point 1(b), it may only be regained, if all porcine animals of the establishment have been removed.

CHAPTER 2

Member State or zone free from infection with Aujeszky's disease virus

Section 1

Granting of the status

The status free from infection with ADV as regards kept porcine animals may only be granted to a Member State or a zone if:

- (a) vaccination against AD has been prohibited for kept porcine animals for the previous 12 months;

- (b) surveillance has been carried out to demonstrate that no establishment in the respective Member State or zone has had any clinical, virological or serological evidence of infection with ADV for at least the previous 24 months; and
- (c) in case, infection with ADV is known to be established in wild porcine animals, measures have been implemented to prevent any transmission of ADV from wild to kept porcine animals.

Section 2

Maintenance of the status

1. The status free from infection with ADV as regards kept porcine animals of a Member State or a zone may only be maintained if:
 - (a) the requirements defined in points (a) and (c) of Section 1 continue to be fulfilled; and
 - (b) surveillance is carried out annually based on random sampling to allow at least for the detection, with a 95 % level of confidence, of establishments infected with ADV at a target prevalence rate of 0,2 %. The number of blood or meat juice samples to be taken from the porcine animals kept in an establishment must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 20 %.
2. By way of derogation from point 1, the status free from infection with ADV in the porcine population of a Member State or zone may be maintained in the event of an outbreak, if:
 - (a) all the porcine animals in the affected establishments have been removed;
 - (b) an epidemiological enquiry and investigations including clinical examination and serological or virological testing has been carried out by the competent authority:
 - (i) in all establishments keeping porcine animals that have been directly or indirectly in contact with the infected establishment to rule out infection; and
 - (ii) in all establishments keeping porcine animals located within at least a 2-kilometre radius of an infected establishment, to demonstrate that these establishments are not infected. The number of blood or meat juice samples to be taken from porcine animals kept in these establishments must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 10 %; or
 - (iii) in case a DIVA vaccination has been used, serological testing for antibodies against ADV-gE has been carried out on two occasions at an interval of 2 months in establishments keeping porcine animals located within the vaccinated radius from the infected establishment to demonstrate the absence of infection;
 - (c) the result of the investigation according to point (b) has demonstrated that only a limited number of establishments were involved in the outbreak;
 - (d) the relevant control measures as referred to in Article 24 have been immediately implemented in each establishment infected with ADV, including where necessary vaccination with DIVA vaccines.
3. By way of derogation from point (a) of Section 1, the use of DIVA vaccination may be authorised by the competent authority in the event of an outbreak referred to in point 2, if:
 - (a) its use is limited to control this outbreak as deemed necessary by the competent authority;
 - (b) the porcine animals are DIVA vaccinated under the supervision of the competent authority and the use of DIVA vaccines is documented for each animal;
 - (c) the DIVA vaccinated porcine animals are only moved directly to a slaughterhouse or to an establishment in another Member State or zone where no vaccination ban is in place.
4. By way of derogation from point 1(b), surveillance may be carried out to demonstrate annually the absence of ADV infection taking into account the systems of production and the risk factors identified, provided no outbreaks have been detected for 2 consecutive years following the granting of the status free from infection with ADV in this Member State or zone.

PART VI

BOVINE VIRAL DIARRHOEA

CHAPTER 1

Establishment free from bovine viral diarrhoea

Section 1

Granting of the status

1. The status free from bovine viral diarrhoea (BVD) may only be granted to an establishment keeping bovine animals if:

- (a) during the past 18 months there has been no confirmed case of BVD in a bovine animal kept in the establishment;
- (b) the bovine animals kept in the establishment have been subjected to at least one of the following testing regimes taking into account possible previous vaccinations:

- (i) tests for the detection of BVD virus (BVDV) antigen or genome have been carried out, with negative results, on samples of all bovine animals.

At least from all calves born in the previous 12 months, the samples must have been taken after or at the same time as official identification, but not later than 20 days postpartum. The dams of those calves with negative test results do not need to be tested;

- (ii) serological tests for the detection of antibodies against BVDV have been carried out, with negative results, on samples taken over a period of not less than 12 months on at least three occasions at intervals of not less than 4 months from bovine animals which have been kept in the establishment for at least 3 months prior to testing.

The number of animals tested must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 50 % and must be at least five animals or all the animals if there are fewer than five animals kept.

In case the bovine animals of the establishment are kept in separate groups without direct contact with each other, a respective number of animals of each group must be tested;

- (iii) a combination of the testing regimes set out in points (i) and (ii) has been applied over a period of not less than 12 months.

The capacity of the combined testing regime to detect the disease must be equivalent to that of the testing regimes referred to in points (i) and (ii);

- (c) since the beginning of the sampling referred to in point 1(b), all bovine animals introduced into the establishment:

- (i) originate from establishments free from BVD located in a Member State or zone free from BVD; or

- (ii) originate from establishments free from BVD, where

- serological tests referred to in point 1(c) (ii) or (iii) of Section 2 of Chapter 1 have been carried out, with negative results, within the past 4 months; or

- prior to their dispatch, they have been tested individually to exclude BVDV transmission into the establishment of destination taking into account the testing history and, if relevant, the animal's stage of gestation; or

- (iii) have tested negative in a test for BVDV antigen or genome, and

- have been subjected to quarantine for a period of at least 21 days prior to their dispatch and, in case of pregnant dams, have tested negative for antibodies against BVDV on samples taken after not less than 21 days of quarantine; or

- have tested positive for antibodies against BVDV either prior to their dispatch or, in case of pregnant dams, before insemination preceding the current gestation;

- (d) since the beginning of the sampling referred to in point 1(b) all germinal products of bovine animals introduced into the establishment originate from:
 - (i) establishments free from BVD; or
 - (ii) approved germinal product establishments.

2. By way of derogation from point 1, the status free from BVD may be granted to an establishment if:

- (a) all bovine animals originate from establishments free from BVD located in a Member State or zone free from BVD or in a Member State or zone covered by an approved eradication programme and fulfil the requirements laid down in point 1(c), if relevant; or
- (b) all bovine animals originate from establishments free from BVD, are not intended for breeding and the status free from BVD of the establishment is maintained in accordance with point 2 of Section 2.

Section 2

Maintenance of the status

1. The status free from BVD of an establishment keeping bovine animals may only be maintained if:

- (a) the requirements laid down in point (a), (c) and (d) of point 1 of Section 1 continue to be fulfilled;
- (b) no bovine animal has been vaccinated against BVD since the status free from BVD was granted to the establishment;
- (c) at least one of the following testing regimes is carried out with negative results:
 - (i) each new-born calf is tested negative for BVDV antigen or genome on a sample taken after or at the same time as official identification, but not later than 20 days postpartum;
 - (ii) serological tests for the detection of antibodies against BVDV are carried out at least annually on samples taken from bovine animals that have been kept in the establishment for at least 3 months prior to testing.

The number of animals tested must allow at least for the detection, with a 95 % level of confidence, of seropositive animals at a target prevalence rate of 50 % and must be at least five animals or all the animals if there are fewer than five animals kept;

In case the bovine animals of the establishment are kept in separate groups without direct contact with each other, a respective number of animals of each group must be tested;

- (iii) a combination of the testing regimes laid down in points (i) and (ii) is applied.

The capacity of the combined testing regime to detect the disease must be equivalent to that of the testing regimes referred to in points (i) and (ii);

- (iv) if the establishment is located in a Member State or zone free from BVD, tests are carried out on samples taken in accordance with point 1(b) of Section 2 of Chapter 2 or point 3 of Section 2 of Chapter 2, if relevant;
- (d) only bovine animals that have not been vaccinated against BVD are introduced into the establishment if it is located in a Member State or zone free from BVD.

2. By way of derogation from point 1, the status free from BVD of an establishment keeping bovine animals referred to in point 2(b) of Section 1 may be maintained without testing the bovine animals in accordance with point 1(c) if:

- (a) the requirements laid down in point 2(b) of Section 1 continue to be fulfilled;
- (b) they are not used for breeding;
- (c) they have no contact with animals that are intended or used for breeding and are moved from this establishment to a slaughterhouse,
 - (i) directly, or;
 - (ii) via an assembly operation, which is carried out in the same Member State or zone, and where only animals that comply with the requirements laid down in points (b) and (c) and originate from establishments that comply with the requirement laid down in point (a) are assembled.

Section 3

Suspension and restoring of the status

1. The status free from BVD of an establishment keeping bovine animals must be suspended if:
 - (a) one or more of the requirements laid down in Section 2 are not fulfilled;
 - (b) a case of BVD is suspected in a bovine animal kept in the establishment.
2. The status free from BVD may only be restored if:
 - (a) the requirements laid down in points (c) and (e) of point 1 of Section 1 and points (b), (c), (d) of point 1 and, if relevant, point 2 of Section 2 are fulfilled.
 - (b) the results of further investigations substantiate absence of BVD and the status of all suspected cases has been determined.

Section 4

Withdrawal and regaining of the status

1. The status free from BVD of an establishment keeping bovine animals must be withdrawn if:
 - (a) one or more of the requirements laid down in Section 2 are not fulfilled after the maximum period of time referred to in point (b) of Article 20(3) has lapsed since the status was suspended;
 - (b) a case of BVD has been confirmed in a bovine animal kept in the establishment.
2. If the status free from BVD has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in points (c) and (e) of point 1 of Section 1 and points (b), (c) and (d) of point 1 and, if relevant, point 2 of Section 2 are fulfilled.
3. If the status free from BVD has been withdrawn in accordance with point 1(b), it may only be regained if:
 - (a) all animals tested positive for BVDV have been removed;
 - (b) the status in relation to infection with BVDV of each bovine animal kept in the establishment has been determined;
 - (c) all calves that might have been infected in utero with BVDV were born and kept in isolation until they tested negative for BVDV antigen or genome.

CHAPTER 2

Member State or zone free from bovine viral diarrhoea

Section 1

Granting of the status

The status free from BVD as regards kept bovine animals may only be granted to a Member State or a zone if:

- (a) vaccination against BVD has been prohibited for kept bovine animals;
- (b) no case of BVD has been confirmed in a kept bovine animal for at least the previous 18 months; and
- (c) at least 99,8 % of the establishments representing at least 99,9 % of the bovine population are free from BVD.

Section 2

Maintenance of the status

1. The status free from BVD as regards kept bovine animals of a Member State or a zone may only be maintained if:
 - (a) the requirements laid down in point (a) and (c) of Section 1 continue to be fulfilled; and

- (b) surveillance is carried out annually that must allow at least for the detection, with a 95 % level of confidence, of establishments infected with BVDV at a target prevalence rate of 0,2 % of the establishments or of BVDV infected bovine animals with a target prevalence rate of 0,1 % of the bovine population.
 - 2. By way of derogation from point 1(a), the use of vaccination may be authorised by the competent authority in the event of an outbreak, if:
 - (a) the results of the epidemiological enquiry and investigations according to Article 25 have demonstrated that only a limited number of establishments were involved in the outbreak;
 - (b) only a limited number of bovine animals deemed necessary by the competent authority to control this outbreak are vaccinated under the supervision of the competent authority and the use of vaccination is documented for each animal.
 - 3. By way of derogation from point 1(b), surveillance may be carried out to demonstrate annually the absence of BVD taking into account the systems of production and the risk factors identified, provided no outbreaks have been detected for 5 consecutive years following the granting of the status free from BVD in this Member State or zone.
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ANNEX V

**DISEASE SPECIFIC REQUIREMENTS FOR THE GRANTING AND MAINTENANCE OF THE DISEASE-FREE STATUS
AT THE LEVEL OF MEMBER STATES OR ZONES**

PART I

INFECTION WITH RABIES VIRUS

CHAPTER 1

Technical requirements for the vaccination against rabies

Section 1

Vaccination of kept animals

1. For the purpose of eradication programmes for infection with rabies virus (RABV), anti-rabies vaccination must only be carried out on pet animals that are identified and must fulfil the requirements laid down in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council ⁽¹⁾.
2. For the purpose of eradication programmes for infection with RABV, anti-rabies vaccination of kept animals, other than those referred to in the first paragraph, must be risk-based and carried out with the purpose of protecting humans from being exposed to rabies virus, using vaccines that meet the requirements laid down in points (1)(a) and (1)(b) of Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council.

Section 2

Vaccination of wild animals

1. For the purpose of eradication programmes for infection with RABV the oral vaccination against infection with RABV of wildlife must:
 - (a) be organised and implemented as regular planned or emergency campaigns taking into account the risk assessment provided in point (a) of Article 32(2);
 - (b) be subjected to an adequate vaccine distribution in terms of timing and coverage of the vaccination area, taking into account the biology of the targeted animal population, the epidemiological situation and the topography of the area;
 - (c) be subjected, with the support of geographical information systems, to assessment of the correct geographical distribution of vaccine baits with a frequency that allows, if necessary, the adoption of corrective measures; and
 - (d) be subjected to monitoring of vaccination effectiveness, that may include the detection of the presence of biomarker and serological testing in dead animals from the targeted animal population for the vaccination.
2. For the purpose of eradication programmes for infection with RABV the vaccination against infection with RABV of stray dog populations must:
 - (a) be organised and implemented, if necessary, as part of control and management measures of stray dog populations, taking into account the risk assessment provided for in point (a) of Article 32(2);
 - (b) comply with the requirements of Section 1.

CHAPTER 2

Member State or zone free from infection with rabies virus

Section 1

Granting of the status

1. The status free from infection with RABV may only be granted to a Member State or a zone if:
 - (a) surveillance has been implemented in accordance with the requirements laid down in Article 3(1) at least for the past 24 months; and

⁽¹⁾ Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

- (b) no case of infection with RABV has been confirmed during the past 24 months in the targeted animal population.
- 2. By way of derogation from point 1(b), if a case of infection with RABV has been confirmed, the status may be granted if the infection of the case did not occur in the Member State or in the zone; and
 - (a) the case has been officially confirmed and no epidemiological link may have occurred and resulted in any additional case, which includes detection of the case at a border control post, or in a quarantine establishment or the quarantine facilities of a confined establishment; or
 - (b) epidemiological link may have occurred and no additional case was detected by increased surveillance and epidemiological enquiry and investigations during the 6 months following the death of the case.

Section 2

Maintenance of the status

The status free from infection with RABV of a Member State or a zone may only be maintained if:

- (a) surveillance is implemented in accordance with the requirements laid down in Article 3(1) with the objective of an early detection of the disease; and
- (b) no case of infection with RABV has been confirmed in the targeted animal population or a case occurred and the conditions laid down in point 2 of Section 1 were complied with.

PART II

INFECTION WITH BLUETONGUE VIRUS (SEROTYPES 1-24)

CHAPTER 1

Minimum requirements for the surveillance

Section 1

Surveillance for the detection of serotypes of Bluetongue virus not reported in the previous 2 years

1. The surveillance of infection with bluetongue virus (serotypes 1-24) (infection with BTV) to ensure early detection of introduction or recurrence of infection with any of the serotypes 1-24 of BTV that were not reported during the previous 2 years must include:
 - (a) general surveillance requirements as provided for in point (a) of Article 3(1);
 - (b) active surveillance as provided for in Section 4.
2. The design of the surveillance provided for in point 1 must address:
 - (a) the risk of infection with limited clinical manifestations;
 - (b) the risk of introduction of BTV serotypes associated with the circulation of any of the serotypes 1-24 of BTV in the vicinity; and
 - (c) any other identified relevant risk factor for introduction of any of the serotypes 1-24 of BTV not reported in the previous 2 years.
3. The surveillance in an area(s) adjacent to any infected Member State, zone or third country must be increased in an area of up to 150 km from the limit with the Member State, zone, or third country. The demarcation of the area of increased surveillance may be adapted to relevant ecological or geographical features likely to facilitate or interrupt the transmission of BTV or adapted due to the implementation of disease control measures that supports the choice between a greater or lesser distance.
4. The surveillance provided for in point 1(b) and point 3 must have the capacity at least to detect, with a 95 % level of confidence, the infection in the targeted animal population at a target prevalence rate of 5 %, unless otherwise specified in Section 2 of Chapter 4.

Section 2

Surveillance to determine the extent of infection with BTV

1. The surveillance of infection with BTV to ensure the timely demarcation of the spread of the infection when one or more serotypes of BTV is present and, if necessary, to monitor the prevalence rate must include:
 - (a) general surveillance requirements as provided for in point (a) of Article 3(1); and
 - (b) active surveillance as provided for in Section 4.
2. The design of the surveillance provided for in point 1 must take into account: all available information on the epidemiology of the disease and biology of the vector that prevail on the territory.
3. The target prevalence rate of the surveillance provided for in point 1 must be adapted to the epidemiological situation, taking into the main risk factors such as the targeted animal population and the vector population.

Section 3

Surveillance to demonstrate absence of infection with BTV

1. The surveillance of infection with BTV to demonstrate the absence of infection with any of the serotypes 1-24 that has been previously detected in the territory must include:
 - (a) general surveillance requirements as provided for in point (a) of Article 3(1); and
 - (b) active surveillance as provided for in Section 4.
2. The design of the surveillance provided for in point 1 must address:
 - (a) the risk of infection with limited clinical manifestations;
 - (b) all available information on the epidemiology of the disease and biology of the vector that prevail on the territory; and
 - (c) any specific risk of persistence of the infection identified.
3. The surveillance provided for in point 1(b) must have the capacity at least to detect, with a 95 % level of confidence, the infection in the targeted animal population at a target prevalence rate of 1 %.

Section 4

Requirements for the active surveillance of infection with BTV

1. The geographical units referred to in point (a) of Article 40(1) must be based on a grid of 45 km by 45 km and can be adapted to:
 - (a) the epidemiological situation, how fast the infection is spreading and the shape and size of the zones covered by the eradication programme in the event of confirmation of the infection; and
 - (b) the zones in accordance with point (b) of Article 13(2).
2. Active surveillance must be based on one or a combination of the following activities:
 - (a) monitoring of sentinel animals using serological or virological testing; and
 - (b) structured prevalence surveys, based on a random or risk-based sampling strategy using serological or virological testing.
3. The frequency of the sampling must:
 - (a) at least be annual, in the period of the year when infection or seroconversion is most likely to be detected; and
 - (b) be monthly during the vector activity season where regular information is needed due to the risk of the infection spreading.

4. The animals sampled must:
 - (a) not be vaccinated against the serotype(s) of BTV targeted for surveillance;
 - (b) no longer be covered by maternal immunity in case their mother was vaccinated or infected;
 - (c) be resident for a sufficient time in the relevant geographical unit and not have been protected from exposure to the vector;
 - (d) be representative for the geographical distribution of the targeted animal population in the relevant geographical unit; and
 - (e) be initially seronegative when surveillance is based on serological testing of sentinels.
5. The sample size in each geographical unit must be calculated in accordance with the target prevalence rate based on the objectives assigned in Sections 1-3.
6. When surveillance must be adapted as provided for in point (c) of Article 43(2), it must at least include a survey:
 - (a) on the introduced animals that:
 - (i) must be based on the sampling and testing of all introduced animals;
 - (ii) must take place as soon as possible after their introduction; or
 - (b) on the targeted animal population the most at risk due to the possible circulation of the virus that:
 - (i) must have a capacity at least to detect, with a 95 % level of confidence, infection with BTV at a target prevalence rate of 5 %;
 - (ii) must either:
 - not take place before 21 days has elapsed after the introduction of animals if it is a one-shot survey; or
 - must be conducted with a frequency adapted to the frequency of the movements of the animals that may jeopardise the health status.

This survey is not required if the frequency of the sampling is carried out in accordance with point 3(b).

Section 5

Entomological surveillance

1. Entomological surveillance must consist of at least an active annual programme of vector catching by means of permanently sited aspiration traps intended to determine the population dynamics of the vector and, where relevant, the vector-free period.
2. Aspiration traps equipped with ultraviolet light must be used in accordance with pre-established protocols; the traps must be operated throughout the night and operate at least:
 - (a) one night per week during the month before the expected beginning and during the month before the expected end of the vector-free period; and
 - (b) one night per month during the vector-free period.

On the basis of the evidence obtained in the first 3 years of operating the aspiration traps, the frequency of operation of those traps may be adjusted.

3. At least one aspiration trap must be placed in each geographical unit referred to in point (a) of Article 40(1) throughout the seasonally BTV-free zone. A proportion of the midges collected in the aspiration traps must be sent to a specialised laboratory capable of counting and identifying the suspected vector species or complexes.
4. When entomological surveillance is organised in the context of determination of a vector-free period, a maximum threshold of *Culicoides* species must be defined for the interpretation of the results. In the absence of sound evidence supporting the determination of the maximum threshold, total absence of *Culicoides imicola* specimens and less than five parous *Culicoides* per trap must be used as maximum threshold.

CHAPTER 2

Movement of animals and germinal products

Section 1

Movement of animals

1. The animals originate from a Member State or a zone free from infection with BTV and have not been vaccinated with a live vaccine against infection with BTV in the last 60 days before the date of movement.
2. The animals originate from a Member State or a zone covered by the eradication programme and at least one of the following requirements is complied with:
 - (a) the animals have been kept in a seasonally BTV-free Member State or zone established in accordance with paragraph 3 of Article 40:
 - (i) for at least 60 days prior to the date of movement;
 - (ii) for at least 28 days prior to the date of movement and have been subjected to a serological test, with negative results, carried out on samples collected at least 28 days following the entry date of the animal into the seasonally BTV-free Member State or zone; or
 - (iii) for at least 14 days prior to the date of movement and have been subjected to a PCR test, with negative results, carried out on samples collected at least 14 days following the entry date of the animal into the seasonally BTV-free Member State or zone;
 - (b) the animals have been protected against attacks by the vectors during transportation to the place of destination and they have been kept protected against attacks by vectors in a vector protected establishment:
 - (i) for at least 60 days prior to the date of movement; or
 - (ii) for at least 28 days prior to the date of movement and have been subjected to a serological test, with negative results, carried out on samples collected at least 28 days following the date of the commencement of the period of protection against attacks by vectors; or
 - (iii) for at least 14 days prior to the date of movement and have been subjected to a PCR test, with negative results, carried out on samples collected at least 14 days following the date of commencement of the period of protection against attacks by vectors;
 - (c) the animals have been vaccinated against all serotypes 1-24 of BTV reported during the past 2 years in that Member State or zone, the animals are within the immunity period guaranteed in the specifications of the vaccine and meet at least one of the following requirements:
 - (i) they have been vaccinated more than 60 days before the date of movement; or
 - (ii) they have been vaccinated with an inactivated vaccine and subjected to a PCR test, with negative results on samples collected at least 14 days after the onset of the immunity set in the specifications of the vaccine.
 - (d) the animals have been subjected with positive results to a serological test able to detect specific antibodies against all serotypes 1-24 of BTV reported during the past 2 years in that Member State or zone and:
 - (i) the serological test have been carried out on samples collected at least 60 days before the date of movement; or
 - (ii) the serological test have been carried out on samples collected at least 30 days before the date of the movement and the animals have been subjected to a PCR test, with negative results, carried out on samples collected not earlier than 14 days before the date of movement.
3. The animals originate from a Member State or a zone neither BTV-free nor covered by an eradication programme for infection with BTV and:
 - (a) they comply with point 2(b); or

- (b) the animals have been kept at least for the last 60 days prior to departure either in an area of at least 150 km radius from the establishment where they are kept, or in a Member State, where surveillance in compliance with the requirements laid down in Sections 1 and 2 of Chapter 1 have been carried out at least for the last 60 days prior to departure and:
 - (i) they have been vaccinated in accordance with point 2(c) against all serotypes 1-24 of BTV reported during the past 2 years in an area of at least 150 km radius centred on the place where the animals were kept; or
 - (ii) they have been immunised in accordance with point 2(d) against all serotypes 1-24 of BTV reported during the past 2 years in an area of at least 150 km radius centred on the place where the animals were kept.
- 4. The animals originate from a Member State or a zone not BTV-free, are destined for immediate slaughter and the following requirements apply:
 - (a) no case of infection with BTV has been reported in the establishment of origin for a period of at least 30 days prior to the date of movement;
 - (b) the animals are transported directly from the Member State or zone of origin to the slaughterhouse of destination where they are slaughtered within 24 hours of arrival;
 - (c) the operator of the establishment of origin have informed the operator of the slaughterhouse of destination of the movement at least 48 hours prior to the loading of the animals.
- 5. The animals originate from a Member State or a zone neither BTV-free nor covered by an eradication programme for infection with BTV and the animals comply with the requirements set out in point 2(a).
- 6. The animals originate from a Member State or a zone not BTV-free and:
 - (a) they have been protected from vector attacks by insecticides or repellents for at least 14 days prior to the date of movement; and
 - (b) they have been subjected during that period to a PCR test, with negative results, carried out on samples collected at least 14 days following the date of protection from vector attacks.
- 7. The animals comply with specific animal health requirements defined by the competent authority to ensure they have sufficient immunological protection prior to departure.
- 8. The animals comply with any of the requirements provided for in points 2, 3 5, 6 or 7 only for the serotypes of BTV reported for the past 2 years in the Member State or zone of origin and not in the Member State or zone of destination during the same period.

Section 2

Movement of germinal products

- 1. The donor animals have been kept at least for a period of 60 days prior to and during the collection of germinal products in a Member State or a zone free from infection with BTV.
- 2. The germinal products originate from a Member State or a zone covered by the eradication programme for infection with BTV and at least one of the requirements set out in point (a) for semen, point (b) for in vivo derived embryos of bovine animals or point (c) for embryos other than in vivo derived embryos of bovine animals and oocytes is complied with:
 - (a) semen have been obtained from donor animals that comply with at least one of the following requirements:
 - (i) they have been protected against attacks by vectors in a vector protected establishment for a period of at least 60 days before commencement of collection and during collection of the semen;
 - (ii) they have been kept in a seasonally BTV-free Member State or zone for a period of at least 60 days before commencement of collection and during collection of the semen;
 - (iii) they have been subjected to a serological test, with negative results, on samples collected between 28 and 60 days from the date of each collection of the semen;

- (iv) they have been subjected, with negative results, to a direct diagnostic method carried out on samples collected:
 - at commencement and final collection of the semen to be consigned; and
 - during the period of semen collection: at least every 7 days in the case of a virus isolation test, or at least every 28 days, in the case of a PCR test;
 - (b) in vivo derived embryos of bovine animals have been obtained from donor animals that do not show any clinical signs of infection with BTV on the day of collection and are collected, processed and stored in accordance with Part 2 of Annex III of Commission Delegated Regulation (EU) 2020/686 ⁽²⁾;
 - (c) embryos other than in vivo derived embryos of bovine animals and oocytes have been obtained from donor animals that comply with at least one of the following requirements:
 - (i) they have been protected against attacks by vectors in a vector protected establishment for at least 60 days before commencement of collection and during collection of the embryos/oocytes;
 - (ii) they have been subjected to a serological test, with negative results, on samples collected between 28 and 60 days from the date of each collection of the embryos/oocytes;
 - (iii) they have been subjected to a PCR test, with negative results, on samples collected on the day of collection of the embryos/oocytes;
 - (iv) they have been kept in a seasonally BTV-free Member State or zone for a period of at least 60 days before collection of the embryos/oocytes.
3. The germinal products originate from a Member State or a zone neither BTV-free nor covered by an eradication programme for infection with BTV and comply with the requirements set out either in point 2(a)(i), 2(a)(iii), 2(a)(iv), 2(b), 2(c)(i), 2(c)(ii) or 2(c)(iii).
4. The germinal products originate from a Member State or a zone neither BTV-free nor covered by an eradication programme for infection with BTV and must comply with either point 2(a)(ii) or 2(c)(iv).

CHAPTER 3

Vector protected establishment

The status of vector protected establishment may only be granted to an establishment if:

- (a) it has appropriate physical barriers at entry and exit points;
- (b) openings must be vector screened with mesh of appropriate gauge which must be impregnated regularly with an approved insecticide according to the manufacturers' instructions;
- (c) vector surveillance and control must be carried out within and around the vector protected establishment;
- (d) measures must be taken to limit or eliminate breeding sites for vectors in the vicinity of the vector protected establishment; and
- (e) standard operating procedures must be in place, including descriptions of back-up and alarm systems, for operation of the vector protected establishment and transport of animals to the place of loading.

CHAPTER 4

Member State or zone free from infection with BTV

Section 1

Granting of the status

1. The status free from infection with BTV may only be granted to a Member State or to a zone, where BTV has never been reported, if:
- (a) surveillance in accordance with Section 1 of Chapter 1 has been conducted at least for the past 24 months; and

⁽²⁾ Commission Delegated Regulation (EU) 2020/686 of 17 December 2019, supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (see page 1 of this Official Journal).

- (b) no case of infection with BTV has been confirmed during the past 24 months in the targeted animal population.
- 2. The status free from infection with BTV may only be granted to a Member State or to a zone where BTV has already been reported if:
 - (a) surveillance in accordance with Section 3 of Chapter 1 has been conducted at least for the past 24 months; and
 - (b) no case of infection with BTV has been confirmed during the past 24 months in the targeted animal population.

Section 2

Maintenance of the status

- 1. The status free from infection with BTV may only be maintained if:
 - (a) the requirements laid down in point 1 of Section 1 are complied with; and
 - (b) animals and germinal products from the targeted animal population are only moved into or through the Member State or zone when the requirements laid down in Articles 43 and 45 are complied with.
- 2. The intensity and frequency of the surveillance referred to in point 1 of Section 1 must be duly adapted to:
 - (a) the health status of neighbouring Member States, zones or third countries in accordance with point 3 of Section 4 of Chapter 1;
 - (b) the introduction of animals from the targeted animal population that may have jeopardised the health status of the Member State or zone, in accordance with point 6 of Section 4 of Chapter 1.
- 3. If no circulation of the infection has been detected for 2 consecutive years following granting of the status free from infection with BTV of a Member State or of a zone, surveillance must be based on:
 - (a) random annual surveillance at least to detect, with a 95 % level of confidence, the infection with BTV at a target prevalence rate of 20 %; or
 - (b) risk-based annual surveillance to detect infection with BTV carried out taking into account the systems of production and the risk factors identified.

CHAPTER 5

Seasonally BTV-free Member State or zone

- 1. The seasonally BTV-free status may only be established in a Member State or zone thereof if:
 - (a) the beginning and the end of the vector-free period and therefore of the seasonally BTV-free period has been demonstrated based on entomological surveillance in accordance with Section 5 of Chapter 1; and
 - (b) the cessation of the transmission of BTV has been demonstrated by:
 - (i) the implementation of surveillance in accordance with Section 2 of Chapter 1 at least for the past 12 months including one full vector activity season; and
 - (ii) the absence of new cases of infection with any of the serotypes 1-24 of BTV since the end of the vector activity season.
- 2. By way of derogation from point 1(a), if the seasonally BTV-free period has been successfully demonstrated for a period of 3 consecutive years, additional criteria such as temperature may replace entomological surveillance to substantiate the beginning and the end of the seasonally BTV-free period on the basis of scientific evidence.
- 3. The seasonally BTV-free Member State or zone must immediately stop when there is evidence of the end of the vector-free period or of circulation of the virus.

PART III

INFESTATION WITH VARROA SPP.

Section 1

Granting of the status to a Member State or zone as free from infestation with *varroa* spp.

The status free from infestation with *Varroa* spp. may only be granted to the relevant honeybee population of a Member State or of a zone if:

- (a) a risk assessment has been conducted, identifying all potential factors for *Varroa* spp. occurrence and its potential presence in the past;
- (b) an ongoing awareness programme has been in place for at least one year to encourage reporting of all cases suggestive of *Varroa* spp.;
- (c) there has been no confirmed case of infestation with *Varroa* spp. either in kept or in wild honeybee colonies;
- (d) for at least one year, an annual surveillance has demonstrated the absence of infestations with *Varroa* spp. on a representative sample of kept honeybees of the Member State or zone thereof that allows at least for the detection, with a 95 % level of confidence, of the infestation with *Varroa* spp. at a target prevalence rate of 1 % of the apiaries and at a within-apiary target prevalence rate of 5 % of the beehives;
- (e) in the presence of a wild self-sustaining population of the species of the genus *Apis* there has been in place for at least one year an ongoing surveillance programme in the wild population which demonstrates no evidence of infestation with *Varroa* spp.; and
- (f) during the whole duration of the surveillance referred to in point (d) the competent authority makes appropriate arrangements for the survey and further handling of honeybees in any stage of their lifecycle, including honeybee brood, which are moved into that Member State or into that zone to prevent the infestation of its population from introduced honeybees of lesser health status.

Section 2

Maintenance of the status of a Member State or zone free from infestation with *varroa* spp.

The status free from infestation with *Varroa* spp. granted to the relevant honeybee population of a Member State or of a zone may only be maintained if:

- (a) the competent authority maintains a surveillance that:
 - (i) demonstrates the absence of infestations with *Varroa* spp. annually on a representative sample of kept honeybees of the free area;
 - (ii) enables the early detection of infestation with *Varroa* spp. in apiaries and beehives;
 - (iii) takes into consideration specifically target areas with higher likelihood of introduction of or infestation with *Varroa* spp., based on a risk assessment;
- (b) all the suspected cases have been investigated and no case of infestation with *Varroa* spp. has been confirmed, either in kept or in wild honeybee colonies;
- (c) either there is no wild self-sustaining population of the species of the genus *Apis* or there is an ongoing surveillance programme in the wild population which demonstrates no evidence of infestation with *Varroa* spp.; and
- (d) the honeybees in any stage of their lifecycle, including honeybee brood, are only moved into the free area when:
 - (i) they come from a Member State or zone thereof or from a third country or territory with disease-free status regarding infestation with *Varroa* spp.; and
 - (ii) they are protected from infestation with *Varroa* spp. during transport.

PART IV

STATUS FREE FROM INFECTION WITH NEWCASTLE DISEASE VIRUS- WITHOUT VACCINATION

Section 1

Granting of status free from infection with Newcastle disease virus without vaccination

The status free from infection with Newcastle disease virus (NDV) status without vaccination in the population of poultry and captive birds of *Galliformes* species may only be granted to a Member State or to a zone if for at least the past 12 months:

- (a) vaccination against infection with NDV in poultry and in captive birds of *Galliformes* species has been prohibited;
- (b) no poultry and no captive birds of *Galliformes* species vaccinated against infection with NDV has been kept in establishments keeping poultry or captive birds of *Galliformes* species;
- (c) general surveillance requirements have been carried out in accordance with point (a) of Article 3(1) for the early detection of infection with NDV;
- (d) one of the following testing regime has applied:
 - (i) all establishments keeping breeding poultry have been tested for the presence of antibodies against infection with NDV with negative results, on blood samples from at least 60 birds randomly chosen from each establishment and tested serologically by Haemagglutination inhibition (HI) test; or
 - (ii) a survey has been conducted on a representative sample of establishments which has at least the capacity at least to detect, with a 95 % level of confidence, the infection at a target prevalence rate of 1 % in the poultry establishments and at a within-establishment prevalence rate of seropositive birds of 10 %; and
- (e) no case of infection with NDV has been confirmed in poultry and captive birds of *Galliformes* species.

Section 2

Maintenance of the status

1. The status free from infection with NDV without vaccination granted to a Member State or to a zone may only be maintained if the requirements in points (a) to (e) of Section 1 continue to be fulfilled.
 2. By way of derogation from paragraph 1, the status free from infection with NDV without vaccination granted to a Member State or to a zone may be maintained in the event of the confirmation of a case of infection with NDV if:
 - (a) the relevant disease control measures have been immediately implemented on each establishment with suspected or confirmed cases until the incident has been resolved;
 - (b) the competent authority has concluded that only a limited number of establishments, epidemiologically linked to the first detected outbreak, were infected; and
 - (c) during a period of 12 months, the disease control measures referred to in point (a) were not applied for a duration longer than three months.
 3. The status free from infection with NDV without vaccination granted to a Member State or to a zone is not affected by the confirmation of the infection in another bird population, provided the competent authority has assessed, taking into account the implementation of all necessary measures to prevent transmission of infection with NDV to poultry and captive birds of *Galliformes* species, that the status was not jeopardised.
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ANNEX VI

SPECIFIC REQUIREMENTS AS REGARDS DISEASES OF AQUATIC ANIMALS

PART I

RISK-BASED SURVEILLANCE

CHAPTER 1

Minimum requirements for risk-based surveillance in certain approved aquaculture establishments**1. General approach**

- 1.1. Risk-based health surveillance which includes health visits and possible sampling is applied in certain approved aquaculture establishments and in certain approved groups of aquaculture establishments in a manner that is appropriate to the nature of the production and which has the objective of detecting:
 - (a) increased mortality;
 - (b) listed diseases;
 - (c) emerging diseases.
- 1.2. The frequency of such visits will depend on the risk the approved aquaculture establishment or approved group of aquaculture establishments poses in relation to contracting and spreading disease. This risk applies to listed diseases and to potential emerging diseases and will therefore include aquaculture establishments and groups of aquaculture establishments keeping listed species and in certain cases, aquaculture establishments and groups of aquaculture establishments keeping non-listed species. The competent authority must determine the risk posed by each approved aquaculture establishment or approved group of aquaculture establishments and rank them as high, medium or low risk.

Chapter 2 provides details of the risk factors to be taken into account during the risk ranking process. Such risk ranking will be repeated and updated if any of the risk factors outlined in points (a) to (l) indicate that the risk posed by the establishment has changed.
- 1.3. Chapter 3 sets out the minimum frequency of health visits which must be completed, based on whether the competent authority has designated an establishment to be high, medium or low risk.
- 1.4. Risk-based animal health surveillance in aquaculture establishments and groups of aquaculture establishments may be combined with health visits and sampling which are carried out:
 - (a) as part of compulsory or optional eradication programmes for one or more listed diseases; or
 - (b) to demonstrate and maintain disease free status for one or more listed diseases; or
 - (c) as part of a surveillance programme for one or more category C diseases.

CHAPTER 2

Risk ranking to be applied in certain approved aquaculture establishments

The risk ranking referred to in point 1.2 of Chapter 1 must as a minimum, take into account the risk factors referred to in points (a) and (b). Where relevant, points (c) to (l) will also be considered:

- (a) possibility of the direct spread of pathogens via water;
- (b) movements of aquaculture animals;
- (c) type of production;
- (d) species of aquaculture animals kept;
- (e) biosecurity system, including staff competence and training;

- (f) density of aquaculture establishments and processing establishments in the area around the establishment concerned;
- (g) proximity of establishments with a lower health status than the establishment concerned;
- (h) disease history of the establishment concerned and of other local establishments;
- (i) presence of infected wild aquatic animals in the area around the establishment concerned;
- (j) risk posed by human activities in the proximity of the establishment concerned for example angling, the presence of transport routes, ports at which ballast water is exchanged;
- (k) access to the establishment concerned by predators which may cause disease spread;
- (l) track record of the establishment as regards compliance with the requirements of the competent authority.

CHAPTER 3

Frequency of risk-based animal health visits

The frequency of risk-based health visits which must be carried out in certain approved establishments and approved groups of establishments depends upon the risk ranking referred to in Chapter 2 and shall be carried out as follows:

- (a) at least once per year in high risk establishments;
- (b) at least once every two years in medium risk establishments;
- (c) at least once every three years in low risk establishments.

PART II

DISEASE- SPECIFIC REQUIREMENTS FOR DISEASE-FREE STATUS OF AQUATIC ANIMALS

Part II covers the disease-specific requirements for disease-free status as regards the following listed diseases:

Viral haemorrhagic septicaemia (VHS)	Chapter 1
Infectious haematopoietic necrosis (IHN)	Chapter 1
Infection with HPR-deleted infectious salmon anaemia virus	Chapter 2
Infection with <i>Marteilia refringens</i>	Chapter 3
Infection with <i>Bonamia exitiosa</i>	Chapter 4
Infection with <i>Bonamia ostreae</i>	Chapter 5
Infection with white spot syndrome virus (WSSV)	Chapter 6

CHAPTER 1

Eradication, disease-free status and diagnostic methods for viral haemorrhagic septicaemia (VHS) and infectious hematopoietic necrosis (IHN)

Section 1

General requirements for health visits and sampling

Health visits and sampling for the surveillance referred to in point (b)(ii) of Article 3(2) must comply with the following requirements:

- (a) health visits and, where appropriate sampling, must be carried out during the period of the year when the water temperature is below 14 °C or when temperatures below 14 °C are not reached, samples must be taken at the lowest annual temperatures;

- (b) when targeted surveillance in wild populations is required due to the small number of aquaculture establishments in an eradication programme, the number and geographical distribution of sampling points must be determined to obtain a reasonable coverage of the Member State, zone or compartment. The sampling points must be representative of the different ecosystems where wild populations of susceptible species are located;
- (c) when establishments or wild populations are to be subject to health visits or sampled more than once per year, in accordance with Sections 2 to 4, the intervals between the health visits and between the collection of samples must be at least 4 months, or as long as possible, taking into account the temperature requirements provided for in point (a);
- (d) all production units, such as ponds, tanks and net cages, must be examined for the presence of dead, weak or abnormally behaving fish. Particular attention must be paid to the water outlet area where weak fish tend to accumulate because of the water current;
- (e) fish of listed species to be collected as samples must be selected as follows:
 - (i) if rainbow trout are present, only fish of that species must be selected for sampling, except where other susceptible species are present which show typical signs of VHS or IHN; if rainbow trout are not present, the sample must be representative of all other susceptible species which are present;
 - (ii) if weak, abnormally behaving or freshly dead but not decomposed fish are present, such fish must be selected; if more than one water source is utilised for fish production, fish representing all water sources must be included in the sample;
 - (iii) the fish selected must include fish collected in such a way that all production units, such as net cages, tanks and ponds, of the establishment, as well as all year classes, are proportionally represented in the sample.

Section 2

Granting of the status free from VHS or free from IHN in Member States, zones and compartments of unknown health status

The status free from VHS or free from IHN may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to VHS or IHN if:

- (a) all establishments and, when required, sampling points in wild populations selected in accordance with point (b) of Section 1, have been subject to one of the following scheme:

- (i) model A — 2-year scheme

The establishments or sampling points must have been subject to health visits and sampled for a minimum period of 2 consecutive years as laid down in Table 1.A.

During that 2-year period, the testing of all samples using the diagnostic methods set out in point 2 of section 5 must have produced negative results for VHS or IHN, and any suspicion of VHS or IHN must have been ruled out in accordance with the sampling and diagnostic methods set out in point 3 of Section 5;

- (ii) model B — 4-year scheme with reduced sample size

The establishments or sampling points must have been subject to health visits and sampled for a minimum period of 4 consecutive years as laid down in Table 1.B. During that 4-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 must have produced negative results for VHS or IHN and any suspicion of VHS or IHN must have been ruled out in accordance with the sampling and diagnostic methods set out in point 3 of Section 5;

- (b) if VHS or IHN have been detected during the surveillance referred to in point (a); before starting a new 2-year or 4-year scheme, relevant establishments in the Member State, zone or compartment must:

- (i) be subject to the minimum disease control measures laid down in Articles 58 to 65;
 - (ii) be repopulated with fish from an establishment in a Member State, zone or compartment with status free from VHS or status free from IHN or from an establishment in a Member State, zone or compartment covered by an eradication programme for VHS or IHN.

Table 1.A

Scheme for Member States, zones and compartments for the 2-year control period referred to in point (a)(i) which precedes the achievement of status free from VHS and status free from IHN

Type of establishment	Number of health visits per year to each establishment	Number of samplings per year in each establishment	Number of fish in the sample ⁽¹⁾	
			Number of growing fish	Number of broodstock fish ⁽²⁾
(a) Establishments with broodstock	2	2	50 (first visit) 75 (second visit)	30 (first or second visit)
(b) Establishments with broodstock only	2	1	0	75 (first or second visit)
(c) Establishments without broodstock	2	2	75 (first AND second visit)	0

Maximum number of fish per pool: 10

⁽¹⁾ In the case of coastal zones or coastal compartments, the samples must be collected no sooner than 3 weeks after the transfer of the fish from fresh to saltwater.

⁽²⁾ Ovarian or seminal fluid of broodstock shall be collected at the time of maturation, in connection with stripping.

Table 1.B

Scheme for Member States, zones or compartments using a reduced sample size for the 4-year control period referred to in point (a)(ii) which precedes the achievement of status free from VHS and status free from IHN

Type of establishment	Number of health visits per year to each establishment	Number of samplings per year in each establishment	Number of fish in the sample ⁽¹⁾	
			Number of growing fish	Number of broodstock fish ⁽²⁾

First 2 years

(a) Establishments with broodstock	2	1	30 (second visit)	0
(b) Establishments with broodstock only	2	1	0	30 (first or second visit)
(c) Establishments without broodstock	2	1	30 (first or second visit)	0

Last 2 years

(a) Establishments with broodstock	2	2	30 (first visit)	30 (second visit)
(b) Establishments with broodstock only	2	2		30 (first AND second visit)
(c) Establishments without broodstock	2	2	30 (first AND second visit)	

Maximum number of fish per pool: 10

⁽¹⁾ In the case of coastal zones or coastal compartments, the samples must be collected no sooner than 3 weeks after the transfer of the fish from fresh to saltwater.

⁽²⁾ Ovarian or seminal fluid of broodstock shall be collected at the time of maturation, in connection with stripping.

Section 3

Granting of the status free from VHS or free from IHN in Member States, zones and compartments known to be infected with either VHS or IHN

1. The status free from VHS or free from IHN may only be granted to a Member State, a zone or a compartment known to be infected with VHS or IHN, if all establishments keeping listed species within that Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:
 - (a) the minimum control measures laid down in Articles 55 to 65 must have been effectively applied and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate, divided into a protection zone and surveillance zone; must have been established in the vicinity of the establishment(s) declared infected with VHS or IHN, taking into account the requirements set out in point 2;
 - (b) all establishments keeping listed species within the protection zone, or where a protection zone has not been established, the restricted zone, not infected with VHS or IHN must be subject to an investigation comprising at least the following elements:
 - (i) the collection of samples for testing of 10 fish, when clinical signs or *post-mortem* lesions consistent with infection with VHS or IHN are observed or minimum 30 fish, when clinical signs or *post-mortem* lesions are not observed;
 - (ii) in those establishments where the tests referred to in (i) have produced negative results; health visits must continue once per month during the period when the water temperature is below 14 °C, except when fish ponds, tanks, raceways or net cages are covered with ice, until the protection zone is withdrawn in accordance with point (c);
 - (c) relevant establishments must be emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63 and fallowed in accordance with Article 64.

The duration of the fallowing period referred to in point (a) of Article 64(2) must be at least 6 weeks. When all establishments infected within the same protection zone, or where a protection zone has not been established, the restricted zone, are emptied, at least 3 weeks of synchronised fallowing must be carried out.

When fallowing of the infected establishments is carried out, the restricted zone or the protection zone, when it has been established, must be converted into a surveillance zone until the scheme set out in Section 2 is completed;
 - (d) repopulation may only take place when all infected establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);
 - (e) all establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme and when surveillance in wild populations is required, all sampling points selected in accordance with point (b) of Section 1, must subsequently be subject to the scheme laid down in Section 2;
 - (f) an individual establishment which keeps listed species and which has a health status which is independent of the health status of the surrounding waters is not required to comply with the scheme laid down in Section 2 following a disease outbreak, provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is repopulated with fish sourced from Member States, zones or compartments with status free from VHS or status free from IHN.
2. The restricted zone must have been defined on a case-by-case basis and:
 - (a) it must take into account factors influencing the risks for the spread of VHS or IHN to kept and wild fish, such as:
 - (i) the number, rate and distribution of the mortalities of fish on the establishment infected with VHS or IHN, or in other aquaculture establishments;
 - (ii) the distance to and density of neighbouring establishments;
 - (iii) the proximity to slaughterhouses;
 - (iv) contact establishments;
 - (v) species present at the establishments;
 - (vi) the farming practices applied in the infected establishments and the neighbouring establishments;

- (vii) the hydrodynamic conditions; and
 - (viii) other factors of epidemiological significance identified;
- (b) the geographical demarcation in coastal areas must comply with the following minimum requirements:
- (i) the protection zone must consist of an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment infected with VHS or IHN, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data; and
 - (ii) the surveillance zone must consist of an area surrounding the protection zone, of overlapping tidal excursion zones; or an area surrounding the protection zone and included in a circle of radius 10km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;
- or
- (iii) where separate protection and surveillance zones are not established, the restricted zone must consist of an area comprising both the protection zone and the surveillance zone;
- (c) the geographical demarcation in inland areas must comprise the entire water catchment area in which the establishment infected with VHS or IHN is located. The competent authority may limit the extent of the restricted zone to parts of the water catchment area, provided this limitation does not compromise the disease control measures with respect to VHS or IHN.

Section 4

Maintenance of status free from VHS and status free from IHN

- When targeted surveillance is required in order to maintain the status free from VHS or free from IHN of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and fish must be sampled in accordance with Table 1.C, taking into account the risk level of the establishment for the contraction of VHS or IHN.
- When determining the frequency of health visits required to maintain the status free from VHS or the status free from IHN of compartments, where the health status regarding VHS or IHN is dependent on the health status of the aquatic animal populations in surrounding natural waters, the risk for the contraction of VHS or IHN must be regarded as high.
- Disease-free status must only be maintained as long as all samples tested, using the diagnostic methods set out in point 2 of Section 5, have produced negative results for VHS or IHN and any suspicion of VHS or IHN has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5.

Table 1.C

Scheme for Member States, zones or compartments to maintain status free from VHS or status free from IHN

Risk level ⁽¹⁾	Number of health visits per year to each establishment	Number of fish in the sample ⁽²⁾ , ⁽³⁾
High	1 every year	30
Medium	1 every 2 years	30
Low	1 every 3 years	30

Maximum number of fish per pool: 10

⁽¹⁾ Risk level assigned to the establishment by the competent authority as set out in Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.

⁽²⁾ One sample to be taken during every health visit.

⁽³⁾ In the case of coastal zones or coastal compartments, the samples must be collected no sooner than 3 weeks after the transfer of the fish from fresh to saltwater.

Section 5

Diagnostic and sampling methods

1. The organs or tissue material to be sampled and examined must be the spleen, the anterior kidney, and either heart or encephalon. When sampling broodstock, ovarian or seminal fluid may also be examined.

In case of small fry, whole fish may be sampled.

Samples from a maximum of 10 fish may be pooled.

2. The diagnostic method for the granting or the maintenance status free from VHS or status free from IHN in accordance with Sections 2 to 4 must be:
 - (a) virus isolation in cell culture with subsequent identification of the virus using ELISA, indirect fluorescent antibody test (IFAT), virus neutralisation test or virus genome detection; or
 - (b) Reverse Transcription quantitative PCR (RT-qPCR) detection.

The detailed procedures to carry out these diagnostic methods must be those approved by the EURL for fish diseases.

3. When a suspicion of VHS or IHN is required to be confirmed or ruled out in accordance with Article 55, the following health visit, sampling and testing procedures must comply with the following requirements:
 - (a) the suspected establishment must be subject to at least one health visit and one sampling of 10 fish, when clinical signs or *post-mortem* lesions consistent with infection with VHS or IHN are observed or minimum 30 fish, when clinical signs or *post-mortem* lesions are not observed. Samples shall be tested using one or more of the diagnostic methods set out in points 2(a) and 2(b) in accordance with the detailed diagnostic methods and procedures approved by the EURL for fish diseases;
 - (b) the presence of VHS must be considered as confirmed, if one or more of those diagnostic methods are positive for VHSV. The presence of IHN must be considered as confirmed, if one or more of those diagnostic methods are positive for IHNV. The confirmation of the first case of VHS or IHN in Member States, zones or compartments previously not infected must be based on conventional virus isolation in cell culture with subsequent immunochemical or molecular identification or with genome detection including confirmation by sequencing of the amplification (RT-PCR) product;
 - (c) Suspicion of VHS or IHN may be ruled out, if cell cultivation or RT-qPCR tests reveal no further evidence of the presence of VHSV or IHNV.

CHAPTER 2

Eradication, disease-free status and diagnostic methods for infection with HPR-deleted infectious salmon anaemia virus (HPR-deleted ISAV)

Section 1

General requirements for health visits and sampling

Health visits and sampling for the surveillance referred to in point (b)(ii) of Article 3(2) must comply with the following requirements:

- (a) when health visits and sampling of establishments must be carried out more than once per year in accordance with Sections 2 to 4, the intervals between the health visits or collection of samples shall be as long as possible;
- (b) when targeted surveillance in wild populations is required due to the low number of aquaculture establishments in the eradication programme, the number and geographical distribution of sampling points must be determined to obtain a reasonable coverage of the Member State, zone or compartment;
- (c) the sampling points must be representative of the different ecosystems where the wild populations of susceptible species are located;
- (d) all production units, such as ponds, tanks and net cages, must be examined for the presence of dead, weak or abnormally behaving fish. Particular attention must be paid to the edge of cages or the water outlet area as relevant, where weak fish tend to accumulate because of the water current;

- (e) fish of listed species to be collected as samples must be selected as follows:
- (i) if Atlantic salmon are present, only fish of that species must be selected for sampling, except where other susceptible species are present which show typical signs of infection with HPR-deleted ISAV. If there are no Atlantic salmon in the establishment, the sample must be representative of all other susceptible species which are present;
 - (ii) if moribund or freshly dead, but not decomposed fish are present, such fish must be selected, in particular fish demonstrating anaemia, haemorrhages or other clinical signs suggesting circulatory disturbances; if more than one water source is utilised for fish production, fish representing all water sources must be included in the sample;
 - (iii) the fish selected must include fish collected in such a way that all production units, such as net cages, tanks and ponds, of the establishment as well as all year classes are proportionally represented in the sample.

Section 2

Granting of the status free from infection with HPR-deleted ISAV in Member States, zones and compartments of unknown health status

The status free from infection with HPR-deleted ISAV may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to infection with HPR-deleted ISAV if all establishments and, when required, selected sampling points in wild populations selected in accordance with (b) of Section 1, have been subject to the following scheme:

- (a) the establishments or sampling points have been subject to health visits and sampled for a minimum period of 2 consecutive years as laid down in Table 2.A;
- (b) during that 2-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 must have produced negative results for HPR-deleted ISAV and any suspicion of infection must have been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5;
- (c) If infection with HPR-deleted ISAV is detected during the surveillance referred to in point (a); before re-starting the scheme, relevant establishments within the Member State, zone or compartment must:
 - (i) be subject to the minimum disease control measures laid down in Articles 58 to 65;
 - (ii) be repopulated with fish from an establishment in a Member State, zone or compartment free from infection with HPR-deleted ISAV or from an establishment in a Member State, zone or compartment covered by an eradication programme for that disease.

Table 2.A

Scheme for Member States, zones and compartments for the 2-year control period which precedes the achievement of status free from infection with HPR-deleted ISAV

Year of surveillance	Number of health visits per year to each establishment	Number of laboratory examinations per year ⁽¹⁾	Number of fish in the sample
Year 1	6	2	75
Year 2	6	2	75

⁽¹⁾ Samples must be collected during spring and autumn each year.

Maximum number of fish per pool: 5.

Section 3

Granting of the status free from infection with HPR-deleted ISAV in Member States, zones and compartments known to be infected with HPR-deleted ISAV

1. The status free from infection with HPR-deleted ISAV may only be granted to a Member State, a zone or a compartment known to be infected with HPR-deleted ISAV if all establishments keeping listed species within the Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:

- (a) the minimum control measures laid down in Articles 55 to Article 65 have been applied and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate, divided into a protection zone and a surveillance zone, must have been established in the vicinity of the establishment(s) infected with HPR-deleted ISAV, taking into account the requirements set out in point 2;
- (b) all establishments keeping listed species within the protection zone, or where a protection zone has not been established, the restricted zone, not infected with HPR-deleted ISAV must be subject to an investigation comprising at least the following elements:
 - (i) the collection of samples for testing of minimum 10 moribund fish, when clinical signs or *post-mortem* lesions consistent with infection with HPR-deleted ISAV are observed, or minimum 30 fish when clinical signs or *post mortem* lesions are not observed;
 - (ii) in those establishments where the tests referred to in (i) have produced negative results, the health visits must continue once per month until the protection zone is withdrawn in accordance with point (c);
- (c) relevant establishments must be emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63 and fallowed in accordance with Article 64.

The duration of the fallowing period referred to in point (b) of Article 64(2) shall be at least 3 months. When all establishments infected within the same protection zone, or where a protection zone has not been established, the restricted zone, are emptied, at least 6 weeks of synchronised fallowing must be carried out.

When fallowing of the infected establishments is carried out, the restricted zone or the protection zone, when it has been established, must be converted into a surveillance zone until the scheme set out in Section 2 is completed;

- (d) repopulation may only take place when all infected establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);
 - (e) all establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme and when surveillance in wild populations is required, all sampling points selected in accordance with point (b) of Section 1, must subsequently be subject to the scheme set out in Section 2;
 - (f) an individual establishment which keeps listed species and which has a health status which is independent of the health status of the surrounding waters is not required to comply with the scheme set out in Section 2 following a disease outbreak provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is re-populated with fish sourced from Member States, zones or compartments with status free from infection with HPR-deleted ISAV.
2. The restricted zone must have been defined on a case-by-case basis and:
- (a) it must take into account factors influencing the risks for the spread of infection with HPR-deleted ISAV to kept and wild fish, such as:
 - (i) the number, rate and distribution of the mortalities on the establishment infected with HPR-deleted ISAV or in other aquaculture establishments;
 - (ii) the distance to and density of neighbouring establishments;
 - (iii) the proximity to slaughterhouses;
 - (iv) contact establishments;
 - (v) species present at the establishments;
 - (vi) the farming practices applied in the infected establishments and in the neighbouring establishments to the infected establishment;
 - (vii) the hydrodynamic conditions; and
 - (viii) other factors of epidemiological significance identified;
 - (b) the geographical demarcation in coastal areas must comply with the following minimum requirements:
 - (i) the protection zone must consist of an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment infected with HPR-deleted ISAV, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data; and

- (ii) the surveillance zone must consist of an area surrounding the protection zone, of overlapping tidal excursion zones; or an area surrounding the protection zone and included in a circle of radius 10km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;
- or
- (iii) where separate protection and surveillance zones are not established, the restricted zone must consist of an area comprising both the protection zone and the surveillance zone;
- (c) the geographical demarcation in inland areas must comprise the entire water catchment area in which the establishment infected with HPR-deleted ISAV is located. The competent authority may limit the extent of the restricted zone to parts of the water catchment area, provided this limitation does not compromise the disease control measures with respect to infection with HPR-deleted ISAV.

Section 4

Maintenance of status free from infection with HPR-deleted ISAV

- When targeted surveillance is required in order to maintain the status free from infection with HPR-deleted ISAV of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and fish must be sampled in accordance with Table 2.B, taking into account the risk level of the establishment for the contraction of infection with HPR-deleted ISAV.
- When determining the frequency of health visits required to maintain the status free from infection with HPR-deleted ISAV of compartments where the health status is dependent on the health status of the aquatic animal population in surrounding natural waters, the risk for the contraction of infection with HPR-deleted ISAV must be regarded as high.
- Disease-free status must only be maintained as long as all samples tested, using the diagnostic methods set out in point 2 of Section 5, have produced negative results for HPR-deleted ISAV and any suspicion of infection with HPR-deleted ISAV has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5.

Table 2.B

Scheme for Member States, zones or compartments to maintain status free from infection with HPR-deleted ISAV ⁽¹⁾

Risk level ⁽²⁾	Number of health visits per year	Number of laboratory examinations per year ⁽³⁾ , ⁽⁴⁾	Number of fish in the sample
High	2	2	30
Medium	1	1	30
Low	1 every 2 years	1 every 2 years	30

⁽¹⁾ Shall not apply to establishments rearing only rainbow trout (*Oncorhynchus mykiss*) or brown trout (*Salmo trutta*) or both rainbow trout and brown trout, and where the water supply is exclusively based on fresh water sources which are not populated with Atlantic salmon (*Salmo salar*).

⁽²⁾ Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.

⁽³⁾ Samples must be collected during spring and autumn when two samples are required each year

⁽⁴⁾ Samples must be collected during spring or autumn when one sample per year is required.

Maximum number of fish per pool: 5

Section 5

Diagnostic and sampling methods

1. The organs or tissue material to be sampled and examined must be:
 - (a) Histology: anterior-kidney, liver, heart, pancreas, intestine, spleen and gill;
 - (b) Immunohistochemistry: mid-kidney and heart including valves and *bulbus arteriosus*;
 - (c) RT-qPCR analysis: mid-kidney and heart;
 - (d) Virus culture: mid-kidney, heart, liver and spleen.

Organ pieces from a maximum of five fish may be pooled.

2. The diagnostic method to be used to grant or to maintain status free from infection with HPR-deleted ISAV in accordance with Sections 2 to 4 must be RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene of positive samples in accordance with the detailed methods and procedures which must be those approved by the EURL for fish diseases.

In the case of a positive RT-qPCR result, further samples must be tested before the implementation of the initial control measures provided for in Articles 55 to 65.

Those samples must be tested as follows in accordance with the detailed methods and procedures approved by the EURL for fish diseases:

- (a) screening of the samples by RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene to verify HPR-deletion; and
 - (b) detection of ISAV antigen in tissue preparations by means of specific antibodies against ISAV; or
 - (c) isolation in cell culture and subsequent identification of HPR-deleted ISAV.
3. When a suspicion of infection with HPR-deleted ISAV must be confirmed or ruled out in accordance with Article 55, the following visit, sampling and testing procedure must comply with the following requirements:
 - (a) the suspected establishment must be subject to at least one health visit and one sampling of 10 moribund fish, when clinical signs or *post-mortem* lesions consistent with infection with HPR-deleted ISAV are observed, or minimum 30 fish when clinical signs or *post-mortem* lesions are not observed. Samples shall be tested using one or more of the diagnostic methods set out in point 2 in accordance with the detailed diagnostic methods and procedures approved by the EURL for fish diseases;
 - (b) in the case of a positive result of RT-qPCR for HPR-deleted ISAV, further samples shall be tested before the implementation of the initial control measures provided in Article 58. A suspected case of infection with HPR-deleted ISAV shall be confirmed in accordance with the following criteria using the detailed methods and procedures approved by the EURL for fish diseases:
 - (i) Detection of ISAV by RT-qPCR, followed by sequencing of the HE-gene to verify HPR-deletion, and detection of ISAV in tissue preparations by means of specific antibodies against ISAV;
 - (ii) detection of ISAV by RT-qPCR, including sequencing of the HE-gene to verify HPR-deletion; and isolation and identification of ISAV in cell culture from at least one sample from any fish from the establishment;
 - (c) where the presence of clinical, gross pathological or histopathological findings consistent with infection are observed, the findings must be corroborated by virus detection by two diagnostic methods with independent principles of detection, such as RT-qPCR and IHC, in accordance with the procedures approved by the EURL for fish diseases.

The suspicion of HPR-deleted ISAV may be ruled out, if tests and health visits over a period of 12 months from the date of the suspicion are found to reveal no further evidence of the presence of the virus.

CHAPTER 3

Eradication, disease-free status and diagnostic methods for infection with *Marteilia refringens*

Section 1

General requirements for health visits and sampling

Health visits and sampling for the surveillance referred to in point (b)(ii) of Article 3(2) must comply with the following requirements:

- (a) health visits and, where appropriate, the sampling must be carried out in the period of the year when prevalence of the parasite in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling must be carried out just after the water temperature has exceeded 17 °C;
- (b) when molluscs must be sampled in accordance with the requirements set out in Sections 2 to 4, the following selection criteria must apply:
 - (i) if *Ostrea* spp. are present, only oysters of that species must be selected for sampling. If *Ostrea* spp. are not present, the sample must be representative of all other susceptible species present;
 - (ii) if weak, gaping or freshly dead but not decomposed molluscs are present in the production units, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;
 - (iii) when sampling in mollusc establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;
 - (iv) when sampling in mollusc establishments or groups of establishments, molluscs from a sufficient number of sampling points, must be included in the sample in such a way that all parts of the establishment or group of establishments are proportionally represented in the sample. The main factors to be considered for the selection of these sampling points are previous sampling points where *Marteilia refringens* was detected, stocking density, water flows, presence of susceptible species, presence of vector species, bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments must be included in the sampling.

Section 2

Granting of the status free from infection with *Marteilia Refringens* in Member States, zones and compartments of unknown health status

1. The status free from infection with *Marteilia refringens* may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to infection with *Marteilia refringens* if all establishments or groups of establishments keeping listed species within the Member State, zone or compartment and where required, sampling points in wild populations, have been subject to the following 3-year scheme:
 - (a) the establishments or groups of establishments keeping listed species have been subject to health visits and sampled for a minimum period of 3 consecutive years as laid down in Table 3.A;
 - (b) during that 3-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Marteilia refringens* and any suspicion of *Marteilia refringens* has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5;
 - (c) when *Ostrea edulis* sourced from a Member State, zone or compartment of disease-free status are to be included in the sample, they must have been introduced into the establishment or group of establishments at least in the spring just preceding the period when the scheme is carried out.
2. If *Marteilia refringens* is detected during the 3-year scheme set out in point 1, before starting a new 3-year scheme, relevant establishments in the Member State, zone or compartment must:
 - (a) be subject to the minimum disease control measures laid down in Articles 58 to 65;

- (b) be repopulated with molluscs from an establishment in a Member State, zone or compartment free from infection with *Marteilia refringens* or from an establishment in a Member State, zone or compartment covered by an eradication programme for that disease.

Table 3.A

Scheme for Member States, zones or compartments for the 3-year control period which precedes the achievement of status free from infection with *Marteilia refringens*

Year of surveillance	Number of health visits per year to each establishment/group of establishments	Number of laboratory examinations per year	Number of molluscs in the sample
Year 1	1	1	150
Year 2	1	1	150
Year 3	1	1	150

Section 3

Granting of the status free from infection with *Marteilia refringens* in Member States, zones and compartments known to be infected with *Marteilia refringens*

1. The status free from infection with *Marteilia refringens* may only be granted to a Member State, a zone or a compartment known to be infected with *Marteilia refringens*, where the competent authority judges that eradication of this disease to be feasible, if all establishments or groups of establishments keeping listed species within that Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:
 - (a) the minimum control measures laid down in Articles 55 to 65 have effectively been applied and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate divided into a protection zone and surveillance zone, must have been established in the vicinity of the establishment(s) or group of establishments infected with *Marteilia refringens*, taking into account the requirements set out in point 2;
 - (b) all establishments and groups of establishments keeping listed species within the protection zone, or where a protection zone has not been established, the restricted zone, not infected with *Marteilia refringens* must be subject to an investigation comprising at least the collection of samples for the testing of 150 molluscs after the beginning of the transmission period of *Marteilia refringens*. When the transmission period is not known, the sampling must begin in the period after the temperature of the water exceeds 17 °C;
 - (c) relevant establishments and groups of establishments must be emptied in accordance with Articles 62, and if possible cleaned and disinfected in accordance with Article 63.

Fallowing must be carried out in accordance with Article 64 and the duration of the fallowing period must be at least:

- (i) 2 months in case of the establishments and groups of establishments which can be fully drained and thoroughly cleaned and disinfected such as hatcheries and nurseries;
- (ii) 2 months in case of the establishments and groups of establishments which cannot be drained and thoroughly cleaned and disinfected provided that the infected molluscs of the listed species and those molluscs of the listed species with epidemiological links with the infected establishment or group of establishments have been harvested or removed before the period of the year when the prevalence of *Marteilia refringens* is known to be maximal, or when that period is not known, before the period when water temperature exceeds 17 °C;
- (iii) 14 months in case of the establishments and groups of establishments which cannot be drained and thoroughly cleaned and disinfected if the infected molluscs of the listed species and those molluscs of the listed species with epidemiological links with the infected establishment or group of mollusc establishments have not been harvested or removed before the period of the year when the prevalence of *Marteilia refringens* is known to be maximal or when such data is not known, when molluscs of the susceptible species have not been harvested or removed before the period when water temperature exceeds 17 °C.

When all infected establishments and infected groups of establishments are emptied, at least 4 weeks of synchronised fallowing must be carried out;

- (d) repopulation may only take place when all infected establishments or infected groups of establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);
- (e) all establishments and groups of establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme, must subsequently be subject to the scheme set out in Section 2;
- (f) an individual establishment which keeps listed species and which has a health status which is independent of the health status of the surrounding waters is not required to comply with the scheme set out in Section 2 following a disease outbreak provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is repopulated with molluscs sourced from Member States, zones or compartments with status free from infection with *Marteilia refringens*.

2. The restricted zone must have been defined on a case-by-case basis and:

- (a) it must take into account factors influencing the risks for the spread of infection with *Marteilia refringens* including other establishments and wild molluscs, such as:
 - (i) the number, age, rate and distribution of the mortalities of molluscs on the establishment or group of establishments infected with *Marteilia refringens*;
 - (ii) the distance to and density of neighbouring establishments or groups of establishments and wild molluscs;
 - (iii) the proximity to processing establishments, contact establishments or groups of establishments;
 - (iv) the species, especially susceptible species and vector species, present at the establishments or groups of establishments;
 - (v) the farming practices applied in the affected and neighbouring establishments and groups of establishments;
 - (vi) the hydrodynamic conditions; and
 - (vii) other factors of epidemiological significance identified;
 - (b) the geographical demarcation must comply with the following minimum requirements:
 - (i) the protection zone must consist of an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment infected with *Marteilia refringens*, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data; and
 - (ii) the surveillance zone must consist of an area surrounding the protection zone, of overlapping tidal excursion zones; or an area surrounding the protection zone and included in a circle of radius 10km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;
- or
- (iii) where separate protection and surveillance zones are not established, the restricted zone must consist of an area comprising both the protection zone and the surveillance zone.

Section 4

Maintenance of status free from infection with *Marteilia refringens*

1. When targeted surveillance is required in order to maintain the status free from infection with *Marteilia refringens* of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and molluscs must be sampled in accordance with Table 3.B, taking into account the risk level of the establishment for the contraction of infection with *Marteilia refringens*.

2. When determining the frequency of health visits required to maintain the status free from infection with *Marteilia refringens* of compartments, where the health-status regarding that disease is dependent on the health-status of the aquatic animal populations in surrounding natural waters, the risk for the contraction of infection with *Marteilia refringens* must be regarded as high.
3. The status free from infection with *Marteilia refringens* may only be maintained as long as all samples tested, using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Marteilia refringens* and any suspicion of infection with *Marteilia refringens* has been ruled out in accordance with the diagnostic methods set out in point 3 of section 5.

Table 3.B

Scheme for Member States, zones or compartments to maintain disease-free status for *Marteilia refringens*

Risk level ⁽¹⁾	Number of health visits to each establishment/group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 3 years	1 every 3 years	150

⁽¹⁾ Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.

Section 5

Diagnostic and sampling methods

1. The whole animal must be submitted to the laboratory for the performance of the diagnostic tests provided for in points 2 and 3.
2. The diagnostic methods to be used to grant or maintain status free from infection with *Marteilia refringens* in accordance with Sections 2 to 4 must follow the detailed diagnostic methods and procedures approved by the EURL for Mollusc Diseases and must be histopathology, tissue imprints or PCR.
3. When a suspicion of infection with *Marteilia refringens* is required to be confirmed or ruled out in accordance with Article 55 the following visit, sampling and testing procedure must be complied with:
 - (a) the investigation must include at least one sampling of 30 molluscs of susceptible species if the suspicion is based on a mortality report or if not, 150 molluscs of susceptible species after the beginning of the transmission period of *Marteilia refringens*. When the transmission period is not known, the sampling must begin in the period after the temperature of the water exceeds 17 °C;
 - (b) samples must be tested using the diagnostic methods set out in point (i) following the detailed diagnostic methods and procedures approved by the EURL for Mollusc Diseases:
 - (i) the presence of *Marteilia refringens* must be considered as confirmed when a positive result by histopathology, tissue imprints or *in situ* hybridisation is combined with a positive PCR result completed by sequencing. If biological material is not available for histopathology, tissue imprints or *in situ* hybridisation, the presence of *Marteilia refringens* must be considered as confirmed when positive results are obtained using two PCR assays targeting different fragments of the parasite genome and completed by sequencing;
 - (ii) the suspicion of infection with *Marteilia refringens* may be ruled out, if the tests referred to in (i) reveal no further evidence of the presence of *Marteilia refringens*.

CHAPTER 4

Eradication, disease-free status and diagnostic methods for infection with *Bonamia exitiosa*

Section 1

General requirements for health visits and sampling

Health visits and sampling for the surveillance referred to in point (b)(ii) of Article 3(2) must comply with the following requirements:

- (a) health visits and, where appropriate, the sampling must be carried out in the period of the year when prevalence of the parasite in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling shall be carried out twice a year, in spring and autumn;
- (b) when molluscs are to be sampled in accordance with the requirements set out in Sections 2 to 4, the following criteria must apply:
 - (i) if *Ostrea* spp. are present, only oysters of that species must be selected for sampling. If *Ostrea* spp. are not present, the sample must be representative of all other susceptible species present;
 - (ii) if weak, gaping or freshly dead but not decomposed molluscs are present, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;
 - (iii) when sampling in establishments or groups of establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;
 - (iv) when sampling in mollusc establishments or groups of establishments, molluscs from a sufficient number of sampling points must be included in the sample in such a way that all parts of the establishment or group of establishments are proportionally represented in the sample. The main factors to be considered for the selection of those sampling points are previous points where *Bonamia exitiosa* was detected, stocking density, water flows, the presence of susceptible species, the presence of vector species (e.g. *Crassostrea gigas*), bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments shall be included in the sampling.

Section 2

Granting of the status free from infection with *Bonamia exitiosa* in Member States, zones and compartments of unknown health status

1. The status free from infection with *Bonamia exitiosa* may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to infection with *Bonamia exitiosa* if all establishments or groups of establishments keeping listed species within the Member State, zone or compartment and where required, sampling points in wild populations, have been subject to the following 3-year scheme:
 - (a) the establishments and groups of establishments keeping listed species have been subject to health visits and sampled for a minimum period of 3 consecutive years as laid down in Table 4.A;
 - (b) during that 3-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Bonamia exitiosa* and any suspicion of *Bonamia exitiosa* has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5;
 - (c) when *Ostrea edulis* sourced from a Member State, zone or compartment of disease-free status are to be included in the sample, they must have been introduced into the establishment or group of establishments at least one year before the scheme is carried out.
2. If infection with *Bonamia exitiosa* is detected during the 3-year scheme referred to in point 1; before starting a new 3-year scheme, relevant establishments in the Member State, zone or compartment must:
 - (a) be subject to the minimum disease control measures laid down in Articles 58 to 65;

- (b) be repopulated with molluscs from an establishment in a Member State, zone or compartment free from infection with *Bonamia exitiosa* or from an establishment in a Member State, zone or compartment covered by an eradication programme for that disease.

Table 4.A

Scheme for Member States, zones or compartments for the 3-year control period which precedes the achievement of status free from infection with *Bonamia exitiosa*

Year of surveillance	Number of health visits per year to each establishment or group of establishments	Number of laboratory examinations per year	Number of molluscs in the sample
Year 1	2	2	150
Year 2	2	2	150
Year 3	2	2	150

Section 3

Granting of the status free from infection with *Bonamia exitiosa* in Member States, zones and compartments known to be infected with *Bonamia exitiosa*

1. The status free from infection with *Bonamia exitiosa* may only be granted to a Member State, a zone or a compartment known to be infected with *Bonamia exitiosa*, where the competent authority judges that eradication of this disease to be feasible, if all establishments or groups of establishments keeping listed species within that Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:

- (a) the minimum control measures laid down in Articles 55 to 65 must have been effectively applied, and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate, divided into a protection zone and surveillance zone; must have been established in the vicinity of the establishment or group of establishments declared infected with *Bonamia exitiosa* taking into account the requirements set out in point 2;
- (b) all establishments and groups of establishments keeping listed species within the protection zone or where a protection zone has not been established, within the restricted zone, not infected with *Bonamia exitiosa* must be subject to an investigation comprising at least the collection of samples for testing of 150 molluscs of susceptible species after the beginning of the transmission period of *Bonamia exitiosa*. When the transmission period is not known, the sampling must be done on oysters which have spent at least one year within the protection zone;
- (c) relevant establishments and groups of establishments must be emptied in accordance with Article 62, and if possible, cleaned and disinfected in accordance with Article 63.

Fallowing must be carried out in compliance with Article 64 and the duration of the fallowing period must be at least 6 months.

When all infected establishments or infected groups of establishments are emptied, at least 4 weeks of synchronised fallowing must be carried out;

- (d) repopulation may only take place when all infected establishments or infected groups of establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);
- (e) all establishments and groups of establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme, must subsequently be subject to the scheme set out in Section 2;
- (f) an individual establishment which keeps listed species and which has a health-status which is independent of the health-status of the surrounding waters is not required to comply with the scheme set out in Section 2 following a disease outbreak provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is repopulated with molluscs sourced from Member States, zones or compartments with status free from infection with *Bonamia exitiosa*.

2. The restricted zone must have been defined on a case-by-case basis and:
 - (a) it must take into account factors influencing the risks for the spread of infection with *Bonamia exitiosa* including other establishments and wild molluscs, such as:
 - (i) the number, age, rate and distribution of the mortalities of molluscs on the establishment or group of establishments infected with *Bonamia exitiosa*;
 - (ii) the distance to and density of neighbouring establishments or groups of establishments and wild molluscs;
 - (iii) the proximity to processing establishments, contact establishments or groups of establishments;
 - (iv) the species, especially susceptible species and vector species, present at the establishments or groups of establishments;
 - (v) the farming practices applied in the affected and neighbouring establishments and groups of establishments;
 - (vi) the hydrodynamic conditions; and
 - (vii) other factors of epidemiological significance identified;
 - (b) the geographical demarcation must comply with the following minimum requirements:
 - (i) the protection zone must consist of an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment infected with *Bonamia exitiosa*, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data; and
 - (ii) the surveillance zone must consist of an area surrounding the protection zone, of overlapping tidal excursion zones; or an area surrounding the protection zone and included in a circle of radius 10km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;
- or
- (iii) where separate protection and surveillance zones are not established, the restricted zone must consist of an area comprising both the protection zone and the surveillance zone.

Section 4

Maintenance of status free from infection with *Bonamia exitiosa*

1. When targeted surveillance is required in order to maintain the status free from infection with *Bonamia exitiosa* of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and molluscs must be sampled in accordance with Table 4.B, taking into account the risk level of the establishment for the contraction of infection with *Bonamia exitiosa*
2. When determining the frequency of health visits required to maintain the status free from infection with *Bonamia exitiosa* of compartments where the health status regarding that disease is dependent on the health status of the aquatic animal populations in surrounding natural waters, the risk for the contraction of infection with *Bonamia exitiosa* must be regarded as high.
3. The status free from infection with *Bonamia exitiosa* may only be maintained as long as all samples, using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Bonamia exitiosa* and any suspicion of infection with *Bonamia exitiosa* has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5.

Table 4.B

Scheme for Member States, zones or compartments to maintain status free from infection with *Bonamia exitiosa*

Risk level ⁽¹⁾	Number of health visits to each establishment/group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 3 years	1 every 3 years	150

(¹) Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.

Section 5

Diagnostic and sampling methods

1. The whole animal must be submitted to the laboratory for the performance of the diagnostic tests provided for in points 2 and 3.
2. The diagnostic methods to be used to grant or maintain status free from infection with *Bonamia exitiosa*, in accordance with Sections 2 to 4 must follow the detailed diagnostic methods and procedures approved by the EURL for Mollusc Diseases and must be histopathology, tissue imprints or PCR.
3. When a suspicion of infection with *Bonamia exitiosa* is required to be confirmed or ruled out in accordance with Article 58, the following visit, sampling and testing procedure must be complied with:
 - (a) the investigation must include at least one sampling of 30 molluscs of susceptible species if the suspicion is based on a mortality report, or if not, 150 molluscs of susceptible species after the beginning of the transmission period of *Bonamia exitiosa*. When the transmission period is not known, the sampling shall be carried out twice a year, in spring and autumn;
 - (b) the samples must be tested using the diagnostic methods set out in point (i) following the detailed diagnostic methods and procedures which have been approved by the EURL for Mollusc Diseases:
 - (i) the presence of *Bonamia exitiosa* must be considered as confirmed when a positive result by histopathology, tissue imprints or *in situ* hybridisation is combined with a positive result by PCR followed by sequencing. If biological material is not available for histopathology, tissue imprints or *in situ* hybridisation, the presence of *Bonamia exitiosa* must be considered as confirmed when positive results are obtained using two PCR assays targeting different fragments of the parasite genome and completed by sequencing;
 - (ii) the suspicion of the presence of infection with *Bonamia exitiosa* must be ruled out, if those tests reveal no further evidence of the presence of *Bonamia exitiosa*.

CHAPTER 5

Eradication, disease-free status and diagnostic methods for infection with *Bonamia ostreae*

Section 1

General requirements for health visits and sampling

Health visits and sampling for the surveillance referred to in point (b)(ii) of Article 3(2) must comply with the following requirements:

- (a) health visits and, where appropriate, the sampling must be carried out in the period of the year when prevalence of the parasite in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling must be carried out in winter or at the beginning of spring;

- (b) when molluscs are to be sampled in accordance with the requirements set out in Sections 2 to 4, the following criteria must apply:
- (i) if *Ostrea edulis* are present, only oysters of that species must be selected for sampling. If *Ostrea edulis* are not present, the sample must be representative of all other susceptible species present;
 - (ii) if weak, gaping or freshly dead but not decomposed molluscs are present, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;
 - (iii) when sampling in establishments or groups of establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;
 - (iv) when sampling in mollusc establishments or groups of establishments, molluscs from a sufficient number of sampling points must be included in the sample in such a way that all parts of the establishment or group of establishments are proportionally represented in the sample. The main factors to be considered for the selection of those sampling points are previous points where *Bonamia ostreae* was detected, stocking density, water flows, the presence of susceptible species, the presence of vector species, bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments shall be included in the sampling.

Section 2

Granting of the status free from infection with *Bonamia ostreae* in Member States, zones and compartments of unknown health status

1. The status free from infection with *Bonamia ostreae* may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to infection with *Bonamia ostreae* if all establishments or groups of establishments keeping listed species within the Member State, zone or compartment and where required, sampling points in wild populations, have been subject to the following 3-year scheme:
 - (a) the establishments and groups of establishments keeping listed species have been subject to health visits and sampled for a minimum period of 3 consecutive years as laid down in Table 5.A;
 - (b) during that 3-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Bonamia ostreae* and any suspicion of *Bonamia ostreae* has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5;
 - (c) when *Ostrea edulis* sourced from a Member State, zone or compartment of disease-free status are to be included in the sample, they must have been introduced into the establishment or group of establishments at least one year before the scheme is carried out.
2. If infection with *Bonamia ostreae* is detected during the 3-year scheme referred to in point 1; before starting a new 3-year scheme, relevant establishments in the Member State, zone or compartment must:
 - (a) be subject to the minimum disease control measures laid down in Articles 58 to 65;
 - (b) be repopulated with molluscs from an establishment in a Member State, zone or compartment free from infection with *Bonamia ostreae* or from an establishment in a Member State, zone or compartment covered by an eradication programme for that disease.

Section 3

Granting of the status free from infection with *Bonamia ostreae* in Member States, zones and compartments known to be infected with *Bonamia ostreae*

1. The status free from infection with *Bonamia ostreae* may only be granted to a Member State, a zone or a compartment known to be infected with *Bonamia ostreae*, where the competent authority judges that eradication of this disease to be feasible, if all establishments or groups of establishments keeping listed species within that Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:
 - (a) the minimum control measures laid down in Articles 55 to 65 must have been effectively applied, and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate, divided into a protection zone and surveillance zone; must have been established in the vicinity of the establishment or group of establishments declared infected with *Bonamia ostreae* taking into account the requirements set out in point 2;

- (b) all establishments and groups of establishments keeping listed species within the protection zone or where a protection zone has not been established, within the restricted zone, not infected with *Bonamia ostreae* must be subject to an investigation comprising at least the collection of samples for testing of 150 molluscs of susceptible species after the beginning of the transmission period of *Bonamia ostreae*. When the transmission period is not known, the sampling must begin in winter or at the beginning of spring;
- (c) relevant establishments and groups of establishments must be emptied in accordance with Article 62, and if possible, cleaned and disinfected in accordance with Article 63.

Fallowing must be carried out in compliance with Article 64 and the duration of the fallowing period must be at least 6 months.

When all infected establishments or infected groups of establishments are emptied, at least 4 weeks of synchronised fallowing must be carried out;

- (d) repopulation may only take place when all infected establishments or infected groups of establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);
- (e) all establishments and groups of establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme, must subsequently be subject to the scheme set out in Section 2;
- (f) an individual establishment which keeps listed species and which has a health status which is independent of the health status of the surrounding waters is not required to comply with the surveillance scheme set out in Section 2 following a disease outbreak provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is repopulated with molluscs sourced from Member States, zones or compartments with status free from infection with *Bonamia ostreae*.

2. The restricted zone must have been defined on a case-by-case basis and:

- (a) it must take into account factors influencing the risks for the spread of infection with *Bonamia ostreae* including other establishments and wild molluscs, such as:
 - (i) the number, age, rate and distribution of the mortalities of molluscs on the establishment or group of establishments infected with *Bonamia ostreae*;
 - (ii) the distance to and density of neighbouring establishments or groups of establishments and wild molluscs;
 - (iii) the proximity to processing establishments, contact establishments or groups of establishments;
 - (iv) the species, especially susceptible species and vector species, present at the establishments or groups of establishments;
 - (v) the farming practices applied in the affected and neighbouring establishments and groups of establishments;
 - (vi) the hydrodynamic conditions; and
 - (vii) other factors of epidemiological significance identified;
 - (b) the geographical demarcation must comply with the following minimum requirements:
 - (i) the protection zone must consist of an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment infected with *Bonamia ostreae*, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data; and
 - (ii) the surveillance zone must consist of an area surrounding the protection zone, of overlapping tidal excursion zones; or an area surrounding the protection zone and included in a circle of radius 10km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;
- or
- (iii) where separate protection and surveillance zones are not established, the restricted zone must consist of an area comprising both the protection zone and the surveillance zone.

Table 5.A

Scheme for Member States, zones or compartments for the 3-year control period which precedes the achievement of status free from infection with *Bonamia ostreae*

Year of surveillance	Number of health visits per year to each establishment or group of establishments	Number of laboratory examinations per year	Number of molluscs in the sample
Year 1	1	1	150
Year 2	1	1	150
Year 3	1	1	150

Section 4

Maintenance of status free from infection with *Bonamia ostreae*

1. When targeted surveillance is required in order to maintain the status free from infection with *Bonamia ostreae* of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and molluscs must be sampled in accordance with Table 5.B, taking into account the risk level of the establishment for the contraction of infection with *Bonamia ostreae*.
2. When determining the frequency of health visits required to maintain the status free from infection with *Bonamia ostreae* of compartments where the health status regarding that disease is dependent on the health status of the aquatic animal populations in surrounding natural waters, the risk for the contraction of infection with *Bonamia ostreae* must be regarded as high.
3. The status free from infection with *Bonamia ostreae* may only be maintained as long as all samples, using the diagnostic methods set out in point 2 of Section 5 have produced negative results for *Bonamia ostreae* and any suspicion of infection with *Bonamia ostreae* has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5.

Table 5.B

Scheme for Member States, zones or compartments to maintain status free from infection with *Bonamia ostreae*

Risk level ⁽¹⁾	Number of health visits to each establishment/group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 3 years	1 every 3 years	150

⁽¹⁾ Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.

Section 5

Diagnostic and sampling methods

1. The whole animal must be submitted to the laboratory for the performance of the diagnostic tests provided for in points 2 and 3.
2. The diagnostic methods to be used to grant or maintain status free from infection with *Bonamia ostreae*, in accordance with Sections 2 to 4 must follow the detailed diagnostic methods and procedures approved by the EURL for Mollusc Diseases and must be histopathology, tissue imprints or PCR.

3. When a suspicion of infection with *Bonamia ostreae* is required to be confirmed or ruled out in accordance with Article 58, the following visit, sampling and testing procedure must be complied with:
 - (a) the investigation must include at least one sampling of 30 molluscs of susceptible species if the suspicion is based on a mortality report, or if not, 150 molluscs of susceptible species after the beginning of the transmission period of *Bonamia ostreae*. When the transmission period is not known, the sampling shall begin in the winter or at the beginning of spring;
 - (b) the samples must be tested using the diagnostic methods set out in point (i) following the detailed diagnostic methods and procedures which have been approved by the EURL for Mollusc Diseases:
 - (i) the presence of *Bonamia ostreae* must be considered as confirmed when a positive result by histopathology, tissue imprints or *in situ* hybridisation is combined with a positive result by PCR followed by sequencing. If biological material is not available for histopathology, tissue imprints or *in situ* hybridisation, the presence of *Bonamia ostreae* must be considered as confirmed when positive results are obtained using two PCR assays targeting different fragments of the parasite genome and completed by sequencing;
 - (ii) the suspicion of the presence of infection with *Bonamia ostreae* must be ruled out, if those tests reveal no further evidence of the presence of *Bonamia ostreae*.

CHAPTER 6

Eradication, disease-free status and diagnostic methods for infection with white spot syndrome virus (WSSV)

Section 1

General requirements for health visits and sampling

Health visits and sampling for the surveillance referred to in point (b)(ii) of Article 3(2) must comply with the following requirements:

- (a) the sampling of crustaceans for laboratory examination must be carried out whenever the water temperature is likely to reach its highest annual point. That requirement concerning water temperature must also apply to health visits where these are feasible;
- (b) when farmed crustaceans must be sampled in accordance with the requirements set out in Sections 2 to 4, the following criteria must apply:
 - (i) if weak or moribund crustaceans are present in the production units, such crustaceans must primarily be selected. If such crustaceans are not present, those selected must include crustaceans of different size cohorts namely juveniles and adults of the selected susceptible species, proportionally represented in the sample;
 - (ii) if more than one water source is utilised for crustacean production, susceptible crustaceans representing all water sources must be included for sampling;
- (c) when targeted surveillance in wild populations is required due to the small number of establishments covered by the eradication programme, the number and geographical distribution of the sampling points must be determined to obtain a reasonable coverage of the Member State, zone or compartment. The sampling points must also be representative of the different ecosystems where the wild populations of susceptible species are located namely marine, estuary, river and lake systems. In such situations, the crustaceans to be sampled must be selected as follows:
 - (i) in marine and estuary systems areas, one or more of the following species must be selected: *Carcinus maenas*, *Cancer pagurus*, *Eriocheir sinensis*, *Liocarcinus depurator*, *Liocarcinus puber*, *Crangon crangon*, *Homarus gammarus*, *Palaemon adspersus* or penaeid shrimp species namely *Penaeus japonicus*, *Penaeus kerathurus*, *Penaeus semisulcatus*. If those species are not present, the sample must be representative of other susceptible decapod species present;
 - (ii) in river and lake systems, one or more of the following species must be selected: *Pacifastacus leniusculus*, *Astacus leptodactylus*, *Austropotamobius pallipes* or *Orconectes limosus*. If those species are not present, the sample must be representative of other susceptible decapod species present;
 - (iii) if weak or moribund crustaceans are present, such crustaceans must primarily be selected. If such crustaceans are not present, those selected must include crustaceans of different size cohorts namely juveniles and adults of the selected susceptible species, proportionally represented in the sample.

Section 2

Granting of the status free from infection with WSSV in Member States, zones and compartments of unknown health status

1. The status free from infection with WSSV may only be granted to a Member State, a zone or a compartment with an unknown health status with regard to infection with WSSV if all establishments or groups of establishments keeping listed species within the Member State, zone or compartment and where required, sampling points in wild populations, have been subject to the following 2-year scheme:
 - (a) the establishments or groups of establishments have been subject to health visits and sampled for a minimum period of 2 consecutive years as laid down in Table 6.A;
 - (b) during that 2-year period, the testing of all samples using the diagnostic methods set out in point 2 of Section 5 have produced negative results for infection with WSSV and any suspicion of infection with WSSV has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5;
2. If infection with WSSV is detected during the 2-year scheme referred to in point 1, before starting a new 2-year scheme, relevant establishments in the Member State, zone or compartment must:
 - (a) be subject to the minimum disease control measures laid down in Articles 58 to 65;
 - (b) be repopulated with crustaceans from an establishment in a Member State, zone or compartment free from infection with WSSV or from an establishment in a Member State, zone or compartment covered by an eradication programme for that disease.

Section 3

Granting of the status free from infection with WSSV in Member States, zones and compartments known to be infected with WSSV

1. The status free from infection with WSSV may only be granted to a Member State, a zone or a compartment known to be infected with WSSV if all establishments keeping listed species within that Member State, zone or compartment have been subject to an eradication programme that complies with the following requirements:
 - (a) the minimum control measures laid down in Articles 55 to 65 must have been effectively applied, and a restricted zone of an appropriate size as provided for in point (c) of Article 58(1), where appropriate, divided into a protection zone and surveillance zone; must have been established in the vicinity of the establishment(s) declared infected with WSSV taking into account the requirements set out in point 2;
 - (b) all establishments keeping listed species within the protection zone, or where a protection zone has not been established, the restricted zone, not infected with WSSV must be subject to an investigation comprising at least the following:
 - (i) the collection of samples for testing of 10 crustaceans, when clinical signs or post-mortem lesions consistent with infection WSSV are observed, or 150 crustaceans, when clinical signs or post-mortem lesions are not observed; and
 - (ii) health visits; in those establishments where the tests referred to in (i) have produced negative results, health visits must continue once per month during the season when the water temperature is likely to reach its highest annual points, until the protection zone has been withdrawn in accordance with point (c);
 - (c) relevant establishments must be emptied in accordance with Articles 62, cleaned disinfected in accordance with Article 63 and fallowed in accordance with Article 64. The duration of the fallowing period must be at least 6 weeks. When all infected establishments are emptied, at least 3 weeks of synchronous fallowing shall be carried out.

When fallowing of the officially declared infected establishments is carried out, the protection zones shall be converted into surveillance zones;

- (d) repopulation may only take place when all infected establishments have been emptied, cleaned, disinfected and fallowed in accordance with point (c);

- (e) all establishments other than those referred to in point (f) which keep listed species within the Member State, zone or compartment covered by the eradication programme and, when surveillance in wild populations is required, all sampling points selected to provide the greatest coverage of the geographical area included in the eradication programme must be subject at least to the scheme set out in Section 2;
 - (f) an individual establishment which keeps listed species and which has a health status which is independent of the health status of the surrounding waters is not required to comply with the scheme set out in Section 2 following a disease outbreak provided the establishment complies with the requirements set out in paragraph 3 of Article 80 and is repopulated with crustaceans sourced from Member States, zones or compartments with status free from infection with WSSV.
2. The restricted zone must have been defined on a case-by-case basis taking into account factors influencing the risks for the spread of WSSV to farmed and wild crustaceans, such as:
- (i) the number, age, rate and distribution of the mortalities of crustaceans on the establishment or group of establishments infected with WSSV including other establishments and wild crustaceans;
 - (ii) the distance to and density of neighbouring establishments or groups of establishments including wild crustaceans;
 - (iii) the proximity to processing establishments, contact establishments or groups of establishments;
 - (iv) the species, especially susceptible species and vector species, present at the establishments or groups of establishments;
 - (v) the farming practices applied in the affected and neighbouring establishments and groups of establishments;
 - (vi) the hydrodynamic conditions; and
 - (vii) other factors of epidemiological significance identified.

Table 6. A

Scheme for Member States, zones and compartments for the 2-year control period which precedes the achievement of status free from infection with WSSV

Year of surveillance	Number of health visits per year to each establishment or group of establishments	Number of laboratory examinations per year	Number of crustaceans in the sample
Year 1	1	1	150
Year 2	1	1	150

Section 4

Maintenance of status free from infection with WSSV

1. When targeted surveillance is required in order to maintain the status free from infection with WSSV of a Member State, a zone or a compartment, in accordance with Article 81, all establishments keeping listed species within the Member State, zone or compartment concerned must be subject to health visits and crustaceans must be sampled in accordance with Table 6.B, taking into account the risk level of the establishment for the contraction of infection with WSSV.
2. In Member States, zones or compartments where the number of establishments is limited and targeted surveillance in those establishments does not provide sufficient epidemiological data, the surveillance to maintain disease-free status must include sampling points selected in accordance with the requirements laid down in point (b) of Section 1.
3. When determining the frequency of health visits required to maintain the status free from infection with WSSV of compartments where the health status regarding that disease is dependent on the health status of the aquatic animal populations in surrounding natural waters, the risk for the contraction of infection with WSSV must be regarded as high.
4. The status free from infection with WSSV may only be maintained as long as all samples, using the diagnostic methods set out in point 2 of Section 5 have produced negative results for WSSV and any suspicion of infection with WSSV has been ruled out in accordance with the diagnostic methods set out in point 3 of Section 5.

Table 6. B

Scheme for Member States, zones or compartments to maintain status free from infection WSSV

Risk level ⁽¹⁾	Number of health visits to each establishment/group of establishments	Number of laboratory examinations	Number of crustaceans in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 2 years	1 every 4 years	150

⁽¹⁾ Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I other than in the case of dependent compartments where all establishments are deemed to be high risk.

Section 5

Diagnostic and sampling methods

1. Samples of integumental epidermis, either dissected or contained within walking legs, pleopods, mouthparts or gills of the test animal must be fixed in 95 % ethanol prior to the preparation of samples for PCR.

Other samples, fixed for histology and transmission electron microscopy may be collected to support diagnostic data arising from PCR.

2. The diagnostic method and procedures to be used to grant or to maintain disease-free status with regard to infection with WSSV must be PCR followed by sequencing. When applying these diagnostic methods, the corresponding detailed methods and procedures which have been approved by the EURL for Crustacean Diseases must be followed.

In the case of a positive result from the PCR test, the result must be followed by sequencing of the amplicon before the initial control measures provided for in Article 63 of Regulation (EU) 2016/429 are implemented.

3. When a suspicion of infection with WSSV is required to be confirmed or ruled out in accordance with Article 58, the following visit, sampling and testing procedure must be complied with:
 - (a) the investigation must include at least one health visit and one sampling of 10 crustaceans when clinical signs or post-mortem lesions consistent with infection with WSSV are observed or 150 crustaceans when clinical signs or post-mortem lesions are not observed. The samples must be tested using the diagnostic method set out in point 2;
 - (b) the presence of WSSV must be considered as confirmed when PCR followed by sequencing, carried out in accordance with the detailed methods and procedures which have been approved by the EURL for Crustacean Diseases test positive for WSSV.

The suspicion of infection with WSSV may be ruled out, if those tests reveal no further evidence of the presence of the virus.

PART III

REQUIREMENTS FOR DEMONSTRATING THE IMPLEMENTATION OF SURVEILLANCE PROGRAMMES FOR CATEGORY C DISEASES AND FOR RESTARTING THOSE PROGRAMMES AFTER A DISEASE OUTBREAK

Part III covers the requirements for establishments to demonstrate the implementation of a surveillance programme for a particular disease and the requirements to restart that surveillance programme following a disease outbreak.

Viral haemorrhagic septicaemia (VHS)	Chapter 1
Infectious haematopoietic necrosis (IHN)	Chapter 1
Infection with HPR-deleted infectious salmon anaemia virus	Chapter 2
Infection with <i>Marteilia refringens</i>	Chapter 3
Infection with <i>Bonamia exitiosa</i>	Chapter 4
Infection with <i>Bonamia ostreae</i>	Chapter 5
Infection with white spot syndrome virus (WSSV)	Chapter 6

CHAPTER 1

Requirements for establishments to demonstrate the implementation of a surveillance programme for VHS or IHN and requirements to re-start that programme following a disease outbreak

Section 1

General requirements for health visits and sampling for VHS and IHN

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

- (a) health visits and sampling must be carried out during the period of the year when the water temperature is below 14 °C or when temperatures below 14 °C are not reached, samples must be taken at the lowest annual points;
- (b) all production units, such as ponds, tanks and net cages, must be examined for the presence of dead, weak or abnormally behaving fish. Particular attention must be paid to the water outlet area where weak fish tend to accumulate because of the water current;
- (c) fish of listed species to be collected as samples must be selected as follows:
 - (i) if rainbow trout are present, only fish of that species must be selected for sampling, except where other susceptible species are present which show typical signs of VHS or IHN; if rainbow trout are not present, the sample must be representative of all other susceptible species which are present;
 - (ii) if weak, abnormally behaving or freshly dead but not decomposed fish are present, such fish must be selected; if more than one water source is utilised for fish production, fish representing all water sources must be included in the sample;
 - (iii) the fish selected must include fish collected in such a way that all parts of the establishment, as well as all year classes, are proportionally represented in the sample.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits must be carried out and fish must be sampled in accordance with Section 1 and Table 1.
2. Samples which are collected in accordance with Section 1 and Table 1 must be tested using the diagnostic methods set out in point 2 of Section 5 of Chapter 1 of Part II and produce negative results for VHS or IHN.

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with VHS or IHN, may restart a surveillance programme for these diseases provided that:

- (a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and
- (b) repopulation occurs using fish that originate from establishments which are:
 - (i) in a Member State, a zone or a compartment free from VHS or IHN;
 - (ii) in a Member State, a zone or a compartment covered by an eradication programme for VHS or IHN; or
 - (iii) implementing a surveillance programme for VHS or IHN.

Table 1

Surveillance programme for VHS/IHN

Risk level ⁽¹⁾	Number of health visits per year to each establishment	Number of fish in the sample ⁽²⁾
High	1 every year	30
Medium	1 every 2 years	30
Low	1 every 3 years	30

⁽¹⁾ In the case of coastal zones or coastal compartments, the samples must be collected no sooner than 3 weeks after the transfer of the fish from fresh to saltwater.

⁽²⁾ Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I. Maximum number of fish per pool: 10

CHAPTER 2

Requirements for establishments to demonstrate the implementation of a surveillance programme for HPR-deleted ISAV and to re-start that programme after a disease outbreak

Section 1

General requirements for health visits and sampling for infection with HPR-deleted ISAV

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

- (a) health visits and sampling must take into account all production units, such as ponds, tanks and net cages, to determine if dead, weak or abnormally behaving fish are present. Particular attention must be paid to the edge of cages or the water outlet area as relevant, where weak fish tend to accumulate because of the water current;
- (b) the fish to be collected as samples must be selected as follows:
 - (i) only moribund or freshly dead but not decomposed fish must be selected; in particular fish demonstrating anaemia, bleeding or other clinical signs suggesting circulatory disturbances must be prioritised for collection;
 - (ii) if Atlantic salmon are present, only fish of that species must be selected for sampling, except where other susceptible species are present which show typical signs of ISA. If there are no Atlantic salmon in the establishment, other listed species must be sampled;
 - (iii) if more than one water source is utilised for fish production, fish representing all water sources must be included in the sample;
 - (iv) the fish selected must include fish collected in such a way that all production units, such as net cages, tanks and ponds, as well as all year classes in the establishment are proportionally represented in the sample.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits must be carried out and fish must be sampled in accordance with Section 1 and Table 2.
2. Samples which are collected in accordance with Section 1 and Table 2 must be tested using the diagnostic methods set out in point 2 of Section 5 of Chapter 2 of Part II and produce negative results for HPR-deleted ISAV.

Table 2

Surveillance programme for HPR-deleted ISAV

Risk level ⁽¹⁾	Number of health visits per year to each establishment	Number of laboratory examinations per year	Number of fish in the sample
High	2	2 ⁽²⁾	30
Medium	1	1 ⁽³⁾	30
Low	1 every 2 years	1 every two years	30

Maximum number of fish per pool: 5

⁽¹⁾ Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I

⁽²⁾ Samples must be collected during spring and autumn when two samples are required each year

⁽³⁾ Samples must be collected during spring or autumn when only one sample is required per year

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with HPR-deleted ISAV may restart a surveillance programme for that diseases provided that:

- (a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and
- (b) repopulation occurs using fish that originate from establishments which are:
 - (i) in a Member State, a zone or a compartment free from infection with HPR-deleted ISAV;
 - (ii) in a Member State, a zone or a compartment covered by an eradication programme for infection with HPR-deleted ISAV; or
 - (iii) implementing a surveillance programme for infection with HPR-deleted ISAV.

CHAPTER 3

Requirements for establishments to demonstrate the implementation of a surveillance programme for infection with *Marteilia refringens* and requirements to re-start that programme following a disease outbreak

Section 1

General requirements for health visits and sampling for infection with *Marteilia refringens*

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

- (a) health visits and sampling for laboratory examination must be carried out in the period of the year when prevalence of the parasite in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling shall be carried out just after the water temperature has exceeded 17 °C;
- (b) when molluscs are to be sampled in accordance with the requirements set out in Table 3, the following criteria must apply:
 - (i) *Ostrea spp.* must be sampled. If *Ostrea spp.* are not present, the sample must be representative of all other listed species present;

- (ii) if weak, gaping or freshly dead but not decomposed molluscs are present in the production units, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;
- (iii) when sampling in mollusc establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;
- (iv) when sampling in mollusc establishments or groups of establishments, molluscs from a sufficient number of sampling points must be included in the sample in such a way that all parts of the establishment or group of establishments are proportionally represented in the sample. The main factors to be considered for the selection of those sampling points are stocking density, water flows, the presence of susceptible species, the presence of vector species, bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments must be included in the sampling.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits must be carried out and molluscs must be sampled in accordance with Section 1 and Table 3.
2. Samples which are collected in accordance with Section 1 and Table 3 must be tested using the diagnostic methods set out in point 2 of Section 5 of Chapter 3 of Part II and produce negative results for *Marteilia refringens*.

Table 3

Surveillance programme for *Marteilia refringens*

Risk level ⁽¹⁾	Number of health visits to each establishment/group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 2 years	1 every 4 years	150

⁽¹⁾ Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with *Marteilia refringens* may re-start a surveillance programme for that disease provided that:

- (a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and
- (b) repopulation occurs using fish that originate from establishments which are:
 - (i) in a Member State, a zone or a compartment free from infection with *Marteilia refringens*;
 - (ii) in a Member State, a zone or a compartment covered by an eradication programme for infection with *Marteilia refringens*; or
 - (iii) implementing a surveillance programme for infection with *Marteilia refringens*.

CHAPTER 4

Requirements for establishments to demonstrate the implementation of a surveillance programme for infection with *Bonamia exitiosa* and to re-start that programme following a disease outbreak

Section 1

General requirements for health visits and sampling for infection with *Bonamia exitiosa*

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

- (a) health visits and sampling of production units must be carried out in the period of the year when prevalence of *Bonamia exitiosa* in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling shall be carried out twice a year, in spring and autumn;
- (b) when molluscs are sampled in accordance with the requirements set out in Table 4, the following criteria must apply:
 - (i) if *Ostrea* spp. are present, only oysters of that species must be selected for sampling. If *Ostrea* spp. are not present, the sample must be representative of all other susceptible species present;
 - (ii) if weak, gaping or freshly dead but not decomposed molluscs are present, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;
 - (iii) when sampling in establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;
 - (iv) when sampling in establishments or groups of establishments, molluscs from a sufficient number of sampling points must be included in the sample in such a way that all parts of the establishment or group of establishments are proportionally represented in the sample. The main factors to be considered for the selection of those sampling points are stocking density, water flows, the presence of susceptible species, the presence of vector species (e.g. *Crassostrea gigas*), bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments must be included in the sampling.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits must be carried out and molluscs must be sampled in accordance with Section 1 and Table 4.
2. Samples which are collected in accordance with Section 1 and Table 4 must be tested using the diagnostic methods referred to in point 2 of Section 5 of Chapter 4 of Part II and produce negative results for *Bonamia exitiosa*.

Table 4

Surveillance programme for infection with *Bonamia exitiosa*

Risk level ⁽¹⁾	Number of health visits to each establishment/group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 2 years	1 every 4 years	150

⁽¹⁾ Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I.

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with *Bonamia exitiosa* may re-start a surveillance programme provided that:

- (a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and
- (b) repopulation occurs using fish that originate from establishments which are:
 - (i) in a Member State, a zone or a compartment free from infection with *Bonamia exitiosa*;
 - (ii) in a Member State, a zone or a compartment covered by an eradication programme for infection with *Bonamia exitiosa*; or
 - (iii) implementing a surveillance programme for infection with *Bonamia exitiosa*.

CHAPTER 5

Requirements for establishments to demonstrate the implementation of a surveillance programme for infection with *Bonamia ostreae* and to re-start that programme following a disease outbreak

Section 1

General requirements for health visits and sampling for infection with *Bonamia ostreae*

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

- (a) health visits and sampling of production units shall be carried out in the period of the year when prevalence of *Bonamia ostreae* in the Member State, zone or compartment is known to be maximal. When such data is not available, sampling shall be carried out in winter or at the beginning of spring;
- (b) when molluscs are to be sampled in accordance with the requirements set out in Table 5, the following criteria must apply:
 - (i) if *Ostrea edulis* are present, only oysters of that species must be selected for sampling. If *Ostrea edulis* are not present, the sample must be representative of all other susceptible species present;
 - (ii) if weak, gaping or freshly dead but not decomposed molluscs are present, such molluscs must primarily be selected. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;
 - (iii) when sampling in establishments which utilise more than one water source for mollusc production, molluscs representing all water sources must be included for sampling in such a way that all parts of the establishment are proportionally represented in the sample;
 - (iv) when sampling in mollusc establishments or groups of establishments, molluscs from a sufficient number of sampling points must be included in the sample. The main factors to be considered for the selection of those sampling points are stocking density, water flows, the presence of susceptible species, the presence of vector species, bathymetry and management practices. Natural beds within or adjacent to the establishment or group of establishments must be included in the sampling.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits must be carried out and molluscs must be sampled in accordance with Section 1 and Table 5.
2. Samples which are collected in accordance with Section 1 and Table 5 must be tested using the diagnostic methods referred to in point 2 of Section 5 of Chapter 5 of Part II and produce negative results for *Bonamia ostreae*.

Table 5

Surveillance programme for infection with *Bonamia ostreae*

Risk level ⁽¹⁾	Number of health visits to each establishment/group of establishments	Number of laboratory examinations	Number of molluscs in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 2 years	1 every 4 years	150

⁽¹⁾ Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with *Bonamia ostreae* may re-start the surveillance programme for that disease provided that:

- (a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and
- (b) repopulation occurs using fish that originate from establishments which are:
 - (i) in a Member State, a zone or a compartment free from infection with *Bonamia ostreae*;
 - (ii) in a Member State, a zone or a compartment covered by an eradication programme for infection with *Bonamia ostreae*; or
 - (iii) implementing a surveillance programme for infection with *Bonamia ostreae*.

CHAPTER 6

Requirements for establishments to demonstrate the implementation of a surveillance programme for infection with WSSV and to re-start that programme following a disease outbreak

Section 1

General requirements for health visits and sampling for infection with WSSV

The health visits and sampling referred to in point (b)(iv) of Article 3(2) must comply with the following requirements:

- (a) the sampling of crustaceans for laboratory examination must be carried out whenever the water temperature is likely to reach its highest annual point. That requirement concerning water temperature must also apply to health visits where these are feasible and appropriate;
- (b) when farmed crustaceans are to be sampled in accordance with the requirements set out in Table 6, the following criteria must apply:
 - (i) if weak or moribund crustaceans are present in the production units, such crustaceans must primarily be selected. If such crustaceans are not present, those selected must include crustaceans of different size cohorts namely juveniles and adults, of the selected susceptible species, proportionally represented in the sample;
 - (ii) if more than one water source is utilised for crustacean production, susceptible crustaceans representing all water sources must be included for sampling.

Section 2

Specific requirements to demonstrate the implementation of a surveillance programme

1. Health visits shall be carried out and crustaceans shall be sampled in accordance with Section 1 and Table 6.
2. Samples which are collected in accordance with Section 1 and Table 6 must be tested using the diagnostic methods referred to in point 2 of Section 5 of Chapter 6 of Part II and produce negative results for infection with WSSV.

Table 6

Surveillance programme for infection with WSSV

Risk level ⁽¹⁾	Number of health visits to each establishment/group of establishments	Number of laboratory examinations	Number of crustaceans in the sample
High	1 every year	1 every 2 years	150
Medium	1 every 2 years	1 every 2 years	150
Low	1 every 2 years	1 every 4 years	150

⁽¹⁾ Risk level assigned to the establishment by the competent authority as set out in paragraph 1 of Chapter 2 of Part I

Section 3

Requirements to re-start a surveillance programme after a disease outbreak

An establishment which has been infected with WSSV may re-start a surveillance programme for that disease provided that:

- (a) it has been emptied in accordance with Article 62, cleaned and disinfected in accordance with Article 63, and fallowed in accordance with Article 64; and
- (b) repopulation occurs using fish that originate from establishments which are:
 - (i) in a Member State, a zone or a compartment free from infection with WSSV;
 - (ii) in a Member State, a zone or a compartment covered by an eradication programme for infection with WSSV; or
 - (iii) implementing a surveillance programme for infection with WSSV.

COMMISSION IMPLEMENTING REGULATION (EU) 2020/690**of 17 December 2019****laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the listed diseases subject to Union surveillance programmes, the geographical scope of such programmes and the listed diseases for which the disease-free status of compartments may be established****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular point (a) of Article 30(1) and point (b) of the first subparagraph of Article 37(4) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of diseases which are transmissible to animals or humans, including rules for surveillance, eradication and granting of disease free-status at compartment level.
- (2) Regulation (EU) 2016/429 establishes a harmonised list of transmissible animal diseases ('listed diseases') which pose a risk to animal or public health in the Union, whether across the whole Union or only in parts.
- (3) Article 28 of Regulation (EU) 2016/429 provides for Union surveillance programmes for certain listed diseases. Article 30 of that Regulation provides for the determination by means of an implementing act which of the listed diseases are to be subject to Union surveillance programmes, including the geographical scope of such programmes.
- (4) Regulation (EU) 2016/429 repeals Council Directive 2005/94/EC ⁽²⁾ as from 21 April 2021. Directive 2005/94/EC provides for mandatory surveillance programmes for avian influenza in poultry and in wild birds. The mandatory surveillance programmes for avian influenza continue to be relevant to ensure a high level of surveillance across the Union due to the impact of highly pathogenic avian influenza on animal health. These programmes should also include the surveillance of certain areas with a heightened risk of mutation of low pathogenic avian influenza viruses to highly pathogenic avian influenza viruses. The surveillance of avian influenza also contributes to the knowledge on viruses posing a potential zoonotic risk. Therefore, this obligation should be reflected within the framework of Regulation (EU) 2016/429 by means of Union surveillance programmes for avian influenza.
- (5) Pursuant to the harmonised list of transmissible animal diseases in Regulation (EU) 2016/429, a distinction is made between highly pathogenic avian influenza and infection with low pathogenic avian influenza viruses. In order to ensure consistency, this distinction should be reflected in the scope of Union surveillance programmes.
- (6) Commission Delegated Regulation (EU) 2020/689 ⁽³⁾ lays down, amongst others, the criteria for establishing the listed diseases subject to Union surveillance programmes and the contents of such programmes. Highly pathogenic avian influenza and infection with low pathogenic avian influenza viruses conform with those criteria.
- (7) Article 37 of Regulation (EU) 2016/429 gives Member States the right to apply for recognition of the disease-free status of compartments for certain listed diseases referred to in points (a), (b) and (c) of Article 9(1) of that Regulation. An implementing act should determine for which of these listed diseases the disease-free status of compartments may be established.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16).

⁽³⁾ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (See page 211 of this Official Journal).

- (8) Regulation (EU) 2016/429 repeals Council Directive 2006/88/EC ⁽⁴⁾ as from 21 April 2021. Directive 2006/88/EC provides for the establishment of disease-free compartments for a list of diseases of aquatic animals, in line with the Aquatic Animal Health Code issued by the World Organisation for Animal Health (OIE). In order to facilitate the maintenance of disease-free status of compartments, the aquatic animal diseases included in that list of diseases should, as far as possible, be used for the purposes of the listed diseases for which disease-free status of compartments may be established within the framework of Regulation (EU) 2016/429.
- (9) As the provisions of Regulation (EU) 2016/429 governing the matters covered by this Regulation apply from 21 April 2021, this Regulation should apply from the same date.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The listed diseases subject to Union surveillance programmes in accordance with Article 28 of Regulation (EU) 2016/429 and the geographical scope of such programmes are set out in Annex I to this Regulation.

Article 2

The listed diseases for which the disease-free status of compartments may be established in accordance with Article 37 of Regulation (EU) 2016/429 are set out in Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 December 2019.

For the Commission

The President

Ursula VON DER LEYEN

⁽⁴⁾ Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

ANNEX I

LISTED DISEASES SUBJECT TO UNION SURVEILLANCE PROGRAMMES	GEOGRAPHICAL SCOPE OF UNION SURVEILLANCE PROGRAMMES
Highly pathogenic avian influenza	Entire territory of Member State
Infection with low pathogenic avian influenza viruses	Entire territory of Member State

ANNEX II

LISTED DISEASES FOR WHICH THE DISEASE-FREE STATUS OF COMPARTMENTS MAY BE ESTABLISHED

Epizootic haematopoietic necrosis

Viral haemorrhagic septicaemia

Infectious haematopoietic necrosis

Infection with highly polymorphic region (HPR) deleted infectious salmon anaemia virus

Infection with *Microcytos mackini*

Infection with *Perkinsus marinus*

Infection with *Bonamia ostreae*

Infection with *Bonamia exitiosa*

Infection with *Marteilia refringens*

Infection with Taura syndrome virus

Infection with yellow head virus

Infection with white spot syndrome virus

COMMISSION DELEGATED REGULATION (EU) 2020/691**of 30 January 2020****supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Articles 176(4), 181(2), 185(5), 189(1) and 279(2) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of diseases which are transmissible to animals or humans, including, inter alia, rules for aquaculture establishments, and for transporters of aquatic animals. Regulation (EU) 2016/429 also provides for the Commission to adopt delegated acts in order to supplement certain non-essential elements of that Regulation. It is therefore necessary to lay down supplementing rules in order to ensure the smooth functioning of the system established within the new legislative framework of Regulation (EU) 2016/429.
- (2) More particularly, the rules laid down in this Regulation should supplement those already laid down in Chapter 1 of Title II of Part IV of Regulation (EU) 2016/429, as regards the approval of aquaculture establishments keeping aquaculture animals posing a significant animal health risk, the registers of aquaculture establishments to be kept by competent authorities, and the record-keeping obligations of operators of aquaculture establishments and transporters of aquatic animals.
- (3) In addition, this Regulation takes into account the repeal of Council Directive 2006/88/EC ⁽²⁾ by Regulation (EU) 2016/429 with effect from 21 April 2021. Regulation (EU) 2016/429 provides that establishments and operators registered or approved in accordance with that Directive, before the date of application of Regulation (EU) 2016/429, are to be deemed to be registered or approved, as required, in accordance with that Regulation, and subject to the relevant obligations laid down therein.
- (4) Accordingly, the rules laid down in this Regulation should supplement the rules laid down in Part IX of Regulation (EU) 2016/429, as regards the necessary transitional measures to protect the acquired rights and legitimate expectations of stakeholders resulting from pre-existing Union acts with regard to aquaculture establishments.
- (5) As the rules laid down in this Regulation all relate to aquaculture establishments and transporters of aquatic animals and are to be applied in tandem, they should be set out in a single act rather than in separate acts with numerous cross-references, in order to facilitate their application, in the interests of transparency, and to avoid a duplication of rules. This is also in keeping with the approach adopted by Regulation (EU) 2016/429.
- (6) Article 176(1) of Regulation (EU) 2016/429 provides that operators of aquaculture establishments are to apply to the competent authority for approval where they keep aquaculture animals with a view to those animals being moved therefrom, either alive or as products of aquaculture animal origin. As a wide variety of aquaculture establishments fall within that category, Article 176(2) of Regulation (EU) 2016/429 provides that Member States may exempt operators of specific types of aquaculture establishments from the requirement for approval provided that such aquaculture establishments do not pose a significant disease risk. In addition, Article 176(4) of that Regulation provides that the Commission may adopt delegated acts concerning derogations from the requirement for approval for certain types of aquaculture establishments, again on the condition that those aquaculture establishments do not pose a significant risk.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

- (7) The level of risk posed by an aquaculture establishment, depends on the activity of that aquaculture establishment and the destination and intended use of the aquaculture animals or products of aquaculture animal origin produced therein. Some aquaculture establishments have already been approved for different purposes, such as aquaculture establishments which have been approved under the hygiene rules in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽³⁾. In certain situations, aquaculture establishments such as purification and dispatch centres or relaying areas only receive molluscs from within the epidemiological area in which the aquaculture establishment is itself located. These aquaculture establishments therefore, pose an insignificant risk from an animal health perspective. Other aquaculture establishments are also engaged in low risk activities, such as keeping aquaculture animals solely for release into the wild after having produced them from broodstock which originated from the water body on which the aquaculture establishment is located, or keeping aquaculture animals in extensive ponds for human consumption or for release into the wild.
- (8) It is necessary to lay down in this Regulation, the specific conditions under which derogations from the requirement for approval should be permitted for aquaculture establishments. In certain cases, derogations should only apply to aquaculture establishments which move aquaculture animals within their own Member State and not to aquaculture establishments which move aquaculture animals between Member States. In all cases, however, derogations from the requirement for an aquaculture establishment to be approved should only be considered when the competent authority has completed a risk assessment which takes into account at least the risk of aquaculture animals on the aquaculture establishment contracting or spreading an aquatic disease via water or via movements and where the risk has been found to be insignificant. Details of additional risk factors which the competent authority may take into account in this risk assessment are set out in Chapter 2 of Part I of Annex VI to Commission Delegated Regulation (EU) 2020/689 ⁽⁴⁾. Therefore, the supplementing rules laid down in this Regulation should be consistent with those laid down in that Delegated Regulation.
- (9) At the same time, certain other types of aquaculture establishments represent a significant risk for the spread of aquatic animal diseases. Such types of aquaculture establishment should be specifically described in this Regulation, and the requirement for the operators of these aquaculture establishments to be approved should be detailed in this Regulation. These include aquaculture establishments keeping ornamental aquaculture animals in open facilities and also in closed facilities where the movement patterns are such that trade within the Union or with third countries potentially present a disease risk. Other types of aquaculture establishments where the risk of disease spread should be mitigated through the requirement for approval by the competent authority, are quarantine establishments, establishments which keep vector species in isolation until such time as they are no longer considered to be vectors, and vessels and other mobile premises where aquaculture animals are treated or undergo other husbandry-related procedures.
- (10) Article 177 of Regulation (EU) 2016/429 provides for the competent authority to grant approval of operators for groups of aquaculture establishments. The supplementing rules laid down in this Regulation should therefore apply to such groups where appropriate, and should set out the details of how the rules should apply directly to, and within, the group.
- (11) Operators of all aquaculture establishments or groups of aquaculture establishments are required to provide information to the competent authority with a view to obtaining approval in compliance with Article 180 of Regulation (EU) 2016/429. In that regard, operators should provide the competent authority with a written biosecurity plan which will be considered during the approval process. This requirement should apply to both individual aquaculture establishments and groups of aquaculture establishments regardless of their size, but the complexity of the biosecurity plan should depend upon the specificities of the individual aquaculture establishment or group thereof, and on the measures which are required to mitigate the associated disease risks.
- (12) Certain aquaculture establishments and groups of aquaculture establishments should, on the basis of the rules laid down in Chapter 1 of Part I to Annex VI of Delegated Regulation (EU) 2020/689, participate in a risk-based surveillance scheme which is put in place by the competent authority in accordance with Article 26 of Regulation (EU) 2016/429. Without such participation, aquaculture establishments or groups of aquaculture establishments should not be approved. In line with Article 27 of Regulation (EU) 2016/429, risk-based surveillance may take into account the surveillance conducted by operators themselves in accordance with Article 24, including the animal health visits referred to in Article 25 of that Regulation. Risk-based surveillance may also be carried out at the same time as surveillance connected with particular listed diseases, in order to maximise resources.

⁽³⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes and disease-free status for certain listed and emerging diseases (see page 211 of this Official Journal).

- (13) The frequency of risk-based surveillance should be based on the ranking of the aquaculture establishment by the competent authority as 'high', 'medium' or 'low' risk, following an assessment of the circumstances of the establishment. Factors to be taken into account and considered by the competent authority when risk ranking establishments, as well as the frequency of surveillance which attaches to each risk ranking are set out in Part I of Annex VI to Delegated Regulation (EU) 2020/689. The objective of including aquaculture establishments which keep non-listed species but which participate in a significant amount of trade and which are therefore ranked as 'high' risk, in the risk-based surveillance scheme, is to maximise the chances of identifying and controlling emerging diseases, should they appear in aquaculture animals of those non-listed species.
- (14) As risk-based surveillance is also carried out in approved groups of aquaculture establishments, it is important to set out how this should be completed at group level so that the outcome of the surveillance is epidemiologically meaningful. Accordingly, this Regulation should lay down rules concerning the approach which the competent authority should take to carrying out such surveillance.
- (15) Apart from the requirement for operators to present a biosecurity plan to the competent authority as part of the approval process, and for certain aquaculture establishments to participate in a risk-based surveillance scheme, the aquaculture establishments that are required to be approved should also meet certain requirements in relation to their facilities and equipment. The particular combination of requirements with regard to biosecurity, surveillance, and facilities and equipment which apply to a specific category of aquaculture establishment or to a specific category of group of aquaculture establishments should therefore, be set out in this Regulation.
- (16) Article 178 of Regulation (EU) 2016/429 provides that operators of aquaculture establishments wishing to obtain the status of a confined aquaculture establishment may only move aquaculture animals to or from their aquaculture establishments after they have obtained the approval of that status from the competent authority in accordance with the rules laid down in that Regulation. As these aquaculture establishments may exchange aquaculture animals amongst themselves with fewer movement requirements than for other types of aquaculture establishments, it is appropriate that they should have a contracted veterinarian who will supervise the activities of the aquaculture establishment and be responsible for its health surveillance, so they can provide robust health guarantees to each other. Article 181(2) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts laying down supplementing rules for the approval of such aquaculture establishments, and such rules should be laid down in this Regulation.
- (17) Article 179 of Regulation (EU) 2016/429 provides for the approval of disease control aquatic food establishments. These aquaculture establishments facilitate the sanitary slaughter and sanitary processing of aquatic animals, which may be infected with a listed or emerging disease. Therefore, they represent a significant disease risk and should be approved by the competent authority. During the periods when these aquaculture establishments are receiving aquatic animals which are infected or suspected of being infected with a listed or emerging disease, they should comply with stringent biosecurity measures with the aim of ensuring that disease agents are not released into open waters without appropriate treatment. Article 181(2) of that Regulation provides for the Commission to adopt delegated acts laying down supplementing rules for the approval of these aquaculture establishments and accordingly those supplementing rules should be laid down in this Regulation.
- (18) Certain purification centres, relaying areas, and dispatch centres for live molluscs should be considered as aquaculture establishments which require approval in accordance with Article 176(1) of Regulation (EU) 2016/429. Those establishments which receive live molluscs from outside their own epidemiological area, represent a higher risk of spreading listed or emerging diseases and should be treated as such during the approval process. This Regulation should therefore lay down supplementing rules in that respect.
- (19) Commission Implementing Regulation (EU) 2018/1882 ⁽⁵⁾ lays down definitions for categories A, B, C, D and E diseases, and it provides that the disease prevention and control rules for listed diseases referred to in Article 9(1) of Regulation (EU) 2016/429 are to apply to the categories of listed diseases for the listed species, and groups of listed species referred to in the table set out in the Annex to Implementing Regulation (EU) 2018/1882. That table provides that certain species of aquatic animals which are listed in column 4 thereof are only to be considered as vectors when they are kept in an aquaculture establishment where the species listed in column 3 thereof are also kept, or in the case of wild aquatic animals, when they have been exposed to species listed in column 3 in a wild habitat. However, if these species are subsequently kept in isolation from the species listed in column 3 and from infected water sources for an appropriate period of time, they are no longer to be regarded as vectors. If this period of isolation cannot be carried out in a quarantine establishment approved in compliance with Article 15 of this Regulation, then such

⁽⁵⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

aquatic animals may instead be kept in another type of aquaculture establishment which does not have all of the biosecurity measures which are required for quarantine establishments, but where they are kept in isolation from potential pathogens until such time as they are no longer to be regarded as vectors. Article 181(2) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts laying down supplementing rules for the approval of such aquaculture establishments taking into account those requirements. Accordingly, those requirements should be laid down in this Regulation.

- (20) Article 185(5) of Regulation (EU) 2016/429 empowers the Commission to adopt delegated acts regarding additional information to be included in the registers of registered and approved aquaculture establishments kept by the competent authority and public access to those registers. Subject to the data protection requirements laid down in Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽⁶⁾, the information which should be made publicly available by the competent authority should reflect the requirements set out in Article 185(2)(a),(c),(e) and (f) of Regulation (EU) 2016/429 which in turn, largely reflect the details which Member States have already provided in a public register in compliance with Commission Decision 2008/392/EC ⁽⁷⁾.
- (21) More specific information should, however, also be included in the public register of the competent authority regarding the health status of each approved establishment in order to facilitate safe trade and to ensure stakeholders know whether or not a given aquaculture establishment is free from a specific category B or C disease, is subject to an eradication programme for a specific category B or C disease, is in a surveillance programme for a specific category C disease, or if it has none of those health statuses. Given the scope of the requirements which are set out in this Regulation with regard to the public availability of information on approved aquaculture establishments, this Regulation should repeal Decision 2008/392/EC.
- (22) Articles 186 and 187 of Regulation (EU) 2016/429 lay down the minimum record-keeping obligations for operators of aquaculture establishments. As aquatic animals are generally not individually identifiable, record-keeping in relation to their production and movement is crucial. Whilst there are some common elements between the records kept by operators of different types of aquaculture establishments, specific types of aquaculture establishments should keep records which are particular to them and the type of aquaculture activity they are engaged in. As Article 189(1) of that Regulation provides for the Commission to adopt delegated acts laying down supplementing rules for the record-keeping obligations, different record-keeping requirements should therefore, be set out in this Regulation for each type of approved aquaculture establishment.
- (23) Article 188 of Regulation (EU) 2016/429 lays down the minimum record-keeping obligations for transporters of aquatic animals intended for aquaculture establishments and of aquatic animals which are moved between habitats. Transporters of aquatic animals represent a particular risk for the spread of disease and it is crucial that these operators keep records to ensure the traceability of the aquatic animals they transport, as well as to provide documentary evidence that they are employing appropriate biosecurity measures. Accordingly, this Regulation should lay down supplementing rules for their record-keeping obligations.
- (24) This Regulation should apply from 21 April 2021 in accordance with the date of application of Regulation (EU) 2016/429,

HAS ADOPTED THIS REGULATION:

PART I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation supplements the rules laid down in Regulation (EU) 2016/429 as regards registered and approved aquaculture establishments keeping aquaculture animals and transporters of aquatic animals.

⁽⁶⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1.)

⁽⁷⁾ Commission Decision 2008/392/EC of 30 April 2008 implementing Council Directive 2006/88/EC as regards an internet-based information page to make information on aquaculture production businesses and authorised processing establishments available by electronic means (OJ L 138, 28.5.2008, p. 12).

2. Part II lays down requirements in:

- (a) Chapter 1 of Title I, on the approval by the competent authority of aquaculture establishments posing a significant risk for diseases affecting aquatic animals, and certain derogations for operators of establishments that pose an insignificant risk for those diseases;
- (b) Chapter 2 of Title I, on the requirements for aquaculture establishments and groups thereof, and the granting of approval by the competent authority;
- (c) Chapter 1 of Title II, on the information obligations of the competent authority as regards registers of aquaculture establishments registered in accordance with Article 173 of Regulation (EU) 2016/429;
- (d) Chapter 2 of Title II, on the information obligations of the competent authority as regards registers of approved aquaculture establishments;
- (e) Chapter 1 of Title III, for the record-keeping obligations of operators of aquaculture establishments and disease control aquatic food establishments registered or approved by the competent authority, in addition to those provided for in Articles 186(1) and 187(1) of Regulation (EU) 2016/429;
- (f) Chapter 2 of Title III, on the record-keeping obligations of transporters of aquatic animals, in addition to those provided for in Article 188(1) of Regulation (EU) 2016/429.

3. Part III lays down certain transitional measures as regard to Directive 2006/88/EC and Decision 2008/392/EC in relation to the registration and approval of aquaculture establishments.

Article 2

Definitions

For the purposes of this Regulation, the definitions set out in Article 1 of Implementing Regulation (EU) 2018/1882 shall apply.

The following definitions shall also apply:

- (1) 'extensive pond' means a traditional pond or lagoon which is natural or artificial and where the food source for the animals kept in these ponds or lagoons is natural other than in exceptional circumstances, and where no measures are taken to increase the production beyond the natural capacity of the environment;
- (2) 'purification centre' means an establishment with tanks fed by clean seawater in which molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption;
- (3) 'dispatch centre' means an on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of molluscs intended for human consumption;
- (4) 'relaying area' means any freshwater, sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of molluscs;
- (5) 'in isolation' means keeping aquaculture animals in an aquaculture establishment where they do not come into contact with any other species of aquatic animals either directly through co-habitation or indirectly through the water supply;
- (6) 'closed facility' means an aquaculture establishment, the waste water from which, is subjected to treatment which is capable of inactivating agents of listed diseases or emerging diseases, before it is discharged into open waters;
- (7) 'open facility' means an aquaculture establishment, the waste water from which, is discharged directly into open waters without being treated to inactivate agents of listed diseases or emerging diseases;
- (8) 'epidemiological area' means a defined geographical area where the aquatic animals have the same health status and are exposed to the same risk of contracting a listed disease or an emerging disease;
- (9) 'biosecurity plan' means a documented plan which identifies the routes by which a disease agent can enter an aquaculture establishment, spread within it and transfer from it; it takes account of the specificities of the establishment and identifies measures which will mitigate the biosecurity risks which have been identified;
- (10) 'common biosecurity measures' means the measures included in a biosecurity plan which has been devised for, and implemented by, each aquaculture establishment in a group of aquaculture establishments which has been approved by the competent authority in accordance with Article 177 of Regulation (EU) 2016/429;

- (11) 'unique registration number' means a number assigned to a registered aquaculture establishment or group of aquaculture establishments as referred to in Article 173 of Regulation (EU) 2016/429;
- (12) 'unique approval number' means a number assigned by the competent authority to an aquaculture establishment or group of aquaculture establishments approved by it in accordance with Article 173 of Regulation (EU) 2016/429;
- (13) 'IMO ship identification number' means a unique number assigned to sea-going vessels by the International Maritime Organisation (IMO);
- (14) 'hygiene barrier' means footbaths, hand washes, changes of clothing or other biosecurity measures, the effects of which are to create barriers to the spread of disease into, within or from an aquaculture establishment;
- (15) 'production units' means troughs, ponds, raceways, tanks, cages, pens, or similar structures which contain groups of aquaculture animals in an aquaculture establishment;
- (16) 'increased mortality' means unexplained mortalities above the level considered normal for the aquaculture establishment or group of aquaculture establishments in question, under prevailing conditions;
- (17) 'surveillance programme' means a voluntary programme of testing and control measures undertaken in relation to a category C disease at an aquaculture establishment which is not participating in an eradication programme to achieve disease-free status, but where testing indicates that the aquaculture establishment is not infected with that category C disease.

PART II

REGISTRATION, APPROVAL, REGISTERS AND RECORD-KEEPING

TITLE I

APPROVAL OF OPERATORS OF AQUACULTURE ESTABLISHMENTS BY THE COMPETENT AUTHORITY

CHAPTER 1

Approval of aquaculture establishments posing a significant risk for the spread of disease and derogations from the requirement for approval

Article 3

Derogations from the requirement on operators to apply to the competent authority for approval of aquaculture establishments

1. By way of derogation from Article 176(1)(a) of Regulation (EU) 2016/429, operators of the following types of aquaculture establishments shall not be required to apply to the competent authority for approval of their aquaculture establishments:
 - (a) aquaculture establishments where aquaculture animals are kept solely for release into the wild;
 - (b) extensive ponds where aquaculture animals are kept for direct human consumption or for release into the wild;
 - (c) purification centres which:
 - (i) are approved in accordance with Article 4 of Regulation (EC) No 853/2004; and
 - (ii) receive molluscs only from within the epidemiological area in which the establishment is located;
 - (d) dispatch centres which:
 - (i) are approved in accordance with Article 4 of Regulation (EC) No 853/2004; and
 - (ii) receive molluscs only from within the epidemiological area in which the establishment is located;
 - (e) relaying areas which:
 - (i) are approved in accordance with Article 4 of Regulation (EC) No 853/2004; and
 - (ii) receive molluscs only from within the epidemiological area in which the establishment is located.

2. Derogations from the requirement to apply to the competent authority for approval provided for in paragraph 1 of this Article shall only apply to aquaculture establishments from which aquaculture animals are not moved to another Member State, other than molluscs for direct human consumption and when the competent authority has completed a risk assessment:

- (a) taking into account at least the risk factors set out in points (a) and (b) of Chapter 2 of Part I of Annex VI to Commission Delegated Regulation (EU) 2020/689; and
- (b) which has found the risk of the aquaculture animals on the aquaculture establishment either contracting or spreading a listed disease or an emerging disease to be insignificant.

Article 4

Types of aquaculture establishments required to be approved by the competent authority

Operators of the following types of aquaculture establishments shall apply to the competent authority for approval in accordance with Article 176(1)(b) of Regulation (EU) 2016/429:

- (a) quarantine establishments for aquaculture animals;
- (b) aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation, until such time as they are no longer regarded as being vectors;
- (c) aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes, which because of their movement patterns, create a significant disease risk;
- (d) aquaculture establishments keeping aquaculture animals for ornamental purposes in open facilities;
- (e) vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry-related procedure.

CHAPTER 2

Requirements and granting of approval of aquaculture establishments

Article 5

Requirement for approved aquaculture establishments and groups thereof to have a biosecurity plan

The competent authority shall only approve aquaculture establishments referred to in Article 7 and Articles 9 to 19, or groups of aquaculture establishments referred to in Article 8, if their operators have developed and documented a biosecurity plan, which complies with the following requirements:

- (a) it identifies the routes whereby a disease agent can enter the aquaculture establishment or group of aquaculture establishments, spread within it and transfer from it to the environment or to other aquaculture establishments;
- (b) it takes account of the specificities of the individual aquaculture establishment or group of aquaculture establishments and identifies risk-mitigation measures for each biosecurity risk which has been identified;
- (c) it considers or takes into account, where appropriate, the elements set out in point 1(a) of Parts 1 to 7 and Parts 9 to 12, and in point 1(b) of Part 8 of Annex I, when this plan for the aquaculture establishment or group of aquaculture establishments is being developed.

Article 6

Requirement for approved aquaculture establishments and groups thereof to participate in a risk-based surveillance scheme

1. The competent authority shall only approve aquaculture establishments referred to in Articles 7, 17 and 18 of this Regulation if the operators comply with risk-based surveillance conducted by the competent authority in accordance with Article 26 of Regulation (EU) 2016/429, in the form of a risk-based surveillance scheme as set out in Part 1 and in point 1 of Part 2 of Annex II to this Regulation.

2. The competent authority shall only approve groups of aquaculture establishments referred to in Article 8 of this Regulation when operators comply with risk based surveillance conducted by the competent authority in accordance with Article 26 of Regulation (EU) 2016/429, in the form of a risk-based surveillance scheme as set out in Part 1 and in point 2 of Part 2 of Annex II to this Regulation.

3. When granting approval of aquaculture establishments or groups thereof as provided for in paragraphs 1 and 2, the competent authority shall take account of the following elements, and include them in the risk-based surveillance scheme:

- (a) the outcome of the surveillance conducted by the operator in accordance with Article 24 of Regulation (EU) 2016/429;
- (b) the information obtained through the animal health visits carried out by a veterinarian in accordance with Article 25 of Regulation (EU) 2016/429, when the operators make such information available.

Article 7

Requirements for granting approval of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin, other than those aquaculture establishments for which specific requirements are laid down in Articles 12 to 19

When granting approval, the competent authority shall ensure that aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin, other than those aquaculture establishments referred to in Articles 12 to 19, comply with the requirements set out in:

- (a) Article 6(1), in relation to risk-based surveillance;
- (b) point 1 of Part 1 of Annex I, in relation to biosecurity measures;
- (c) point 2 of Part 1 of Annex I, in relation to facilities and equipment.

Article 8

Requirements for granting approval of groups of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin

When granting approval, the competent authority shall ensure that groups of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin comply with the requirements set out in:

- (a) Article 6(2), in relation to risk-based surveillance;
- (b) point 1 of Part 2 of Annex I, in relation to biosecurity measures for the aquaculture establishments in the group;
- (c) point 2 of Part 2 of Annex I, in relation to facilities and equipment.

Article 9

Requirements for granting approval of confined aquaculture establishments

When granting approval, the competent authority shall ensure that confined aquaculture establishments comply with the requirements set out in:

- (a) Article 10, in relation to arrangements for facilities where post-mortem examinations are carried out and securing the services of an establishment veterinarian;
- (b) point 1 of Part 3 of Annex I, in relation to biosecurity measures;
- (c) point 2 of Part 3 of Annex I, in relation to surveillance and control;
- (d) point 3 of Part 3 of Annex I, in relation to facilities and equipment.

*Article 10***Obligations of operators of confined aquaculture establishments**

Before approval is granted by the competent authority, operators of confined aquaculture establishments shall:

- (a) put in place arrangements to perform veterinary post-mortem examinations in appropriate facilities in the confined aquaculture establishment or in a laboratory;
- (b) secure by contract or by another legal instrument, the services of an establishment veterinarian who shall be responsible for:
 - (i) the supervision of the activities of the confined aquaculture establishment and compliance with the requirements for approval laid down in Article 9;
 - (ii) the review of the disease surveillance plan referred to in point 2(a) of Part 3 of Annex I at least annually.

*Article 11***Requirements for granting approval of disease control aquatic food establishments**

When granting approval, the competent authority shall ensure that disease control aquatic food establishments comply with the requirements set out in:

- (a) point 1 of Part 4 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 4 of Annex I, in relation to facilities and equipment.

*Article 12***Requirements for granting approval of purification centres other than those referred to in Article 3(1)(c)**

When granting approval, the competent authority shall ensure that purification centres other than those referred to in Article 3(1)(c) comply with the requirements set out in:

- (a) point 1 of Part 5 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 5 of Annex I, in relation to facilities and equipment.

*Article 13***Requirements for granting approval of dispatch centres other than those referred to in Article 3(1)(d)**

When granting approval, the competent authority shall ensure that dispatch centres other than those referred to in Article 3(1)(d) comply with the requirements set out in:

- (a) point 1 of Part 6 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 6 of Annex I, in relation to facilities and equipment.

*Article 14***Requirements for granting approval of relaying areas other than those referred to in Article 3(1)(e)**

When granting approval, the competent authority shall ensure that relaying areas other than those referred to in Article 3(1)(e) comply with the requirements set out in:

- (a) point 1 of Part 7 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 7 of Annex I, in relation to facilities and equipment.

*Article 15***Requirements for granting approval of quarantine establishments**

When granting approval, the competent authority shall ensure that quarantine establishments comply with the requirements set out in:

- (a) point 1 of Part 8 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 8 of Annex I, in relation to surveillance and control measures;
- (c) point 3 of Part 8 of Annex I, in relation to facilities and equipment.

*Article 16***Requirements for granting approval of aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation, until such time as they are no longer regarded as vectors**

When granting approval, the competent authority shall ensure that aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation, until such time as they are no longer regarded as vectors, comply with the requirements set out in:

- (a) point 1 of Part 9 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 9 of Annex I, in relation to surveillance and control measures;
- (c) point 3 of Part 9 of Annex I, in relation to facilities and equipment.

*Article 17***Requirements for granting approval of aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes which, because of their movement patterns, create a significant disease risk**

When granting approval, the competent authority shall ensure that aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes which, because of their movement patterns, create a significant disease risk, comply with the requirements set out in:

- (a) Article 6(1), in relation to risk-based surveillance;
- (b) point 1 of Part 10 of Annex I, in relation to biosecurity measures;
- (c) point 2 of Part 10 of Annex I, in relation to facilities and equipment.

*Article 18***Requirements for granting approval of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes**

When granting approval, the competent authority shall ensure that aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes comply with the requirements set out in:

- (a) Article 6(1), in relation to risk-based surveillance;
- (b) point 1 of Part 11 of Annex I, in relation to biosecurity measures;
- (c) point 2 of Part 11 of Annex I, in relation to facilities and equipment.

*Article 19***Requirements for granting approval of vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry-related procedure**

When granting approval, the competent authority shall ensure that vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry-related procedure comply with the requirements set out in:

- (a) point 1 of Part 12 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 12 of Annex I, in relation to facilities and equipment.

TITLE II

REGISTERS TO BE KEPT BY THE COMPETENT AUTHORITY OF REGISTERED AND APPROVED AQUACULTURE ESTABLISHMENTS

CHAPTER 1

Registers of aquaculture establishments kept by the competent authority*Article 20***Information obligation of the competent authority as regards the register of registered aquaculture establishments**

In addition to the information required by Article 185(2) of Regulation (EU) 2016/429, the competent authority shall include the following information in the register of aquaculture establishments provided for in Article 185(1)(a) of that Regulation, for each aquaculture establishment it registers:

- (a) the unique registration number assigned to it by the competent authority;
- (b) the date of registration by the competent authority;
- (c) the address and geographical coordinates (latitude and longitude) of the location of the aquaculture establishment;
- (d) a description of its facilities and equipment;
- (e) categories of aquaculture animals which are kept in the aquaculture establishment;
- (f) the approximate number or the maximum biomass or both, of the aquaculture animals which may be kept in the aquaculture establishment;
- (g) the period during which aquaculture animals are kept in the aquaculture establishment if it is not continuously occupied, including when relevant, information on seasonal occupation or occupation during particular events;
- (h) the date of any cessation of activity when the operator has informed the competent authority thereof.

CHAPTER 2

Registers of aquaculture establishments approved by the competent authority*Article 21***Information obligation of the competent authority as regards the register of approved aquaculture establishments**

1. In addition to the information required by Article 185(2) of Regulation (EU) 2016/429, the competent authority shall include the following information in the register of approved aquaculture establishments provided for in Article 185(1)(b) and (c) of that Regulation, for each aquaculture establishment or group of aquaculture establishments it approves:

- (a) the unique approval number assigned to it by the competent authority

- (b) the date of approval granted by the competent authority or of any suspension or withdrawal of approval by the competent authority;
- (c) the address and geographical coordinates (latitude and longitude) of the location of the approved aquaculture establishment or group of aquaculture establishments;
- (d) a description of its relevant facilities and equipment;
- (e) categories of aquaculture animals which are kept in the aquaculture establishment or in the group of aquaculture establishments;
- (f) the approximate number or the maximum biomass, or both, of the aquaculture animals which may be kept in the aquaculture establishment or in the group of aquaculture establishments;
- (g) the period during which aquaculture animals are kept in the aquaculture establishment or group of aquaculture establishments if not continuously occupied, including when relevant, information on seasonal occupation or occupation during particular events;
- (h) the date of any cessation of activity when the operator has informed the competent authority thereof.

2. In addition to the information required by Article 185(3) of Regulation (EU) 2016/429, the competent authority shall include up-to-date information on the health status of the aquaculture animals kept in aquaculture establishments or groups of aquaculture establishments which are approved in accordance with Article 181(1) of that Regulation, in an internet-based information page which is publicly available.

That up-to-date health information shall at least set out the health status of the aquaculture establishment or group of aquaculture establishments for each relevant listed disease and for each relevant category thereof, as follows:

- (a) whether it is free from a category B disease or category C disease;
- (b) if it is in an eradication programme for a category B disease or category C disease;
- (c) if it is in a voluntary surveillance programme for a category C disease; or
- (d) any other information which pertains to a category B, category C or category D disease, other than the information which is set out in points (a), (b) and (c).

TITLE III

RECORD-KEEPING OBLIGATIONS OF OPERATORS IN ADDITION TO THOSE PROVIDED FOR IN REGULATION (EU) 2016/429

CHAPTER I

Records to be kept by operators of registered or approved aquaculture establishments

Article 22

Record-keeping obligations of operators of registered aquaculture establishments

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of registered aquaculture establishments shall record and keep the following information:

- (a) the unique registration number assigned to the aquaculture establishment by the competent authority;
- (b) details of any investigations that were carried out following the occurrence of increased mortality or suspicion of the presence of disease;
- (c) self-declaration documents issued in accordance with Article 218 of Regulation (EU) 2016/429, received with consignments of aquaculture animals which have arrived at the aquaculture establishment or which have been sent with such consignments which have been dispatched from the aquaculture establishment, as relevant;
- (d) where relevant, any other documents accompanying aquatic animals.

*Article 23***Record-keeping obligations of operators of approved aquaculture establishments where aquaculture animals are kept with a view to their being moved therefrom, either alive or as products of aquaculture animal origin other than those which are referred to in Articles 27 to 34**

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin other than those aquaculture establishments referred to in Articles 27 to 34 of this Regulation, shall record and keep the following information:

- (a) the unique approval number issued to the aquaculture establishment by the competent authority;
- (b) the current risk categorisation of the aquaculture establishment, as assigned by the competent authority;
- (c) details of the implementation and results of the risk-based surveillance provided for in Article 6(1);
- (d) details of movements to the aquaculture establishment including:
 - (i) the unique approval or registration number of the aquaculture establishment of origin of all aquaculture animals which have been received from another aquaculture establishment; or
 - (ii) the location of the habitat from which wild aquatic animals have been collected before being dispatched to the aquaculture establishment;
- (e) details of movements from the aquaculture establishment including:
 - (i) aquaculture animals and products of aquaculture animal origin and, in the case of movements of aquaculture animals, including the unique registration or approval number of the aquaculture establishment of destination; or
 - (ii) in the case of movements into the wild, details of the habitat into which the aquaculture animals will be released;
- (f) the name and address of transporters who deliver aquatic animals to or collect aquaculture animals from the establishment;
- (g) the biosecurity plan for the approved aquaculture establishment and evidence of its implementation;
- (h) self-declaration documents issued in compliance with Article 218 of Regulation (EU) 2016/429 received with consignments of aquaculture animals which have arrived at the aquaculture establishment or which have been sent with consignments which have been dispatched from the aquaculture establishment, as relevant;
- (i) where relevant, any other documents accompanying aquatic animals.

*Article 24***Record-keeping obligations of operators of an approved group of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin**

1. In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of aquaculture establishments in a group of aquaculture establishments approved in accordance with point (a) of Article 177 of Regulation (EU) 2016/429 shall record and keep the following information:

- (a) the unique approval number issued to the aquaculture establishment by the competent authority;
- (b) the current risk categorisation of the group of aquaculture establishments, as assigned by the competent authority;
- (c) details of the implementation and results of the risk-based surveillance provided for in Article 6(2);
- (d) details of movements to the aquaculture establishment including:
 - (i) the unique approval or registration number of the aquaculture establishment of origin for all aquaculture animals which have been received from an aquaculture establishment outside the group; or
 - (ii) the location of the habitat from which wild aquatic animals have been collected before being dispatched to the aquaculture establishment;

- (e) details of movements from the group of aquaculture establishments including:
 - (i) aquaculture animals and products of aquaculture animal origin from aquaculture animals and, in the case of movements of aquaculture animals, including the unique registration or approval number of the establishment of destination, where aquaculture animals are dispatched to another establishment outside the group; or
 - (ii) in the case of movements into the wild, details of the habitat into which the aquaculture animals will be released;
 - (f) the name and address of transporters who deliver aquatic animals to, or collect aquaculture animals from, the aquaculture establishment;
 - (g) details of the biosecurity plan employed and evidence of its implementation;
 - (h) self-declaration documents issued in compliance with Article 218 of Regulation (EU) 2016/429, received with consignments of aquaculture animals which have arrived at the aquaculture establishment or which have been sent with consignments which have been dispatched from the aquaculture establishment, as relevant;
 - (i) where relevant, any other documents accompanying the aquatic animals.
2. The operator of a group of aquaculture establishments approved in accordance with point (b) of Article 177 of Regulation (EU) 2016/429 shall record or keep the information set out in paragraph 1(a) to (i) of this Article on behalf of each aquaculture establishment in the group.

Article 25

Record-keeping obligations of operators of approved confined aquaculture establishments

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved confined aquaculture establishments shall record and keep the following information:

- (a) the unique approval number issued to the confined aquaculture establishment by the competent authority;
- (b) details of movements to and from the confined aquaculture establishment including the unique registration or approval number of the aquaculture establishment of origin or destination of all aquaculture animals received from or dispatched to another aquaculture establishment;
- (c) the name and address of transporters who deliver aquaculture animals to, or collect aquaculture animals from, the confined aquaculture establishment;
- (d) details of the implementation and results of the disease surveillance plan provided for in point 2 of Part 3 of Annex I;
- (e) the results of clinical and laboratory tests and of post-mortem examinations completed when increased mortalities or suspicion of the presence of disease are investigated;
- (f) where relevant, details of the vaccination or treatment of aquaculture animals provided for in point 2(c) of Part 3 of Annex I;
- (g) details of isolation or quarantine of incoming aquaculture animals, instructions, if any, of the competent authority as regards isolation and quarantine and relevant observations made during any isolation or quarantine period;
- (h) the biosecurity plan for the confined aquaculture establishment;
- (i) where relevant, any other documents accompanying the aquaculture animals.

Article 26

Record-keeping obligations of operators of disease control aquatic food establishments

In addition to the information required by Article 187(1) of Regulation (EU) 2016/429, operators of disease control aquatic food establishments shall record and keep the following information:

- (a) the unique approval number issued to the disease control aquatic food establishment by the competent authority;
- (b) the biosecurity plan for the disease control aquatic food establishment and evidence of its implementation;

- (c) maintenance records for the waste water treatment system used in the disease control aquatic food establishment;
- (d) records to verify the efficacy of the water treatment system;
- (e) the name and address of transporters who deliver aquatic animals to the disease control aquatic food establishment;
- (f) where relevant, any other documents accompanying the aquatic animals.

Article 27

Record-keeping obligations of operators of approved purification centres

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved purification centres shall record and keep the following information:

- (a) the unique approval number issued to the approved purification centre by the competent authority;
- (b) the biosecurity plan for the approved purification centre and evidence of its implementation;
- (c) maintenance records for the waste water treatment system used in the approved purification centre;
- (d) records to verify the efficacy of the water treatment system;
- (e) where relevant, any other documents accompanying aquatic animals.

Article 28

Record-keeping obligations of operators of approved dispatch centres

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved dispatch centres shall record and keep the following information:

- (a) the unique approval number issued to the approved dispatch centre by the competent authority;
- (b) the biosecurity plan for the approved dispatch centre and evidence of its implementation;
- (c) maintenance records for the waste water treatment system used in the approved dispatch centre;
- (d) records to verify the efficacy of the water treatment system;
- (e) where relevant, any other documents accompanying aquatic animals.

Article 29

Record-keeping obligations of operators of approved relaying areas

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved relaying areas shall record and keep the following information:

- (a) the unique approval number issued to the approved relaying area by the competent authority;
- (b) the biosecurity plan for the approved relaying area and evidence of its implementation;
- (c) where relevant, any other documents accompanying aquatic animals.

Article 30

Record-keeping obligations of operators of approved quarantine establishments for aquaculture animals

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved quarantine establishments for aquaculture animals shall record and keep the following information:

- (a) the unique approval number issued to the quarantine establishment by the competent authority;

- (b) details of movements to the approved quarantine establishment including:
 - (i) the unique registration or approval number of the aquaculture establishment of origin of all aquaculture animals received from another aquaculture establishment; or
 - (ii) the location of the habitat from which aquatic animals have been collected before being dispatched to the approved quarantine establishment;
- (c) details of movements from the approved quarantine establishment including:
 - (i) the unique registration or approval number of the aquaculture establishment of destination; or
 - (ii) the location of the habitat into which aquaculture animals have been released into the wild;
- (d) the name and address of transporters who deliver aquatic animals to, or collect aquaculture animals from, the approved quarantine establishment;
- (e) details of the implementation and results of the disease surveillance provided for in point 2 of Part 8 of Annex I;
- (f) the results of clinical and laboratory tests and of post-mortem examinations provided for in point 2 of Part 8 of Annex I;
- (g) instructions, if any, of the competent authority as regards observations made during any isolation or quarantine period;
- (h) the biosecurity plan for the approved quarantine establishment and evidence of its implementation;
- (i) evidence showing that the environmental parameters in the approved quarantine establishment are conducive to the expression of the relevant listed or emerging disease(s);
- (j) where relevant, any other documents accompanying the aquatic animals.

Article 31

Record-keeping obligations of operators of approved aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation, until such time as they are no longer regarded as vectors

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation, until such time as they are no longer regarded as vectors, shall record and keep the following information:

- (a) the unique approval number issued to the aquaculture establishment by the competent authority;
- (b) details of movements to the approved aquaculture establishment including:
 - (i) the unique registration or approval number of the aquaculture establishment of origin of all aquaculture animals received from another aquaculture establishment; or
 - (ii) the location of the habitat from which aquatic animals have been collected before being dispatched to the approved aquaculture establishment;
- (c) details of movements from the approved aquaculture establishment including:
 - (i) the unique registration or approval number of the aquaculture establishment of destination; or
 - (ii) in the case of movements into the wild, details of the habitat into which the aquaculture animals will be released;
- (d) the name and address of transporters who deliver aquatic animals to, or collect aquaculture animals from, the approved aquaculture establishment;
- (e) details of the implementation and results of the disease surveillance provided for in point 2 of Part 9 of Annex I;
- (f) the results of clinical and laboratory tests and of post-mortem examinations provided for in point 2 of Part 9 of Annex I;
- (g) instructions, if any, of the competent authority as regards observations made during the 90 day isolation period referred to in point 2 of Part 9 of Annex I;
- (h) the biosecurity plan for the approved aquaculture establishment and evidence of its implementation;
- (i) where relevant, any other documents accompanying the aquatic animals.

*Article 32***Record-keeping obligations of operators of approved aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes**

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes shall record and keep the following information:

- (a) the unique approval number issued to the aquaculture establishment by the competent authority;
- (b) the current risk categorisation of the approved aquaculture establishment, as assigned by the competent authority;
- (c) details of the implementation and results of the risk based surveillance provided for in Article 6(1), where relevant;
- (d) details of movements to the approved aquaculture establishment including the unique registration or approval number of the aquaculture establishment of origin of all aquaculture animals received from another aquaculture establishment;
- (e) details of movements from the approved aquaculture establishment, including the unique registration or approval number of the aquaculture establishment of destination other than when these movements take place to households;
- (f) the name and address of transporters who deliver aquatic animals to, or collect aquaculture animals from, the approved aquaculture establishment, other than when these movements take place to households;
- (g) the biosecurity plan for the approved aquaculture establishment and evidence of its implementation;
- (h) self-declaration documents issued in accordance with Article 218 of Regulation (EU) 2016/429, received with consignments of aquaculture animals which have arrived at the approved aquaculture establishment or which have been sent with consignments which have been dispatched from the approved aquaculture establishment, as relevant;
- (i) where relevant, any other documents accompanying aquaculture animals.

*Article 33***Record-keeping obligations of operators of approved aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes**

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes shall record and keep the following information:

- (a) the unique approval number issued to the aquaculture establishment by the competent authority;
- (b) the current risk categorisation of the approved aquaculture establishment, as assigned by the competent authority;
- (c) details of the implementation and results of the risk based surveillance provided for in Article 6(1), where relevant;
- (d) details of movements to the approved aquaculture establishment including the unique registration or approval number of the aquaculture establishment of origin of all aquaculture animals which have been received from another aquaculture establishment;
- (e) details of movements from the approved aquaculture establishment including the unique registration or approval number of the aquaculture establishment of destination except when these movements take place to households;
- (f) the name and address of transporters who deliver aquatic animals to, or collect aquaculture animals from, the approved aquaculture establishment, other than when these movements take place to households;
- (g) the biosecurity plan for the approved aquaculture establishment and evidence of its implementation;
- (h) self-declaration documents issued in accordance with Article 218 of Regulation (EU) 2016/429, received with consignments of aquaculture animals which have arrived at the approved aquaculture establishment or which have been sent with consignments which have been dispatched from the approved aquaculture establishment, as relevant;
- (i) where relevant, any other documents accompanying aquatic animals.

*Article 34***Record-keeping obligations of operators of approved vessels or other approved mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry-related procedure**

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved vessels or other approved mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry-related procedure, shall record and keep the following information:

- (a) the unique approval number issued to the vessel or other mobile premises by the competent authority;
- (b) the dates and times of loading of aquaculture animals at the approved vessel or other approved mobile premises;
- (c) where relevant, the name, address and unique registration or approval number of each aquaculture establishment where aquaculture animals were loaded and unloaded;
- (d) the dates and places at which the vessel or other mobile premises was filled with water before loading and where relevant, exchanged between loading and unloading;
- (e) where relevant, details of the route taken between one aquaculture establishment and another;
- (f) details of each treatment or husbandry-related procedure which takes place in the approved vessel or other approved mobile premises;
- (g) the biosecurity plan for the approved vessel or other approved mobile premises and evidence of its implementation;
- (h) where relevant, any other documents accompanying aquaculture animals.

*CHAPTER 2***Records to be kept by transporters***Article 35***Record-keeping obligations of transporters of aquatic animals**

In addition to the information required by Article 188 of Regulation (EU) 2016/429, transporters of aquatic animals shall record and keep the following information for each means of transport used to move aquatic animals:

- (a) its licence plate number in the case of transport by land, its IMO ship identification number in the case of transport by sea, or any other means of identification which uniquely identifies other means of transport in which aquatic animals are transported;
- (b) the dates and times of loading of aquatic animals at the aquaculture establishment or habitat of origin;
- (c) the name, address and unique registration or approval number of each aquaculture establishment visited;
- (d) the location of each habitat from which wild aquatic animals were collected;
- (e) the dates and times of unloading of aquatic animals at the aquaculture establishment or habitat of destination;
- (f) the dates, times and places of water exchange, when this has occurred;
- (g) the biosecurity plan for the means of transport and evidence of its implementation;
- (h) the reference numbers of the documents accompanying the consignments of aquatic animals.

*PART III***TRANSITIONAL AND FINAL PROVISIONS***Article 36***Repeal**

Decision 2008/392/EC is repealed with effect from 21 April 2021.

References to the repealed act shall be construed as references to this Regulation.

*Article 37***Transitional measures regarding the information in the registers of existing aquaculture establishments and operators kept by competent authorities**

Member States shall ensure that, for the existing aquaculture establishments and operators referred to in Article 279(1) of Regulation (EU) 2016/429 which fall within the scope of Articles 20 and 21 of this Regulation, the information required by Articles 20 and 21 has been included for each such aquaculture establishment and operator in the registers of registered and approved aquaculture establishments kept by competent authorities before 21 April 2021.

*Article 38***Entry into force and application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 30 January 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

REQUIREMENTS FOR GRANTING APPROVAL OF AQUACULTURE ESTABLISHMENTS, AS REFERRED TO IN CHAPTER 2 OF TITLE I OF PART II

PART 1

Requirements for granting approval of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin as referred to in Article 7

1. The requirements in relation to biosecurity measures of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin as referred to in point (b) of Article 7, shall be the following:
 - (a) operators shall implement a biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the aquaculture establishment;
 - (ii) where the following functional units exist within the same aquaculture establishment, they must be separated using appropriate hygiene barriers:
 - hatchery units,
 - fattening units,
 - processing units,
 - dispatch centre;
 - (iii) work clothing and footwear for personnel must be kept solely for use at the aquaculture establishment and cleaned and disinfected regularly;
 - (iv) equipment must not be shared between aquaculture establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be followed;
 - (v) visitors to the aquaculture establishment must be controlled in cases where they pose a disease risk; these visitors must either:
 - wear protective clothing and footwear provided at the aquaculture establishment, or
 - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (vi) dead animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum but which is practicable given the production method used, and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽¹⁾;
 - (vii) as far as possible, equipment in the aquaculture establishment must be cleaned and disinfected at the end of each production cycle;
 - (viii) where aquaculture establishments receive fertilised eggs from other establishments, and where biologically feasible, these eggs must be disinfected appropriately on arrival and all packaging must be disinfected or disposed of in a biosecure manner;
 - (ix) the cleaning and disinfection records of transporters must be verified before aquatic animals are loaded or unloaded at the aquaculture establishment;
 - (b) operators shall nominate a named person to be in charge of implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters.

⁽¹⁾ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

2. The requirements in relation to facilities and equipment of aquaculture establishments as referred to in point (c) of Article 7, shall be the following:
 - (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept on the aquaculture establishment;
 - (b) the aquaculture establishment must provide for good standards of hygiene and allow adequate health monitoring to be carried out;
 - (c) as far as possible, equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
 - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose and the environmental constraints of the aquaculture establishment;
 - (e) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport.

PART 2

Requirements for granting approval of groups of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin as referred to in Article 8

1. The requirements in relation to biosecurity measures of groups of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom as referred to in point (b) of Article 8, shall be the following:
 - (a) operators shall implement a biosecurity plan in accordance with Article 5, and in developing their biosecurity plan, the operators must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in each aquaculture establishment in the group;
 - (ii) where the following functional units exist within the same aquaculture establishment, they must be separated using appropriate hygiene barriers:
 - hatchery units,
 - fattening units,
 - processing units,
 - dispatch centre;
 - (iii) work clothing and footwear for personnel must be kept solely for use at each aquaculture establishment and cleaned and disinfected regularly;
 - (iv) equipment must not be shared between aquaculture establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be followed;
 - (v) visitors to the aquaculture establishment must be controlled where they pose a disease risk; these visitors must either:
 - wear protective clothing and footwear provided at each aquaculture establishment, or
 - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (vi) dead aquaculture animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum but which is practicable given the production method used, and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
 - (vii) as far as possible, equipment in each aquaculture establishment must be cleaned and disinfected at the end of each production cycle;

- (viii) where aquaculture establishments receive fertilised eggs from other establishments, and where biologically feasible, these eggs must be disinfected appropriately on arrival and all packaging must be disinfected or disposed of in a biosecure manner;
 - (ix) the cleaning and disinfection records of transporters must be verified before aquaculture animals are loaded or unloaded at the aquaculture establishment;
 - (b) responsibility for the implementation of the measures set out in the biosecurity plan shall be with:
 - (i) the operator of each individual aquaculture establishment in a group of aquaculture establishments approved in accordance with point (a) of Article 177 of Regulation (EU) 2016/429;
 - (ii) the operator of a group of aquaculture establishments approved in accordance with point (b) of Article 177 of Regulation (EU) 2016/429.
- 2. The requirements in relation to facilities and equipment of groups of aquaculture establishments as referred to in point (c) of Article 8, shall be the following:
 - (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept in each aquaculture establishment in the group;
 - (b) each aquaculture establishment in the group must have good standards of hygiene and allow health monitoring to be carried out;
 - (c) equipment and facilities in each aquaculture establishment in the group must be made from materials which can be readily cleaned and disinfected;
 - (d) appropriate predator control measures must be put in place in each aquaculture establishment in the group, taking into account the risk of disease spread these predators pose and the environmental constraints of the aquaculture establishment;
 - (e) appropriate equipment must be available in each aquaculture establishment in the group for cleaning and disinfection of facilities, equipment and means of transport.

PART 3

Requirements for granting approval of confined aquaculture establishments referred to in Article 9

- 1. The requirements in relation to the biosecurity measures of confined aquaculture establishments as referred to in point (b) of Article 9, shall be the following:
 - (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the confined aquaculture establishment;
 - (ii) where different functional units exist within the same confined aquaculture establishment, they must be kept separate using hygiene barriers;
 - (iii) work clothing and footwear for personnel must be kept at the confined aquaculture establishment and cleaned and disinfected regularly;
 - (iv) visitors must wear protective clothing and footwear provided by the operator;
 - (v) equipment shall not be shared with other aquaculture establishments;
 - (vi) dead animals must be removed at a frequency that ensures infective pressure is kept to a minimum, and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
 - (vii) the equipment in the confined aquaculture establishment must be cleaned and disinfected at an appropriate frequency;

- (viii) where confined aquaculture establishments receive fertilised eggs from other establishments, where biologically feasible and where it does not interfere with research objectives, these eggs must be disinfected appropriately on arrival, and all packaging must be disinfected or disposed of in a biosecure manner;
 - (ix) the cleaning and disinfection records of transporters must be verified before aquaculture animals are loaded or unloaded at the establishment;
 - (b) operators shall nominate a named person to be in charge of implementing the biosecurity plan for the confined aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters.
- 2. The requirements in relation to surveillance and control measures of confined aquaculture establishments as referred to in point (c) of Article 9, shall be the following:
 - (a) a disease surveillance plan must be implemented, which must include appropriate controls for diseases of aquaculture animals, and it must be updated according to the number and species of the aquaculture animals present in the confined aquaculture establishment, and to the epidemiological situation in and around the confined aquaculture establishment as regards listed and emerging diseases;
 - (b) aquaculture animals suspected of being infected with listed or emerging disease agents must be subjected to clinical, laboratory or post-mortem testing;
 - (c) the vaccination and treatment of aquaculture animals against transmissible diseases is carried out as appropriate.
- 3. The requirements in relation to facilities and equipment of confined aquaculture establishments as referred to in point (d) of Article 9, shall be the following:
 - (a) the boundaries of the confined aquaculture establishments must be clearly demarcated and the access of aquatic animals and humans to animal facilities must be controlled;
 - (b) where necessary, adequate facilities suited for the quarantine of aquaculture animals introduced from other establishments must be available;
 - (c) adequate means for isolating aquaculture animals must be available;
 - (d) tanks and other holding facilities must be of a suitable standard and constructed so that:
 - (i) contact with aquatic animals outside is prevented and that inspections and any necessary treatments can be easily carried out;
 - (ii) floors, walls and all other material or equipment can be readily cleaned and disinfected;
 - (e) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept in the confined aquaculture establishment;
 - (f) the confined aquaculture establishment must provide for good standards of hygiene and allow adequate health monitoring to be carried out;
 - (g) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport;
 - (h) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose;
 - (i) appropriate disinfection equipment must be in place to ensure that all wastewater which is discharged from the confined aquaculture establishment is treated to a level which ensures that any infectious agents of listed or emerging diseases which are present are fully inactivated before discharge.

PART 4

Requirements for granting approval of disease control aquatic food establishments referred to in Article 11

1. The requirements in relation to biosecurity measures of disease control aquatic food establishments as referred to in point (a) of Article 11, shall be the following:
 - (a) operators shall implement the biosecurity plan for the disease control aquatic food establishment in accordance with Article 5, which must take account of at least the following elements when animals which are infected with a listed or emerging disease are slaughtered or processed on the premises:
 - (i) visitors to the establishment must be avoided, but when such visits are unavoidable, they must be controlled and protective clothing and footwear must be provided by the operator which are safely disposed of or cleaned and disinfected after use;
 - (ii) the personnel of the disease control aquatic food establishment must wear work clothing and footwear which must be cleaned and disinfected at an appropriate frequency;
 - (iii) an appropriate disinfection system must be in place to ensure that waste water from the disease control aquatic food establishment is appropriately treated so that any disease agents which are present are inactivated before the water is discharged;
 - (iv) an appropriate system must be in place to ensure the collection and appropriate disposal of animal by-products; such by-products shall be processed as Category 1 or Category 2 material in compliance with Article 12 or Article 13 of Regulation (EC) No 1069/2009;
 - (v) appropriate cleaning and disinfecting operations must be completed prior to the arrival of any new consignment of aquatic animals for processing;
 - (vi) appropriate measures must be in place to ensure that all means of transport and their containers which are used to deliver aquatic animals to a disease control aquatic food establishment are cleaned and disinfected before they leave the establishment.
2. The requirements in relation to facilities and equipment of disease control aquatic food establishments as referred to in point (b) of Article 11, shall be the following:
 - (a) floors, walls and all other material or equipment must be easily cleaned and disinfected;
 - (b) appropriate disinfection equipment must be in place to ensure that all waste water which is discharged from the disease control aquatic food establishment is treated to a level which ensures that any infectious agents of listed or emerging diseases which are present are fully inactivated before discharge;
 - (c) appropriate equipment, compatible with the type of production activities conducted, must be available for the cleaning and disinfection of facilities, equipment and means of transport;
 - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose.

PART 5

Requirements for granting approval of purification centres as referred to in Article 12

1. The requirements in relation to biosecurity measures of purification centres as referred to in point (a) of Article 12, shall be the following:
 - (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the purification centre;
 - (ii) the work clothing and footwear for personnel must be kept solely for use at the purification centre and cleaned and disinfected regularly;
 - (iii) equipment must not be shared between establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;

- (iv) visitors to the purification centre must be controlled where they pose a risk for the spread of disease; these visitors must either:
 - wear protective clothing and footwear provided at the purification centre; or
 - clean and disinfect any protective clothing and footwear they bring onto the purification centre on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (v) equipment in the purification centre must be cleaned and disinfected at the end of the purification cycle;
 - (vi) wastewater from the purification centre must not be discharged without appropriate treatment directly into water bodies when the health status of aquatic animals may be jeopardised with respect to listed or emerging diseases.
2. The requirements in relation to facilities and equipment of purification centres as referred to in point (b) of Article 12, shall be the following:
- (a) the purification centre must provide for good standards of hygiene;
 - (b) equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
 - (c) appropriate equipment must be available for cleaning and disinfection of facilities, equipment and means of transport;
 - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose;
 - (e) appropriate disinfection equipment must be put in place to ensure that wastewater which is discharged from the purification centre is treated when required to ensure that any agents of listed or emerging diseases which are present are inactivated prior to discharge.

PART 6

Requirements for granting approval of dispatch centres as referred to in Article 13

1. The requirements in relation to biosecurity measures of dispatch centres as referred to in point (a) of Article 13, shall be the following:
- (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the dispatch centre;
 - (ii) work clothing and footwear for personnel must be kept solely for use at the dispatch centre and cleaned and disinfected regularly;
 - (iii) equipment must not be shared between establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;
 - (iv) visitors to the dispatch centre must be controlled in cases where they pose a risk for the spread of disease; these visitors must either:
 - wear protective clothing and footwear provided at the establishment, or
 - clean and disinfect any protective clothing and footwear they bring onto the establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (v) equipment in the dispatch centre must be cleaned and disinfected at the end of the dispatch operation;
 - (vi) wastewater from the dispatch centre must not be discharged without appropriate treatment directly into water bodies when the health status of aquatic animals may be jeopardised with respect to listed or emerging diseases.
2. The requirements in relation to facilities and equipment of dispatch centres as referred to in point (b) of Article 13, shall be the following:
- (a) the dispatch centre must provide for good standards of hygiene;
 - (b) equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;

- (c) appropriate equipment must be available for cleaning and disinfection of facilities, equipment and means of transport;
- (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose;
- (e) appropriate disinfection equipment must be in place to ensure that waste water which is discharged from the dispatch centre is treated when required to ensure that any agents of listed or emerging diseases which are present are inactivated prior to discharge.

PART 7

Requirements for granting approval of relaying areas as referred to in Article 14

1. The requirements in relation to biosecurity measures of relaying areas as referred to in point (a) of Article 14, shall be the following:
 - (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the relaying area;
 - (ii) work clothing and footwear for personnel must be kept solely for use at the relaying area and cleaned and disinfected regularly;
 - (iii) equipment must not be shared between aquaculture establishments but in cases where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;
 - (iv) visitors to the relaying area must be controlled in cases where they pose a risk for the spread of disease; these visitors must either:
 - wear protective clothing and footwear provided at the relaying area, or
 - clean and disinfect any protective clothing and footwear they bring onto the relaying area on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (v) as far as possible, equipment in the relaying area must be cleaned and disinfected at the end of the purification cycle.
2. The requirements in relation to facilities and equipment of relaying areas as referred to in point (b) of Article 14, shall be the following:
 - (a) as far as possible, the relaying area must provide for good standards of hygiene;
 - (b) as far as possible, equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
 - (c) appropriate equipment must be available for cleaning and disinfection of facilities where relevant, and equipment and means of transport;
 - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose and the environmental constraints of the relaying area.

PART 8

Requirements for granting approval of quarantine establishments as referred to in Article 15

1. The requirements in relation to biosecurity measures of quarantine establishments for aquatic animals as referred to in point (a) of Article 15 shall be the following:
 - (a) the quarantine establishment must be located at a secure distance from other quarantine establishments, aquaculture establishments or groups of aquaculture establishments by a distance specified by the competent authority on the basis of a risk assessment which must take into account the epidemiology of the relevant listed and emerging diseases;

- (b) the operator shall implement the biosecurity plan which is provided for in Article 5 and which must include at least the following elements:
 - (i) disinfection points must be installed at critical locations as identified in the biosecurity plan;
 - (ii) where they exist within the same quarantine establishment, measures must be taken to ensure that quarantine units remain epidemiologically separate from each other;
 - (iii) work clothing and footwear for personnel must be kept at the quarantine establishment and cleaned and disinfected regularly;
 - (iv) equipment must not be shared between quarantine units within the quarantine establishment, but in cases where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place; equipment must not be shared with other establishments;
 - (v) only authorised persons may enter the quarantine establishment;
 - (vi) persons entering the quarantine establishment must wear the protective clothing and footwear provided and these must be safely disposed of or cleaned and disinfected after use;
 - (vii) dead animals must be removed from all quarantine units at a frequency that ensures infective pressure is kept to a minimum and disposed of as Category 1 or Category 2 material in compliance with Article 12 or Article 13 of Regulation (EC) No 1069/2009;
 - (viii) all equipment in the quarantine establishments must be cleaned and disinfected at the end of each quarantine period;
 - (ix) the required quarantine period must start when the last aquatic animal in the cohort to be quarantined is introduced;
 - (x) each quarantine unit must be emptied of animals, cleaned and disinfected at the end of the quarantine period and be kept free of animals for a period of at least seven days before new aquatic animals are introduced;
 - (xi) precautions must be taken to prevent cross-contamination between incoming and outgoing consignments of aquatic animals;
 - (xii) animals released from the quarantine establishment must meet the requirements for movements of aquaculture animals between Member States;
 - (c) a named person must be in charge of implementing the biosecurity plan for the quarantine establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to surveillance and control measures of quarantine establishments for aquaculture animals, as referred to in point (b) of Article 15, shall be the following:
- (a) environmental conditions which are conducive to the clinical expression of the relevant listed or emerging disease must be kept in the quarantine establishment throughout the entire quarantine period;
 - (b) all aquaculture animals that die or show symptoms of disease *during* the quarantine period must be clinically inspected by a veterinarian and testing of samples must be carried out at a laboratory designated by the competent authority for that purpose;
 - (c) fish, molluscs and crustaceans of listed species must be quarantined under the conditions set out in point (a) for a period of at least 90 days;
 - (d) within a period of 15 days from the date of expiry of the quarantine period, samples must be taken from a number of aquaculture animals that will ensure the detection of the relevant pathogen with a 95 % confidence if the target prevalence is 2 %. These aquaculture animals may be taken from the cohort which is undergoing quarantine or from co-habiting sentinel aquaculture animals which are susceptible to the relevant listed or emerging disease and which are used as a diagnostic aid during the quarantine period.
3. The requirements in relation to facilities and equipment of quarantine establishments for aquaculture animals, as referred to in point (c) of Article 15, shall be the following:
- (a) the water supply to the quarantine establishment must be free of agents of the relevant listed or emerging disease;

- (b) the waste water from the quarantine establishment must be treated appropriately to ensure that the infectious agent(s) of listed and emerging diseases are inactivated before discharge;
- (c) the waste water treatment system must be fitted with a fail-safe backup mechanism to ensure its continuous operation and the complete containment of the relevant infectious agent(s);
- (d) the quarantine establishments must be clearly demarcated and the access of animals and humans must be controlled;
- (e) staff responsible for carrying out veterinary checks must have sufficiently equipped premises at their disposal, where necessary, including changing rooms and showers;
- (f) adequate means for isolating aquaculture animals must be available for use when required;
- (g) floors, walls and all other material or equipment must be constructed so that they can be adequately cleaned and disinfected;
- (h) an appropriate system must be in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009;
- (i) appropriate predator control measures are put in place, taking into account the risk of disease spread that these predators pose;
- (j) the part of the quarantine establishment accommodating the aquaculture animals must be of a suitable standard and so constructed that contact with water and animals outside is prevented and that inspection and any necessary husbandry procedures can be easily carried out.

PART 9

Requirements for granting approval of aquaculture establishments keeping aquaculture animals of vector species in isolation, until such time as they are no longer regarded as vectors, as referred to in Article 16

1. The requirements in relation to biosecurity measures of aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation until such time as they are no longer regarded as vectors, as referred to in point (a) of Article 16 shall be the following:
 - (a) operators shall implement the biosecurity plan in accordance Article 5, which must include at least the following elements:
 - (i) disinfection points must be installed at critical locations in the aquaculture establishment;
 - (ii) where different isolation units exist within the same aquaculture establishment, appropriate measures must be taken to ensure they remain epidemiologically separate from each other;
 - (iii) work clothing and footwear for personnel must be kept solely for use at the aquaculture establishment and cleaned and disinfected regularly;
 - (iv) equipment must not be shared between isolation units within the aquaculture establishment but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place; equipment must not be shared with other establishments;
 - (v) only authorised persons must enter the aquaculture establishment;
 - (vi) persons entering the aquaculture establishment must wear the protective clothing and footwear provided and these must be safely disposed of or cleaned and disinfected after use;
 - (vii) dead animals must be removed from all production units in the establishment at a frequency that ensures infective pressure is kept to a minimum, and must be disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
 - (viii) all equipment in the aquaculture establishment, or in the relevant isolation unit, if the aquaculture establishment consists of more than one such unit, must be cleaned and disinfected at the end of each isolation period;
 - (ix) the isolation period referred to in point 2 shall only start when the last animal in the cohort is introduced to the aquaculture establishment, or when there are a number of isolation units in the aquaculture establishment, the isolation period shall only start when the last animal in the cohort is introduced to the isolation unit;

- (x) each isolation unit in the aquaculture establishment must be emptied of animals, and cleaned and disinfected at the end of the isolation period;
 - (xi) precautions must be taken to prevent cross-contamination between incoming and outgoing consignments of aquatic animals;
 - (xii) animals released from the aquaculture establishment in which the isolation period has been undergone shall meet the requirements for movements of aquatic animals between Member States.
- (b) operators shall ensure that a named person is charged with implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to surveillance and control measures of establishments keeping aquaculture animals of listed species which are vectors in isolation until such time as they are no longer regarded as vectors, as referred to in point (b) of Article 16, shall be the following:
- (a) fish, molluscs and crustaceans of listed species shall be kept in isolation for a period of at least 90 days;
 - (b) all aquaculture animals that die or show symptoms of disease during the 90 day isolation period must be clinically inspected by a veterinarian and testing of samples must be carried out at a laboratory designated by the competent authority for that purpose.
3. The requirements in relation to facilities and equipment of aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation until such time as they are no longer regarded as vectors, as referred to in point (c) of Article 16, shall be the following:
- (a) adequate means of keeping aquaculture animals in isolation must be available;
 - (b) the water supply to the aquaculture establishment must be free of listed species and of agents of the relevant listed and emerging diseases;
 - (c) where this is necessary so as not to jeopardise the health status of receiving waters, the waste water from the aquaculture establishment must be treated appropriately to ensure that the infectious agent(s) of listed and emerging diseases are inactivated before discharge;
 - (d) the access of animals to the aquaculture establishment is controlled;
 - (e) floors, walls and all other material or equipment are constructed so that they can be adequately cleaned and disinfected;
 - (f) an appropriate system is in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009;
 - (g) appropriate predator control measures are put in place, taking into account the risk of disease spread that these predators pose.

PART 10

Requirements for granting approval of aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes as referred to in Article 17

1. The requirements in relation to biosecurity measures of aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes which, because of their movement patterns, create a significant disease risk, as referred to in Article 17 shall be the following:
- (a) the operator shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the establishment;
 - (ii) work clothing and footwear for personnel must be kept solely for use at the aquaculture establishment and cleaned and disinfected regularly;

- (iii) visitors to the aquaculture establishment must be controlled in cases where they pose a disease risk. These visitors must either:
 - wear protective clothing and footwear provided at the aquaculture establishment, or
 - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (iv) dead animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009.
 - (b) a named person must be in charge of implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to facilities and equipment of the aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes which, because of their movement patterns, create a significant disease risk, as referred to in point (c) of Article 17, shall be the following:
- (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the animals kept in the establishment;
 - (b) the aquaculture establishment must provide for good standards of hygiene and allow health monitoring to be carried out;
 - (c) the equipment and facilities must be made from materials which can be readily cleaned and disinfected;
 - (d) appropriate equipment must be available for cleaning and disinfection of facilities, equipment and means of transport;
 - (e) appropriate predator control measures must be put in place, taking into account the risk of disease spread that these predators pose;
 - (f) an appropriate system must be in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009.

PART 11

Requirements for granting approval of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes as referred to in Article 18

1. The requirements in relation to biosecurity measures of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes as referred to in point (b) of Article 18, shall be the following:
- (a) the operator shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the aquaculture establishment;
 - (ii) where they exist within the same aquaculture establishment, functional units must be kept separate using appropriate hygiene measures;
 - (iii) work clothing and footwear for personnel must be kept at the aquaculture establishment and cleaned and disinfected regularly;
 - (iv) equipment must not be shared between aquaculture establishments but in cases where this unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;
 - (v) visitors to the aquaculture establishment must be controlled in cases where they pose a disease risk. These visitors must either:
 - wear protective clothing and footwear provided at the aquaculture establishment, or
 - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;

- (vi) dead animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
 - (vii) as far as possible, equipment in the aquaculture establishment must be cleaned and disinfected at the end of each production cycle;
 - (viii) the cleaning and disinfection records of transporters must be verified before animals are loaded or unloaded at the aquaculture establishment;
- (b) operators shall ensure that a named person is charged with implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to facilities and equipment of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes as referred to in point (c) of Article 18, shall be the following:
- (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the animals kept in the aquaculture establishment;
 - (b) the establishment must provide for good standards of hygiene and allow adequate health monitoring to be carried out;
 - (c) as far as possible, equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
 - (d) appropriate predator control measures must be put in place, taking into account the risk these predators pose and the environmental constraints of the aquaculture establishment;
 - (e) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport;
 - (f) an appropriate system is in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009.

PART 12

Requirements for granting approval of vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry related procedure as referred to in Article 19

1. The requirements in relation to biosecurity measures of vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry related procedure as referred to in point (a) of Article 19, shall be the following:
- (a) the operator shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) the vessel or mobile premises and all equipment used during the treatment process must be cleaned and disinfected when a treatment has been completed and before it moves to another aquaculture establishment;
 - (ii) work clothing and footwear for personnel must be kept at the aquaculture establishment and cleaned and disinfected regularly;
 - (iii) equipment must not be shared with other aquaculture establishments but in cases where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place and evidence of its implementation kept;
 - (iv) visitors to the aquaculture establishment must be controlled in cases where they cause a disease risk; these visitors must either:
 - wear protective clothing and footwear provided at the aquaculture establishment, or
 - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;

- (v) the cause of any mortality which occurs during a treatment must be recorded and dead animals must be removed from the aquaculture establishment at a frequency that minimises infective pressure and which is practicable given the treatment schedule for the aquaculture animals concerned;
 - (vi) dead animals are removed at a frequency that ensures infective pressure is kept to a minimum and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009.
 - (b) operators shall ensure that a named person is charged with implementing the biosecurity plan for the establishment, with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to facilities and equipment of vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry-related procedure as referred to in point (b) of Article 19, shall be the following:
- (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept in the establishment;
 - (b) as far as possible, equipment and facilities must be made from materials which can be readily cleaned and disinfected;
 - (c) appropriate equipment must be available for cleaning and disinfection of facilities and equipment;
 - (d) where automated cleaning and disinfection systems are used, their efficacy must be validated before their initial use and at appropriate frequencies thereafter;
 - (e) an appropriate system is in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009.
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ANNEX II

RISK-BASED SURVEILLANCE TO BE CARRIED OUT IN CERTAIN APPROVED ESTABLISHMENTS

PART 1

Risk-based surveillance in aquaculture establishments and groups thereof referred to in Articles 7, 8, 17 and 18

Risk-based surveillance shall be implemented as follows in the aquaculture establishments, and groups thereof, which are referred to in Articles 7, 8, 17 and 18:

- (a) aquaculture establishments keeping listed species of aquaculture animals other than the species referred to in point (b)(ii) of this Part, shall implement risk-based surveillance according to their ranking as 'high', 'medium' or 'low' risk as a result of a risk assessment carried out in accordance with Part I of Annex VI to Delegated Regulation (EU) 2020/689;
- (b) aquaculture establishments keeping the species of aquaculture animals referred to in points (i) and (ii) shall implement risk-based surveillance if they have been ranked as 'high' risk as a result of a risk assessment carried out in accordance with Part I of Annex VI to Delegated Regulation (EU) 2020/689:
 - (i) non-listed species;
 - (ii) listed species referred to in the fourth column of the table set out in the Annex to Implementing Regulation (EU) 2018/1882; but those listed species must be in contact with the listed species referred to in the third column of that table in order to be classified as vectors species, and that contact has not occurred.

PART 2

Content of risk-based surveillance at aquaculture establishments or groups thereof conducted in accordance with Article 26 of Regulation (EU) 2016/429

1. Record checks, clinical inspections and laboratory examinations at the approved aquaculture establishments referred to in Articles 7, 17 and 18 shall be carried out as follows:
 - (a) the relevant records kept in accordance with the record-keeping obligations of Article 186 of Regulation (EU) 2016/429 and with Articles 23, 32 and 33 of this Regulation must be examined to assess if there are any indications of increased mortality or the presence of a listed or emerging disease in the aquaculture establishment which must be taken into account during the visit by a veterinarian;
 - (b) all parts of the aquaculture establishment must be examined with particular attention being paid to those production units where increased mortalities have been indicated in the records referred to in point (a);
 - (c) where there are no indications of the presence of a listed or emerging disease either from an examination of the records or from the clinical inspection of all production units, there shall be no requirement to take samples for laboratory examination;
 - (d) where recently dead or moribund aquaculture animals are identified, a representative selection of these aquaculture animals must be examined clinically, both externally and internally, to determine if pathological changes are present; that examination must in particular, aim at detecting listed or emerging diseases;
 - (e) if the outcome of the clinical examination provided for in point (d) leads to a suspicion of the presence of such a listed or emerging disease in an aquaculture establishment in a Member State, zone or compartment in which an eradication programme is being implemented, or which has been declared free from that particular disease, a sample of aquaculture animals from that aquaculture establishment shall be collected and subjected to a laboratory examination in accordance with the relevant Chapter of Part II of Annex VI to Delegated Regulation (EU) 2020/689;
 - (f) if the outcome of the clinical examination provided for in point (d) leads to a suspicion of the presence of a listed disease in an aquaculture establishment in which a surveillance programme is being implemented for that particular category C disease, a sample of aquaculture animals from the aquaculture establishment shall be collected and subjected to a laboratory examination in accordance with the relevant Chapter of Part III of Annex VI to Delegated Regulation (EU) 2020/689;

- (g) if the outcome of the clinical examination provided for in point (d) leads to the suspicion of an emerging disease, a sample of aquaculture animals from the aquaculture establishment shall be collected and subjected to a laboratory examination with the objective of identifying the emerging disease in question.
2. Record checks and clinical and laboratory examinations at the approved groups of aquaculture establishments referred to in Article 8 shall be carried out as follows:
- (a) the relevant records kept by or on behalf of each aquaculture establishment in the group of aquaculture establishments in accordance with Article 186 of Regulation (EU) 2016/429 and with Article 24 of this Regulation, must be examined to assess if there are indications of increased mortality or of the presence of a listed or emerging disease which must be taken into account when deciding which aquaculture establishment in the group is required to be visited for the purpose of risk-based surveillance;
 - (b) when the examination of records referred to in point (a) indicates increased mortality or the presence of a listed or emerging disease in a particular aquaculture establishment within the group, that establishment must be visited for the purpose of risk based surveillance; the steps outlined in point 1(b) to (g) must be followed during that visit;
 - (c) when the examination of records referred to in point (a) does not indicate increased mortality or the presence of a listed or emerging disease in any aquaculture establishment within the group, the risk-based surveillance visit or visits shall be carried out either:
 - (i) after risk assessment, in the aquaculture establishment or aquaculture establishments within the group which pose the highest risk of disease introduction; or
 - (ii) to the establishment which has had the greatest number of movements of aquaculture animals for further farming, since the last risk-based surveillance visit was carried out.

In either case, the steps outlined in point 1 (c) to (g) must be followed during the risk-based surveillance visit.

COMMISSION DELEGATED REGULATION (EU) 2020/692**of 30 January 2020****supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Articles 234(2), 237(4) and 239(2) thereof,

Whereas:

- (1) Union legislation in the area of animal health was recently updated by the adoption of the 'Animal Health Law'. That Regulation, which came into force on 20 April 2016, and which applies from 21 April 2021, repealed and replaced around 40 basic acts. It also requires the adoption of many Commission delegated and implementing regulations to repeal and replace around 400 Commission acts that existed in the area of animal health before the new legal framework established by the 'Animal Health Law'.
- (2) Trading conditions have evolved since the adoption of the first animal health rules at Union level, with the volume of trade in animals, germinal products and products of animal origin increasing significantly, both within the Union and with third countries. During the same period, as a result of Union animal health policies and rules, certain diseases have been eradicated in the Union and other diseases have been prevented or controlled in many Member States. However, on several occasions, emerging diseases have posed new challenges for the Union animal health status, trade and the local economy in the areas affected by those diseases.
- (3) The rules laid down in this act, supplement those already laid down in the 'Animal Health Law'. They should provide the necessary guarantees to ensure that consignments of animals, germinal products and products of animal origin entering the Union do not present an animal health risk for kept and wild animals that could jeopardise the Union health status as regards animal diseases and have a detrimental economic impact on the sectors involved.
- (4) Article 234 of the 'Animal Health Law' provides that pending the adoption of delegated acts laying down animal health requirements as regards a particular species and category of animal, germinal product or product of animal origin, Member States may, following evaluation of the risks involved, apply national rules if they comply with certain requirements laid down in that Regulation. Therefore, the entry into the Union of species and categories of animals, germinal products and products of animal origin not covered by this Regulation may be subject to such national rules applied by Member States.
- (5) The existing animal health rules, laid down in previous Commission acts concerning the entry into the Union of animals, germinal products and products of animal origin have proved to be effective, therefore the aim and substance of those existing rules should be maintained in this Regulation, but updated to take account of the rules on better regulation, of the new animal health framework laid down in the 'Animal Health Law' and of newly available scientific knowledge, international standards and experience in applying previous Union acts.
- (6) To avoid unnecessary trade disruptions, the animal health requirements for entry into the Union of consignments falling within the scope of this Regulation should ensure a smooth transition from the requirements laid down in pre-existing Union acts.
- (7) The 'Animal Health Law' lays down rules for the prevention and control of animal diseases transmissible to animals or to humans. In particular, Chapter 1 of Part V of that Regulation, which lays down the animal health requirements for entry into the Union of consignments of animals, germinal products and products of animal origin, provides for the Commission to adopt delegated acts to supplement the animal health requirements already laid down in it.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

- (8) Article 229(1) of the 'Animal Health Law' lays down the requirements under which Member States are to permit the entry into the Union of consignments of animals, germinal products and products of animal origin. The requirements cover conditions concerning the third country or territory of origin, the establishment of origin, the animal health requirements that those consignments are required to comply with, as well as the animal health certificate, declarations or other document that should accompany such consignments.
- (9) In addition, Article 234(1) of the 'Animal Health Law' stipulates that the animal health requirements for entry into the Union of consignments of species and categories of animals, germinal products and products of animal origin from third countries or territories or zones thereof must be at least as stringent as those laid down in that Regulation, and in delegated acts adopted pursuant to it, applicable to movements within the Union of those species and categories of those commodities. If the requirements are not as stringent as those in the Regulation, they must offer equivalent guarantees to the animal health requirements provided for in Part IV of that Regulation.
- (10) Article 234(2) of the 'Animal Health Law' provides for delegated acts to be adopted to supplement the rules laid down in that Regulation, as regards the animal health requirements for entry into the Union of species and categories of animals, germinal products and products of animal origin from third countries and territories, and for the movement within the Union and handling of those commodities after their entry into the Union, in order to mitigate the possible risks involved.
- (11) Article 237(1) of the 'Animal Health Law' provides that Member States are only to permit the entry into the Union of consignments of animals, germinal products and products of animal origin if such consignments are accompanied by the animal health certificates and the declarations or other documents required under that Regulation. Article 237(2) of that Regulation stipulates that the animal health certificate must have been verified and signed by an official veterinarian in the third country or territory of origin. In this context, Article 237(4) of the 'Animal Health Law' provides for the Commission to adopt delegated acts concerning derogations from the animal health certificate requirements laid down in Article 237(1) and Article 237(2) of that Regulation, and to lay down rules requiring such consignments to be accompanied by declarations or other documents.
- (12) Article 239(2) of the 'Animal Health Law' provides for the Commission to adopt delegated acts concerning special rules and additional requirements for certain specific types of entry into the Union of consignments of animals, germinal products and products of animal origin, and provides for derogations from the general animal health requirements laid down in Articles 229(1) and 237(1) of that Regulation, and in the supplementing rules laid down in delegated acts adopted pursuant to Articles 234(2) and 237(4) thereof.
- (13) The supplementing rules to be laid down in this Regulation pursuant to Articles 234(2) and 239(2) of the 'Animal Health Law' are interrelated. Article 234(2) provides for the Commission to lay down the general requirements for entry into the Union of consignments of animals, germinal products and products of animal origin, while Article 239(2) provides for the Commission to lay down the special rules and additional requirements for derogations from those general requirements.
- (14) The animal health certificate requirements provided for in Article 237 of the 'Animal Health Law' are part of the framework of rules relating to the entry into the Union of consignments of animals, germinal products and products of animal origin. The empowerment granted to the Commission under Article 237(4) of that Regulation to grant derogations from the animal health requirements is part of that general framework of rules.
- (15) The 'Animal Health Law' already provides a number of definitions. In addition, this Regulation should also have regard to the definitions laid down in other Union acts in the related areas of food hygiene and official controls, such as the definitions laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽²⁾. However, for the purpose of laying down the animal health requirements for entry into the Union of animals, germinal products and products of animal origin it is appropriate to include particular definitions, including definitions for certain categories of animals, germinal products and products of animal origin. These definitions are needed to clarify which categories of animals, germinal products and products of animal origin represent an animal health risk and are therefore subject to the animal health requirements for entry into the Union.

⁽²⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

- (16) In the interests of consistency of Union legislation, and based on the animal health risk they represent, the definition for 'fresh meat' for the purpose of this Regulation should incorporate the definitions for 'fresh meat', 'minced meat' and 'meat preparations' laid down in Annex I to Regulation (EC) No 853/2004.
- (17) In addition, the definition for 'meat products' for the purpose of this Regulation should incorporate the definitions for 'meat products', 'treated stomachs', 'bladders', 'intestines', 'rendered animal fats' and 'meat extracts' laid down in Regulation (EC) No 853/2004. This is because from an animal health point of view, all of those commodities represent the same animal health risk and should be subjected to the same risk-mitigating measures.
- (18) The definition for 'carcase' laid down in Regulation (EC) No 853/2004 should be adapted to define 'carcase of an ungulate' in order to differentiate it from 'offal'. This is because those two commodities represent different animal health risks, with 'offal' representing a higher risk.
- (19) 'Casings' should be defined in this Regulation and that definition should take into account the definition included in the glossary of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE). The definition should clarify which products of animal origin must be considered as casings and therefore undergo the specific risk-mitigating treatments provided for in this Regulation.
- (20) Article 229(1) of the 'Animal Health Law' provides that consignments of animals, germinal products and products of animal origin are only to be permitted to enter into the Union if they come from third countries or territories listed for entry into the Union of the particular species and category of animals, germinal products or products of animal origin, in accordance with the criteria laid down in Article 230(1), and if the consignments comply with the animal health requirements provided for in Article 234 and subsequent delegated acts. This Regulation should make it the responsibility of the competent authority to verify that such consignments entering the Union comply with those requirements.
- (21) Article 237(1) the 'Animal Health Law' provides that the entry into the Union of consignments of species and categories of animals, germinal products and products of animal origin from third countries or territories is only to be permitted where those consignments are accompanied either by an animal health certificate, issued by the competent authority of the third country or territory, or by declarations or other documents, or by all of those documents. This Regulation should, therefore, clarify which documents are required in each case and should make it the responsibility of the competent authority to verify that such consignments entering the Union comply with that general requirement.
- (22) The information to be contained in the animal health certificates, declarations and other documents accompanying consignments of animals, germinal products and products of animal origin must accurately reflect whether or not those consignments comply with the general requirements provided for in the 'Animal Health Law' and the relevant requirements laid down in this Regulation. This Regulation should, therefore, lay down the obligations for operators responsible for entry into the Union of such consignments and for the competent authorities of the Member State of entry into the Union, as regards the validity of the documents accompanying the consignments and the eligibility of such consignments to enter the Union.
- (23) Taking into account animal health risks such as incubation periods for diseases, and in order to avoid the misuse of animal health certificates, it is necessary to establish a time limit for the validity of those certificates only in the case of animals and hatching eggs. This is because these pose a higher animal health risk than products of animal origin, which may have undergone risk-mitigating measures, and germinal products which are transported frozen in closed and sealed containers. However, as the transport by sea of live animals and hatching eggs may take long time, the validity period of the certificate in this case should be extended provided that certain risk-mitigating measures have been taken.
- (24) The animal health requirements that need to be complied with, and the guarantees to be provided by third countries and territories, for entry into the Union of consignments of animals, germinal products and products of animal origin depend on the diseases listed in Article 5 and in Annex II to the 'Animal Health Law' and their categorisation as provided for in Article 9(1) of that Regulation and in the Annex to Commission Implementing Regulation (EU) 2018/1882 ⁽³⁾. That Regulation lays down the definitions of category A, B, C, D and E diseases and states that the disease prevention and control rules for the listed diseases referred to in Article 9(1) of Regulation (EU) 2016/429 are to be applied to listed species and groups of listed species referred to in its Annex.

⁽³⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

- (25) Chapter 1 of Part II of the 'Animal Health Law' lays down the rules on disease notification and reporting to ensure early detection and effective disease control in the Union. This Regulation should specify the details on the notification and reporting systems to be in place in the third countries or territories to guarantee equivalent systems to those implemented in the Union, including the diseases that should be notifiable and reportable. In this sense, while live animals can transmit the diseases for which they are a listed species in Implementing Regulation (EU) 2018/1882, not all products of animal origin and germinal products obtained from those animals can transmit all those diseases. This Regulation should clarify which are the animal diseases of concern and therefore notifiable and reportable for each particular species and category of animals, germinal products and products of animal origin intended for entry into the Union.
- (26) The animal health requirements laid down in this Regulation should be based on different levels of protection from the animal health risks. The different requirements vary depending on whether they relate to a third country of origin, to a territory of origin, to a zone within that third country or territory, to a compartment within that third country or territory in the case of aquaculture animals, to the establishment of origin of the animals or the products of animal origin, or to the establishment or centre for collection of germinal products.
- (27) Disease surveillance and traceability in the establishments are key elements of the disease control policy in the Union. This Regulation should include certain basic requirements on traceability and animal health visits in the establishments of origin of the animals intended for entry into the Union, and in the establishment of origin of the animals from which the germinal products and products of animal origin intended for entry into the Union were obtained. These requirements should be equivalent to those laid down in Regulation (EU) 2016/429, and in delegated and implementing acts adopted pursuant to that Regulation.
- (28) Furthermore, where a certain type of establishment keeping animals or germinal products in a third country or territory poses a particular animal health risk, it should obtain specific approval by the competent authority in the third country or territory in order to export to the Union, providing equivalent guarantees as those provided in Articles 92 to 100 of Regulation (EU) 2016/429 for certain establishments in the Union.
- (29) Consignments of animals, germinal products and products of animal origin intended for entry into the Union should not be considered as representing an animal health risk in their country or territory of origin and should not be subject to national eradication programmes or any other national restrictions based on animal health concerns.
- (30) The animal health requirements for entry into the Union of consignments of animals, germinal products and products of animal origin must provide effective protection against the introduction and spread of transmissible animal diseases in the Union. The entry into the Union of those consignments should not be permitted from third countries or territories or zones or in the case of aquaculture animals, compartments thereof, infected with certain listed diseases for which the Union has disease-free status, and which consequently present a serious risk for the health of animals within the Union.
- (31) It is for the Union to assess whether a third country, territory or zone or, in the case of aquaculture animals, compartment of origin is free from a specific disease. The Union's assessment should be based on information related to disease surveillance provided by the competent authority of the third country or territory, and taking into account Union animal health rules as provided for in Part II of the 'Animal Health Law' and Commission Delegated Regulation (EU) 2020/689 ⁽⁴⁾. Specific conditions for certain diseases and circumstances may be required as additional risk-mitigating measures.
- (32) The freedom from a particular disease of a third country or territory or zone thereof must be based on internationally recognised diagnostic tests and methods performed under the same standards and procedures as those applied within the Union.

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (see page 211 of this Official Journal).

- (33) It is necessary to ensure that the health status of animals, germinal products and products of animal origin intended for entry into the Union complies with the guarantees provided by the third country, territory or zone of origin. This Regulation should therefore provide for a minimum residency period for animals in the third country, territory, zone or establishment of origin, and a minimum period without contact with commodities of a lower health status, before being dispatched to the Union. The length of the minimum period of residency should take into account the incubation period of relevant diseases, and the intended destination and use of the animals, germinal products and products of animal origin.
- (34) In the case of dogs, cats and ferrets, the residency period is unnecessary as vaccination against rabies, the disease of greatest concern for those species, is required in all cases. Registered horses intended for competitions, races and equestrian cultural events should also be exempted from certain requirements as regards the residency period, if they comply with additional guarantees. This exemption is based on the expectation that such horses will have a high level of health.
- (35) The health status of animals, germinal products and products of animal origin intended for entry into the Union may be jeopardised during transport from the place of origin to the place of entry into the Union if they enter into contact with animals or products not complying with the same requirements or if they transit through third countries, territories or zones with a lower health status than the country or territory of origin or zone thereof. Therefore certain preventive measures should be applied in order to preserve their health status.
- (36) To ensure that only healthy animals are dispatched to the Union, animals in consignments should undergo an clinical inspection carried out by an official veterinarian before they are dispatched. The time frame for performing this inspection should be adapted for certain species and their inherent risk.
- (37) Terrestrial animals, hatching eggs and aquatic animals intended for entry into the Union should only be transported through, or unloaded in, third countries, territories or zones also listed for entry into the Union of the same species and categories of animals and hatching eggs. Those countries, territories or zones' inclusion on the list indicates that they provide equivalent animal health guarantees as the third country or territory of origin or zone thereof.
- (38) The transport of terrestrial animals and hatching eggs by means of aircraft or vessel could encounter unforeseen events such as mechanical problems in the means of transport, strikes in airports and seaports or unforeseen delays. It is therefore appropriate to provide for derogations in those cases where guarantees can be given. This will allow the transport of the terrestrial animals and hatching eggs to the Union to continue, while ensuring the health status of those commodities and preventing additional animal health risks.
- (39) In the case of equine animals, as transshipments and stopovers in non-listed countries are part of the usual transport operations, they should be allowed under certain preventive measures.
- (40) Cleaning and disinfection of means of transport is a key activity to prevent the risk of spreading animal diseases. When transporting consignments of live animals destined for the Union, cleaning and disinfection of means of transport should be carried out immediately before the loading of the animals for their dispatch to the Union.
- (41) Assembly operations of animals in third countries or territories of origin may pose an additional risk to the health status of animals intended for entry into the Union, as a result of the animals mixing with and coming into contact with animals of different origins. Therefore, the number, duration of such operations and species allowed to undergo them should be limited to a minimum and to those species with reliable traceability systems.
- (42) In addition to general animal health requirements, it is necessary to provide specific requirements taking into account the animal health risks linked to the different species and categories of terrestrial animals falling within the scope of this Regulation.
- (43) Different species of ungulates, as defined in the 'Animal Health Law', are listed as susceptible species for different listed diseases in Implementing Regulation (EU) 2018/1882. Listed diseases are also set out in different categories for different species of ungulates in the same Regulation. Therefore this Regulation should clearly establish the specific requirements and guarantees in relation to listed diseases for the different species and categories of ungulates.

- (44) To prevent the occurrence of category A diseases, from which the Union is considered free, the general requirement for the third country or territory of origin or zone thereof of ungulates should be an equivalent freedom from disease for a period of time that guarantees that the entry of animals from the third country, territory or zone does not jeopardise the Union's disease freedom. For category B diseases, for which the Union has compulsory eradication programmes, this Regulation should provide for risk-mitigating measures where the third country or territory of origin is not completely free of such diseases.
- (45) Where consignments of ungulates are intended for entry into Member States which are officially disease-free, or which have an approved eradication programme for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, bovine viral diarrhoea or infection with Aujeszky's disease virus, those consignments should comply with additional requirements to ensure that the animals do not jeopardise the health status of those specific Member States as regards those diseases.
- (46) Special rules as regards the third country or territory of origin and additional animal health requirements should apply where ungulates originate from a confined establishment and are intended for entry into a confined establishment in the Union. The special rules should take into account the specificity of those confined establishments and the specific conditions they comply with in order to be approved by the competent authority of the third country or territory of origin and by the competent authority of the Member States of destination.
- (47) The confined establishment of origin could be located in a third country or territory which is not listed for entry into the Union of the specific species of ungulates. However, the national legislation and the veterinary services of the third country or territory will need to have been assessed. In addition, the establishment of origin should comply with additional requirements as regards disease surveillance, veterinary supervision, record keeping and operations. To ensure that those guarantees can be provided, this Regulation should lay down specific conditions for the approval of those confined establishments by the competent authority in the third country or territory. A list of such confined establishments should be drawn up by the Member State of destination, following the favourable outcome of a risk assessment by the competent authority in that Member State of all relevant information provided by the establishment as regards the animal health risks involved.
- (48) Specific animal health requirements should apply for entry into the Union of poultry and captive birds to address the particular risks posed by the relevant listed diseases for those animals. These requirements should take account of the category, species and intended use of poultry and captive birds, and provide effective protection against the spread into the Union of diseases of concern from third countries or territories.
- (49) To facilitate the trade of consignments of small amounts of poultry, specific requirements and derogations should be established for consignments with less than 20 heads of poultry other than ratites.
- (50) Taking into account the activities and animal health risks associated with captive birds, consignments of those animals should only be permitted to enter the Union if they come from establishments approved by the competent authorities in the third country or territory of origin of the captive birds or zone thereof. The captive birds should be quarantined upon their arrival in the Union in order to confirm the absence of any disease of concern.
- (51) In addition, where consignments of birds and hatching eggs are intended for Member States with status free from infection with Newcastle disease virus without vaccination, such consignments should comply with additional requirements to ensure that those consignments do not jeopardise the health status for that disease of those specific Member States.
- (52) The infestation with the small hive beetle (*Aethina tumida*) is one of the diseases of most concern for bees. It is largely exotic to the Union but has spread globally in recent decades, creating serious problems for the apiculture industry and potentially also affecting bumble bees. *Tropilaelaps* mites (*Tropilaelaps* spp.) are potentially devastating pathogens of honeybees. They are also exotic to the Union. Effective and safe treatments against these diseases are at present not available. If these diseases entered the Union by entering consignments, they would pose a risk to the sustainability of the apiculture sector and beyond, potentially affecting agriculture and the environment which benefits from pollination services by kept and wild bees.
- (53) American foulbrood occasionally occurs in the Union but is controlled with regard to trade of honeybees, while certain areas in the Union have been recognised as free of *Varroa* mites and protected by additional trade guarantees to keep places of destination in the Union safe. Rules at Union level have been and remain essential to mitigate the risk of entry into the Union of the above pathogens as associated with consignments of honeybees and bumble bees. Therefore such rules should be laid down in this Regulation.

- (54) Only queen honeybees without a brood and accompanied by a small number of attendants in single queen cages can be easily checked for infestation with small hive beetle or with *Tropilaelaps* mites, therefore the entry into the Union of honeybees should be limited to such consignments.
- (55) Colonies of bumble bees bred and reared in environmentally isolated establishments are often traded for the horticultural industry. Given the commonly used facilities, procedures and closed containers used for the shipped colonies, the entry into the Union of bumble bees (*Bombus* spp.) should be permitted only for colonies that are bred, reared and packaged solely under environmentally controlled conditions in establishments and which can be checked to ensure that they are free of the small hive beetle.
- (56) Because of its potential effects on humans and animals, rabies is the listed disease of most concern in the Union affecting dogs, cats and ferrets. Member States are therefore required to carry out a compulsory eradication programme against rabies infection in accordance with Delegated Regulation (EU) 2020/689. To prevent any possibility of rabies being introduced into the Union, vaccination should be required for all consignments of dogs, cats and ferrets entering it, taking into account the availability and effectiveness of existing vaccines against the disease.
- (57) Dogs intended for entry into a Member State with disease-free status or with an approved eradication programme for *Echinococcus multilocularis* should comply with additional requirements to ensure the protection of that status in those Member States. In this regard, a preventive treatment should be applied to such dogs before they enter the Union. However, where dogs, cats and ferrets are intended for a confined establishment in the Union, special rules as regards rabies and infestation with *Echinococcus multilocularis* and additional animal health requirements should apply, taking into account the specificity of such establishments' activities and the specific conditions under which animals are kept in them.
- (58) Germinal products may pose a significant risk for the spread of animal diseases. This is particularly true for semen, but also to a less extent to oocytes and embryos. As germinal products are collected or produced from a limited number of donors but used widely in the general animal population they can, if not handled properly or not classified with the correct health status, be a source of diseases for many animals. Such cases have occurred in the past and have caused substantial economic losses. Therefore, animal health requirements need to be put in place for entry into the Union of germinal products of certain kept terrestrial animals.
- (59) The requirements for entry into the Union of germinal products of ungulates should be based on the requirements for entry into the Union of live animals.
- (60) Specific requirements for germinal product establishments where germinal products of ungulates eligible for entry into the Union are collected, produced, processed and stored should reflect those established for the movements within the Union. The same approach applies to the traceability and animal health requirements for germinal products.
- (61) Due to the need to move germinal products from confined establishments located in third countries to confined establishments located in the Union, this Regulation should lay down special traceability and animal health requirements for such entry.
- (62) Animal health requirements for entry into the Union of hatching eggs should address the risks as regards listed diseases that the different categories of hatching eggs could introduce into the Union. Therefore such requirements should correspond to those for entry into the Union of the respective species or categories of birds.
- (63) Where hatching eggs of poultry are intended for entry into Member States with status-free from infection with Newcastle disease virus without vaccination, the eggs should comply with additional requirements to ensure that they do not jeopardise the status of those specific Member States.
- (64) Products of animal origin can transmit disease agents to animals and products. The animal health risk linked to fresh and raw products of animal origin is obviously higher than those that have been processed and treated. Therefore the animal health requirements for the third country or territory of origin of fresh meat, raw milk, colostrum and colostrum-based products should be stricter than those for meat products and dairy products. However, the treatment applied to those treated products needs to be effective in order to mitigate the risk they pose depending on the species of origin of the product and the country or territory of origin.

- (65) The risk-mitigating treatments applicable for products of animal origin originating in restricted zones established in the event of confirmation of category A diseases in the Union are laid down in Commission Delegated Regulation (EU) 2020/687 ⁽⁵⁾, based on the available scientific knowledge and experience gained in the application of previous legislation. Therefore, the same risk-mitigating treatments should apply to those products originating in third countries, territories or zones thereof posing an equivalent animal health risk.
- (66) The risks linked to fresh meat entering the Union should be mitigated by requirements on the freedom from diseases of the third country or territory of origin and by requirements on animal diseases for the live animals from which the meat is obtained, on the dispatch of the kept animals to slaughter, on slaughter and killing operations, and on handling and preparation operations.
- (67) Fresh meat of terrestrial animals can be obtained from kept animals, including farmed game as defined in Regulation (EC) No 853/2004, and from wild animals. However, in the Union, meat obtained from animals kept as production animals, particularly, animals belonging to the species *Bos taurus*, *Capra hircus*, *Ovis aries* and *Sus scrofa*, must be obtained in a slaughterhouse. To provide adequate and equivalent guarantees, it is therefore appropriate to exclude those species from the possibility to be categorised as farmed game or wild animals when fresh meat intended for entry into the Union originates from them.
- (68) When an outbreak of a relevant animal disease occurs in a third country or territory, the date and location of slaughter of kept animals or the date of killing of wild animals or farmed game are key to establishing the possible animal health risks associated with those animals and products of animal origin obtained from them. Therefore, the date of slaughter or killing needs to be established, in order to verify that the animals have been slaughtered or killed in a period of time without outbreaks of disease and when the third country or territory was listed as being authorised to enter fresh meat into the Union.
- (69) The type of treatment to be applied to products of animal origin should be in line with the risk posed by the third country or territory or zone thereof manufacturing the product. Entry into the Union of processed products of animal origin which have undergone treatments whose effectiveness in eliminating the risks linked to the listed diseases of concern for the particular category of product of animal origin has not been proven, should only be authorised from third countries or territories or zones thereof that provide all guarantees of freedom from the relevant diseases. For third countries or territories or zones thereof that do not provide all those guarantees, the entry into the Union of products of animal origin should be permitted only if those products have undergone a specific treatment.
- (70) In some cases, a third country or territory or zone thereof will source raw meat to produce meat products from a third country or territory or zone thereof listed for entry into the Union of meat products of the relevant species subject to a specific treatment. In such cases, the meat product should always undergo the most severe specific treatment in order to mitigate all possible animal health risks.
- (71) Meat products containing poultry meat from a third country or territory or zone thereof where there has been an outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus should undergo a treatment that is effective at mitigating the risk in the third country or territory or zone thereof listed for entry into the Union. In this way, trade can be allowed to continue before measures for control such as regionalisation are implemented. The immediate application of a risk-mitigating treatment after an outbreak decreases the animal health risks and at the same time reduces the impact on trade.
- (72) When meat products are manufactured from fresh meat from different species the treatment applied should eliminate any possible animal health risks. Therefore, if the treatment is applied before mixing, the different types of fresh meat should receive the relevant treatment assigned to the species of origin of the fresh meat. However, if the treatment is applied after mixing, the final meat product should undergo the treatment assigned to the fresh meat ingredient with the highest animal health risk.
- (73) Treatments to mitigate specific animal health risks linked to the entry of casings should be reviewed and updated taking into account the conclusions and recommendations of the latest scientific evidence assessed by the European Food Safety Authority (EFSA) Panel on Animal Health and Welfare ⁽⁶⁾.

⁽⁵⁾ Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (see page 64 of this Official Journal).

⁽⁶⁾ EFSA Panel on Animal Health and Welfare (AHAW); Scientific Opinion on animal health risk mitigation treatments as regards imports of animal casings. *EFSA Journal* 2012; 10(7):2820. [32pp.] doi:10.2903/j.efsa.2012.2820. Available online: www.efsa.europa.eu/efsajournal

- (74) The conditions for entry into the Union of raw milk, dairy products, colostrum and colostrum-based products are based on the animal health risks represented by these products. Such risks are linked to the country or territory of origin or zone thereof and to the species of animals from which they were obtained. Foot and mouth disease and infection with rinderpest virus are the two diseases of concern in the case of milk and colostrum, therefore raw milk and colostrum should only enter from third countries or territories or zones thereof which are free from those diseases. Colostrum-based products should also only originate from those third countries, territories or zones as there are no scientific-based risk-mitigating treatments to ensure the destruction of the disease agent in that category of products.
- (75) For milk obtained from *Bos taurus*, *Ovis aries*, *Capra hircus*, *Bubalus bubalis* and *Camelus dromedarius*, the risk related to foot and mouth disease can be mitigated with the application of well-known specific risk-mitigating treatments. However, as the effectiveness of certain of those treatments for dairy products from animal species other than *Bos taurus*, *Ovis aries*, *Capra hircus*, *Bubalus bubalis* and *Camelus dromedarius* cannot be ensured, they should undergo the most severe risk-mitigating treatment.
- (76) Treatments for products of animal origin should always be carried out in the third country or territory of origin or zone thereof listed for entry of those products into the Union.
- (77) Aquatic animals of listed species are sometimes transported by sea in vessels, including well-boats which may exchange water during the journey. In such cases, in addition to a health certificate, the animals should also be accompanied by a declaration signed by the master of the vessel outlining details of the ports of origin and destination and of any other ports visited during the journey. This declaration should confirm that the animals of listed species on board the vessel have not been exposed to any conditions that could have altered their health status during the journey to their final destination.
- (78) Aquatic animals may enter the Union for many different purposes. Given the disease risk associated with the movement of live animals, such animals entering the Union for human consumption should be treated in the same way as if they were entering the Union for other purposes such as farming or release into the wild. Products of animal origin from aquatic animals other than live aquatic animals represent a lower risk than aquatic animals, and the measures to be taken in relation to such products entering the Union for further processing, are therefore, less rigorous than those which apply to live animals.
- (79) Releasing aquatic animals into the wild in natural waters is a high-risk activity if those animals are infected with a listed disease. For that reason, for category A and B diseases specifically, the third country or territory of origin or zone or compartment thereof should be free of those diseases when aquatic animals are intended for release into the wild in natural waters of the Union. In addition, aquatic animals brought into the Union to be released into the wild in natural waters should in all cases, originate from a third country or territory or zone or compartment declared free of a category C disease even when the Member State or zone or compartment of destination is not free from that disease.
- (80) In the case of aquatic diseases, Member States may take national measures under Article 226 of the 'Animal Health Law' designed to limit the impact of diseases other than listed diseases, within their own territory. In such cases, consignments of species susceptible to the diseases to which those national measures apply will also need to originate from third countries, territories, zones or compartments thereof, which are free of those diseases.
- (81) Article 226 of the 'Animal Health Law' reflects the same intent as Article 43 of Council Directive 2006/88/EC ⁽⁷⁾ as it allows Member States to take national measures against diseases which are not listed. It is therefore appropriate, to continue to recognise the list of diseases and the relevant species for which those measures have been put in place. These details should be set out in this Regulation.
- (82) Certain rules apply within the Union in relation to the registration and approval of aquaculture establishments. The differentiation between whether an establishment can be registered or whether it should be approved depends upon the risk it presents of contracting or spreading disease. It is important therefore, that aquaculture animals which enter the Union from aquaculture establishments in a third country, territory, zone or compartment thereof, should originate from aquaculture establishments which are assessed in a similar way. In that context, such establishments should comply with registration or approval requirements which are at least as stringent as those laid down for such establishments within the Union.

⁽⁷⁾ Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

- (83) It is not mandatory in all situations to apply the requirement that aquatic animals of listed species and products of animal origin from those animals originate from a third country or territory or zone or compartment thereof free from disease. Certain risk-mitigation measures can be taken to facilitate the entry into the Union of aquatic animals and certain products of animal origin thereof which do not have such an origin. Certain risk-mitigation measures are acceptable for aquatic animals of listed species and given the lower level of risk associated with such movements, different, less stringent risk-mitigation measures are acceptable for products of animal origin from aquatic animals other than live aquatic animals.
- (84) The mitigation measures that apply to aquatic animals include their being consigned to a disease control aquatic food establishment, a confined establishment or an approved quarantine establishment after entry into the Union. A number of other risk-mitigating measures apply to molluscs and crustaceans of listed species which enter the Union alive and in compliance with Regulation (EU) No 853/2004 but which represent an acceptable risk because of how they were treated or packaged before dispatch or because they are not intended for storage in the Union, prior to processing.
- (85) It is possible to derogate from the requirements that certain products of animal origin from aquatic animals other than live aquatic animals, have to originate in a third country or territory or zone or compartment thereof which is free from the relevant listed diseases. The risk-mitigation measures allowing such trade to occur may consist of consigning the products of animal origin to a disease control aquatic food establishment in the Union for further processing, or of ensuring that the products of animal origin consist of fish which were slaughtered and eviscerated before being dispatched to the Union. In either case, the risk posed by the products of animal origin is assessed as negligible.
- (86) Implementing Regulation (EU) 2018/1882 establishes a list of aquatic species and groups of species that pose a considerable risk for the spread of the diseases listed in Article 5 and Annex II to the 'Animal Health Law'. The list also includes a list of vector species, which is set out in column 4 of the table in the Annex to that Regulation. Many of those species do not, however, act as vectors in all circumstances. In relation to movements, details of the circumstances in which those species are considered to be vectors of the listed diseases are set out in Annex XXX to this Regulation. In circumstances where aquatic animals of listed species do not fulfil the conditions to be vectors, they are not covered by the rules set out in this Regulation. In addition, given the lower level of risk posed by products of animal origin from aquatic animals other than live aquatic animals, the measures set out in this Regulation in relation to these products do not apply to the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882.
- (87) All derogations and handling requirements provided for in this Regulation in relation to aquatic animals of listed species and to products of animal origin from those listed species other than live aquatic animals, should also apply to the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882 for which Member States have taken national measures under Article 226 of the 'Animal Health Law'. Likewise, these derogations and handling requirements should also apply to certain susceptible species.
- (88) It is important that aquatic animals of listed species, and the water in which they are transported, are handled appropriately after entry into the Union to ensure that they do not pose a disease risk. Appropriate handling includes ensuring that the animals are transported directly to the place of destination and are not released or otherwise immersed in natural waters of the Union, where they could cause a potential disease risk.
- (89) In certain cases, however, the competent authority at the place of destination may allow authorisation for such animals to be released into natural waters. In all such cases, it should be for the competent authority to ensure that the release or immersion does not jeopardise the health status at the place of release. Furthermore, even if the receiving waters are not free of a specific category C disease, the animals to be released should be disease-free, in order to ensure the best overall health status is achieved for wild populations in natural waters of the Union.
- (90) In relation to the animal health risk involved, all transit movements through the Union should be considered as movements for entry into the Union as they imply the same level of risk. Transit movements should therefore comply with all the relevant requirements for entry into the Union. However, derogations and special rules for transit should be established under specific risk-mitigating conditions linked to the place of origin. Such derogations and special rules are intended to cover situations where the Union is not the final destination for the animals and products thereof and to take into account geographical constraints and geopolitical factors.
- (91) Derogations and special rules should also be established for the transit of consignments of animals and products thereof via a third country or territory between Member States. This is to cover situations where such type of entry into the Union is required by a Member State.

- (92) In some cases commodities originating in the Union are refused by the competent authorities of a third country or territory following controls carried out at their border. Special rules should be adopted under Article 239 of the 'Animal Health Law' to allow the return of those commodities on the grounds that they have been produced under the Union's animal health legislation.
- (93) Special rules are also necessary for the return to the Union of registered horses after temporary export to third countries in order to participate in races, competitions and equestrian cultural events.
- (94) With a view to the uniform application of Union legislation on entry into the Union of animals, germinal products and products of animal origin and to ensure that the legislation is clear and transparent, this Regulation should repeal Commission Regulation (EU) No 206/2010 ⁽⁸⁾, Commission Implementing Regulation (EU) No 139/2013 ⁽⁹⁾, Commission Regulation (EU) No 605/2010 ⁽¹⁰⁾, Commission Regulation (EC) No 798/2008 ⁽¹¹⁾, Commission Decision 2007/777/EC ⁽¹²⁾, Commission Regulation (EC) No 119/2009 ⁽¹³⁾, Commission Regulation (EU) No 28/2012 ⁽¹⁴⁾ and Commission Implementing Regulation (EU) 2016/759 ⁽¹⁵⁾.
- (95) The rules contained in this regulation are linked and complement those of the 'Animal Health Law' that applies from 21 April 2021. For this reason and to facilitate the application of the new animal health legal framework this Regulation should also apply from 21 April 2021,

HAS ADOPTED THIS REGULATION:

PART I

GENERAL RULES

TITLE 1

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation lays down supplementing animal health rules concerning the entry into the Union of consignments of certain species and categories of animals, germinal products and products of animal origin from third countries or territories or zones thereof, or compartments in the case of aquaculture animals. It also lays down rules concerning the movement and handling of those consignments after their entry in the Union.

⁽⁸⁾ Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).

⁽⁹⁾ Commission Implementing Regulation (EU) No 139/2013 of 7 January 2013 laying down animal health conditions for imports of certain birds into the Union and the quarantine conditions thereof (OJ L 47, 20.2.2013, p. 1).

⁽¹⁰⁾ Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption (OJ L 175, 10.7.2010, p. 1).

⁽¹¹⁾ Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

⁽¹²⁾ Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC (OJ L 312, 30.11.2007, p. 49).

⁽¹³⁾ Commission Regulation (EC) No 119/2009 of 9 February 2009 laying down a list of third countries or parts thereof, for imports into, or transit through, the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements (OJ L 39, 10.2.2009, p. 12).

⁽¹⁴⁾ Commission Regulation (EU) No 28/2012 of 11 January 2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009 (OJ L 12, 14.1.2012, p. 1).

⁽¹⁵⁾ Commission Implementing Regulation (EU) 2016/759 of 28 April 2016 drawing up lists of third countries, parts of third countries and territories from which Member States are to authorise the introduction into the Union of certain products of animal origin intended for human consumption, laying down certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC (OJ L 126, 14.5.2016, p. 13).

2. Part I lays down:

- (a) the obligations on the competent authority of Member States to permit the entry into the Union of consignments of animals, germinal products and products of animal origin of species and categories of animals covered by Parts II to VI (Articles 3 and 4);
- (b) the obligations on the operators regarding the entry into the Union, and the movement and handling after entry, of consignments of animals, germinal products and products of animal origin covered by Parts II to VI (Article 5);
- (c) the general animal health requirements for entry into the Union, and the movement and handling after the entry of the consignments referred to in points (a) and (b), and derogations from those general requirements, applicable to all the species and categories of animals, germinal products and products of animal origin covered by Parts II to VI (Articles 6 to 10).

3. Part II lays down the general animal health requirements for entry into the Union, as well as the movement and handling after the entry, and derogations from such requirements for certain terrestrial animals (Title 1).

In addition, it lays down specific animal health requirements that are also applicable to each of those species and categories of terrestrial animals, in particular:

- (a) kept ungulates of listed species (Title 2);
- (b) poultry and captive birds, except captive birds imported for conservation programmes approved by the competent authority of the Member State of destination (Title 3);
- (c) honeybees (*Apis mellifera*) and bumble bees (*Bombus* spp.) (Title 4);
- (d) dogs, cats and ferrets (Title 5).

4. Part III lays down the general animal health requirements for entry into the Union, as well as the movement and handling after the entry, and derogations from such requirements for germinal products of the following species and categories of kept terrestrial animals:

- (a) bovine, porcine, ovine, caprine and equine animals (Title 1);
- (b) poultry and captive birds (Title 2);
- (c) animals other than those listed in points (a) and (b) (Title 3).

5. Part IV lays down the general animal health requirements for entry into the Union, as well as the movement and handling after the entry, and derogations from those requirements for products of animal origin of the following species and categories of terrestrial animals:

- (a) kept and wild ungulates of listed species;
- (b) poultry;
- (c) game birds.

6. Part V lays down the animal health requirements for entry into the Union, as well as the movement and handling after the entry, and derogations from those requirements for the following species of aquatic animals at all life stages as well as their products of animal origin, other than wild aquatic animals and products of animal origin from those wild aquatic animals landed from fishing vessels for direct human consumption:

- (a) fish of listed species belonging to the superclass *Agnatha* and to the classes *Chondrichthyes*, *Sarcopterygii* and *Actinopterygii*;
- (b) aquatic molluscs of listed species belonging to the phylum *Mollusca*;
- (c) aquatic crustaceans of listed species belonging to the subphylum *Crustacea*;
- (d) aquatic animals of species listed in Annex XXIX which are susceptible to the aquatic diseases for which certain Member States have national measures to limit the impact of diseases other than listed diseases, as provided for in Article 226 of Regulation (EU) 2016/429.

7. Part VI lays down the general rules, certain derogations and additional requirements for transit through the Union and for the return to the Union of certain species and categories of animals, germinal products and products of animal origin.

8. Part VII lays down final provisions.

Article 2

Definitions

For the purposes of this Regulation, the definitions laid down in Implementing Regulation (EU) 2018/1882 and Annex I to Regulation (EC) No 853/2004 shall apply, except where those definitions cover terms that are defined in the second paragraph of this Article.

In addition, the following definitions shall also apply:

- (1) 'listed third country, territory or zone thereof' means a third country, territory or zone thereof included in a list of third countries, territories or zones thereof, or compartments in the case of aquaculture animals, from which the entry into the Union of a particular species and category of animals, germinal products and products of animal origin is permitted in accordance with implementing acts adopted pursuant to Article 230(1) of Regulation (EU) 2016/429;
- (2) 'the list' means the list of third countries, territories or zones thereof, or compartments in the case of aquaculture animals, authorised for entry into the Union of consignments of a particular species and category of animals, germinal products or products of animal origin by implementing acts adopted pursuant to Article 230(1) of Regulation (EU) 2016/429;
- (3) 'means of transport' means road or rail vehicle, vessels and aircrafts;
- (4) 'container' means any crate, box, receptacle or other rigid structure used for the transport of animals, germinal products or products of animal origin which is not the means of transport;
- (5) 'bovine animal' means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species;
- (6) 'ovine animal' means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species;
- (7) 'caprine animal' means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species;
- (8) 'porcine animal' means an animal of the species of ungulates belonging to the family *Suidae* listed in Annex III to Regulation (EU) 2016/429;
- (9) 'equine animal' means an animal of species of solipeds belonging to the genus *Equus* (including horses, asses, and zebras) and the offspring of crossings of those species;
- (10) 'camelid animal' means an animal of the species of ungulates belonging to the family *Camelidae* listed in Annex III to Regulation (EU) 2016/429;
- (11) 'cervid animal' means an animal of the species of ungulates belonging to the family *Cervidae* listed in Annex III to Regulation (EU) 2016/429;
- (12) 'registered equine animal' means:
 - (a) a purebred breeding animal of the species *Equus caballus* and *Equus asinus* entered or eligible for entry in the main section of a breeding book established by a breed society or breeding body recognised in accordance with Article 4 or 34 of Regulation (EU) 2016/1012;
 - (b) a kept animal of the species *Equus caballus* registered with an international association or organisation, either directly or through its national federation or branches, which manages horses for competition or racing ('registered horse');

- (13) 'animals intended for slaughter' means kept terrestrial animals to be transported, either directly or after undergoing an assembly operation, to a slaughterhouse;
- (14) 'disease has not been reported' means that no animal or group of animals of relevant species kept on the establishment has been classified as a confirmed case of that disease and any suspect case of that disease has been ruled out;
- (15) 'sanitary group' means a group of listed third countries in which common animal health risks as regards diseases listed for equine animals prevail that require specific risk-mitigating measures and health guarantees when equine animals enter into the Union;
- (16) 'flock' means all poultry or captive birds of the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit; in housed poultry, this includes all birds sharing the same airspace.
- (17) 'breeding poultry' means poultry 72 hours old or more, intended for the production of hatching eggs;
- (18) 'productive poultry' means poultry 72 hours old or more, reared for the production of meat, eggs for consumption or other products or for restocking supplies of game birds;
- (19) 'day-old chicks' means poultry less than 72 hours old;
- (20) 'honeybee' means an animal of the *Apis mellifera* species;
- (21) 'bumble bee' means an animal of the species belonging to the genus *Bombus*;
- (22) 'dog' means a kept animal of the *Canis lupus* species;
- (23) 'cat' means a kept animal of the *Felis silvestris* species;
- (24) 'ferret' means a kept animal of the *Mustela putorius furo* species;
- (25) 'unique approval number' means a number assigned by the competent authority;
- (26) 'specified pathogen-free eggs' means hatching eggs derived from 'chicken flocks free from specified pathogens', as described in the European Pharmacopoeia and which are intended solely for diagnostic, research or pharmaceutical use;
- (27) 'consignment of semen, oocytes or embryos' or 'consignment of germinal products' means a quantity of semen, oocytes, *in vivo* derived embryos or *in vitro* produced embryos dispatched from a single approved germinal product establishment covered by a single animal health certificate;
- (28) 'semen' means the ejaculate of an animal or animals, either in the unaltered state or prepared or diluted;
- (29) 'oocytes' means the haploid stages of the ootidogenesis including secondary oocytes and ova;
- (30) 'embryo' means the initial stage of development of an animal while it is capable of being transferred to a recipient dam;
- (31) 'approved germinal product establishment' means a semen collection centre, an embryo collection team, an embryo production team, a germinal product processing establishment or a germinal product storage centre;
- (32) 'centre veterinarian' means the veterinarian responsible for the activities carried out at the semen collection centre, at the germinal product processing establishment or at the germinal product storage centre as provided for in this Regulation;
- (33) 'team veterinarian' means the veterinarian responsible for the activities carried out by an embryo collection team or by an embryo production team as provided for in this Regulation;
- (34) 'quarantine accommodation' means a facility authorised by the competent authority for the purpose of the isolation of bovine, porcine, ovine or caprine animals for a period of at least 28 days before they are admitted to a semen collection centre;
- (35) 'semen collection centre' means a germinal product establishment approved by the competent authority for the collection, processing, storage and transport of semen of bovine, porcine, ovine, caprine or equine animals intended for entry into the Union;

- (36) 'embryo collection team' means a germinal product establishment comprised of a group of professionals or structure approved by the competent authority for the collection, processing, storage and transport of *in vivo* derived embryos intended for entry into the Union;
- (37) 'embryo production team' means a germinal product establishment comprised of a group of professionals or structure approved by the competent authority for the collection, processing, storage and transport of oocytes, and the *in vitro* production, where applicable with stored semen, processing, storage and transport of embryos, both intended for entry into the Union;
- (38) 'germinal product processing establishment' means a germinal product establishment approved by the competent authority for the processing, including semen sex-sorting where appropriate, and the storage of semen, oocytes or embryos of one or more species, or any combination of those types of germinal products or species, intended for entry into the Union;
- (39) 'germinal product storage centre' means a germinal product establishment approved by the competent authority for the storage of semen, oocytes or embryos of one or more species, or any combination of those types of germinal products or species, intended for entry into the Union;
- (40) 'meat' means all parts of ungulates, poultry and game birds which are suitable for human consumption, including blood;
- (41) 'fresh meat' means meat, minced meat and meat preparations, including vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any preserving process other than chilling, freezing or quick-freezing;
- (42) 'carcase of an ungulate' means the whole body of a slaughtered or killed ungulate after:
- (a) bleeding, in the case of slaughtered animals;
 - (b) evisceration;
 - (c) removal of the limbs at the carpus and tarsus;
 - (d) removal of the tail, the udder, the head and the skin, except in porcine animals.
- (43) 'offal' means fresh meat other than that of a carcase of an ungulate even if it remains naturally connected to the carcase;
- (44) 'meat products' means processed products, including treated stomachs, bladders, intestines, rendered animal fats and meat extracts, resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat;
- (45) 'casings' means the bladders and intestines that after cleaning have been processed by tissue scraping, defatting and washing and have been treated with salt or dried;
- (46) 'colostrum' means the fluid secreted by the mammary glands of kept animals up to 3 to 5 days post-parturition that is rich in antibodies and minerals, and precedes the production of raw milk;
- (47) 'colostrum-based products' means processed products resulting from the processing of colostrum or from the further processing of such processed products;
- (48) 'well-boat' means a vessel used by the aquaculture industry which has a well or tank for the storage and transport of live fish in water;
- (49) 'IMSOC' means the information management system for official controls provided for in Article 131 of Regulation (EU) 2017/625 ⁽¹⁶⁾.

⁽¹⁶⁾ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

TITLE 2

GENERAL ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION, AND MOVEMENT AND HANDLING AFTER THE ENTRY OF CONSIGNMENTS OF ANIMALS, GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN*Article 3***Obligations of the competent authorities of Member States**

The competent authority shall permit the entry into the Union of consignments of animals, germinal products and products of animal origin of species and categories covered by Parts II to VI, which are presented for the purpose of official controls as provided for in Article 47(1) of Regulation (EU) 2017/625, provided that:

- (a) the consignments come from:
 - (i) in the case of terrestrial animals, a listed third country or territory or zone thereof for the particular species and category of animals, germinal products and products of animal origin;
 - (ii) in the case of aquatic animals, a listed third country or territory or zone thereof for the particular species and category of animals and products of animal origin, and in the case of aquaculture animals, a listed third country or territory or zone or compartment thereof listed for that purpose;
- (b) the competent authority of the third country or territory of origin has certified that the consignments comply with:
 - (i) the general animal health requirements for entry into the Union of animals, germinal products and products of animal origin laid down in this Article, Article 4 and Articles 6 to 10;
 - (ii) the animal health requirements applicable to the particular species and category of animals, germinal products and products of animal origin and intended use, as laid down in Parts II to VI;
- (c) the consignments are accompanied by the following documents whereby the competent authority of the third country or territory of origin has provided the necessary guarantees as regards compliance with the animal health requirements referred to in point (b):
 - (i) an animal health certificate issued by an official veterinarian of the third country or territory of origin, specific for the particular species and category of animals, germinal products and products of animal origin and their intended use;
 - (ii) a declaration and other documents, where required in this Regulation.

In the case of consignments of animals and hatching eggs, the animal health certificate, referred to in point (c)(i) must have been issued within the period of 10 days prior to the date of arrival of the consignment at the border control post; however, in the case of transport by sea that period may be extended by an additional period corresponding to the duration of the journey by sea.

*Article 4***The date of certification of consignments**

1. Consignments of animals, germinal products and products of animal origin of species and categories falling within the scope of this Regulation shall only be permitted to enter the Union provided that such consignments were certified for dispatch to the Union not earlier than the date on which the third country or territory of origin or zone thereof, or compartment thereof in the case of aquaculture animals, was listed for entry into the Union of the particular species and category of animals, germinal products and products of animal origin.

2. Consignments of animals, hatching eggs and products of animal origin originating from a third country or territory or zone thereof, or compartment thereof in the case of aquaculture animals, shall not be permitted to enter the Union from the date on which it no longer complies with the animal health requirements for entry into the Union of the particular species and category of animals, hatching eggs or products of animal origin, unless specific conditions have been assigned by the Union in the list to the listed third country, territory or zone thereof and to the particular species and categories of animals, hatching eggs or products of animal origin.

*Article 5***Obligations of operators**

1. Operators responsible for entry into the Union of consignments of animals, germinal products and products of animal origin of the species and categories falling within the scope of this Regulation, shall present those consignments to the competent authority in the Union for the purpose of official controls, as provided for in Article 47(1) of Regulation (EU) 2017/625, and shall ensure that such consignments comply with the following requirements:

- (a) the general animal health requirements for entry into the Union of the animals, germinal products and products of animal origin laid down in Articles 3 and 4 and Articles 6 to 10;
- (b) the animal health requirements applicable to the particular species and category of the animals, germinal products and products of animal origin of the consignment and its intended use, as laid down in Parts II to VI.

2. Operators responsible for the movement of consignments of animals, germinal products and products of animal origin of the species and categories falling within the scope of this Regulation from the point of entry in the Union to their place of destination, and those responsible for the handling of such consignments after their entry into the Union shall ensure that the consignments:

- (a) are permitted to enter the Union by the competent authority in accordance with Article 3;
- (b) comply with the animal health requirements for the movement and handling of such consignments after the entry into the Union for the specific species and categories of animals, germinal products and products of animal origin laid down in Parts II to VI;
- (c) are not diverted for uses other than those for which they were certified by the competent authority of the third country or territory of origin for entry into the Union.

*Article 6***National legislation and animal health systems of the third country or territory of origin**

1. Consignments of animals, germinal products and products of animal origin shall only be permitted to enter the Union from a third country or territory where:

- (a) any suspicion and confirmed case of a listed disease referred to in Annex I, relevant for the listed species of animals in the consignment or for the listed species of animals of origin of the germinal products or products of animal origin in the consignment authorised to enter the Union, are required by law to be notified and reported to the competent authority;
- (b) there are systems in place to detect emerging diseases;
- (c) there are systems in place to ensure that swill feeding is not a source of the listed diseases referred to in Annex I for:
 - (i) the animals intended for entry into the Union;
 - or
 - (ii) the animals from which the germinal products intended for entry into the Union are obtained;
 - or
 - (iii) the animals from which the products of animal origin intended for entry into the Union are obtained.

2. Consignments of animals, germinal products and products of animal origin intended for entry into the Union shall only be permitted to enter the Union from a third country or territory or zone thereof where such consignments may be lawfully placed on the market and traded in that third country or territory of origin or zone thereof.

*Article 7***General requirements as regards the health status of the animals, germinal products and products of animal origin**

1. Consignments of animals shall only be permitted to enter the Union if the animals of the consignment:
 - (a) are not animals to be killed under a national programme carried out in the third country or territory of origin for the eradication of diseases, including the relevant listed diseases referred to in Annex I and emerging diseases;
 - (b) did not show symptoms of transmissible diseases at the time of loading for the dispatch to the Union;
 - (c) originate from an establishment which, at the time of their dispatch from that establishment to the Union, was not subject to national restriction measures:
 - (i) for animal health reasons;
 - (ii) in the case of aquaculture animals, for animal health reasons or due to the occurrence of abnormal mortalities with an undetermined cause.
2. Consignments of germinal products shall only be permitted to enter the Union if they were obtained from animals which at the time of collection:
 - (a) did not show symptoms of transmissible diseases;
 - (b) were kept on an establishment which was not subject to national restriction measures for animal health reasons, including restrictions related to the relevant listed diseases referred to in Annex I and emerging diseases.
3. Consignments of products of animal origin shall only be permitted to enter the Union if they were obtained from animals which:
 - (a) in the case of terrestrial animals, did not show symptoms of transmissible diseases at the time of:
 - (i) killing or slaughter, for the production of fresh meat and meat products;or
 - (ii) the collection of milk or eggs;
 - (b) in the case of aquatic animals, did not show symptoms of transmissible diseases at the time of slaughter or collection for the production of products of animal origin.
 - (c) were not killed, slaughtered or, in the case of molluscs and live crustaceans removed from the water, under a national programme for the eradication of diseases;
 - (d) were kept on an establishment which was not subject to national restriction measures for animal health reasons, including where relevant, listed diseases referred to in Annex I and emerging diseases, at the time of:
 - (i) the killing or slaughter of those animals for the production of fresh meat and meat products or products of animal origin from aquatic animals; or
 - (ii) the collection of milk and eggs.

*Article 8***General requirements as regards the establishment of origin of the animals**

In addition to the specific requirements laid down in Parts II to V, consignments of animals, germinal products and products of animal origin shall only be permitted to enter the Union if the establishment of origin of the kept animals, or the establishment of origin of the kept animals from which the germinal products or products of animal origin were obtained, complies with the following requirements:

- (a) it must be registered by the competent authority of the third country or territory of origin and assigned a unique registration number;
- (b) it must be approved by the competent authority of the third country or territory of origin, where required by and under the conditions provided for in this Regulation, and assigned a unique approval number;

- (c) it must be under the control of the competent authority of the third country or territory of origin;
 - (d) it must have a system in place to maintain and to keep, for a minimum period of 3 years, up-to-date records containing at least the following information:
 - (i) the species, categories, number and where relevant, identification of animals on the establishment;
 - (ii) movements of animals into and out of the establishment;
 - (iii) mortality in the establishment.
 - (e) it must receive regular animal health visits from a veterinarian for the purpose of the detection of, and information on, signs indicative of the occurrence of diseases, including those listed diseases referred to in Annex I relevant for the particular species and category of animal, germinal product or product of animal origin and emerging diseases.
- Such animal health visits shall take place at frequencies that are proportionate to the risks posed by the establishment concerned.

Article 9

Sampling, laboratory tests and other tests

Consignments of animals, germinal products and products of animal origin shall only be permitted to enter the Union if sampling, laboratory tests and other tests required by this Regulation have been carried out:

- (a) on samples taken by or under the control of the competent authority of:
 - (i) the third country or territory of origin when sampling and testing are required prior to entry into the Union;
 - or
 - (ii) the Member State of destination when sampling and testing are required after the entry into the Union;
- (b) in accordance with:
 - (i) the relevant procedures and methods set out in Delegated Regulation (EU) 2020/689 and Delegated Regulation (EU) 2020/688 ⁽¹⁷⁾;
 - or
 - (ii) for the purpose of entry into the Union of germinal products of bovine, porcine, ovine, caprine and equine animals, the procedures and methods set out in Annex II to Commission Delegated Regulation (EU) 2020/686 ⁽¹⁸⁾;
 - or
 - (iii) the procedures described in this Regulation, where specifically required;
- (c) in an official laboratory, designated in accordance with Article 37 of Regulation (EU) 2017/625.

Article 10

Disease freedom of the place of origin and specific conditions

1. Consignments of animals, germinal products and products of animal origin shall only be permitted to enter the Union if the freedom from particular diseases of the third country or territory of origin or zone thereof or of the establishment of origin of the animals, germinal products or products of animal origin, required by this Regulation has been demonstrated by the competent authority of the third country or territory of origin:

- (a) in accordance with Delegated Regulation (EU) 2020/689;
- or

⁽¹⁷⁾ Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (see page 140 of this Official Journal).

⁽¹⁸⁾ Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (see page 1 of this Official Journal).

- (b) for diseases not falling within the scope of Delegated Regulation (EU) 2020/689, in accordance with specific rules, where such rules are laid down in this Regulation, and the disease surveillance programme implemented by the third country or territory of origin, which must have been:
- (i) submitted to the Commission for assessment and contain at least the information referred to in Annex II;
 - (ii) assessed by the Commission as providing the necessary guarantees as regards disease freedom based on:
 - the rules on disease surveillance laid down in Articles 24, 25, 26 and 27 of Regulation (EU) 2016/429,
 - the supplementing rules on surveillance design and the rules for disease confirmation and case definition laid down in Sections 1 and 2 and Article 10 of Chapter 1 of Part II of Delegated Regulation (EU) 2020/689;
 - (iii) in place for a sufficient period of time for it to be fully implemented and properly supervised.
2. In the case of aquaculture animals and products of animal origin from aquaculture animals, where disease freedom from particular diseases is required for the compartment of origin, consignments of those commodities shall only be permitted to enter the Union if the competent authority of the third country of origin has demonstrated disease freedom in accordance with paragraph 1(a) and (b).
3. Where specific conditions related to the disease freedom from particular diseases of the third country or territory of origin, or zone thereof, are required in this Regulation:
- (a) the competent authority of the third country or territory of origin must have previously guaranteed its compliance;
 - (b) those specific conditions shall have been specifically assigned by the Union in the list to the listed third country or territory, zone or compartment thereof and to the particular species and category of animals, germinal products and products of animal origin.

PART II

ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF KEPT TERRESTRIAL ANIMALS AS REFERRED TO IN ARTICLES 3 AND 5

TITLE 1

GENERAL ANIMAL HEALTH REQUIREMENTS FOR KEPT TERRESTRIAL ANIMALS

Article 11

The residency period required for kept terrestrial animals

Consignments of kept terrestrial animals other than dogs, cats and ferrets, shall only be permitted to enter the Union subject to compliance with the following requirements:

- (a) the animals complied with the relevant residency period set out in the following tables of Annex III for a continuous period of time immediately prior to the date of dispatch to the Union:
 - (i) Table 1 in the case of ungulates, honeybees and bumble bees;
 - (ii) Table 2 in the case of poultry and captive birds;
- (b) the animals:
 - (i) remained continuously in the third country or territory of origin or zone thereof during the period indicated in the second column of Table 1 in Annex III and the third column of Table 2 in Annex III;
 - (ii) remained continuously in the establishment of origin, and no animals were introduced into that establishment during the period indicated in the third column of Table 1 in Annex III and the fourth column of Table 2 in Annex III;
 - (iii) had no contact with animals of a lower health status during the period indicated in the fourth column of Table 1 in Annex III and the fifth column of Table 2 in Annex III.

*Article 12***Derogations regarding the residency period for registered horses for competition, races and cultural events**

1. By way of derogation of point (b)(i) of Article 11, equine animals other than equine animals intended for slaughter shall be regarded as complying with the residency period provided for in Table 1 of Annex III, if prior to their dispatch to the Union they have been resident during the period indicated in the second column of Table 1 of Annex III in addition to the third country or territory of origin or zone thereof also in:

(a) a Member State;

or

(b) in case of registered horses, a listed third country or territory of intermediate residency, or zone thereof, from where the entry into the Union of registered horses is authorised for that purpose and provided that they were introduced into the third country or territory of origin, or zone thereof, in accordance with animal health requirements providing animal health guarantees at least as stringent as those applicable to the direct entry into the Union of registered horses for competition and races from that third country or territory of intermediate residence, or zone thereof.

2. By way of derogation from point (b)(ii) of Article 11, registered horses for competition, races and cultural equestrian events shall be regarded as complying with the residency requirements provided for in the third column of Table 1 of Annex III if they have been resident in the third country of origin or the third country of intermediate residence in establishments other than the establishment of origin provided that the other establishments:

(a) have been under supervision of the official veterinarian in a third country or territory;

(b) were not subject to national restriction measures for animal health reasons, including restrictions relating to the relevant diseases referred to in Annex I and relevant emerging diseases;

(c) comply with the animal health requirements laid down in Article 23.

3. Also by way of derogation from point (b)(ii) of Article 11, registered horses for competition, races and cultural equestrian events that have had contact with equine animals which were entered into the third country, territory or zone thereof from another third country territory, or zone thereof, or from another zone in the third country or territory of origin shall be permitted to enter the Union provided that:

(a) those equine animals were introduced into the third country or territory of origin or zone thereof in accordance with animal health requirements at least as stringent as those applicable to the direct entry into the Union of those equine animals;

(b) the possibility of direct contact with other animals is limited to the period of the competition, races or cultural equestrian events and the related training, warm-up and pre-racing presentation.

*Article 13***Inspection of terrestrial animals prior to dispatch to the Union**

1. Consignments of terrestrial animals shall only be permitted to enter the Union if the animals of the consignment have been subjected to a clinical inspection, carried out by an official veterinarian in the third country or territory of origin or zone thereof within the period of 24 hours prior to the time of loading for dispatch to the Union for the purpose of the detection of signs indicative of the occurrence of diseases, including the relevant listed diseases referred to in Annex I and emerging diseases.

In the case of poultry and captive birds, that inspection shall cover both the animals intended for dispatch to the Union and the flock of origin.

2. By way of derogation from the first subparagraph of paragraph 1, in the case of registered equine animals the inspection referred to therein may be carried out within 48 hours prior to the time of loading for dispatch to the Union or on the last working day prior to dispatch to the Union.

3. By way of derogation from the first subparagraph of paragraph 1, in the case of dogs, cats and ferrets the inspection referred to therein may be carried out within the period of 48 hours prior to the time of loading for dispatch to the Union.

Article 14

General rules for the dispatch to the Union of terrestrial animals

1. Consignments of terrestrial animals shall only be permitted to enter the Union if, from the time of loading at the establishment of origin for dispatch to the Union until the time of their arrival in the Union, the animals of the consignment have not been in contact with other terrestrial animals of:

- (a) the same species, not intended for entry into the Union;
- (b) other species listed for the same diseases, not intended for entry into the Union;
- (c) a lower health status.

2. When transported by air, sea, railway, road or on foot, the consignments referred to in paragraph 1 shall only be permitted to enter the Union if they have not been transported through, unloaded or transhipped in a third country or territory or zone thereof which is not listed for entry into the Union of the specific species and category of animals and their intended use in the Union.

3. When transported by sea, even for part of the journey, the consignments referred to in paragraph 1 shall only be permitted to enter the Union if they arrive to the Union accompanied by a declaration, attached to the animal health certificate accompanying the animals and signed by the master of the vessel, providing the following information:

- (a) the port of departure in the third country or territory of origin or zone thereof;
- (b) the port of arrival in the Union;
- (c) the ports of call, where the vessel called at ports outside the third country or territory of origin or zone thereof of the animals;
- (d) confirmation of compliance with the following requirements during the journey to the Union:
 - (i) the animals have remained on board;
 - (ii) the animals have not been into contact with animals of a lower health status while on board.

Article 15

Derogation for the transhipment of terrestrial animals other than equine animals in non-listed third countries or territories in the event of a technical problem or another unforeseen incident

1. By way of derogation from Article 14(2), the competent authority shall authorise the entry into the Union of consignments of terrestrial animals, other than equine animals, which have been transhipped from the original means of transport of dispatch into another means of transport for onward travel in a third country or territory or zone thereof which is not a listed third country or territory or zone thereof for entry of the particular species and category of animals into the Union, only if the transhipment operation took place because of the occurrence of a technical problem or another unforeseen incident causing logistic problems during the transport of the animals to the Union by sea or by air, in order to complete the transport to the point of entry into Union, provided that:

- (a) the entry into the Union of the consignment of animals is authorised by the competent authority of the Member State of destination and, where applicable, any Member States of passage until their arrival at their place of destination in the Union;
- (b) the transhipment was supervised by an official veterinarian in the third country or territory throughout the operation to ensure that:
 - (i) effective protection measures against vectors of relevant animal diseases were put in place;
 - (ii) effective measures were put in place to avoid direct and indirect contact between the animals intended for entry into the Union and any other animals;

- (iii) no feed, water or bedding, originating from a third country or territory or zone thereof which is not a listed third country or territory or zone thereof for entry of the particular species and category of animals into the Union, has been added in the means of transport for onward travel to the Union;
 - (iv) the animals of the consignment were transferred directly and as quick as possible to a vessel or aircraft for onward travel to the Union, which complies with requirements laid down in Article 17, without leaving the boundaries of the port or airport;
 - (c) the consignment of animals is accompanied by a declaration from the competent authority of the third country or territory where the transfer took place, providing information on the transfer operation and attesting that relevant measures were put in place to comply with the requirements laid down in point (b).
2. The derogation provided for in paragraph 1 shall not apply to consignments of honeybees and bumble bees.

Article 16

Derogation for the transhipment of equine animals in non-listed third countries or territories

By way of derogation from Article 14(2), where consignments of equine animals have been transhipped to another means of transport during the transport of the animals to the Union in a third country or territory or zone thereof which is not a listed third country or territory or zone thereof for entry of the particular category of equine animals, those consignments shall only be permitted to enter the Union if they comply with the following requirements:

- (a) the animals of the consignment were transported to the Union by sea or by air;
- (b) the animals of the consignment were transhipped directly from the original means of transport of dispatch into the other means of transport for onward travel;
- (c) during the transhipment operation:
 - (i) effective protection against vectors of relevant animal diseases was provided and the equine animals did not come into contact with equine animals of a lower health status;
 - (ii) the animals of the consignment were transferred directly and as quickly as possible to the vessel or aircraft to be used for onward travel, which must have complied with the requirements laid down in Article 17, without leaving the boundaries of the port or airport under the direct supervision of an official veterinarian;
- (d) an official veterinarian must have certified that the consignment complied with the requirements laid down in point (a), (b) and (c).

Article 17

General requirements regarding means of transport of terrestrial animals

1. Consignments of kept terrestrial animals shall only be permitted to enter the Union if the means of transport used for their transport are:
- (a) constructed in such a way that:
 - (i) the animals cannot escape or fall out;
 - (ii) visual inspection of the space where animals are kept is possible;
 - (iii) the escape of animal excrements, litter or feed is prevented or minimised;
 - (iv) in the case of poultry and captive birds, the escape of feathers is prevented or minimised;
 - (b) cleaned and disinfected, with a disinfectant authorised by the competent authority of the third country or territory of dispatch, and dried or allowed to dry immediately before every loading of animals intended for entry into the Union.
2. Paragraph 1 shall not apply to the transport of consignments of honeybees and bumble bees intended for entry into the Union.

*Article 18***Requirements regarding containers in which terrestrial animals are transported to the Union**

Consignments of kept terrestrial animals shall only be permitted to enter the Union if the containers in which kept terrestrial animals are transported to the Union in the means of transport:

- (a) comply with the requirements in Article 17(1)(a);
- (b) contain only animals of the same species and category coming from the same establishment;
- (c) are either:
 - (i) unused and purpose-designed disposable containers to be destroyed after first use;
 - or
 - (ii) cleaned and disinfected and dried or allowed to dry before loading of animals intended for entry into the Union.

*Article 19***Movement and handling after entry of terrestrial animals**

1. Following their entry into the Union, consignments of terrestrial animals shall be transported directly without delay to:
 - (a) their establishment of destination in the Union, where they shall remain at least for the period of time required in the relevant specific articles in Parts II to V;
 - (b) the slaughterhouse of destination in the Union, if they are intended for slaughter, where they must be slaughtered within a period of 5 days from the date of their arrival in the Union.
2. Where the destination of the consignments of terrestrial animals entered from a third country or territory or zone thereof is a slaughterhouse, an approved quarantine establishment or a confined establishment in the Union, the transport to and arrival at the place of the destination of the consignment shall be monitored in accordance with Article 2 and 3 of Commission Delegated Regulation (EU) 2019/1666 ⁽¹⁹⁾.
3. Paragraphs 1 and 2 shall not apply to the entry into the Union of registered equine animals from third countries and to the re-entry after temporary export of registered horses.

TITLE 2

ANIMAL HEALTH REQUIREMENTS FOR UNGULATES

CHAPTER 1

Specific animal health requirements for ungulates*Article 20***Dispatch of ungulates to the Union**

1. Consignments of ungulates shall only be permitted to enter the Union if such consignments have been dispatched from the establishment of origin to the Union without passing through any other establishment.
2. By way of derogation of paragraph 1, consignments of ungulates coming from more than one establishment of origin may be permitted to enter the Union if the animals of the consignment have undergone a single assembly operation in the third country or territory of origin or zone thereof subject to compliance with the following conditions:
 - (a) the ungulates belong to one of the following species and categories:
 - (i) *Bos taurus*, *Ovis aries*, *Capra hircus* or *Sus scrofa*;
 - or

⁽¹⁹⁾ Commission Delegated Regulation (EU) 2019/1666 of 24 June 2019 supplementing Regulation (EU) 2017/625 of European Parliament and the Council as regards conditions for monitoring the transport and arrival of consignments of certain goods from the border control post of arrival to the establishment at the place of destination in the Union (OJ L 255, 4.10.2019, p. 1).

- (ii) *Equidae* intended for slaughter;
- (b) the assembly operation took place in an establishment:
 - (i) approved for conducting assembly operations of ungulates by the competent authority in the third country or territory in accordance with requirements which are at least as stringent as to those laid down with Article 5 of Commission Delegated Regulation (EU) 2019/2035 ⁽²⁰⁾;
 - (ii) listed for that purpose by the competent authority of the third country or territory of dispatch, including the information provided for in Article 21 of Delegated Regulation (EU) 2019/2035;
- (iii) where the following records are maintained up-to-date and kept for a period of at least 3 years:
 - the origin of the animals,
 - the dates of arrival and dispatch to and from the assembly centre,
 - the identification code of the animals,
 - the registration number of the establishment of origin of the animals,
 - the registration number of the transporters and the means of transport delivering or collecting the consignment of ungulates to and from that centre;
- (iv) which complies with the requirements provided for in Article 8 and Article 23(1);
- (c) the assembly operation in the assembly centre took no longer than 6 days; this period shall be considered as part of the timeframe for sampling for testing prior to dispatch to the Union, where such sampling is required by this Regulation;
- (d) the ungulates must have arrived in the Union within a period of 10 days from the date of dispatch from the establishment of origin.

Article 21

Identification of ungulates

1. Consignments of ungulates, other than equine animals, shall only be permitted to enter the Union if the animals of the consignment were individually identified prior to being dispatched from the establishment of origin, by a physical means of identification with a visible, legible and indelible display of:
 - (a) the identification code of the animal which establishes an unequivocal link between the animal and the accompanying animal health certificate;
 - (b) the code of the exporting country in accordance with ISO Standard 3166 in the format of two-letter code.
2. Consignments of equine animals shall only be permitted to enter the Union if the animals of the consignment were individually identified prior to being dispatched from the establishment of origin at least by one of the following methods:
 - (a) an injectable transponder or ear tag, with a visible, legible and indelible display of:
 - (i) the identification code of the animal which establishes an unequivocal link between the animal and the accompanying animal health certificate;
 - (ii) the ISO-3166 two-digit alpha or three-digit numeric country code of the exporting country;
 - (b) in the case of equine animals other than those intended for slaughter, an identification document, issued at the latest at the time of certification for entry into the Union, which:
 - (i) describes and depicts the animal, including the alternative methods of identification, so as to establish an unequivocal link between the animal and the accompanying identification document;
 - (ii) contains information on the individual code emitted by an implanted injectable transponder in the case where this code does not comply with the specifications in point (a).

⁽²⁰⁾ Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115).

3. By way of derogation from paragraph 1, consignments of ungulates intended for confined establishments may be permitted to enter the Union if those animals are individually identified by an injectable transponder or an alternative method of identification which ensures an unequivocal link between the animal and its accompanying entry documentation.

4. Where ungulates are identified with an electronic identifier which does not comply with ISO Standards 11784 and 11785 the operator responsible for entry into the Union of the consignments of ungulates shall provide the reading device which enables at any time the verification of the identification of the animal.

Article 22

The third country or territory of origin of ungulates or zone thereof

1. Consignments of ungulates, other than equine animals, shall only be permitted to enter the Union if the animals of the consignment originate from a third country or territory or zone thereof free from the category A diseases referred to in the table set out in point 1 of Part A of Annex IV for the period referred to in that table.

2. Consignments of equine animals shall only be permitted to enter the Union if the animals of the consignment originate from a third country or territory or zone thereof:

- (a) free from the listed diseases referred in the table set out in point 2 of Part A of Annex IV for the period referred to in that table;
- (b) where none of the listed diseases referred to in the table set out in point 3 of Part A of Annex IV has been reported during the referred period.

3. The periods referred to in paragraph 1 and 2 may be reduced for diseases included in Part B of Annex IV under the relevant specific conditions referred therein.

4. Consignments of ungulates shall only be permitted to enter the Union if the animals of the consignment originate from a third country or territory or zone thereof where vaccination against the category A diseases referred to in Part C of Annex IV has not been carried out in accordance with the details set out in:

- (a) point 1 of that Annex in the case of ungulates, other than equine animals;
- (b) point 2 of that Annex in the case of equine animals.

5. As regards infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae*, *M. tuberculosis*), consignments of bovine animals shall only be permitted to enter the Union if the animals of the consignment either:

- (a) originate from a third country or territory or zone thereof free from that disease without vaccination;

or

- (b) comply with the requirements set out in point 1 of Annex V.

6. As regards infection with *Brucella abortus*, *B. melitensis* and *B. suis*, consignments of bovine, ovine and caprine animals shall only be permitted to enter the Union if the animals of the consignment either:

- (a) originate from a third country or territory or zone thereof free from that disease without vaccination;

or

- (b) comply with the requirements set out in point 2 of Annex V.

7. As regards infection with bluetongue virus (serotypes 1-24), consignments of ungulates of listed species shall only be permitted to enter the Union if the animals of the consignment either:

- (a) originate from a third country or territory or zone thereof free from that disease for a period of 2 years prior to the date of dispatch to the Union; or
- (b) comply with one of the specific conditions set out in of Part A of Annex VI.

8. As regards enzootic bovine leukosis, consignments of bovine animals shall only be permitted to enter the Union if those animals either:

(a) originate from a third country or territory or zone thereof free from that disease;

or

(b) comply with the specific conditions set out in Part B of Annex VI.

9. Consignments of ungulates intended for entry into Member States or zones thereof with disease-free status or with an approved eradication programme for the category C diseases referred to in Annex VII, for which the species of ungulates are listed, shall only be permitted to enter the Union if the animals of the consignment:

(a) originate from third country or territory or zone thereof free from those diseases for the relevant species;

or

(b) comply with the relevant additional requirements set out in that Annex.

Article 23

The establishment of origin of ungulates

1. Consignments of ungulates shall only be permitted to enter the Union if the animals of the consignment:

(a) come from an establishment in and around which, including where appropriate the territory of a neighbouring country, none of the listed diseases referred to in Annex VIII, for which the species of ungulates intended for entry into the Union are listed, has been reported in an area and for a period set out in the tables in:

(i) points 1 and 2 of that Annex for ungulates other than equine animals;

or

(ii) points 3 and 4 of that Annex for equine animals;

(b) during the period referred to in point (a), the ungulates have not come into contact with animals with a lower health status.

2. As regards infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae*, *M. tuberculosis*), consignments of bovine, ovine, caprine, camelid and cervid animals shall only be permitted to enter the Union if the establishment of origin of the animals of the consignment complies with the relevant requirements set out in point 1 of Annex IX.

3. As regards infection with *Brucella abortus*, *B. melitensis* and *B. suis*, consignments of bovine, ovine, caprine, porcine, camelid and cervid animals shall only be permitted to enter the Union if the establishment of origin of the animals of the consignment complies with the relevant requirements set out in point 2 of Annex IX.

Article 24

The ungulates of the consignment

1. Consignments of ungulates shall only be permitted to enter the Union if the animals of the consignment comply with the following requirements:

(a) they have not been vaccinated against the category A diseases referred to in the tables set out either in:

(i) point 1 of Part C of Annex IV in the case of ungulates other than equine animals;

or

(ii) point 2 of Part C of Annex IV in the case of equine animals;

- (b) during the period of time from when they were dispatched from their establishment of origin until their arrival to the Union, they must not have been unloaded in any place which does not comply with the requirements laid down in the tables set out either in:
- (i) points 1 and 2 of Annex VIII in the case of ungulates other than equine animals;
 - or
 - (ii) points 3 and 4 of Annex VIII in the case of equine animals.
2. As regards infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae*, *M. tuberculosis*) and infection with *Brucella abortus*, *B. melitensis* and *B. suis* consignments of listed species of ungulates shall only be permitted to enter the Union if the animals of the consignment have not been vaccinated against those diseases.
3. As regards infection with bluetongue virus (serotypes 1-24), consignments of listed species of ungulates shall only be permitted to enter the Union if the animals of the consignment have not been vaccinated with a live vaccine against this disease in the last 60 days prior to the date of movement.
4. Consignments of ungulates intended for entry into Member States or zones thereof with disease-free status or with an approved eradication programme for the category C diseases referred to in Annex VII, for which the species of ungulates are listed, shall only be permitted to enter the Union if the animals of the consignment have not been vaccinated against those diseases.
5. In addition to requirements laid down in paragraph 1, consignments of uncastrated males of ovine animals and ungulates of the family *Tayassuidae* shall only be permitted to enter the Union if the animals of the consignment comply with the relevant specific requirements as regards infection with *Brucella* laid down in Annex X.
6. In addition to requirements laid down in paragraph 1, consignments of equine animals shall only be permitted to enter the Union if the animals of the consignment comply with the specific conditions set out in point 2 of Annex XI, depending on the sanitary group, as determined in accordance with point 1 of Annex XI, to which the third country or territory or zone thereof has been assigned in the list.

Article 25

Derogations and additional requirements for entry into the Union of ungulates for slaughter

By way of derogation from the requirements laid down in Article 22(5) and (6), consignments of ungulates of the species referred to in those paragraphs which do not comply with those requirements shall be permitted to enter the Union provided that the animals of the consignment are only intended for slaughter.

Article 26

Movement and handling of ungulates after their entry into the Union

Following their entry into the Union, ungulates, except horses entering for competition, races and cultural equestrian events, shall remain in their establishment of destination for a period of time of at least 30 days since their arrival to that establishment.

CHAPTER 2

Special rules for entry into the Union of kept ungulates intended for confined establishments

Article 27

Animal health requirements not applicable to ungulates intended for confined establishments

Articles 11, 22, 23, 24 and 26 shall not apply to consignments of ungulates, excluding equine animals, entering the Union under the conditions laid down in Articles 28 to 34.

*Article 28***Specific rules for entry of ungulates intended for confined establishments**

1. Consignments of ungulates intended for confined establishments shall only be permitted to enter the Union if the animals of the consignment comply with the following requirements:
 - (a) they must come from a confined establishment which is included in a list of confined establishments from which the entry of ungulates into the Union is permitted, drawn up in accordance with Article 29;
 - (b) they must have been dispatched directly from the confined establishment of origin to a confined establishment in the Union.
2. The competent authority of the Member State of destination shall grant a specific authorisation for entry of each consignment of ungulates referred to in paragraph 1, following the favourable outcome of an assessment of the potential risks that the entry of such consignment may present for the Union.
3. The entry into the Union and the movement of each consignment of ungulates referred to in paragraph 1 through Member States other than the Member State of destination shall be only permitted subject to the authorisation of the competent authorities of those Member States of passage.

That authorisation shall be granted only on the basis of the favourable outcome of a risk assessment carried out by the competent authority of those Member States of passage, based on the information submitted to them by the Member State of the place of destination in the Union.

4. The Member State of the place of destination of the consignments referred to in paragraph 1 shall notify the Commission and the other Member States within the framework of the Standing Committee on Plants, Animals, Food and Feed and notify directly the point of entry in the Union of the ungulates, of the authorisations granted pursuant to paragraph 1 and 2, prior to any possible movement through other Member States and prior to the arrival of such ungulates into their territory.

*Article 29***Listing of confined establishments of origin of ungulates in third countries or territories**

1. Member States may draw up a list of confined establishments in third countries and territories, from which the entry of ungulates into their territory shall be permitted.

That list shall specify the species of ungulates permitted to enter the territory of the Member State from each confined establishment in the third country or territory.

2. Member States may include in their list of confined establishments provided for in paragraph 1, confined establishments that are already included in such lists of other Member States.

Except as provided for in the first subparagraph, Member States shall only include a confined establishment in a third country or territory in the list of confined establishments provided for in paragraph 1, following the favourable outcome of a complete assessment based on the following:

- (a) compliance by the confined establishment with the requirement to be approved by the competent authority of the third country or territory of origin laid down in Article 30;
 - (b) the competent authority of the third country or territory of origin must have provided sufficient information to guarantee that the confined establishment complies with the requirements concerning the approval of confined establishments laid down in Article 30.
3. Member States shall keep the lists of confined establishments provided for in paragraph 1 up-to-date, taking into account in particular any suspension or withdrawal of the approval granted by the competent authority of a third country or territory of origin as referred to in Article 30, or by the competent authority of another Member State.
 4. Member States shall make the lists provided for in paragraph 1 publicly available on their websites.

*Article 30***Conditions for confined establishments of origin of ungulates in third countries or territories for the purpose of Article 29**

Member States shall only include a confined establishment located in a third country or territory on the list of confined establishments provided for in Article 29, if the confined establishment is approved by the competent authority of the third country or territory and complies with the following conditions:

- (a) it must be clearly demarcated and the access of animals and humans to animal facilities must be controlled;
- (b) it must have adequate means for catching, confining and isolating animals, and have available and adequate quarantine facilities and approved standard operating procedures for new incoming animals;
- (c) the animal accommodation areas must be of a suitable standard and constructed in such a way that:
 - (i) contact with animals outside the confined establishment is prevented and inspections and any necessary treatment can be easily carried out;
 - (ii) the floors, walls and all other material or equipment can be cleaned and disinfected easily;
- (d) as regards disease surveillance and control measures:
 - (i) it must implement an appropriate disease surveillance programme which must include control measures against zoonosis, and update it according to the number and species of the animals present in the confined establishment and to the epidemiological situation in and around the confined establishment as regards listed diseases and emerging diseases;
 - (ii) it must subject to clinical examinations, laboratory testing or post-mortem examinations those ungulates suspected of being infected or contaminated by disease agents of listed diseases or emerging diseases;
 - (iii) it must carry out, as appropriate, the vaccination and treatment of susceptible ungulates against transmissible diseases;
- (e) it must keep, for a minimum period of 3 years, up-to-date records indicating:
 - (i) the number and identity (namely, the estimated age, sex, species and individual identification, where appropriate) of the ungulates of each species present on the confined establishment;
 - (ii) the number and identity (namely, the estimated age, sex, species and individual identification code where appropriate) of ungulates arriving or leaving the confined establishment, together with information on the establishment of origin or destination of such animals, the means of transport and the health status of those animals;
 - (iii) details of the implementation and results of the disease surveillance and control programme provided for in point (d)(i);
 - (iv) the results of clinical examinations, laboratory tests and of post-mortem examinations provided for in point (d)(ii);
 - (v) details of the vaccination and treatment provided for in point (d)(iii);
 - (vi) instructions, if any, of the competent authority of the third country or territory of origin as regards observations made during any period of isolation or quarantine;
- (f) it must ensure the disposal of the dead bodies of ungulates which die of a disease or are euthanised;
- (g) it must secure by contract or other legal instrument the services of an establishment veterinarian who shall be responsible for:
 - (i) the supervision of the activities of the establishment and compliance with the conditions for approval laid down in of this Article;
 - (ii) the review of the disease surveillance programme referred to in point (d)(i) at least annually;
- (h) by way of derogation from Article 9(c), either has:
 - (i) an arrangement with a laboratory approved by the competent authority of the third country or territory to perform post-mortem examinations;or
 - (ii) one or more appropriate premises where post-mortem examinations may be performed under the authority of the establishment veterinarian.

*Article 31***Derogation from the requirement of listing of the third country or territory and the listing of the confined establishment of origin of ungulates**

1. By way of derogation from the requirements laid down Article 3(1) and Article 28(1), consignments of ungulates from establishments in third countries or territories which do not comply with those requirements shall be permitted to enter the Union if they are intended for a confined establishment and provided that:

- (a) exceptional unforeseen circumstances render compliance with those requirements impossible;
- (b) those consignments comply with the conditions laid down in Article 32.

2. The Member State of the place of destination of the consignment referred to in paragraph 1 shall notify the Commission and the Member States within the framework of the Standing Committee on Plants, Animals, Food and Feed and notify directly the point of entry in the Union of the ungulates, of the authorisations granted pursuant to paragraph 1, prior to any possible movement through other Member States and prior to the arrival of such ungulates into their territory.

*Article 32***Additional requirements to be fulfilled by establishments of origin of ungulates intended for a confined establishment pursuant to the derogation laid down in Article 31**

The competent authority of a Member State of destination shall only authorise derogations, as provided for in Article 31, for consignments of ungulates that comply with the following additional conditions:

- (a) a prior application to the competent authority of the Member State of destination for a specific derogation as provided for in Article 31 was made by the owner, or a natural person representing that owner, and the Member State of destination granted that authorisation after having carried out a risk assessment that has indicated that the introduction of such a consignment of ungulates would not present an animal health risk for the Union;
- (b) the ungulates have been quarantined in the third country or territory of origin under the supervision of the competent authority for the necessary period of time required for them to comply with the specific animal health requirements laid down in Articles 33 and 34:
 - (i) at a place approved by the competent authority of the third country or territory of origin of the ungulates;
 - (ii) in accordance with the arrangements specified in the authorisation referred to in point (a) that must provide at least the same guarantees as those provided for by Article 28(2) to (4) and by Articles 33 and 34;
- (c) the ungulates must be quarantined in the confined establishment of destination for a period of at least 6 months from the date of entry into the Union, during which period the actions provided for in Article 138(2) of Regulation (EU) 2017/625 and in particular in its points 2(a), (d) and (k) may be taken by the competent authority of the Member State of destination.

*Article 33***Animal health requirements for the confined establishment of origin of ungulates as regards listed diseases**

Consignments of ungulates intended for a confined establishment located in the Union shall only be permitted to enter the Union if the confined establishment of origin complies with the following requirements as regards listed diseases:

- (a) as regards the confined establishment of origin of the ungulates, listed diseases referred to in the table set out in Part A of Annex XII have not been reported for the periods specified for those listed diseases in that table;
- (b) as regards the area in and around the confined establishment, listed diseases referred to in the table set out in Part B of Annex XII have been not reported for the periods specified for those listed diseases in that table.

*Article 34***Animal health requirements for the ungulates of the consignment as regards listed diseases**

Consignments of ungulates intended for a confined establishment located in the Union shall only be permitted to enter the Union if the animals of the consignment comply with the following additional animal health requirements:

- (a) they must comply with a residency period in the confined establishment of origin for a continuous period of 6 months or since birth if they are less than 6 months of age;

- (b) they must not have been in contact with animals of a lower health status during:
 - (i) the period of 30 days prior to the date of dispatch to the Union, or since birth if the animals are less than 30 days of age;
 - (ii) their transport from the approved confined establishment of origin to the place of dispatch to the Union;
- (c) as regards the diseases referred to in the table set out in Part C of Annex XII, they must either:
 - (i) originate from a third country or territory or zone thereof which complies with the disease freedom periods for the relevant diseases set out in that table;or
 - (ii) comply with the relevant additional requirements set out in Part D of Annex XII;
- (d) they must not have been vaccinated as referred to in the table set out in Part E of Annex XII;
- (e) if they have been vaccinated against anthrax and rabies, information on the date of vaccination, the vaccine used and the possible test performed to show a protective immune response, must have been provided by the competent authority of the third country or territory of origin;
- (f) they must have been treated against internal and external parasites at least twice during the period of 40 days prior to date of dispatch to the Union.

Where the specific guarantees referred to in point (c)(ii) include a quarantine period in a vector-protected facility in the confined establishment, this facility must comply with the requirements set out in Part F of Annex XII.

Article 35

Movement and handling of ungulates intended to confined establishments after the entry

Following their entry into the Union, ungulates originating from a confined establishment in a third country or territory, as referred to in Article 27, must remain in the confined establishment of destination for a period of at least 6 months prior to the date of movement to another confined establishment in the Union, unless they are exported from the Union or moved for slaughter.

TITLE 3

ANIMAL HEALTH REQUIREMENTS FOR POULTRY AND CAPTIVE BIRDS

CHAPTER 1

Specific animal health requirements for poultry

SECTION 1

ANIMAL HEALTH REQUIREMENTS FOR ALL SPECIES AND CATEGORIES OF POULTRY

Article 36

Poultry imported into the third country or territory of origin or zone thereof prior to entry into Union

1. The following consignments shall only be permitted to enter the Union where the competent authority of the third country or territory of origin has provided guarantees in accordance with paragraph 2:
 - (a) poultry imported into the third country or territory of origin or zone thereof from another third country or territory or zone thereof;
 - (b) day-old chicks from parent flocks that were imported into the third country or territory of origin or zone thereof from another third country or territory or zone thereof.

2. Consignments of animals referred to in paragraph 1 shall only be permitted to enter the Union if the competent authority of the third country or territory of origin of the poultry has provided guarantees that:

- (a) those poultry and parent flocks referred to in that paragraph were imported from a third country or territory or zone thereof, which is listed for entry into Union of such consignments;
- (b) the import of the poultry and parent flocks referred to paragraph 1 into that third country or territory or zone thereof took place in accordance with animal health requirements that are at least as stringent as those applicable to consignments of those animals entering directly into the Union.

Article 37

Requirements concerning the third country or territory of origin of poultry or zone thereof

Consignments of poultry shall only be permitted to enter the Union if such consignments originate from a third country or territory or zone thereof which complies with the following requirements:

- (a) it has a disease surveillance programme for highly pathogenic avian influenza in place for a period of at least 6 months prior to the date of dispatch of the consignment to the Union and that surveillance programme complies with the requirements laid down in either:
 - (i) Annex II to this Regulation;or
 - (ii) the relevant Chapter of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE);
- (b) it is considered to be free from highly pathogenic avian influenza in accordance with Article 38;
- (c) where it carries out vaccination against highly pathogenic avian influenza, the competent authority of the third country or territory of origin has provided guarantees that:
 - (i) the vaccination programme complies with the requirements set out in Annex XIII;
 - (ii) the surveillance programme referred to in point (a) of this Article, in addition to the requirements set out in Annex II, complies with the requirements set out in point 2 of Annex XIII;
 - (iii) it has undertaken to inform the Commission of any change to the vaccination programme in the third country or territory or zone thereof;
- (d) which:
 - (i) in the case of poultry other than ratites, it is considered free from infection with Newcastle disease virus in accordance with Article 39;
 - (ii) in the case of ratites:
 - it is considered free from infection with Newcastle disease virus in accordance with Article 39,or
 - it is not considered free from infection with Newcastle disease virus in accordance with Article 39, but the competent authority of the third country or territory of origin has provided guarantees regarding compliance with the requirements for infection with Newcastle disease virus in relation to isolation, surveillance and testing, as set out in Annex XIV;
- (e) where vaccination against infection with Newcastle disease virus is carried out, the competent authority of the third country or territory has provided guarantees that:
 - (i) the vaccines used comply with the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV;or

- (ii) the vaccines used comply with the general criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the poultry meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
- (f) it has undertaken that following any outbreak of highly pathogenic avian influenza or an outbreak of infection with Newcastle disease virus, to submit the following information to the Commission:
 - (i) information on the disease situation within 24 hours of confirmation of any initial outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus;
 - (ii) regular updates on the disease situation;
- (g) which has undertaken to submit virus isolates from initial outbreaks of highly pathogenic avian influenza and infection with Newcastle disease virus to the European Union Reference Laboratory for Avian Influenza and Newcastle disease.

Article 38

Freedom from highly pathogenic avian influenza of the third country or territory of origin or zone thereof

1. A third country or territory or zone thereof shall be considered as being free from highly pathogenic avian influenza when it has provided the following guarantees to the Commission:
 - (a) a surveillance programme for highly pathogenic avian influenza, in accordance with Article 37(a) has been carried out during a period of at least 6 months preceding the date of certification of the consignment by the official veterinarian for dispatch to the Union;
 - (b) no outbreak of highly pathogenic avian influenza has occurred in poultry in that third country or territory or zone thereof for a period of at least 12 months preceding the date of certification of the consignment by the official veterinarian for dispatch to the Union.
2. Following an outbreak of highly pathogenic avian influenza in a third country or territory or zone thereof previously considered as free of that disease, as referred to in paragraph 1, that third country or territory or zone thereof shall again be considered as free from highly pathogenic avian influenza, subject to compliance with the following conditions:
 - (a) a stamping out policy has been implemented to control highly pathogenic avian influenza;
 - (b) adequate cleaning and disinfection has been carried out on all previously infected establishments;
 - (c) during a period of at least 3 months following the completion of the stamping out policy and cleaning and disinfection referred to in points (a) and (b), the competent authority of the third country or territory has carried out a surveillance programme, providing at least the confidence by a randomised representative sample of the populations at risk to demonstrate the absence of infection taking into account the specific epidemiological circumstances in relation to the occurred outbreak(s), with negative results.

Article 39

Freedom from infection with Newcastle disease virus of the third country or territory of origin or zone thereof

1. A third country or territory or zone thereof shall be considered free from infection with Newcastle disease virus when no outbreak of infection with Newcastle disease virus has occurred in poultry in that third country or territory or zone thereof for a period of at least 12 months preceding the date of certification of the consignment by the official veterinarian for dispatch to the Union.

2. When an outbreak of infection with Newcastle disease virus occurs in a third country or territory or zone thereof previously free from that disease, as referred to in paragraph 1, that third country or territory or zone thereof shall again be considered as free from that infection with Newcastle disease virus subject to compliance with the following conditions:

- (a) a stamping out policy has been implemented to control the disease;
- (b) adequate cleaning and disinfection has been carried out on all previously infected establishments;
- (c) during a period of at least 3 months following the completion of the stamping out policy and cleaning and disinfection referred to in points (a) and (b), the competent authority of the third country or territory has demonstrated the absence of that disease in the third country or territory or zone thereof by intensified investigations including laboratory testing in relation to the outbreak.

Article 40

The establishment of origin of poultry

1. Consignments of breeding poultry and productive poultry shall only be permitted to enter into the Union if the animals of the consignment come from establishments approved by the competent authority of the third country or territory of origin in accordance with requirements which are at least as stringent as to those laid down in Article 8 of Delegated Regulation (EU) 2019/2035, and:

- (a) the approval of which has not been suspended or withdrawn;
- (b) within a 10 km radius of which, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus during the period of at least 30 days prior to the date of loading for dispatch to the Union;
- (c) in which no confirmed case of infection with low pathogenic avian influenza viruses has been reported during the period of at least 21 days prior to the date of loading for dispatch to the Union.

2. Consignments of poultry intended for slaughter shall only be permitted to enter into the Union if the animals of the consignment come from establishments:

- (a) within a 10 km radius of which, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus during the period of at least 30 days prior to the date of loading for dispatch to the Union;
- (b) in which no confirmed case of infection with low pathogenic avian influenza viruses has been reported during the period of at least 21 days prior to the date of loading for dispatch to the Union.

3. Consignments of day-old chicks shall only be permitted to enter into the Union if the animals of the consignment:

- (a) have been hatched in establishments approved by the competent authority of the third country or territory of origin in accordance with requirements which are at least as stringent as to those laid down in Article 7 of Delegated Regulation (EU) 2019/2035; and
 - (i) the approval of which has not been suspended or withdrawn;
 - (ii) within a 10 km radius of which, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus during the period of at least 30 days prior to the date of dispatch to the Union;
- (b) come from flocks which have been kept in establishments approved by the competent authority of the third country or territory of origin in accordance with requirements which are at least as stringent as to those laid down in Article 8 of Delegated Regulation (EU) 2019/2035, and
 - (i) the approval of which had not been suspended or withdrawn at the time the hatching eggs, from which the day-old chick were hatched, were sent to the hatchery;
 - (ii) in which no confirmed case of infection with low pathogenic avian influenza viruses has been reported during the period of at least 21 days prior to the date of collection of the hatching eggs from which the day-old chicks were hatched.

*Article 41***Specific preventive measures for the containers in which poultry are transported**

Consignments of poultry shall only be permitted to enter into the Union if such consignments have been transported in containers which, in addition to the requirements of Article 18, comply with the following requirements:

- (a) they are closed in accordance with the instructions of the competent authority of the third country or territory of origin in order to avoid any possibility of substitution of the contents;
- (b) they bear the information for the particular species and category of poultry set out in Annex XVI;
- (c) in the case of day-old chicks, they are disposable, clean and used for the first time.

*Article 42***Entry of poultry into Member States with status free from infection with Newcastle disease virus without vaccination**

1. Consignments of breeding poultry and productive poultry intended for a Member State with status free from infection with Newcastle disease virus without vaccination shall only be permitted to enter into the Union if the animals of the consignment comply with the following requirements:

- (a) they have not been vaccinated against infection with Newcastle disease virus;
- (b) they have been kept in isolation during a period of at least 14 days prior to the date of loading of the consignment for dispatch to the Union in the establishment of origin or quarantine establishment under the supervision of an official veterinarian, where:
 - (i) no poultry has been vaccinated against infection with Newcastle disease virus during a period of at least 21 days prior to the date of loading of the consignment;
 - (ii) no bird which does not form part of the consignment has entered into the establishment during period referred to in point (i);
 - (iii) no vaccination has been carried out;
- (c) they have tested negative, during the period of at least 14 days prior to the date of loading for dispatch to the Union, to serological tests to detect antibodies against Newcastle disease virus, performed on blood samples at a level which gives 95 % confidence of detecting infection at 5 % prevalence.

2. Consignments of poultry intended for slaughter intended for a Member State with status free from infection with Newcastle disease virus without vaccination, shall only be permitted to enter into the Union if the animals of the consignment come from flocks which:

- (a) have not been vaccinated against infection with Newcastle disease virus and have tested negative, during a period of at least 14 days prior to the date of loading of the consignment for dispatch to the Union, to serological tests to detect antibodies against Newcastle disease virus performed on blood samples at a level which gives 95 % confidence of detecting infection at 5 % prevalence;

or

- (b) have been vaccinated against infection with Newcastle disease virus but not with a live vaccine during the period of at least 30 days prior to the date of loading of the consignment for dispatch to the Union and underwent a virus isolation test for infection with Newcastle disease virus in the 14 days prior to that date on a random sample of cloacal swabs or faeces samples taken from at least 60 birds and tested negative.

3. Consignments of day-old chicks intended for a Member State with status free from infection with Newcastle disease virus without vaccination shall only be permitted to enter into the Union if the animals of the consignment:

- (a) have not been vaccinated against infection with Newcastle disease virus;
- (b) come from hatching eggs coming from flocks which comply with one of the following:
 - (i) they have not been vaccinated against infection with Newcastle disease virus;

or

- (ii) they have been vaccinated against infection with Newcastle disease virus using an inactivated vaccine;
 - or
 - (iii) they have been vaccinated against infection with Newcastle disease virus using a live vaccine at the latest 60 days prior to the date the eggs were collected;
- (c) come from a hatchery where working practices ensure that the eggs of day-old chicks intended for entry into the Union are incubated at completely separate times and locations from eggs not satisfying the requirements laid down in point (b).

SECTION 2

SPECIFIC ANIMAL HEALTH REQUIREMENTS FOR BREEDING AND PRODUCTIVE POULTRY

Article 43

Identification of breeding ratites and productive ratites

Consignments of breeding ratites and productive ratites shall only be permitted to enter into the Union if the animals of the consignment are individually identified by neck-tags or an injectable transponder:

- (a) with the code of the third country or territory of origin conforming with ISO Standard 3166 in the format of two-letter;
- (b) which comply with ISO standards 11784 and 11785.

Article 44

Specific animal health requirements for the flock of origin of consignments of breeding and productive poultry

Consignments of breeding poultry and productive poultry shall only be permitted to enter into the Union if the animals of the consignment originate from flocks which comply with the following requirements:

- (a) the flocks have not been vaccinated against highly pathogenic avian influenza;
 - (b) if the flocks have been vaccinated against infection with Newcastle disease virus:
 - (i) guarantees have been provided by the competent authorities of the third country or territory of origin that the vaccines used comply either with:
 - the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV,
 - or
 - the general criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV, and the poultry meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
 - (ii) the information set out in point 4 of Annex XV must be provided for the consignment;
- (c) the flocks have undergone a disease surveillance programme that meets the requirements set out in Annex II of Delegated Regulation (EU) 2019/2035, and were found not to be infected or showed any ground for suspecting any infection by the following agents:
- (i) *Salmonella Pullorum*, *Salmonella Gallinarum* and *Mycoplasma gallisepticum* in case of *Gallus gallus*;
 - (ii) *Salmonella arizonae* (serogroup O:18(k)), *Salmonella Pullorum*, *Salmonella Gallinarum*, *Mycoplasma meleagridis* and *Mycoplasma gallisepticum* in case of *Meleagris gallopavo*;

- (iii) *Salmonella Pullorum* and *Salmonella Gallinarum* in case of *Numida meleagris*, *Coturnix coturnix*, *Phasianus colchicus*, *Perdix perdix*, *Anas* spp.;
- (d) the flocks are kept in establishments which, in case of confirmation of infection with *Salmonella Pullorum*, *S. Gallinarum* and *S. arizonae* during the last 12 months prior to date of loading of the consignment for dispatch to the Union have applied the following measures:
 - (i) the infected flock has been slaughtered or it has been killed and destroyed;
 - (ii) following the slaughter or killing of the infected flock referred to in point (i), the establishment has been cleaned and disinfected;
 - (iii) following the cleaning and disinfection referred to in point (ii), all flocks on the establishment tested negative for infection with *Salmonella Pullorum*, *S. Gallinarum* and *S. arizonae* in two tests performed with an interval of at least 21 days in accordance with the disease surveillance programme referred to in point (c);
- (e) the flocks are kept in establishments which in case of confirmation of avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) during the last 12 months prior to date of loading of the consignment for dispatch to the Union have applied the following measures:

either

 - (i) the infected flock tested negative for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in two tests performed in accordance with the disease surveillance programme referred to in point (c) on the entire flock with an interval of at least 60 days;

or

 - (ii) the infected flock has been slaughtered or it has been killed and destroyed, the establishment has been cleaned and disinfected and following the cleaning and disinfection all flocks on the establishment tested negative for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in two tests performed with an interval of at least 21 days in accordance with the disease surveillance programme referred to in point (c).

SECTION 3

SPECIFIC ANIMAL HEALTH REQUIREMENTS FOR POULTRY INTENDED FOR SLAUGHTER

Article 45

Specific animal health requirements for the flock of origin of consignments of poultry intended for slaughter

Consignments of poultry intended for slaughter shall only be permitted to enter into the Union if the animals of the consignment originate from flocks which comply with the following requirements:

- (a) they have not been vaccinated against highly pathogenic avian influenza;
- (b) if they have been vaccinated against infection with Newcastle disease virus:
 - (i) guarantees have been provided by the competent authority of the third country or territory of origin that:
 - the vaccines used comply with the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV,
 - or
 - the vaccines used comply with the general criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the poultry meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
- (ii) the information set out in point 4 of Annex XV must be provided for each consignment.

SECTION 4

SPECIFIC ANIMAL HEALTH REQUIREMENTS FOR DAY-OLD CHICKS

Article 46

Specific animal health requirements for the flocks of origin of consignments of day-old chicks

Consignments of day-old chicks shall only be permitted to enter into the Union if the animals of the consignment originate from flocks which comply with the following requirements:

- (a) if the flocks have been vaccinated against highly pathogenic avian influenza, guarantees for compliance with the minimum requirements for vaccination programmes and additional surveillance set out in Annex XIII, have been provided by the third country or territory of origin;
- (b) if the flocks have been vaccinated against infection with Newcastle disease virus:
 - (i) guarantees have been provided by the competent authority of the third country or territory of origin that the vaccines used comply either with:
 - the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV,
 - or
 - the general criteria for recognised vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the poultry and hatching eggs from which the day-old chicks originated meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
 - (ii) the information set out in point 4 of Annex XV must be provided for each consignment;
- (c) the flocks have undergone a disease surveillance programme that meets the requirements set out in Annex II of Delegated Regulation (EU) 2019/2035 and were found not to be infected or showed any grounds for suspecting any infection by the following agents:
 - (i) *Salmonella Pullorum*, *Salmonella Gallinarum* and *Mycoplasma gallisepticum* in case of *Gallus gallus*;
 - (ii) *Salmonella arizonae* (serogroup O:18(k)), *Salmonella Pullorum*, *Salmonella Gallinarum*, *Mycoplasma meleagridis* and *Mycoplasma gallisepticum* in case of *Meleagris gallopavo*;
 - (iii) *Salmonella Pullorum* and *Salmonella Gallinarum* in case of *Numida meleagris*, *Coturnix coturnix*, *Phasianus colchicus*, *Perdix perdix*, *Anas* spp.;
- (d) the flocks are kept in establishments which, in case of confirmation of infection with *Salmonella Pullorum*, *S. Gallinarum* and *S. arizonae* during the last 12 months prior to date of loading of the consignment for dispatch to the Union have applied the following measures:
 - (i) the infected flock has been slaughtered or it has been killed and destroyed;
 - (ii) following the slaughter or killing of the infected flock referred to in point (i), the establishment has been cleaned and disinfected;
 - (iii) following the cleaning and disinfection referred to in point (ii), all flocks on the establishment tested negative for infection with *Salmonella Pullorum*, *S. Gallinarum* and *S. arizonae* in two tests performed with an interval of at least 21 days in accordance with the disease surveillance programme referred to in point (c);
- (e) the flocks are kept in establishments which in case of confirmation of avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) during the last 12 months prior to date of loading of the consignment for dispatch to the Union have applied the following measures:
 - either
 - (i) the infected flock tested negative for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in two tests performed in accordance with the disease surveillance programme referred to in point (c) on the entire flock with an interval of at least 60 days;
 - or

- (ii) the infected flock has been slaughtered or it has been killed and destroyed, the establishment has been cleaned and disinfected and following the cleaning and disinfection all flocks on the establishment tested negative for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in two tests performed with an interval of at least 21 days in accordance with the disease surveillance programme referred to in point (c).

Article 47

Specific animal health requirements for the hatching eggs of origin of consignments of day-old chicks

Consignments of day-old chicks shall only be permitted to enter into the Union if the animals of the consignment originate from hatching eggs which:

- (a) comply with the animal health requirements for entry into the Union laid down in Title 2 of Part III;
- (b) prior to being dispatched to the hatchery, the hatching eggs had been marked in accordance with the instruction of the competent authority;
- (c) had been disinfected in accordance with the instructions of the competent authority;
- (d) have had no contact with poultry or hatching eggs of a lower health status, captive birds or wild birds, either during transport to the hatchery or in the hatchery.

Article 48

Specific animal health requirements for the day-old chicks

Consignments of day-old chicks shall only be permitted to enter into the Union if the animals of the consignment have not been vaccinated against avian influenza.

SECTION 5

SPECIFIC ANIMAL HEALTH REQUIREMENTS FOR LESS THAN 20 HEADS OF POULTRY

Article 49

Derogation and specific requirements for consignments of less than 20 heads of poultry, other than ratites

By way of derogation from Article 14(3), Article 17, Article 18, Article 40 and Article 41 and Articles 43 to 48, consignments containing less than 20 heads of poultry other than ratites, shall be permitted to enter the Union provided that such consignments comply with the following requirements:

- (a) the poultry come from establishments where:
 - (i) no confirmed case of infection with low pathogenic avian influenza viruses has been reported during the period of at least 21 days prior to date of loading of the consignment for dispatch to the Union or the date of collection of the hatching eggs from which the day-old chicks were hatched;
 - (ii) within a 10 km radius of the establishment, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus for a period of at least 30 days prior to date of loading of the consignment for dispatch to the Union;
- (b) the poultry or, in the case of day-old chicks, the flock of origin of the day-old chicks, have been isolated on the establishment of origin for a period of at least 21 days prior to the date of loading of the consignment for dispatch to the Union;
- (c) as regards vaccination against highly pathogenic avian influenza:
 - (i) the poultry not been vaccinated against highly pathogenic avian influenza;
 - (ii) where the parent flocks of the day-old chicks have been vaccinated against highly pathogenic avian influenza, guarantees for compliance with the minimum requirements for vaccination programmes and additional surveillance set out in Annex XIII have been provided by the third country or territory of origin;

- (d) where the poultry or the parent flock of the day-old chicks have been vaccinated against infection with Newcastle disease virus:
 - (i) guarantees have been provided by the competent authority of the third country or territory of origin that the vaccines used comply either with:
 - the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV,
 - or
 - the general criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the poultry meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
 - (ii) the information set out in point 4 of Annex XV must be provided for each consignment;
- (e) the poultry or, in the case of day-old chicks the flock of origin of the day-old chicks, were found not to be infected or showed any grounds for suspecting any infection by the following agents in tests performed in accordance with the requirements for testing of consignments of less than 20 heads of poultry other than ratites and less than 20 hatching eggs thereof prior to the entry into the union, set out in Annex XVII:
 - (i) *Salmonella Pullorum*, *Salmonella Gallinarum* and *Mycoplasma gallisepticum* in case of *Gallus gallus*;
 - (ii) *Salmonella arizonae* (serogroup O:18(k)), *Salmonella Pullorum*, *Salmonella Gallinarum*, *Mycoplasma meleagridis* and *Mycoplasma gallisepticum* in case of *Meleagris gallopavo*;
 - (iii) *Salmonella Pullorum* and *Salmonella Gallinarum* in case of *Numida meleagris*, *Coturnix coturnix*, *Phasianus colchicus*, *Perdix perdix*, *Anas* spp.

SECTION 6

SPECIFIC ANIMAL HEALTH REQUIREMENTS FOR MOVEMENT AND HANDLING OF POULTRY AFTER THE ENTRY INTO THE UNION

Article 50

Obligations on operators at the establishment of destination following the entry into the Union of consignments of poultry

1. Operators at the establishment of destination shall keep breeding poultry, productive poultry, except productive poultry for restocking supplies of game birds, and day-old chicks which have entered into the Union from a third country or territory or zone thereof on the establishments of destination from their date of arrival for a continuous period of at least:
 - (a) 6 weeks;
 - or
 - (b) until the day of slaughter, when the animals are slaughtered within 6 weeks of the date of arrival.
2. In the case of poultry other than ratites, the 6-week period provided for in paragraph 1(a), may be reduced to 3 weeks, provided that, at the request of the operator, sampling and testing in accordance with Article 51(b) have been carried out with favourable results.
 3. Operators at the establishment of destination shall ensure that poultry referred to in paragraph 1, undergo a clinical inspection carried out by an official veterinarian on the establishment of destination no later than the date of expiry of the relevant periods provided for in that paragraph.
 4. During the periods provided for in paragraph 1, operators shall keep poultry which have entered into the Union from a third country or territory or zone thereof, separate from other flocks of poultry.

5. Where poultry referred to in paragraph 1 are placed in the same flock as other poultry present at the establishment of destination, the periods referred to in paragraph 1(a) and (b) shall commence from the date of introduction of the last bird on the establishment of destination and no poultry present shall be moved from the flock before the expiry of those periods.

Article 51

Obligation on the competent authorities as regards sampling and testing of consignments of poultry after entry into the Union

The competent authority of the Member State of destination shall ensure that:

- (a) during the periods provided for in Article 50(1), breeding poultry, productive poultry, except productive poultry for restocking supplies of game birds, and day-old chicks which have entered into the Union from a third country or territory or zone thereof, undergo a clinical inspection carried out by an official veterinarian on the establishment of destination no later than the date of expiry of the relevant periods provided for in that Article and, where necessary, sampled for testing to monitor their health status;
- (b) in the case of poultry other than ratites and when it is requested by the operator as referred to in Article 50(2), sampling and testing of poultry other than ratites is carried out in accordance with Annex XVIII.

Article 52

Obligation on the competent authorities as regards sampling and testing following the entry into the Union of consignments of ratites originating from a third country or territory or zone thereof not free from infection with Newcastle disease virus

The competent authority of the Member State of destination shall ensure that breeding ratites, productive ratites and day-old chicks of ratites that have entered into the Union from a third country or territory or zone thereof that is not free from infection with Newcastle disease virus, during the periods provided for in Article 50(1):

- (a) they are subject to a virus detection test for infection with Newcastle disease virus carried out by the competent authority on a cloacal swab or faeces sample from each ratite;
- (b) in the case of consignments of ratites destined for a Member State with status free from infection with Newcastle disease virus without vaccination from a third country or territory or zone thereof not free from infection with Newcastle disease virus, in addition to the requirements referred to in point (a), they are subject to a serological test for infection with Newcastle disease virus carried out by the competent authority on each ratite;
- (c) all ratites shall have tested negative to the tests provided for in points (a) and (b) prior to their release from isolation.

CHAPTER 2

Specific animal health requirements for captive birds

SECTION 1

ANIMAL HEALTH REQUIREMENTS FOR CAPTIVE BIRDS

Article 53

Requirements concerning the identification of captive birds

Consignments of captive birds shall only be permitted to enter the Union if the animals of the consignment are identified with an individual identification number by means of a unique marked closed leg-ring or an injectable transponder, which contains at least the following information:

- (a) the code of the third country or territory of origin conforming with ISO Standard 3166 in the format of two-letter;
- (b) a unique serial number.

*Article 54***Specific preventive measures for the containers in which captive birds are transported**

Consignments of captive birds shall only be permitted to enter the Union if such consignments have been transported in containers which, in addition to the requirements regarding containers laid down in Article 18, comply with the following requirements:

- (a) they are closed in accordance with the instructions of the competent authority of the third country or territory of origin in order to avoid the possibility of any substitution of the contents;
- (b) they bear the information for the particular species and category of birds set out in Annex XVI;
- (c) they are used for the first time.

*Article 55***Requirements concerning the establishment of origin of the consignment of captive birds**

Consignments of captive birds shall only be permitted to enter the Union if the animals of the consignment come from an establishment which complies with the following requirements:

- (a) it has been approved by the competent authority of the third country or territory of origin as meeting the specific animal requirements laid down in Article 56, and that approval has not been suspended or withdrawn;
- (b) it has been assigned a unique approval number by the competent authority of the third country or territory of origin, which has been communicated to the Commission;
- (c) the name and approval number of the establishment of origin appears on a list of establishments drawn up and published by the Commission;
- (d) within a 10 km radius of the establishment, including, where appropriate, the territory of any neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus for a period of at least the preceding 30 days prior to the date of loading for dispatch to the Union;
- (e) in the case of psittacidae, either:
 - (i) avian chlamydiosis has not been confirmed on the establishment for a period of at least the 60 days prior to the date of loading for dispatch to the Union and in case avian chlamydiosis has been confirmed on the establishment during the last 6 months prior to the date of loading for dispatch to the Union, the following measures have been applied:
 - infected birds and birds likely to be infected have received treatment,
 - following the completion of the treatment, they have been found negative to laboratory testing for avian chlamydiosis,
 - after the completion of the treatment, the establishment has been cleaned and disinfected,
 - at least 60 days have elapsed from the completion of the cleaning and disinfection referred to in the third indent;
 - or
 - (ii) the animals have been kept under veterinary supervision for the 45 days prior to the date of loading for dispatch to the Union and were treated against avian chlamydiosis.

*Article 56***Specific animal health requirements for the approval, maintenance of approval and suspension, withdrawal or re-granting of the approval of the establishments of origin of the consignment of captive birds**

1. Consignments of captive birds shall only be permitted to enter into the Union if the animals of the consignment come from establishments approved by the competent authority of the third country or territory of origin as referred to in Article 55, and that comply with the following requirements set out in Annex XIX:

- (a) point 1, in relation to biosecurity measures;

- (b) point 2, in relation to facilities and equipment;
- (c) point 3, in relation to record keeping;
- (d) point 4, in relation to personnel;
- (e) point 5, in relation to health status.

2. Consignments of captive birds shall only be permitted to enter into the Union if the animals of the consignment come from establishments which are under the control of an official veterinarian of the competent authority of the third country or territory, who shall:

- (a) ensure that the conditions set out in this Article are met;
- (b) visit the premises of the establishment at least once per year;
- (c) audit the activity of the veterinarian of the establishment and the implementation of the annual disease surveillance programme;
- (d) verify that the results of the clinical, post-mortem and laboratory tests on the animals have revealed no occurrence of highly pathogenic avian influenza, infection with Newcastle disease virus or avian chlamydiosis.

3. The approval of an establishment of captive birds shall be suspended or withdrawn where that establishment no longer complies with the conditions set out in paragraphs 1 and 2, or there has been a change of use so that it is no longer used exclusively for captive birds.

4. The approval of an establishment of captive birds shall be suspended when the competent authority of the third country or territory has received notification of the suspicion of highly pathogenic avian influenza, infection with Newcastle disease virus or avian chlamydiosis, and until the suspicion has been officially ruled out. Following the notification of suspicion, the necessary measures to confirm or rule out the suspicion and to avoid any spread of disease shall be taken, in accordance with the requirements of Delegated Regulation (EU) 2020/687.

5. When the approval of an establishment has been suspended or withdrawn, the establishment shall again be approved provided the following conditions are met:

- (a) the disease and the source of infection has been eradicated;
- (b) adequate cleaning and disinfection has been carried out on previously infected establishments;
- (c) the establishment fulfils the conditions laid down in paragraph 1.

6. Consignments of captive birds shall only be permitted to enter into the Union when the third country or territory of origin has undertaken to inform the Commission of the suspension, withdrawal or re-granting of approval of any establishment.

Article 57

Specific animal health requirements for the captive birds

Consignments of captive birds shall only be permitted to enter the Union if the animals of the consignment:

- (a) have not been vaccinated against highly pathogenic avian influenza;
- (b) have been vaccinated against infection with Newcastle disease virus and the competent authority of the third country or territory of origin has provided guarantees that the vaccines used comply with the general and specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV;
- (c) have been subjected to a virus detection test for highly pathogenic avian influenza and Newcastle disease with negative results, within a period of 7 to 14 days prior to the date of loading for dispatch to the Union.

*Article 58***Requirements concerning the entry of consignments of captive birds into Member States with status free from infection with Newcastle disease virus without vaccination**

Consignments of captive birds of galliformes species intended for a Member State with status free from infection with Newcastle disease virus without vaccination, shall only be permitted to enter the Union if the animals of the consignment:

- (a) have not be vaccinated against infection with Newcastle disease virus;
- (b) have been kept in isolation for a period of at least 14 days prior to the date of loading of the consignment for dispatch to the Union in the establishment of origin or quarantine establishment in the third country or territory of origin under the supervision of an official veterinarian, where:
 - (i) no bird has been vaccinated against infection with Newcastle disease virus during the period of 21 days preceding the date of dispatch of the consignment;
 - (ii) no bird which was not intended for the consignment has entered into the establishment during that time;
 - (iii) no vaccination has been carried out on the establishment;
- (c) have tested negative, during the period of 14 days prior to the date of loading for dispatch to the Union, to serological tests to detect the presence of antibodies against Newcastle disease virus, performed on blood samples at a level which gives 95 % confidence of detecting infection at 5 % prevalence.

SECTION 2

*SPECIFIC ANIMAL HEALTH REQUIREMENTS FOR MOVEMENT AND HANDLING OF CAPTIVE BIRDS AFTER THEIR ENTRY INTO THE UNION**Article 59***Requirements concerning the movement of captive birds after entry into the Union**

Following their entry into the Union, consignments of captive birds shall be transported without delay directly to a quarantine establishment approved in accordance with Article 14 of Delegated Regulation (EU) 2019/2035, as follows:

- (a) the total journey from the point of entry into the Union to the quarantine establishment must not exceed 9 hours;
- (b) vehicles used for the transport of the consignment to the quarantine establishment must be sealed by the competent authority in such a way that prevents the possibility of any substitution of the contents.

*Article 60***Obligation on operators at the quarantine establishment following the entry into the Union of consignments of captive birds**

Operators of the quarantine establishment for the captive birds referred to in Article 59 shall:

- (a) keep captive birds quarantined for a period of at least 30 days;
- (b) where sentinel birds are used for examination, sampling and testing procedures, ensure that:
 - (i) a minimum number of 10 sentinel birds are used in each unit of the quarantine establishment;
 - (ii) they are at least 3 weeks old and used only once for those purposes;
 - (iii) they are either leg-banded for identification purposes or identified with another non-removable means of identification;
 - (iv) they are unvaccinated and have been found sero-negative for highly pathogenic avian influenza and infection with Newcastle disease virus within a period of 14 days prior to the date of commencement of quarantine;
 - (v) they are placed in the approved quarantine establishment before the arrival of the captive birds in the common air space and as close as possible to the captive birds so that close contact between the sentinel birds and the excrements of the captive birds in quarantine is ensured;
 - (vi) release the captive birds from quarantine only on the written authorisation of an official veterinarian.

*Article 61***Obligation on the competent authorities following the entry into the Union of consignments of captive birds**

Following the arrival of the captive birds in the quarantine establishment referred to in Article 59, the competent authority shall:

- (a) inspect the conditions of quarantine, including an examination of the mortality records and a clinical inspection of the captive birds, at least at the beginning and the end of quarantine period;
- (b) subject the captive birds to testing for highly pathogenic avian influenza and infection with Newcastle disease virus, in accordance with the examination, sampling and testing procedures set out in Annex XX.

SECTION 3

*DEROGATIONS FROM THE ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF CAPTIVE BIRDS AND FOR MOVEMENT AND HANDLING OF THOSE BIRDS AFTER THEIR ENTRY INTO THE UNION**Article 62***Derogation from animal health requirements for captive birds originating from certain third countries or territories**

By way of derogation from requirements laid down in Articles 3 to 10 of Part I, except point (a)(i) of Article 3, Articles 11 to 19 and Articles 53 to 61, consignments of captive birds which do not comply with those requirements shall be permitted to enter the Union if they originate from third countries or territories specifically listed for the entry into the Union of captive birds based on equivalent guarantees.

TITLE 4

ANIMAL HEALTH REQUIREMENTS FOR HONEYBEES AND BUMBLE BEES

CHAPTER 1

General animal health requirements for honeybees and bumble bees*Article 63***Authorised categories of bees**

Only consignments of the following categories of bees shall be permitted to enter the Union:

- (a) queen honeybees;
- (b) bumble bees.

*Article 64***Dispatch to the Union of honeybees and bumble bees**

Consignments of queen honeybees and bumble bees shall only be permitted to enter the Union if they comply with the following requirements:

- (a) the packaging material and queen cages used to dispatch the honeybees and bumble bees into the Union must:
 - (i) be new;
 - (ii) not have been in contact with any bees and brood combs;
 - (iii) have been subject to all precautions to prevent their contamination with pathogens causing diseases of honeybees or bumble bees;
- (b) the feedingstuff accompanying the honeybees and bumble bees must be free from pathogens causing their diseases;
- (c) the packaging material and accompanying products must have undergone a visual examination prior to dispatch to the Union to ensure that they do not pose an animal health risk and do not contain:

- (i) in the case of honeybees, *Aethina tumida* (Small hive beetle) and *Tropilaelaps* mite in any of their life stages;
- (ii) in the case of bumble bees, *Aethina tumida* (Small hive beetle), in any of their life stages.

CHAPTER 2

Specific animal health requirements for queen honeybees

Article 65

The apiary of origin of queen honeybees

Consignments of queen honeybees shall only be permitted to enter the Union if the honeybees of the consignment originate from an apiary which is situated in an area:

- (a) of at least a 100 km radius, including where appropriate the territory of a neighbouring third country:
 - (i) where infestation with *Aethina tumida* (Small hive beetle) or infestation with *Tropilaelaps* spp. has not been reported;
 - (ii) there are no restrictions in place due to a suspicion, case or outbreak of the diseases referred to in (i);
- (b) of at least 3 km radius, including where appropriate the territory of a neighbouring third country:
 - (i) American foulbrood has not been reported for a period of at least 30 days prior to the date of loading for dispatch to the Union;
 - (ii) there are no restrictions in place due to a suspicion or a confirmed case of American foulbrood during the period referred to in point (i);
 - (iii) where there had been a previous confirmed case of American foulbrood before the period referred to in point (i), all hives were subsequently checked by the competent authority in the third country or territory of origin and all infected hives were treated and subsequently inspected with favourable results within a period of 30 days from the date of last recorded case of that disease.

Article 66

The hive of origin of queen honeybees

Consignments of queen honeybees shall only be permitted to enter the Union if the honeybees of the consignment originate from hives from which samples of the comb have been tested for American foulbrood with negative results within the period of 30 days prior to the date of loading for dispatch to the Union.

Article 67

The consignment of queen honeybees

Consignments of queen honeybees shall only be permitted to enter the Union if such consignments are in closed cages, each containing one single queen honeybee with a maximum of 20 accompanying attendants.

Article 68

Additional guarantees for queen honeybees destined to certain Member States or zone as regards the infestation with *Varroa* spp. (*Varroosis*)

Consignments of queen honeybees destined to a Member State or zone with disease-free status for infestation with *Varroa* spp. (*Varroosis*) shall only be permitted to enter the Union if such consignments comply with the following requirements:

- (a) the honeybees of the consignment must originate from a third country or territory or zone thereof free from infestation with infestation with *Varroa* spp. (*Varroosis*);
- (b) in the third country or territory of origin or zone thereof, infestation with *Varroa* spp. (*Varroosis*) has not been reported for a period of 30 days prior to the date of loading for dispatch to the Union;
- (c) every precaution has been taken to avoid contamination of the consignment with *Varroa* spp. during loading and dispatch to the Union.

CHAPTER 3

Specific animal health requirements for bumble bees

Article 69

The establishment of origin of bumble bees

Consignments of bumble bees shall only be permitted to enter the Union if the bumble bees of the consignment:

- (a) have been bred and kept in an environmentally isolated bumble bee production establishment which:
 - (i) has facilities which ensure that the production of bumble bees is carried out inside of a flying insect-proof building;
 - (ii) has facilities and equipment which ensure that the bumble bees are further isolated in separate epidemiological units and each colony in closed containers within the building throughout the whole production;
 - (iii) the storage and handling of pollen within the facilities is isolated from the bumble bees throughout the whole production of bumble bees until it is fed to them;
 - (iv) has standard operating procedures to prevent the entry of small hive beetle into the establishment and to regularly survey for the presence of small hive beetle within the establishment;
- (b) within the establishment referred to in point (a), the bumble bees must come from an epidemiological unit in which infestation with *Aethina tumida* (Small hive beetle) has not been detected.

Article 70

The consignment of bumble bees

Consignments of bumble bees shall only be permitted to enter the Union if such consignments have been dispatched to the Union in closed containers, each containing a colony of a maximum of 200 adult bumble bees, with or without a queen.

CHAPTER 4

Specific animal health requirements for handling after the entry of queen honeybees and bumble bees

Article 71

Handling after the entry of queen honeybees and bumble bees

1. Following their entry into the Union, queen honeybees must not be introduced in local colonies unless they are transferred from the transport cage to new cages in accordance with paragraph 2 with the permission and, as appropriate, under the direct supervision of the competent authority.
2. Following the transfer in new cages as referred to in paragraph 1, the transport cages, attendants, and other material that accompanied the queen honeybees from the third country of origin must be submitted to an official laboratory for examination to rule out the presence of *Aethina Tumida* (Small hive beetle), including eggs and larvae, and any signs of the *Tropilaelaps* mite.
3. Operators receiving bumble bees shall destroy the container and the packaging material that accompanied them from the third country or territory of origin but they may keep them in the container in which they entered into the Union until the end of the lifespan of the colony.

Article 72

Specific obligations for the competent authorities in the Member States

The competent authority of the Member State of the place of destination of consignments of honeybees or bumble bees shall:

- (a) supervise the transfer from the transport cage to the new cages referred to in Article 71(1);
- (b) ensure the submission by the operator of the materials referred to in Article 71(2);

- (c) ensure that the official laboratory referred to in Article 71(2) have arrangements in place to destroy the cages, attendants and the material after the laboratory examination provided for in that provision.

TITLE 5

ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF DOGS, CATS AND FERRETS

Article 73

Dispatch of the dogs, cats and ferrets to the Union

1. Consignments of dogs, cats and ferrets shall only be permitted to enter the Union if such consignments have been dispatched from their establishment of origin to the Union, without passing through any other establishment.
2. By way of derogation from paragraph 1, consignments of dogs, cats and ferrets coming from more than one establishment of origin may be permitted to enter the Union if the animals of the consignment have undergone a single assembly operation in the third country or territory of origin or zone thereof subject to compliance with the following conditions:
 - (a) the assembly operation took place in an establishment:
 - (i) approved for conducting assembly operations of dogs, cats and ferrets by the competent authority in the third country or territory in accordance with requirements at least as stringent as those laid down in Article 10 of Delegated Regulation (EU) 2019/2035;
 - (ii) which has a unique approval number assigned by the competent authority of the third country or territory;
 - (iii) listed for that purpose by the competent authority of the third country or territory of dispatch, including the information provided for in Article 21 of Delegated Regulation (EU) 2019/2035;
 - (iv) where the following records are kept up-to-date for a period of at least 3 years:
 - the origin of the animals,
 - the dates of arrival and dispatch to and from the assembly centre,
 - the identification code of the animals,
 - the registration number of the establishment of origin of the animals,
 - the registration number of the transporters and the means of transport delivering or collecting the consignment of dogs, cats and ferrets to and from that centre;
 - (b) the assembly operation in the assembly centre took no longer than 6 days; this period shall be considered as part of the timeframe for sampling for testing prior to dispatch to the Union, where such sampling is required by this Regulation;
 - (c) the animals must have arrived in the Union within a period of 10 days from the date of dispatch from the establishment of origin.

Article 74

Identification of dogs, cats and ferrets

1. Consignments of dogs, cats and ferrets shall only be permitted to enter the Union if the animals of the consignment have been individually identified by means of an injectable transponder implanted by a veterinarian which fulfils the technical requirements for means of identification of animals laid down in implementing acts adopted by the Commission pursuant Article 120 of Regulation (EU) 2016/429.
2. Where the implanted injectable transponder referred to in paragraph 1 does not fulfil the technical specifications referred to in that paragraph, the operator responsible for entry into the Union of the consignment shall provide the reading device which enables the verification of the individual identification of the animal at any time.

Article 75

The third country or territory of origin or zone thereof of dogs, cats and ferrets

Consignments of dogs, cats and ferrets shall only be permitted to enter the Union if the animals of the consignment originate from a third country or territory or zone thereof where rules on the prevention and control of infection with rabies virus are in force and implemented effectively to minimise the risk of infection of dogs, cats and ferrets, including rules on imports of those species from other third countries or territories.

Article 76

The dogs, cats and ferrets

1. Consignments of dogs, cats and ferrets shall only be permitted to enter the Union if the animals of the consignment comply with the following requirements:

- (a) they have received a vaccination against infection with rabies virus that complies with the following conditions:
 - (i) the animals must be at least 12 weeks old at the time of vaccination;
 - (ii) the vaccine must comply with the requirements set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council ⁽²¹⁾;
 - (iii) at the day of dispatch to the Union, at least 21 days must have elapsed since the completion of the primary vaccination against infection with rabies virus;
 - (iv) a certified copy of the vaccination details must be attached to the animal health certificate referred to in Article 3(1)(c)(i);
- (b) they must have undergone a valid rabies antibody titration test, in accordance with point 1 of Annex XXI.

2. By way of derogation of paragraph 1(b), dogs, cats and ferrets originating in third countries or territories or zones thereof included in the list set out in Commission Implementing Regulation (EU) No 577/2013 ⁽²²⁾ shall be permitted to enter the Union without being subjected to the rabies titration test.

3. Consignments of dogs shall be permitted to enter into a Member State with disease-free status for *Echinococcus multilocularis* or an approved eradication programme for infestation with that disease, if the animals of the consignment have been treated against this infestation in accordance with Part 2 of Annex XXI.

Article 77

Derogation for dogs, cats and ferrets intended for a confined or a quarantine establishment

By way of derogation from Article 76, consignments of dogs, cats and ferrets which do not comply with the requirements regarding vaccination against rabies and requirements regarding infestation with *Echinococcus multilocularis* shall be permitted to enter the Union provided that such consignments are intended for direct entry either to:

- (a) a confined establishment;
- or
- (b) an approved quarantine establishment in the Member State of destination.

⁽²¹⁾ Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

⁽²²⁾ Commission Implementing Regulation (EU) No 577/2013 of 28 June 2013 on the model identification documents for the non-commercial movement of dogs, cats and ferrets, the establishment of lists of territories and third countries and the format, layout and language requirements of the declarations attesting compliance with certain conditions provided for in Regulation (EU) No 576/2013 of the European Parliament and of the Council (OJ L 178, 28.6.2013, p. 109).

*Article 78***Moving and handling after the entry into the Union of dogs, cats and ferrets intended for a confined or a quarantine establishment**

1. Consignments of dogs, cats and ferrets intended to a confined establishment in the Union shall be maintained in the confined establishment of destination for a period of at least 60 days after the date of their entry into the Union.
2. Consignments of dogs, cats and ferrets intended for direct entry to an approved quarantine establishment as referred to in Article 77(b) shall be maintained in that establishment for a period of:
 - (a) not less than 6 months from the date of their arrival in the case of non-compliance with the requirements for vaccination against infection with rabies virus provided for in Article 76(1);or
 - (b) in the case of dogs not complying with the requirements for infestation with *Echinococcus multilocularis* provided for in Article 76(3), 24 hours following a treatment against infestation with *Echinococcus multilocularis* in accordance with point 2 of Annex XXI.

PART III

ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF GERMINAL PRODUCTS AS REFERRED TO IN ARTICLES 3 AND 5

TITLE 1

ANIMAL HEALTH REQUIREMENTS FOR GERMINAL PRODUCTS OF UNGULATES

CHAPTER 1

General animal health requirements for germinal products of ungulates*Article 79***The third country or territory of origin or zone thereof**

Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if they were collected from animals which come from third countries or territories which comply with the animal health requirements laid down in Article 22.

*Article 80***The residency period of donor animals**

Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if they were collected from animals which:

- (a) remained for a period of at least 6 months prior to the date of collection in a third country or territory or zone thereof which is listed for entry into the Union of the particular species and category of germinal product;
- (b) for a period of at least 30 days prior to the date of first collection of the germinal products and during the collection period:
 - (i) were kept on establishments not situated in a restricted zone established due to the occurrence in bovine, porcine, ovine, caprine and equine animals of a category A disease or of an emerging disease relevant for the bovine, porcine, ovine, caprine or equine animals;
 - (ii) were kept on a single establishment on which no category D diseases relevant for the bovine, porcine, ovine, caprine or equine animals were reported;

- (iii) were not in contact with animals from establishments, situated in a restricted zone referred to in (i) or from establishments referred to in (ii);
- (iv) were not used for natural breeding.

Article 81

Identification of donor animals

Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if they were collected from animals which were identified in accordance with Article 21.

Article 82

The germinal product establishments

1. Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if they were dispatched from approved germinal product establishments which are listed by competent authorities of listed third countries or territories or zones thereof.
2. Consignments of germinal products shall only be permitted to enter the Union from approved germinal product establishments referred to in paragraph 1 that comply with the following requirements set out in Annex I to Delegated Regulation (EU) 2020/686:
 - (a) Part 1 of that Annex, in respect of a semen collection centre;
 - (b) Part 2 of that Annex, in respect of an embryo collection team;
 - (c) Part 3 of that Annex, in respect of an embryo production team;
 - (d) Part 4 of that Annex, in respect of a germinal product processing establishment;
 - (e) Part 5 of that Annex, in respect of a germinal product storage centre.

Article 83

The germinal products

Consignments of semen, oocytes and embryos of animals of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if those germinal products comply with the following requirements:

- (a) they are marked in such a way that the following information can be readily established:
 - (i) the date of collection or production of those germinal products;
 - (ii) the species and identification of the donor animal(s);
 - (iii) the unique approval number, which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted;
 - (iv) any other relevant information;
- (b) they fulfil animal health requirements for the collection, production, processing and storage set out in Annex III to Delegated Regulation (EU) 2020/686.

Article 84

The transport of germinal products

1. Consignments of semen, oocytes and embryos of animals of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if:
 - (a) they were placed in a container which complies with the following requirements:
 - (i) it was sealed and numbered prior to the dispatch from the approved germinal product establishment under the responsibility of a centre or a team veterinarian, or by an official veterinarian;

- (ii) it was cleaned and either disinfected or sterilised before use, or is single-use container;
 - (iii) it was filled in with the cryogenic agent which was not previously used for other products;
 - (b) only one type of germinal products of one species was placed in the container referred to in point (a).
2. By the way of derogation from paragraph 1(b), operators may place in one container semen, oocytes and embryos of the same species provided that:
- (a) straws or other packages in which germinal products are placed are securely and hermetically sealed;
 - (b) the germinal products of different types are separated from each other by physical compartments or by being placed in secondary protective bags.
3. By way of derogation from paragraph 1(b), operators may place in one container semen, oocytes and embryos of ovine and caprine animals.

Article 85

Additional requirements for the transport of semen

Consignments of semen bovine, porcine, ovine and caprine animals which has been collected from more than one donor animal and placed in a single straw or another package for the purposes of entry into the Union shall only be permitted to enter the Union if:

- (a) that semen was collected and dispatched from a single semen collection centre where it was collected;
- (b) there were procedures in place as regards processing of that semen in order to ensure that it complies with the marking requirements of point (a) of Article 83.

CHAPTER 2

Specific animal health requirements for germinal products of bovine animals

Article 86

The establishment of origin of donor bovine animals

Consignments of semen, oocytes and embryos of bovine animals shall only be permitted to enter the Union if they were collected from animals which came from establishments that comply with the following requirements and those animals have never been kept previously in any establishment of a lower health status:

- (a) comply with the requirements of Article 23;
- (b) in the case of donor animals of semen prior to their admission to a quarantine accommodation, were free from the following diseases:
 - (i) infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*);
 - (ii) infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
 - (iii) enzootic bovine leukosis;
 - (iv) infectious bovine rhinotracheitis/infectious pustular vulvovaginitis.

Article 87

Derogations from the requirements for the establishment of origin of donor bovine animals

1. By the way of derogation from Article 86(b)(iii), consignments of semen of bovine animals shall be permitted to enter the Union if a donor animal comes from an establishment which is not free from enzootic bovine leukosis and:
- (a) is younger than 2 years of age and which has been produced by a dam which has been subjected, with negative results, to a serological test for enzootic bovine leukosis after removal of the animal from the dam;

or

(b) has reached the age of 2 years and has been subjected, with a negative result, to a serological test for enzootic bovine leukosis.

2. By the way of derogation from Article 86(b)(iii), consignments of oocytes and embryos of bovine animals shall be permitted to enter the Union if a donor animal comes from an establishment which is not free from enzootic bovine leukosis and is less than 2 years of age, and provided that the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of enzootic bovine leukosis during a period of at least the preceding 3 years.

3. By the way of derogation from Article 86(b)(iv), consignments of semen, oocytes and embryos of bovine animals shall be permitted to enter the Union if a donor animal comes from an establishment which is not free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, provided that:

- (a) in the case of semen, the animal has been subjected, with a negative result, to a test required in accordance with point 1(b)(iv) of Chapter I of Part 1 of Annex II to Delegated Regulation (EU) 2020/686;
- (b) in the case of oocytes or embryos, the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis during a period of at least the preceding 12 months.

Article 88

Specific animal health requirements for donor bovine animals

Consignments of semen, oocytes or embryos shall only be permitted to enter the Union if they were collected from donor bovine animals that comply with the animal health requirements laid down in Part 1 and Chapters I, II and III of Part 5 of Annex II to Delegated Regulation (EU) 2020/686.

CHAPTER 3

Specific animal health requirements for germinal products of porcine animals

Article 89

The establishment of origin of donor porcine animals

1. Consignments of semen, oocytes and embryos of porcine animals shall only be permitted to enter the Union if they were collected from animals which came from establishments:

- (a) which comply with the requirements laid down in Article 23;
- (b) in the case of donor animals of semen prior their admission to a quarantine accommodation, in which no clinical, serological, virological or pathological evidence of infection with Aujeszky's disease virus had been detected during the period of at least the preceding 12 months.

2. Consignments of semen of porcine animals shall only be permitted to enter the Union if they were collected from animals:

- (a) prior to their admission to a quarantine accommodation, which came from establishments which were free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* in accordance with requirements laid down in Chapter IV of Part 5 of Annex II to Delegated Regulation (EU) 2020/686;
- (b) which were kept at a quarantine accommodation which on the date of admission was free of infection with *Brucella abortus*, *B. melitensis* and *B. suis* for a period of at least the 3 months preceding that date;
- (c) which were kept in a semen collection centre in which no clinical, serological, virological or pathological evidence of infection with Aujeszky's disease virus was reported for the period of at least 30 days prior to the date of admission and of at least 30 days immediately prior to the date of collection;
- (d) which were kept, since birth or for at least 3 months prior to the date of entry into the quarantine accommodation, in an establishment in which no animals were vaccinated against infection with porcine reproductive and respiratory syndrome virus and no infection with porcine reproductive and respiratory syndrome virus was detected within that period.

*Article 90***Specific animal health requirements for donor porcine animals**

Consignments of semen, oocytes or embryos shall only be permitted to enter the Union if they were collected from donor porcine animals that:

- (a) comply with the specific animal health requirements laid down in Part 2 and Chapters I, II, III and IV of Part 5 of Annex II to Delegated Regulation (EU) 2020/686;
- (b) were not vaccinated against infection with porcine reproductive and respiratory syndrome virus.

*CHAPTER 4****Specific animal health requirements for germinal products of ovine and caprine animals****Article 91***The establishment of origin of donor ovine and caprine animals**

Consignments of semen, oocytes and embryos of ovine and caprine animals shall only be permitted to enter the Union if they were collected from donor animals which:

- (a) did not come from an establishment, nor been in contact with animals from an establishment, in the case of a kept donor animal of semen prior to its admission to a quarantine accommodation, which has been subjected to movement restrictions as regards infection with *Brucella abortus*, *B. melitensis* and *B. suis*. The movement restrictions concerning the establishment are lifted after the period comprising at least 42 days from the date of the slaughter and the disposal of the last animal infected or susceptible to that disease;
- (b) come from an establishment, that was free from infection with *B. abortus*, *B. melitensis* and *B. suis* and has never been kept previously in any establishment of a lower status.

*Article 92***Specific animal health requirements for donor ovine and caprine animals**

Consignments of semen, oocytes or embryos of ovine and caprine animal shall only be permitted to enter the Union if they were collected from donor animals that fulfil specific animal health requirements laid down in Part 3 and Chapters I, II and III of Part 5 of Annex II to Delegated Regulation (EU) 2020/686.

*CHAPTER 5****Specific animal health requirements for germinal products of equine animals****Article 93***The establishment of origin of donor equine animals**

Consignments of semen, oocytes and embryos of equine animals shall only be permitted to enter the Union if they were collected from donor animals which come from establishments which comply with the requirements laid down in Article 23.

*Article 94***Specific animal health requirements for donor equine animals**

Consignments of semen, oocytes or embryos of equine animals shall only be permitted to enter the Union if the donor animals of those germinal products comply with the requirements laid down Article 24(1)(a)(ii) and (b)(ii) and Article 24(6) of this Regulation, and the additional specific animal health requirements laid down in Part 4 of Annex II to Delegated Regulation (EU) 2020/686.

CHAPTER 6

Special rules for germinal products of ungulates intended for confined establishments*Article 95***Germinal products intended for confined establishments in the Union**

Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals dispatched from confined establishments in third countries or territories listed in accordance with Article 29 shall only be permitted to enter the Union if they are dispatched to a confined establishment in the Union subject to compliance with the following requirements:

- (a) an assessment was carried out by the competent authority of the Member State of destination of the risks associated with the entry into the Union of those germinal products;
- (b) the donor animals of those germinal products originate from a confined establishment in the third country or territory of origin or zone thereof, which is included in a list established in accordance with Article 29 of confined establishments from which the entry of ungulates into the Union may be authorised;
- (c) the germinal products are destined to a confined establishment in the Union, which is approved in accordance with Article 95 of Regulation (EU) 2016/429;
- (d) the germinal products are transported directly to the confined establishment referred to in point (c).

*Article 96***Specific animal health requirements for donor animals kept in confined establishment**

Consignments of the germinal products referred to in Article 95 shall be only permitted to enter the Union if they were collected from donor animals that comply with the following requirements:

- (a) the donor animals did not come from an establishment, nor been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for the bovine, porcine, ovine, caprine or equine animals;
- (b) the donor animals come from an establishment where none of the category D diseases relevant for bovine, porcine, ovine, caprine or equine animals have been reported for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;
- (c) the donor animals remained in a single confined establishment of origin for a period of at least 30 days prior to the date of collection of semen, oocytes or embryos intended for entry into the Union and during the period of that collection;
- (d) the donor animals were clinically examined by the establishment veterinarian responsible for the activities carried out at confined establishment, and showed no disease symptoms on the day the semen, oocytes or embryos were collected;
- (e) as much as possible, the donor animals were not used for natural breeding during a period of at least 30 days prior to the date of first collection of semen, oocytes or embryos intended for entry into the Union and during the period of that collection;
- (f) the donor animals are identified in accordance with Article 21.

*Article 97***The requirements for germinal products obtained in confined establishments**

Consignments of germinal products referred to in Article 95 shall only be permitted to enter the Union if they are:

- (a) marked in accordance with the information requirements provided for in point (a) of Article 83;
- (b) transported in accordance with Articles 84 and 85.

TITLE 2

ANIMAL HEALTH REQUIREMENTS FOR HATCHING EGGS OF POULTRY AND CAPTIVE BIRDS

CHAPTER 1

Animal health requirements for hatching eggs

Article 98

The residency period

Consignments of hatching eggs shall only be permitted to enter the Union if, immediately prior to the date of loading of the hatching eggs for dispatch to the Union the flock of origin of the hatching eggs has complied, for a continuous period of time, with the residency periods requirements set out in Annex XXII, and during that time the flock of origin has:

- (a) remained in the third country or territory of origin or zone thereof;
- (b) remained in the establishment of origin, and no animals have been introduced into that establishment during that period of time prior to loading;
- (c) had no contact with poultry or hatching eggs of a lower health status, or with captive birds or wild birds.

Article 99

Handling of hatching eggs during transport to the Union

Consignments of hatching eggs shall only be permitted to enter the Union if the germinal products of the consignment comply with the following requirements:

- (a) the hatching eggs intended for entry into the Union must not have come into contact with poultry, captive birds or hatching eggs not intended for entry into the Union or of a lower health status from the time of loading at the establishment of origin for dispatch to the Union until the time of arrival in the Union;
- (b) the hatching eggs must not have been transported, unloaded in, or moved to another means of transport when transported by road, by sea or by air through a third country or territory or zone thereof which is not listed for entry of the particular species and category of hatching eggs into the Union.

Article 100

Derogation and additional requirements for transshipment of hatching eggs in case of an incident in the means of transport by waterway or by air

By way of derogation from point (b) of Article 99, consignments of hatching eggs which have been transhipped from the means of transport of dispatch into another means of transport for onward travel in a third country or territory or zone thereof which is not listed for entry of hatching eggs into the Union, shall only be permitted to enter the Union if the transshipment took place because of the occurrence of a technical problem or another unforeseen incident causing logistic problems during the transport of the hatching eggs to the Union by sea or by air, in order to complete the transport to the point of entry into Union, and provided that:

- (a) the entry into the Union of the hatching eggs is authorised by the competent authority of the Member State of destination and, where applicable, the Member States of passage until their arrival at their place of destination in the Union;
- (b) the transshipment was supervised by an official veterinarian or the responsible customs officer and throughout the operation:
 - (i) effective measures were put in place to avoid any direct or indirect contact between the hatching eggs intended for entry into the Union and any other hatching eggs or animals;
 - (ii) the hatching eggs were transferred directly and as quick as possible to the vessel or aircraft to be used for onward travel to the Union, which complies with requirements laid down in Article 17, without leaving the premises of the port or airport;

- (c) the hatching eggs are accompanied by a declaration from the competent authority of the third country or territory where the transfer took place, providing the necessary information on the transfer operation and attesting that the relevant measures were put in place to comply with the requirements laid down in point (b).

Article 101

Transport by vessel of hatching eggs

1. Consignments of hatching eggs transported by ship, even for part of the journey, shall only be permitted to enter the Union if the germinal products of the consignment comply with the following requirements:

- (a) hatching eggs:
 - (i) have remained on board the vessel during the whole transport;
 - (ii) have not been in contact with birds or other hatching eggs of a lower health status while on board the vessel;
- (b) hatching eggs transported in accordance with point (a) must be accompanied by a declaration, providing the following information:
 - (i) the port of departure in the third country or territory of origin or zone thereof;
 - (ii) the port of arrival in the Union;
 - (iii) where the vessel called at ports outside the third country or territory of origin or zone thereof of the consignment, indicating the ports of call;
 - (iv) that the hatching eggs complied during the transport with the requirements set out in point (a) and (i), (ii) and (iii) of this point.

2. The operator responsible for the consignment of hatching eggs shall ensure that the declaration provided for in paragraph 1, is attached to the animal health certificate and signed by the master of the vessel at the port of arrival on the day of arrival of the vessel.

Article 102

Preventive measures for the means of transport and the containers of hatching eggs

Consignments of hatching eggs shall only be permitted to enter the Union if the germinal products of the consignment comply with the following requirements:

- (a) the hatching eggs must have been transported in vehicles which:
 - (i) are constructed in such a way that hatching eggs cannot fall out;
 - (ii) have been designed to allow cleaning and disinfection;
 - (iii) have been cleaned and disinfected with a disinfectant authorised by the competent authority of the third country or territory of origin, and dried or allowed to dry immediately before every loading of hatching eggs intended for entry into the Union;
 - (b) the hatching eggs must have been transported in containers which comply with the following requirements:
 - (i) the requirements of point (a);
 - (ii) they contain only hatching eggs of the same species, category and type which come from the same establishment;
 - (iii) they were closed in accordance with the instructions of the competent authority of the third country or territory of origin to avoid any possibility of substitution of the content;
 - (iv) they were:
 - cleaned and disinfected before loading in accordance with the instructions of the competent authority of the third country or territory of origin,
- or

- they are disposable, clean and used for the first time;
- (v) they bear the information for the particular species and category of hatching eggs set out in Annex XVI.

Article 103

Movement and handling of hatching eggs after the entry

Following their entry into the Union, operators, including transporters, shall ensure that consignments of hatching eggs are:

- (a) transported directly from the point of entry to their place of destination in the Union;
- (b) comply with the requirements for movement within the Union and handling following their entry into the Union as laid down for the particular species and category of hatching eggs in Chapters 5 and 7 of this Title.

CHAPTER 2

Specific animal health requirements for hatching eggs of poultry

Article 104

Hatching eggs originating from poultry imported into the third country or territory of origin or zone thereof

Consignments of hatching eggs of poultry, which originate from flocks which were imported into the third country, or territory of origin or zone thereof from another third country or territory or zone thereof, shall only be permitted to enter the Union if the competent authority of the third country or territory of origin of the hatching eggs has provided guarantees that:

- (a) the flocks of origin of the hatching eggs were imported from a third country or territory or zone thereof, which is listed for entry into Union of such flocks;
- (b) the import of the flocks of origin of the hatching eggs into that third country or territory or zone thereof took place in accordance with animal health requirements that are at least as stringent as if they were directly entered into the Union.

Article 105

The third country or territory of origin or zone thereof of the hatching eggs

Consignments of hatching eggs of poultry shall only be permitted to enter the Union if they originate from a third country or territory or zone thereof which complies with the following requirements:

- (a) it has a disease surveillance programme for highly pathogenic avian influenza in place for a period of at least 6 months prior to the date of dispatch of the consignment to the Union and that surveillance programme complies with the requirements laid down in either:
 - (i) Annex II to this Regulation;or
 - (ii) the relevant Chapter of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE);
- (b) which is considered to be free from highly pathogenic avian influenza in accordance with Article 38;
- (c) if it carries out vaccination against highly pathogenic avian influenza, the competent authority of the third country or territory of origin has provided guarantees that:
 - (i) the vaccination programme complies with the requirements set out in Annex XIII;
 - (ii) the surveillance programme referred to in point (a) of this Article, in addition to the requirements set out in Annex II, complies with the requirements set out in point 2 of Annex XIII;
 - (iii) it has undertaken to inform the Commission of any change to the vaccination programme in the third country or territory or zone thereof;

- (d) which:
- (i) in the case of hatching eggs of poultry other than ratites, is considered to be free from infection with Newcastle disease virus in accordance with Article 39;
 - (ii) in the case of hatching eggs of ratites:
 - it is considered to be free from infection with Newcastle disease virus in accordance with Article 39,
 - or
 - it is not considered to be free from infection with Newcastle disease virus in accordance with Article 39, but the competent authority of the third country or territory of origin has provided guarantees regarding compliance with the requirements for infection with Newcastle disease virus in relation to isolation, surveillance and testing, as set out in Annex XIV;
- (e) if vaccination against infection with Newcastle disease virus is carried out, the competent authority of the third country or territory has provided guarantees that:
- (i) the vaccines used comply with the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV;
 - or
 - (ii) the vaccines used comply with the general criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the poultry meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
- (f) it has undertaken that following any outbreak of highly pathogenic avian influenza or an outbreak of infection with Newcastle disease virus, to submit the following information to the Commission:
- (i) information on the disease situation within 24 hours of confirmation of any initial outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus;
 - (ii) regular updates of the disease situation;
- (g) which has undertaken to submit virus isolates from initial outbreaks of highly pathogenic avian influenza or infection with Newcastle disease virus to the European Union Reference Laboratory for Avian Influenza and Newcastle disease.

Article 106

The establishment of origin of the hatching eggs

Consignments of hatching eggs of poultry shall only be permitted to enter the Union if they originate from:

- (a) hatcheries approved by the competent authority of the third country or territory of origin in accordance with requirements which are at least as stringent as those laid down in Article 7 of Delegated Regulation (EU) 2019/2035; and
 - (i) the approval of which has not been suspended or withdrawn;
 - (ii) within a 10 km radius of those hatcheries, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus for a period of at least 30 days prior to the time of loading of the hatching eggs for dispatch to the Union;
 - (iii) which have been assigned a unique approval number by the competent authority of the third country or territory of origin;
- (b) flocks which have been kept in establishments approved by the competent authority of the third country or territory of origin in accordance with requirements which are at least equivalent to those laid down in Article 8 of Delegated Regulation (EU) 2019/2035 and
 - (i) the approval of which has not been suspended or withdrawn;
 - (ii) within a 10 km radius of those establishments, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus for a period of at least 30 days prior to the date of collection of the hatching eggs for dispatch to the Union;

- (iii) no confirmed case of infection with low pathogenic avian influenza viruses has been reported in those establishments within a period of at least 21 days prior to the date of collection of the eggs for dispatch to the Union.

Article 107

The flock of origin of the hatching eggs

Consignments of hatching eggs of poultry shall only be permitted to enter the Union if they originate from flocks which comply with the following requirements:

- (a) where they have been vaccinated against highly pathogenic avian influenza, guarantees for compliance with the minimum requirements for vaccination programmes and additional surveillance set out in Annex XIII, have been provided by the third country or territory of origin;
- (b) where they have been vaccinated against infection with Newcastle disease virus:
 - (i) guarantees have been provided by the competent authority of the third country or territory of origin that the vaccines used comply with:
 - the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV, or
 - the general criteria for recognised vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the poultry and hatching eggs from which the day-old chicks originated meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
 - (ii) the information set out in point 4 of Annex XV must be provided for each consignment;
- (c) they have undergone a disease surveillance programme that meets the requirement set out Annex II of Delegated Regulation (EU) 2019/2035 and were found not to be infected or showed any grounds for suspecting any infection by the following agents:
 - (i) *Salmonella* Pullorum, *Salmonella* Gallinarum and *Mycoplasma gallisepticum* in case of *Gallus gallus*;
 - (ii) *Salmonella arizonae* (serogroup O:18(k)), *Salmonella* Pullorum, *Salmonella* Gallinarum, *Mycoplasma meleagridis* and *Mycoplasma gallisepticum* in case of *Meleagris gallopavo*;
 - (iii) *Salmonella* Pullorum and *Salmonella* Gallinarum in case of *Numida meleagris*, *Coturnix coturnix*, *Phasianus colchicus*, *Perdix perdix*, *Anas* spp.;
- (d) they were kept in establishments which, in case of confirmation of infection with *Salmonella* Pullorum, *S. Gallinarum* and *S. arizonae* during the last 12 months prior to date of collection of the eggs for dispatch to the Union have applied the following measures:
 - (i) the infected flock has been slaughtered or it has been killed and destroyed;
 - (ii) following the slaughter or killing of the infected flock referred to in point (i), the establishment has been cleaned and disinfected;
 - (iii) following the cleaning and disinfection referred to in point (ii), all flocks on the establishment tested negative for infection with *Salmonella* Pullorum, *S. Gallinarum* and *S. arizonae* in two tests performed with an interval of at least 21 days in accordance with the disease surveillance programme referred to in point (c);
- (e) they were kept in establishments which in case of confirmation of avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) during the last 12 months prior to date of collection of the eggs for dispatch to the Union have applied the following measures:
 - either
 - (i) the infected flock tested negative for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in two tests performed in accordance with the disease surveillance programme referred to in point (c) on the entire flock with an interval of at least 60 days;
 - or

- (ii) the infected flock has been slaughtered or it has been killed and destroyed, the establishment has been cleaned and disinfected and following the cleaning and disinfection all flocks on the establishment tested negative for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in two tests performed with an interval of at least 21 days in accordance with the disease surveillance programme referred to in point (c);
- (f) they have been subjected to a clinical inspection, carried out by an official veterinarian in the third country or territory of origin or zone thereof, within a period of 24 hours prior to the time of loading of the consignment of hatching eggs for dispatch to the Union for the purpose of the detection of signs indicative of the occurrence of diseases, including the relevant listed diseases referred to in Annex I and emerging diseases and they showed no disease symptoms or grounds for suspecting the presence of any of those diseases.

Article 108

The hatching eggs of the consignment

Consignments of hatching eggs of poultry shall only be permitted to enter the Union if they comply with the following requirements:

- (a) if the hatching eggs have been vaccinated against highly pathogenic avian influenza, guarantees for compliance with the minimum requirements for vaccination programmes and additional surveillance set out in Annex XIII, have been provided by the third country or territory of origin;
- (b) if the hatching eggs have been vaccinated against infection with Newcastle disease virus:
 - (i) guarantees have been provided by the competent authority of the third country or territory of origin that the vaccines used comply with the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV;
 - (ii) the information set out in point 4 of Annex XV must be provided for the consignment;
- (c) the hatching eggs must be marked:
 - (i) using colour ink;
 - (ii) in the case of hatching eggs of poultry other than ratites, with a stamp indicating the unique approval number of the establishment of origin referred to in Article 106;
 - (iii) in the case of hatching eggs of ratites, with a stamp indicating the ISO code of the third country or territory of origin and the unique approval number of the establishment of origin referred to in Article 106;
- (d) the hatching eggs must have been disinfected in accordance with the instructions of the competent authority of the third country or territory of origin.

Article 109

Entry of hatching eggs into Member States with status free from infection with Newcastle disease virus without vaccination

Consignments of hatching eggs intended for a Member State with status free from infection with Newcastle disease virus without vaccination, shall only be permitted to enter the Union if they:

- (a) are not vaccinated against infection with Newcastle disease virus;
- (b) originate from flocks which comply with the requirements set out in one of the following points:
 - (i) they have not been vaccinated against infection with Newcastle disease virus;
 - or
 - (ii) they have been vaccinated against infection with Newcastle disease virus using an inactivated vaccine;
 - or
 - (iii) they have been vaccinated against infection with Newcastle disease virus using a live vaccine at the latest within the period of 60 days prior to the date of collection of the eggs.

CHAPTER 3

Specific animal health requirements for consignments of less than 20 hatching eggs of poultry other than ratites

Article 110

Derogations and special requirements for consignments of less than 20 hatching eggs of poultry other than ratites

By way of derogation from Articles 101, 102, 106, 107 and 108, consignments of less than 20 hatching eggs of poultry other than ratites shall be permitted to enter the Union if they comply with the following requirements:

- (a) they come from establishments:
 - (i) registered by the competent authority of the third country or territory of origin;
 - (ii) where no confirmed case of infection with low pathogenic avian influenza viruses was reported within the period of 21 days prior to the date of collection of the hatching eggs;
 - (iii) within a 10 km radius of the establishments, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus for a period of at least 30 days prior to the date of collection of the hatching eggs;
- (b) in relation to vaccination against highly pathogenic avian influenza:
 - (i) the hatching eggs have not been vaccinated against highly pathogenic avian influenza;
 - (ii) where the flocks of origin have been vaccinated against highly pathogenic avian influenza, guarantees for compliance with the minimum requirements for vaccination programmes and additional surveillance set out in Annex XIII, have been provided by the third country or territory of origin;
- (c) in relation to vaccination against Newcastle disease virus, the hatching eggs have not been vaccinated against Newcastle disease virus and where the flock of origin has been vaccinated against infection with Newcastle disease virus:
 - (i) guarantees have been provided by the competent authority of the third country or territory of origin that the vaccines used comply either with:
 - the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV,or
 - the general criteria for recognised vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the hatching eggs meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
 - (ii) the information set out in point 4 of Annex XV must be provided for the consignment;
- (d) they come from flocks which have been subjected to a clinical inspection, carried out by an official veterinarian in the third country or territory or origin or zone thereof, within 24 hours prior to the time of loading of the consignments of hatching eggs for dispatch to the Union for the purpose of the detection of signs indicative of the occurrence of diseases, including the relevant listed diseases referred to in Annex I and emerging diseases and the flocks showed no disease symptoms or grounds for suspecting the presence of any of those diseases;
- (e) they come from flocks which:
 - (i) have been isolated on the establishment of origin for a period of at least 21 days prior to the collection of the eggs;
 - (ii) were found not to be infected or showed any grounds for suspecting any infection by the following agents, in tests performed in accordance with the requirements for testing of consignments of less than 20 heads of poultry other than ratites and less than 20 hatching eggs thereof prior to the entry into the Union, set out in Annex XVII:
 - *Salmonella Pullorum*, *Salmonella Gallinarum* and *Mycoplasma gallisepticum* in case of *Gallus gallus*,
 - *Salmonella arizonae* (serogroup O:18(k)), *Salmonella Pullorum*, *Salmonella Gallinarum*, *Mycoplasma meleagridis* and *Mycoplasma gallisepticum* in case of *Meleagris gallopavo*,

- *Salmonella Pullorum* and *Salmonella Gallinarum* in case of *Numida meleagris*, *Coturnix coturnix*, *Phasianus colchicus*, *Perdix perdix*, *Anas* spp.

CHAPTER 4

Specific animal health requirements for specified pathogen-free eggs

Article 111

Derogation and special requirements for specified pathogen-free eggs

By way of derogation from the residency period requirements of Article 98, the specific animal health requirements of Articles 105 to 110 and Articles 112 to 114, consignments of specified pathogen-free eggs which do not comply with the animal health requirements laid down in those provisions, shall be permitted to enter the Union if they comply instead with the following animal health requirements:

- (a) they originate from flocks which:
 - (i) are free from specified pathogens as described in the European Pharmacopoeia and the results of all tests and clinical examinations required for this specific status have been favourable, including negative testing results for highly pathogenic avian influenza, infection with Newcastle disease virus and infection with low pathogenic avian influenza viruses carried out within the period of 30 days prior to the date of collection of the eggs for dispatch to the Union;
 - (ii) have been clinically examined at least once a week as described in the European Pharmacopoeia and no disease symptoms or ground for suspecting the presence of any disease were detected;
 - (iii) have been kept for a period of at least 6 weeks prior to the date of collection of the eggs for dispatch to the Union in establishments which comply with the conditions described in the European Pharmacopoeia;
 - (iv) have had no contact with poultry not meeting the requirements of this Article or with wild birds for a period of at least 6 weeks prior to the date of collection of the eggs for dispatch to the Union;
- (b) they have been marked using colour ink with a stamp bearing the ISO code of the third country or territory of origin and the unique approval number of the establishment of origin;
- (c) they have been disinfected in accordance with the instructions of the competent authority of the third country or territory of origin.

CHAPTER 5

Specific animal health requirements for movement and handling of hatching eggs of poultry after entry into the Union and of poultry hatched from those eggs

Article 112

Obligations on operators as regards handling of hatching eggs following their entry into the Union and of poultry hatched from those hatching eggs

1. Operators at the establishment of destination shall place hatching eggs of poultry which have entered into the Union from a third country or territory or zone thereof either in:
 - (a) separate incubators, including separate hatchers, from other hatching eggs;or
 - (b) incubators, including hatchers, where other hatching eggs are already present.
2. Operators, as referred to in paragraph 1, shall ensure that breeding poultry and productive poultry which have been hatched from hatching eggs referred to in that paragraph, are kept for a continuous period of time:
 - (a) in the hatchery for a period of at least 3 weeks from the date of hatching;or

- (b) on the establishments to which the poultry has been sent after hatching, either in the same Member State or in another Member State, for a period of at least 3 weeks from the date of hatching.
- 3. During the periods provided for in paragraph 2, operators shall keep poultry, which have been hatched from hatching eggs that have entered into the Union, separate from other flocks of poultry.
- 4. Where breeding poultry and productive poultry, which have been hatched from hatching eggs that have entered into the Union from a third country or territory or zone thereof, were introduced into premises or enclosures where other poultry are present, the relevant periods provided for in paragraph 2 shall commence from the date of introduction of the last bird and no poultry shall be moved from the premises or enclosures before the end of those periods.
- 5. Where hatching eggs of poultry, which have entered into the Union from a third country or territory or zone thereof, were introduced in incubators, including hatchers, where other hatching eggs were already present:
 - (a) the provisions of paragraphs 2 to 4 shall apply to all poultry hatched from the hatching eggs in the same incubator, including hatcher, as the hatching eggs which have entered into the Union from a third country or territory or zone thereof;
 - (b) the relevant periods referred to in paragraph 2 shall commence from the date of hatching of the last hatching egg that has entered into the Union from a third country or territory or zone thereof.

Article 113

Sampling and testing following the entry into the Union

The competent authority of the Member State of destination shall ensure that breeding poultry and productive poultry which have been hatched from hatching eggs that have entered into the Union from a third country or territory or zone thereof undergo a clinical examination carried out by an official veterinarian on the establishment of destination no later than the date of expiry of the relevant periods as provided for Article 112(2), and, where necessary, shall be sampled for testing to monitor their state of health.

Article 114

Obligation on the competent authorities as regards sampling and testing of ratites from hatching eggs originating from a third country or territory or zone thereof not free from infection with Newcastle disease virus

The competent authority of the Member State of destination shall ensure that ratites which have hatched from hatching eggs that have entered into the Union from a third country or territory or zone thereof that is not free from infection with Newcastle disease virus, during the periods provided for in Article 112(2):

- (a) they undergo a virus detection test for infection with Newcastle disease virus carried out by the competent authority on a cloacal swab or faeces sample from each ratite;
- (b) in the case of ratites destined for a Member State with status free from infection with Newcastle disease virus without vaccination, in addition to the requirements referred to in point (a), they are subjected to a serological test for infection with Newcastle disease virus carried out by the competent authority on each ratite;
- (c) all ratites shall have tested negative to the tests provided for in points (a) and (b) prior to their release from isolation.

CHAPTER 6

Specific animal health requirements for hatching eggs of captive birds

Article 115

The hatching eggs of the consignment

Consignments of hatching eggs of captive birds shall only be permitted to enter the Union if they were obtained from captive birds which comply with the requirements for entry into the Union set out in Articles 55 to 58.

CHAPTER 7

Specific animal health requirements for movement and handling of hatching eggs of captive birds after entry into the Union and of captive birds hatched from those eggs

Article 116

Handling of hatching eggs of captive birds following their entry into the Union and of captive birds hatched from those hatching eggs

Operators at the establishment of destination shall:

- (a) place the hatching eggs of captive birds which have entered into the Union from a third country or territory or zone thereof in separate incubators, including hatchers, from other hatching eggs;
- (b) ensure that captive birds which are hatched from the hatching eggs of captive birds referred to in Article 115 are kept in an approved quarantine establishment in accordance with the requirements of Articles 59 to 61.

TITLE 3

ANIMAL HEALTH REQUIREMENTS FOR GERMINAL PRODUCTS OF ANIMALS OTHER THAN UNGULATES AND OTHER THAN HATCHING EGGS OF POULTRY AND CAPTIVE BIRDS INTENDED FOR CONFINED ESTABLISHMENTS

Article 117

Requirements for entry into the Union of consignments of germinal products of animals other than those referred to in point (a) and (b) of Article 1(4) dispatched from confined establishments

Consignments of semen, oocytes and embryos of animals other than those referred to in point (a) and (b) of Article 1(4) dispatched from confined establishments listed in accordance with Article 29 shall only be permitted to enter the Union if they are dispatched to a confined establishment located in the Union and provided that:

- (a) an assessment has been carried out by the competent authority of the Member State of destination of the risks that the entry of those germinal products may present for the Union;
- (b) the donor animals of those germinal products originate from a third country, territory or zone authorised for entry into the Union of the particular species and category of animals;
- (c) the donor animals of those germinal products originate from a confined establishment in the third country, territory or zone of origin, which is included in a list established in accordance with Article 29 of confined establishments from which the entry of animals of specific species into the Union may be authorised;
- (d) the germinal products are destined to a confined establishment in the Union, which is approved in accordance with Article 95 of Regulation (EU) 2016/429;
- (e) the germinal products are transported directly to the confined establishment referred to in point (d).

Article 118

Specific animal health requirements for donor animals

Consignments of semen, oocytes and embryos referred to in Article 117 shall only be permitted to enter the Union if they were collected from donor animals which comply with the following requirements:

- (a) they do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for the species of those kept terrestrial animals;
- (b) they come from an establishment where no category D disease relevant for the species of those kept terrestrial animals has been reported for a period of at least the preceding 30 days;

- (c) they have remained in a single confined establishment of origin for a period of at least 30 days prior to the collection of the semen, oocytes or embryos intended for entry into the Union;
- (d) they have been clinically examined by the establishment veterinarian responsible for the activities of the confined establishment, and showed no disease symptoms on the day the semen, oocytes or embryos were collected;
- (e) as much as possible, they were not used for natural breeding during a period of at least 30 days prior to the date of first collection and during the period of collection of semen, oocytes or embryos intended for entry into the Union;
- (f) they are identified and registered in accordance with the rules of that confined establishment.

Article 119

The requirements for germinal products

Consignments of semen, oocytes and embryos referred to in Article 117 shall only be permitted to enter the Union if they comply with the following requirements:

- (a) they are marked in such a way that the following information can be readily established:
 - (i) the date of collection or production of those germinal products;
 - (ii) the species, where necessary subspecies, and identification of the donor animal(s);
 - (iii) the unique approval number of the confined establishment, which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted;
 - (iv) any other relevant information;
- (b) they are transported in the container which:
 - (i) is sealed and numbered prior to the dispatch from the confined establishment by the establishment veterinarian responsible for the activities of the confined establishment;
 - (ii) has been cleaned and either disinfected or sterilised before use, or is single-use container;
 - (iii) has been filled in with the cryogenic agent which not have been previously used for other products.

PART IV

ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF PRODUCTS OF ANIMAL ORIGIN AS REFERRED TO IN ARTICLES 3 AND 5

TITLE 1

GENERAL ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF PRODUCTS OF ANIMAL ORIGIN

Article 120

Time constraints for the date of production

Consignments of products of animal origin shall only be permitted to enter the Union if the products of the consignment were not obtained during a period where:

- (a) animal health restriction measures were adopted by the Union for entry of such products from the third country or territory of origin or zone thereof;
- (b) the authorisation for entry into the Union of such products from the third country or territory of origin or zone thereof was suspended.

*Article 121***Treatment requirements for products of animal origin**

1. Consignments of products of animal origin, other than fresh or raw, shall only be permitted to enter the Union if the products of the consignment have been treated in accordance with Titles 3 to 6 of this Part.

The treatment referred to in the first subparagraph must have been:

- (a) specifically assigned by the Union in the list, to the third country or territory of origin or zone thereof and to the species of origin of the product of animal origin;
- (b) applied in a third country or territory or zone thereof listed for entry into the Union of the particular species and category of products of animal origin;
- (c) applied in accordance with requirements for:
 - (i) risk-mitigating treatments for meat products set out in Annex XXVI;
 - (ii) risk-mitigating treatments for dairy products set out in Annex XXVII;
 - (iii) risk-mitigating treatments for egg products set out in Annex XXVIII.

2. After the completion of the treatment provided for in paragraph 1, products of animal origin must be handled until packaged in a way to prevent any cross contamination that could introduce an animal health risk.

*Article 122***Requirements concerning the means of transport of the products of animal origin**

Consignments of products of animal origin shall only be permitted to enter the Union if such consignments were transported in a means of transport designed, constructed and maintained in such a way that the health status of the products of animal origin was not jeopardised during the transport from their place of origin to the Union.

*Article 123***Dispatch of products of animal origin to the Union**

Consignments of products of animal origin shall only be permitted to enter the Union if such consignments have been dispatched to their destination in the Union separated from animals and products of animal origin not complying with the relevant animal health requirements for entry into the Union provided for in this Regulation.

TITLE 2

ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF FRESH MEAT

CHAPTER 1

General animal health requirements for fresh meat*Article 124***Dispatch of kept animals of origin of the fresh meat to a slaughterhouse**

Consignments of fresh meat of kept animals, except those kept as farmed game that have been killed on-the-spot, shall only be permitted to enter the Union if the fresh meat of the consignment has been obtained from kept animals which comply with the following requirements:

- (a) the establishment of origin of the animals is located, either:
 - (i) in the same third country or territory or zone thereof as the slaughterhouse where the fresh meat was obtained;
- or

- (ii) in a third country or territory or zone thereof which at the time of dispatch of the animals to the slaughterhouse was authorised to enter fresh meat of the relevant species of animals to the Union;
- (b) the kept animals were dispatched directly from their establishment of origin to the slaughterhouse;
- (c) during the transport to the slaughterhouse referred to in point (a), the kept animals:
 - (i) did not pass through a third country or territory or zone thereof not listed for entry into the Union of the particular species and category of fresh meat;
 - (ii) did not come into contact with animals of a lower health status;
- (d) the means of transport and containers used to transport the kept animals to the slaughterhouse referred to in point (a) comply with the requirements laid down in Articles 17 and 18.

Article 125

Dispatch of carcasses of wild animals or animals kept as farmed game killed on the spot

Consignments of fresh meat of wild animals or animals kept as farmed game that have been killed on-the-spot shall only be permitted to enter the Union if the fresh meat of the consignment has been obtained from carcasses which comply with the following requirements:

- (a) the carcasses were dispatched directly from the place of killing to a game handling establishment situated in the same listed third country or territory or zone;
- (b) during the transport to the game handling establishment referred to in point (a), the carcasses:
 - (i) did not pass through a third country or territory or zone thereof not listed for entry into the Union of the particular species and category of fresh meat;
 - (ii) did not come into contact with animals or carcasses of a lower health status;
- (c) the carcasses were transported to the game handling establishment referred to in point (a) in means of transport and containers which comply with the following requirements:
 - (i) they were cleaned and disinfected, with a disinfectant authorised by the competent authority of the third country or territory of origin, before the loading of the carcasses for dispatch to the Union;
 - (ii) they were constructed in such a way that the health status of the carcasses was not jeopardised during the transport.

Article 126

The ante-mortem and post-mortem inspections

Consignments of fresh meat of kept and wild animals shall only be permitted to enter the Union if the fresh meat of the consignment has been obtained from animals which have undergone the following inspections:

- (a) in the case of kept animals:
 - (i) an ante-mortem inspection within the period of 24 hours prior to the time of slaughter;
 - (ii) a post-mortem inspection carried out, without delay, after their killing or slaughter.
- (b) in the case of wild animals, a post-mortem inspection carried out, without delay, after their killing.

The inspections referred to in the first paragraph must have been carried out by an official veterinarian in the third country or territory of origin or zone thereof in order to exclude the presence of the relevant diseases referred to in Annex I and of emerging diseases.

Article 127

Handling of the animals of origin of the fresh meat during killing or slaughter

Consignments of fresh meat shall only be permitted to enter the Union if the fresh meat of the consignment originates from animals which had no contact with animals of a lower health status during their killing or slaughter.

*Article 128***Handling and preparation of fresh meat in the establishment of origin of the fresh meat**

Consignments of fresh meat must be kept strictly segregated from fresh meat not complying with the relevant animal health requirements for entry into the Union of fresh meat, provided for in Articles 124 to 146, throughout the operations of slaughter, cutting and until either:

- (a) it was packed for further storage or dispatch to the Union;
- or
- (b) its arrival to the Union, in the case of unpacked fresh meat.

*CHAPTER 2****Animal health requirements for fresh meat of ungulates****SECTION 1**GENERAL ANIMAL HEALTH REQUIREMENTS FOR FRESH MEAT OF KEPT AND WILD UNGULATES**Article 129***The species of animals of origin of the fresh meat of ungulates**

Consignments of fresh meat from ungulates shall only be permitted to enter the Union if the fresh meat of the consignment originates from the following species:

- (a) in the case of kept ungulates, from all species of ungulates;
- (b) in the case of wild ungulates and ungulates kept as farmed game, from all species of ungulates except from *bovine animals, ovine animals, caprine animals and domestic breeds of porcine animals*

*Article 130***Prohibition as regards the entry of fresh blood**

Consignments of fresh blood of ungulates for human consumption shall not be permitted to enter the Union.

*SECTION 2**SPECIFIC ANIMAL HEALTH REQUIREMENTS FOR FRESH MEAT OF KEPT UNGULATES**Article 131***The residency period prior to slaughter or killing of the kept ungulates of origin of the fresh meat**

1. The kept ungulates of origin of the fresh meat intended for entry into the Union shall not be required to comply with a residency period prior to the date of slaughter or killing provided that they were introduced into the third country or territory or zone thereof from:

- (a) another third country or territory or zone which is listed for entry into the Union of fresh meat from the same species of ungulates and the kept ungulates remained there for at least 3 months prior to slaughter;
- or
- (b) a Member State.

2. The kept ungulates of origin of the fresh meat intended for entry into the Union other than those referred to in paragraph 1, must comply, immediately prior to the date of slaughter or killing, with a residency period for a continuous period of time in accordance with Annex XXIII where they:

- (a) remained in the third country or territory of origin or zone thereof;

- (b) remained in the establishment of origin;
- (c) had no contact with ungulates of a lower health status.

Article 132

Derogation from direct dispatch of the kept animals of origin of the fresh meat to a slaughterhouse

By way of derogation from Article 124(b), consignments of fresh meat of kept ungulates not complying with those requirements shall be permitted to enter the Union provided that the fresh meat of the consignment was obtained from bovine animals, ovine animals or caprine animals, and:

- (a) the ungulates passed through one single establishment conducting assembly operations, which complies with the requirements laid down in Article 20(b), after leaving their establishment of origin and prior to their arrival at the slaughterhouse;
- (b) the competent authority of the third country or territory of origin has provided additional guarantees to ensure the animal health status of the ungulates during their movement from their establishment of origin to their arrival at the slaughterhouse has not been jeopardised;
- (c) the third country, territory or zone thereof referred to in point (b) is authorised in the list for such derogation.

Article 133

The third country or territory of origin or zone thereof of the fresh meat of kept ungulates

1. Consignments of fresh meat of kept ungulates shall only be permitted to enter the Union if the fresh meat of the consignment originates from a third country or territory or zone thereof which complies with the minimum periods of disease freedom set out in the table in Part A of Annex XXIV, for the referred listed diseases, for which the species of ungulates from which the fresh meat has been obtained are listed.

The minimum periods referred to in the first subparagraph may be reduced for the diseases listed in Part B of Annex XXIV subject to compliance with the specific conditions provided for therein; these specific conditions must be specifically assigned by the Union in the list, to that third country or territory or zone thereof and to the particular species of origin of the fresh meat.

2. Consignments of fresh meat of ungulates shall only be permitted to enter the Union if the fresh meat of the consignment originates from a third country or territory or zone thereof in which vaccination against listed diseases referred to in paragraph 1 has not been carried out according to the table in Part A of Annex XXV.

3. By way of derogation of paragraph 2, vaccination against foot and mouth disease may have been carried out subject to compliance with the specific conditions to be provided by the competent authority set out in points 1(b) or 3.1(a) of Part B of Annex XXV which must be specifically assigned by the Union in the list, to that third country or territory or zone thereof and to the particular species of origin of the fresh meat.

Article 134

The establishment of origin of the kept ungulates from which the fresh meat has been obtained

1. Consignments of fresh meat of kept ungulates shall only be permitted to enter the Union if the fresh meat of the consignment has been obtained from ungulates which come from an establishment:

- (a) in and around which, including where appropriate the territory of a neighbouring country, none of the listed diseases referred to in Part A of Annex XXIV, for which the species of ungulates of origin of the fresh meat intended for entry into the Union are listed, has been reported in an area of 10 km radius and for a period of 30 days prior to the date of slaughter; or
- (b) which complies with the specific conditions to be provided by the competent authorities where vaccination against foot and mouth disease has been carried out in the third country or territory or zone thereof less than 12 months prior to the date of slaughter set out in points 1(b) or 3.1(a) of Part B of Annex XXV which must have been specifically assigned by the Commission in the list to the third country or territory or zone thereof authorised for entry into the Union of fresh meat of ungulates and to the species of origin of the fresh meat.

2. Consignments of fresh meat of kept ungulates shall only be permitted to enter the Union if the fresh meat of the consignment has been obtained from ungulates which come from an establishment:

- (a) where no animals have been vaccinated according to Part A of Annex XXV; or
- (b) which is located in a third country, territory or zone thereof which complies with the specific conditions set out in point 1 of Part B of Annex XXIV; these conditions must have been specifically assigned by the Commission in the list to the third country or territory or zone thereof listed for entry into the Union of fresh meat of ungulates and to the species of origin of the fresh meat.

Article 135

Specific requirement for fresh meat obtained from kept ungulates of the species *Sus scrofa*

Consignments of fresh meat of kept ungulates of the species *Sus scrofa* shall only be permitted to enter the Union if the fresh meat of the consignment originates from animals which have been kept separated from wild ungulates since birth.

Article 136

The establishment of origin of the fresh meat of kept ungulates

Consignments of fresh meat of kept ungulates shall only be permitted to enter the Union if the fresh meat of the consignment was obtained in a slaughterhouse, or in a game handling establishment, in and around which none of the listed diseases referred to in Part A of Annex XXIV has been reported in an area of 10 km radius, including, where appropriate, the territory of a neighbouring country, for a period of 30 days prior to the date of slaughter or to the date of killing.

SECTION 3

SPECIFIC ANIMAL HEALTH REQUIREMENTS FOR FRESH MEAT OF WILD UNGULATES

Article 137

The country or territory of origin or zone thereof of the fresh meat of wild ungulates

Consignments of fresh meat of wild ungulates shall only be permitted to enter the Union if the fresh meat of the consignment originates from a third country or territory or zone thereof which complies with the animal health requirements laid down in Article 133.

Article 138

The wild ungulates of origin of the fresh meat

Consignments of fresh meat of wild ungulates shall only be permitted to enter the Union if the fresh meat of the consignment was obtained from animals which comply with the following requirements:

- (a) they were killed at a distance that exceeds 20 km from the border of any third country or territory or zone thereof which at that time was not listed for entry into the Union of fresh meat of the species of wild ungulates;
- (b) they were killed in an area of 20 km radius, where, during the preceding 60 days, the diseases referred to in Part A of Annex XXIV have not been reported.

Article 139

The game handling establishment of origin of fresh meat of wild ungulates

Consignments of fresh meat of wild ungulates shall only be permitted to enter the Union if the fresh meat of the consignment has been obtained in a game handling establishment in and around which none of the listed diseases referred to in Part A of Annex XXIV has been reported in an area of 10 km radius, including where appropriate the territory of a neighbouring country, for a period of 30 days prior to the date of killing.

CHAPTER 3

Animal health requirements for fresh meat of poultry and game birds

SECTION 1

SPECIFIC ANIMAL HEALTH REQUIREMENTS FOR FRESH MEAT OF POULTRY

Article 140

The residency period of poultry

Consignments of fresh meat of poultry shall only be permitted to enter the Union if the fresh meat of the consignment has been obtained from poultry which:

- (a) have been kept since hatching and until the date of slaughter in the third country or territory of origin of the fresh meat or zone thereof;

or

- (b) were imported as day-old chicks, breeding poultry, productive poultry or poultry intended for slaughter from a third country or territory or zone thereof which is listed for entry into the Union for those commodities or from a Member State and the import took place in accordance with animal health requirements at least as stringent as the relevant requirements of this Regulation.

Article 141

The third country or territory of origin or zone thereof of the fresh meat of poultry

Consignments of fresh meat of poultry shall only be permitted to enter the Union if the fresh meat of the consignment originates from a third country or territory or zone thereof which complies with the following requirements:

- (a) it has a disease surveillance programme for highly pathogenic avian influenza in place for a period of at least 6 months prior to the date of dispatch of the consignment to the Union and that surveillance programme complies with the requirements laid down in either:

- (i) Annex II to this Regulation;

or

- (ii) the relevant Chapter of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE);

- (b) it is considered to be free from highly pathogenic avian influenza in accordance with Article 38;

- (c) where it carried out vaccination against highly pathogenic avian influenza, the competent authority of the third country or territory of origin has provided guarantees that:

- (i) the vaccination programme complies with the requirements set out in Annex XIII;
 - (ii) the surveillance programme referred to in point (a) of this Article, in addition to the requirements set out in Annex II, complies with the requirements set out in point 2 of Annex XIII;
 - (iii) it has undertaken to inform the Commission of any change to the vaccination programme in the third country or territory or zone thereof;

- (d) which:

- (i) in the case of fresh meat of poultry other than ratites, it is considered to be free from infection with Newcastle disease virus in accordance with Article 39;

- (ii) in the case of fresh meat of ratites, is either:

- considered to be free from infection with Newcastle disease virus in accordance with Article 39,

or

- not considered to be free from infection with Newcastle disease virus in accordance with Article 39, but the competent authority of the third country or territory of origin has provided guarantees regarding compliance with the requirements for infection with Newcastle disease virus in relation to isolation, surveillance and testing, as set out in Annex XIV;
- (e) where vaccination against infection with Newcastle disease virus is carried out, the competent authority of the third country or territory has provided guarantees that:
 - (i) the vaccines used comply with the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV; or
 - (ii) the vaccines used comply with the general criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the poultry from which the fresh meat has been obtained meet the animal health requirements set out in point 3 of Annex XV for fresh meat of poultry originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
- (f) it has undertaken that following an outbreak of highly pathogenic avian influenza or an outbreak of infection with Newcastle disease virus, to submit the following information to the Commission:
 - (i) information on the disease situation within 24 hours of confirmation of any initial outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus;
 - (ii) regular updates of the disease situation;
- (g) which has undertaken to submit virus isolates from initial outbreaks of highly pathogenic avian influenza and infection with Newcastle disease virus to the European Union Reference Laboratory for Avian Influenza and Newcastle disease.

Article 142

The establishment of origin of the poultry

Consignments of fresh meat of poultry shall only be permitted to enter the Union if the fresh meat of the consignment originates from poultry which come from an establishment:

- (a) in which and within a 10 km radius of the establishment, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus during the period of at least 30 days prior to the date of slaughter;
- (b) which, in the case of fresh meat of ratites originating in a third country or territory or zone thereof not free from infection with Newcastle disease virus, complies with the animal health requirements for ratites, hatching eggs thereof and fresh meat of ratites originating in a third country or territory or zone thereof not free from infection with Newcastle disease virus, set out in points 3(b) and (c) of Annex XIV.

Article 143

The poultry of origin of the fresh meat

1. Consignments of fresh meat of poultry shall only be permitted to enter the Union if the fresh meat of the consignment has been obtained from poultry which have not been vaccinated against highly pathogenic avian influenza or infection with Newcastle disease virus, or they comply with the following requirements:

- (a) where they have been vaccinated against highly pathogenic avian influenza, guarantees for compliance with the minimum requirements for vaccination programmes and additional surveillance set out in Annex XIII, have been provided by the third country or territory of origin;
- (b) where they have been vaccinated against infection with Newcastle disease virus:
 - (i) guarantees have been provided by the competent authority of the third country or territory of origin that the vaccines used comply with:
 - the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV, or

- the general criteria for recognised vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the poultry from which the fresh meat has been obtained meet the animal health requirements set out in point 3 of Annex XV for fresh meat of poultry originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;

(ii) the information set out in point 4 of Annex XV must be provided for the consignment.

2. Consignments of fresh meat of poultry which is destined to a Member State or territory with status free from infection with Newcastle disease virus without vaccination, shall only be permitted to enter the Union if the fresh meat of the consignment originates from poultry which have not been vaccinated against Newcastle disease with a live vaccine during the period of 30 days prior to the date of slaughter.

Article 144

The establishment of origin for the fresh meat of poultry

Consignments of fresh meat of poultry shall only be permitted to enter the Union if the fresh meat of the consignment originates from a slaughterhouse which:

- (a) at the time of slaughter, was not under restrictions due to an outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus or under official restrictions under national legislation for animal health reasons;
- (b) within a 10 km radius of the slaughterhouse, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus during the period of at least 30 days prior to the date of slaughter.

SECTION 2

SPECIFIC ANIMAL HEALTH REQUIREMENTS FOR FRESH MEAT OF GAME BIRDS

Article 145

The third country or territory of origin or zone thereof of the fresh meat of game birds

Consignments of fresh meat of game birds shall only be permitted to enter the Union if the fresh meat of the consignment originates from a third country or territory or zone thereof which complies with the following requirements:

- (a) it has a disease surveillance programme for highly pathogenic avian influenza in place for a period of at least 6 months prior to the date of dispatch of the consignment to the Union and that surveillance programme complies with the requirements established in either:
 - (i) Annex II to this Regulation;
 - or
 - (ii) the relevant Chapter of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE);
- (b) where there have been no animal health restrictions due to an outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus during the period of at least 30 days prior to the time of killing.

Article 146

The establishment of origin of the fresh meat of game birds

Consignments of fresh meat of game birds shall only be permitted to enter the Union if the fresh meat of the consignment originates from a game handling establishment:

- (a) which, at the time of dressing, was not under restrictions due to an outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus or under official restrictions for animal health reasons;
- (b) within a 10 km radius of the game handling establishment, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus during the period of at least the 30 days prior to the date of reception of the carcasses.

TITLE 3

ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF MEAT PRODUCTS AND CASINGS

Article 147

Treatment of meat products

Consignments of meat products shall only be permitted to enter the Union if the meat products of the consignment have been treated in accordance with Article 121 as required in Articles 148 or 149.

Article 148

Meat products not subject to a risk-mitigating treatment

Consignments of meat products shall only be permitted to enter the Union if the meat products of the consignment have not undergone a risk-mitigating treatment in accordance with Annex XXVI where:

- (a) the third country or territory of origin or zone thereof is listed for entry into the Union of fresh meat of the relevant species, and specific conditions in accordance with Chapter 1 and 2 of Title 1, Part IV, are not required for entry into the Union of such fresh meat;
- (b) the fresh meat used for the processing of the meat product complied with all the requirements for entry into the Union of fresh meat and therefore was eligible for entry into the Union and originated from:
 - (i) the third country or territory or zone thereof where the meat product was processed;
 - (ii) a third country or territory or zone thereof which is listed for entry into the Union of fresh meat of the relevant species;
 - (iii) a Member State.

Article 149

Meat products subject to a risk-mitigating treatment

1. Consignments of meat products that do not fulfil the requirements provided for in Article 148, shall only be permitted to enter the Union if they have undergone at least the risk-mitigating treatment set out in Annex XXVI specifically assigned by the Union in the list to the third country or territory or zone thereof of origin of the meat product in accordance with Article 121, where the fresh meat used for processing of the meat products originates from:

- (a) the third country or territory or zone thereof where the meat product has been processed;
- (b) a listed third country or territory or zone thereof authorised for entry into the Union of fresh meat of the relevant species;
- (c) a Member State.

2. Consignments of meat products shall only be permitted to enter the Union if they have undergone at least the risk-mitigating treatment 'B', in accordance with Annex XXVI, where the fresh meat used for the processing of the meat products originates from a third country or territory or zone thereof:

- (a) other than the third country or territory or zone thereof in which the meat product is obtained;
- (b) which is also listed for entry into the Union of meat products of the relevant species, subject to a risk-mitigating treatment specifically assigned by the Union in the list, to that third country or territory or zone thereof and to the relevant species, in accordance with Article 121.

3. Consignments of meat products processed from fresh meat of poultry shall only be permitted to enter the Union if they have undergone at least the risk-mitigating treatment 'D', in accordance with Annex XXVI, where the fresh meat used for the processing of the meat products originates from a third country or territory or zone thereof:

- (a) listed for entry into the Union of fresh meat of poultry;

- (b) in which there has been a case or an outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus.
4. Consignments of meat products which have been processed from fresh meat of more than one species of animal from the third country or territory or zone thereof where the meat product was processed, shall only be permitted to enter the Union if they comply with the following requirements:
- (a) the meat products must have undergone the most severe of the risk-mitigating treatments assigned in the list to the third country or territory or zone thereof, in accordance with Article 121, for the different species of animals of origin, where the fresh meat is mixed before the final processing of the meat product takes place; or
- (b) the meat products must have undergone the risk-mitigating treatment assigned in the list to the third country or territory or zone thereof, in accordance with Article 121, for each different species of animals of origin, where the mixing of the meat products have taken place after processing of each ingredient of the meat product.
5. Consignments of meat products which have been processed from fresh meat of more than one species of animal originating from a third country or territory or zone thereof other than the third country or territory or zone thereof where the meat product has been processed, shall only be permitted to enter the Union if they have undergone a risk-mitigating treatment in accordance with paragraphs 1 or 2.

Article 150

The establishment of origin of the animals from which the fresh meat was obtained

Consignments of meat products shall only be permitted to enter the Union if they that have been processed from fresh meat which originate from animals coming from an establishment, or, in the case of wild animals, from a place in and around which, in an area of 10 km radius, including where appropriate the territory of a neighbouring country, none of the listed diseases, relevant for the species of origin of the meat products in accordance with Annex I, has been reported during the period of 30 days prior to the date of dispatch of the consignment to the Union.

Article 151

The entry into Member States with status free from infection with Newcastle disease virus without vaccination

Consignments of meat products of poultry intended for a Member State or territory thereof with a status free from infection with Newcastle disease virus without vaccination shall only be permitted to enter into the Union if they have obtained from poultry which have not been vaccinated with a live vaccine against infection with Newcastle disease virus, during the period of 30 days prior to the date of slaughter.

Article 152

Specific requirements for entry into the Union of casings

Consignments of casings that do not fulfil the requirements provided for in Article 148 shall only be permitted to enter the Union if they have undergone the following risk-mitigating treatments set out in Part 2 of Annex XXVI:

- (a) treatments 'Casing 1' or 'Casing 2', where the bladders and intestines used for the processing of the casings originate from bovine animals, ovine animals, caprine animals or kept porcine animals;
- (b) treatments 'Casing 3', 'Casing 4' or 'Casing 5' where the bladders and intestines used for the processing of the casings originate from animals of species other than those referred to in point (a).

TITLE 4

ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF MILK, DAIRY PRODUCTS, COLOSTRUM AND COLOSTRUM-BASED PRODUCTS

CHAPTER 1

Specific animal health requirements for raw milk, colostrum and colostrum-based products

Article 153

The country of origin of the raw milk, colostrum and colostrum-based products

Consignments of raw milk, colostrum or colostrum-based products shall only be permitted to enter the Union if the raw milk, colostrum and colostrum-based products of the consignment originate from a third country or territory or zone thereof which has been free from foot and mouth disease and infection with rinderpest virus for a period of at least 12 months prior to the date of milking and, during that period, no vaccination against those diseases has been carried out.

Article 154

The animals of origin of the raw milk, colostrum and colostrum-based products

1. Consignments of raw milk, colostrum or colostrum-based products shall only be permitted to enter the Union if the raw milk, colostrum or colostrum-based products of the consignment were obtained from animals of the species *Bos taurus*, *Ovis aries*, *Capra hircus*, *Bubalus bubalis* or *Camelus dromedarius*.
2. Consignments of raw milk, colostrum or colostrum-based products shall only be permitted to enter the Union if the raw milk, colostrum or colostrum-based products of the consignment were obtained from animals that complied with a continuous residency period of at least 3 months prior to the date of milking in the third country or territory of milking or zone thereof.

CHAPTER 2

Specific animal health requirements for dairy products

Article 155

Treatment of dairy products

Consignments of dairy products shall only be permitted to enter the Union if the dairy products of the consignment have been treated in accordance with Article 156 or 157.

Article 156

Dairy products not subject to a risk-mitigating treatment

Consignments of dairy products originating from a third country or territory or zone thereof which is listed for entry into the Union of raw milk shall be permitted to enter the Union without having undergone a specific risk-mitigating treatment if the dairy products of the consignment comply with following requirements:

- (a) the raw milk from which they were processed was obtained from animals of the species *Bos taurus*, *Ovis aries*, *Capra hircus*, *Bubalus bubalis* and *Camelus dromedarius*;
- (b) the raw milk used for the processing of the dairy products complied with the relevant general requirements for entry into the Union laid down in Articles 3 to 10 and the specific requirements for entry into the Union of raw milk provided for in Article 153 and Article 154, and therefore was eligible for entry into the Union and it originates from one of the following:

- (i) the listed third country or territory or zone where the dairy products were processed;
- (ii) a third country or territory or zone thereof other than listed third country or territory or zone thereof where the dairy products were processed and which is authorised for entry into the Union of raw milk; or
- (iii) a Member State.

Article 157

Dairy products subject to a risk-mitigating treatment

1. Consignments of dairy products not complying with the requirements set out in Article 156 shall only be permitted to enter the Union if the dairy products of the consignment have undergone at least one of the risk-mitigating treatments provided for in column A of Annex XXVII, where:

- (a) they were processed from milk obtained from the species *Bos Taurus*, *Ovis aries*, *Capra hircus*, *Bubalus bubalis* or *Camelus dromedarius*;
- (b) the third country or territory of origin or zone thereof has not been free from foot and mouth disease and infection with rinderpest virus for a period of at least 12 months prior to the date of milking, or if during that period vaccination against those diseases has been carried out.

2. Consignments of dairy products shall only be permitted to enter the Union if the dairy products of the consignment have undergone at least one of the risk-mitigating treatments provided for in column B of Annex XXVII where they were processed from milk obtained from species of animals other than those referred to in paragraph 1(a).

3. Consignments of dairy products that have been processed from raw milk or from dairy products obtained from more than one species of animal shall only be permitted to enter the Union if those dairy products have undergone either:

- (a) at least the most severe of the risk-mitigating treatments assigned to the each species of animals of origin, where the mixing of raw milk or dairy products takes place before the final processing of the product; or
- (b) the risk-mitigating treatment assigned to each species of animals of origin, where the mixing of the products takes place after processing of each ingredient of the dairy product.

TITLE 5

ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF EGGS AND EGG PRODUCTS

CHAPTER 1

Specific animal health requirements for eggs

Article 158

The third country or territory of origin or zone thereof of the eggs

Consignments of eggs shall only be permitted to enter the Union if the eggs of the consignment originate from a third country or territory or zone thereof which applies a disease surveillance programme for highly pathogenic avian influenza that complies with the requirements established in either:

- (a) Annex II to this Regulation;

or

- (b) the relevant Chapter of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE).

*Article 159***The establishment of origin of the eggs**

Consignments of eggs shall only be permitted to enter the Union if the eggs of the consignment originate from an establishment that complies with the following requirements:

- (a) during the period of 30 days prior to the date of collection of the eggs and until the date of issue of the certificate for entry into the Union, no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus occurred; and
- (b) within a 10 km radius of the establishment, including, where appropriate, the territory of a neighbouring country there was no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus for a period of at least 30 days prior to the date of collection of eggs and until the date of issue of the certificate for entry into the Union.

*CHAPTER 2****Specific animal health requirements for egg products****Article 160***The third country or territory of origin or zone thereof of the egg products**

Consignments of egg products shall only be permitted to enter the Union if the egg products of the consignment originate from a third country or territory or zone thereof which applies a disease surveillance programme for highly pathogenic avian influenza that complies with the requirements established in either:

- (a) Annex II to this Regulation;

or

- (b) the relevant Chapter of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE).

*Article 161***The establishment of origin of the eggs**

Consignments of egg products shall only be permitted to enter the Union if the egg products of the consignment have been processed from eggs that originated in an establishment:

- (a) in which, during the period of 30 days prior to the date of collection of the eggs, no outbreak of highly pathogenic avian influenza and infection with Newcastle disease virus has occurred;
- (b) within a 10 km radius of the establishment, including, where appropriate, the territory of a neighbouring country, there has either been:
 - (i) no outbreak of highly pathogenic avian influenza for a period of at least 30 days prior to the date of collection of eggs; or
 - (ii) an outbreak of highly pathogenic avian influenza within the period of 30 days prior to the date of collection of eggs and the egg product has undergone one of the risk-mitigating treatments for egg products set out in point 1 of Annex XXVIII;
- (c) within a 10 km radius of the establishments, including, where appropriate, the territory of a neighbouring country, there has either been:
 - (i) no outbreak of infection with Newcastle disease virus for a period of at least 30 days prior to the date of collection of eggs; or
 - (ii) an outbreak of infection with Newcastle disease virus within the period of 30 days prior to the date of collection of eggs and the egg product, has undergone one of the risk-mitigating treatments for egg products set out in point 2 of Annex XXVIII.

TITLE 6

ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF PROCESSED PRODUCTS OF ANIMAL ORIGIN CONTAINED IN COMPOSITE PRODUCTS*Article 162***Composite products containing meat products and non-shelf stable composite products containing dairy and/or egg products**

1. Consignments of the following composite products shall only be permitted to enter the Union if the composite products of the consignment come from a third country or territory or zone thereof listed for entry into the Union of the specific product of animal origin contained in those composite products:

- (a) composite products containing meat products;
- (b) composite products containing dairy products or egg products which have not been processed to become shelf stable.

2. Consignments of composite products shall only be permitted to enter the Union if the processed products of animal origin contained in the composite products referred to in paragraph 1:

- (a) comply with:
 - (i) the relevant general animal health requirements for entry into the Union of products of animal origin laid down in Part 1 of this Regulation;
 - (ii) the animal health requirements for entry into the Union of the specific product of animal origin, as laid down in Titles 3 to 5 of this Part;
- (b) they have been obtained either:
 - (i) in the same listed third country or territory of origin or zone thereof of the composite product;
 - (ii) in the Union; or
 - (iii) in a third country or territory or zone thereof listed for entry into the Union of those products without undergoing a specific risk-mitigating treatment, in accordance with Articles 148 and 156, if the third country or territory or zone thereof where the composite product is produced is also listed for entry into the Union of those products without the obligation to apply a specific risk-mitigating treatment.

*Article 163***Shelf stable composite products containing dairy and/or egg products**

Consignments of composite products containing only dairy or egg products shall only be permitted to enter the Union if the dairy products and the egg products contained in the composite products have been treated to become shelf stable at ambient temperature and they:

- (a) have been subjected to a treatment, at least equivalent to the following treatments:
 - (i) risk-mitigating treatments for dairy products as set out in column B in Annex XXVII;
 - (ii) risk-mitigating treatments for egg products set out in Annex XXVIII;
- (b) by way of derogation of point 1(c)(i) of Article 3, are accompanied by a declaration of the operator of the third country or territory of origin of the composite products, attesting that the dairy products and egg products contained in the composite products have undergone at least the risk-mitigating treatment provided for in point (a).

TITLE 7

SPECIAL RULES FOR ENTRY INTO THE UNION OF PRODUCTS OF ANIMAL ORIGIN INTENDED FOR PERSONAL USE*Article 164***Derogation from animal health requirements and additional requirements for entry of infant milk, infant food and special foods intended for personal use**

By way of derogation from the requirements laid down in Articles 3 to 10 of Part I and Articles 120 to 163, consignments of powdered infant milk, infant food and special foods required for medical reasons, containing products of animal origin which do not comply with those requirements shall be permitted to enter the Union if those products:

- (a) are intended for personal use;
- (b) do not exceed a combined quantity of 2 kilogramme per person;
- (c) do not require refrigeration before opening;
- (d) are packaged proprietary brand products for direct sale to the final consumer;
- (e) maintain the packaging unbroken, unless in current use.

*Article 165***Derogation from animal health requirements for products of animal origin intended for personal use originating from certain third countries or territories or zones thereof**

1. By way of derogation from requirements laid down in Articles 3 to 10 of Part I, except point (a)(i) of Article 3, and Articles 120 to 163, consignments of products of animal origin which do not comply with those requirements shall be permitted to enter the Union if those products are intended for personal use and originate from third countries or territories listed for entry into the Union of specific quantities of products of animal origin intended for personal use based on specific agreements with the Union on trade in agricultural products.
2. The combined specific quantity allowed to enter the Union accompanying a person shall not exceed the maximum specified for the third country or territory in the list.

PART V

ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION AS REFERRED TO IN ARTICLES 3 AND 5 OF AQUATIC ANIMALS OF LISTED SPECIES AND THEIR PRODUCTS OF ANIMAL ORIGIN, AND FOR THEIR MOVEMENT AND HANDLING AFTER THE ENTRY

TITLE 1

GENERAL ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF THE AQUATIC ANIMALS REFERRED TO IN ARTICLE 1(6) AND THEIR PRODUCTS*Article 166***Inspection of aquatic animals prior to dispatch**

Consignments of aquatic animals other than those referred to in points (d), (e) and (f) of Article 172 shall only be permitted to enter the Union if those aquatic animals have been subjected to a clinical inspection by an official veterinarian in the exporting third country or territory, zone or compartment thereof within a period of 72 hours prior to the time of loading for dispatch of the consignment to the Union for the purpose of detection of symptoms of disease and abnormal mortalities.

*Article 167***Dispatch to the Union of aquatic animals**

Consignments of aquatic animals shall only be permitted to enter the Union if the aquatic animals of the consignment comply with the following requirements:

- (a) they were dispatched directly from their establishment of origin to the Union;
- (b) they were not unloaded, moved to another means of transport or unloaded from their container when transported by air, sea, railway or by road, and the water in which they are transported was not changed, in a third country or territory, zone or compartment which is not listed for entry of the particular species and category of aquatic animals into the Union;
- (c) they have not been transported under conditions that have jeopardised their health status, in particular:
 - (i) where relevant, they must have been loaded and transported in water which did not alter their health status;
 - (ii) the means of transport and the containers must have been constructed in such a way that the health status of the aquatic animals was not jeopardised during the transport;
 - (iii) the container or well boat must have been cleaned and disinfected, in accordance with a protocol and with products approved by the competent authority of the third country or territory of origin, prior to loading for dispatch to the Union, which ensure that the health status of the aquatic animals is not jeopardised during transport;
- (d) from the time of loading at the establishment of origin until the time of arrival to the Union, they must not have been transported in the same water or container or well-boat together with aquatic animals which were of a lower health status or which were not intended for entry into the Union;
- (e) where a water exchange is necessary in a third country, territory, zone or compartment which is listed for entry of the particular species and category of aquatic animals into the Union, it must not have jeopardised the health status of the animals being transported and it must have only occurred:
 - (i) in the case of transport on land, at water exchange points approved by the competent authority of the third country or territory where the water exchange takes place;
 - (ii) in the case of transport by well-boat, at a distance which is at least 10 km from any aquaculture establishments which are located en-route from the place of origin to the place of destination in the Union.

*Article 168***Transport by vessel of aquatic animals**

When dispatch to the Union of consignments of aquatic animals, includes transport by vessel or well-boat even for part of the journey, those consignments of aquatic animals transported in accordance with Article 167 shall only be permitted to enter the Union if the aquatic animals of the consignment are accompanied by a declaration, attached to the animal health certificate and signed by the master of the vessel on the day of arrival of the vessel at its port of destination, providing the following information:

- (a) the port of departure in the third country or territory;
- (b) the port of arrival in the Union;
- (c) the ports of call, in the case the vessel called at ports outside the third country or territory of origin or zone thereof;
- (d) confirmation of compliance of the consignment of aquatic animals with the relevant requirements set out in Article 167 throughout the journey from the port of departure in the third country or territory to the port of arrival in the Union.

*Article 169***Specific transport and labelling requirements**

1. Consignments of aquatic animals shall only be permitted to enter the Union if the aquatic animals of the consignment are identified by a legible label on the exterior of the container, or when transported by well-boat, an entry in the vessel's manifest which refers to the animal health certificate that has been issued for that consignment.
2. The legible label referred to in paragraph 1 shall also contain at least the following information:
 - (a) the number of containers in the consignment;
 - (b) the name of the species present in each container;
 - (c) the number of animals in each container for each of the species present;
 - (d) the purpose for which they are intended.
3. Products of animal origin from aquatic animals other than live aquatic animals, intended for entry into the Union shall comply with the following requirements:
 - (a) they must be identified by a legible label on the exterior of the container, which refers to the certificate that has been issued for that consignment;
 - (b) the legible label referred to in point (a) must also contain the following statements, as relevant:
 - (i) fish intended for human consumption in the European Union;
 - (ii) molluscs intended for human consumption in the European Union;
 - (iii) crustaceans intended for human consumption in the European Union.

*Article 170***Requirements regarding the third country or territory of origin or zone or compartment thereof and the establishment of origin**

1. Consignments of aquatic animals and products of animal origin from aquatic animals other than live aquatic animals shall only be permitted to enter the Union if the aquatic animals and products of animal origin of the consignment come from a third country or territory or zone or compartment thereof which complies with the following requirements:
 - (a) it must be free from the following listed diseases:
 - (i) category A diseases and category B diseases of aquatic animals;
 - (ii) relevant category C diseases when the aquatic animals or products of animal origin are destined for Member States, zones or compartments which have disease-free status or an approved eradication programme for the specific diseases;
 - (iii) category C diseases in all cases when the aquatic animals are intended for release into the wild;
 - (iv) where Member States of destination have taken national measures referred to in Article 176 of this Regulation, aquatic animals of the species listed in Annex XXIX must also originate from third countries, territories, zones or compartments that are free from the diseases referred to in that Annex;
 - (b) all the entries of aquatic animals of listed species into the third country or territory, zone or compartment exporting to the Union must originate from a different third country or territory or zone or compartment thereof which is free from the diseases referred to in point (a);
 - (c) vaccination of aquatic animals of listed species against category A diseases, category B or where relevant category C diseases, has not been carried out in the third country or territory of origin.

2. Consignments of aquaculture animals and products of animal origin from aquaculture animals other than live aquaculture animals, shall only be permitted to enter the Union if the aquaculture animals and products of animal origin of the consignment come from an establishment which is:

- (a) registered in accordance with requirements which are at least as stringent as to those laid down in Section 1 of Chapter 1, Title II of Part IV of Regulation (EU) 2016/429;

or

- (b) approved in accordance with requirements which are at least as stringent as to those laid down in Section 2 of Chapter 1, Title II of Part IV of Regulation (EU) 2016/429 and Title I of Part II of Commission Delegated Regulation (EU) 2020/691 ⁽²³⁾.

Article 171

Vector species

1. Aquatic animals of the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882, shall only be regarded as vectors of those diseases under the conditions set out in Annex XXX.

2. Products of animal origin from aquatic animals other than live aquatic animals of the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882, shall not be regarded as vectors of the diseases listed in that Annex when they enter the Union.

Article 172

Derogations for certain categories of aquatic animals of listed species

By way of derogation from Article 170, the requirements laid down in that Article shall not apply to the following categories of aquatic animals:

- (a) aquatic animals which are destined for a disease control aquatic food establishment where they are to be processed for human consumption;
- (b) aquatic animals intended for research purposes which are destined for confined establishments which have been approved for that purpose by the competent authority of the Member State of destination;
- (c) wild aquatic animals other than those referred to in point (b) of this Article provided that they have been subject to quarantine in a quarantine establishment which has been approved for that purpose by the competent authority in:
 - (i) the third country of origin; or
 - (ii) the Union;
- (d) molluscs or crustacea which are packed and labelled for human consumption in accordance with Regulation (EC) No 853/2004 and which are no longer able to survive as living animals if returned to the aquatic environment;
- (e) molluscs or crustacea which are packaged and labelled for human consumption in accordance with Regulation (EC) No 853/2004 and which are intended for further processing without temporary storage at the place of processing;
- (f) live bivalve molluscs or crustacea which are intended for human consumption without further processing, provided that they are packaged for retail sale in compliance with the provisions of Regulation (EC) No 853/2004.

⁽²³⁾ Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for aquaculture establishments and transporters of aquatic animals (see page 345 of this Official Journal).

*Article 173***Derogations for certain products of animal origin from aquatic animals other than live aquatic animals**

By way of derogation from Article 170(1), the requirements laid down in that Article shall not apply to the following products of animal origin from aquatic animals, other than live aquatic animals:

- (a) products of animal origin from aquatic animals, other than live aquatic animals, which are destined for a disease control aquatic food establishment where they are to be processed for human consumption;
- (b) fish intended for human consumption which were slaughtered and eviscerated prior to dispatch to the Union.

*Article 174***Handling of aquatic animals and products of animal origin from aquatic animals other than live aquatic animals after entry into the Union**

1. After their entry into the Union, consignments of aquatic animals and products of animal origin from aquatic animals other than live aquatic animals must be:

- (a) transported directly to the place of destination in the Union;
- (b) handled appropriately to ensure that natural waters are not contaminated.

2. Aquatic animals and products of animal origin from aquatic animals other than live aquatic animals which have entered the Union shall not be released by the operator or otherwise immersed in natural waters within the Union, unless authorised by the competent authority of the Member State in which that release or immersion takes place.

3. The competent authority of the Member State may only grant the authorisation referred to in paragraph 2 of this Article where the release or immersion in natural waters does not jeopardise the health status of the aquatic animals at the place of release and in all cases, release into the wild shall comply with Article 170(a)(iii).

4. Transport water from consignments of aquatic animals shall be handled appropriately by the operator to prevent contamination of natural waters in the Union.

TITLE 2

ANIMAL HEALTH REQUIREMENTS TO LIMIT THE IMPACT OF CERTAIN NON-LISTED DISEASES*Article 175***Additional animal health requirements to limit the impact of non-listed diseases for which Member States have national measures**

1. The competent authority of Member States that have taken national measures against diseases other than listed diseases as provided for in Article 226 of Regulation (EU) 2016/429, shall take measures to prevent the introduction of those non-listed diseases through the application of additional animal health requirements for entry of the aquatic animals and products of animal origin from aquatic animals other than live aquatic animals into those Member States, zones or compartments of the Union.

2. The competent authority referred to in paragraph 1 shall only permit the entry into their Member State of consignments of aquatic animals of species which are susceptible to the diseases referred to in paragraph 1 when vaccination against those diseases has not been carried out in the third country or territory of origin.

3. The competent authority referred to in paragraph 1 shall ensure that aquatic animals of the species referred to in paragraph 2 which are introduced into a third country or territory of origin or zone or compartment thereof shall originate from another third country, zone or compartment which is also free of the relevant disease.

4. The derogations provided for in Articles 172 and 173 shall apply to those aquatic animals and products of animal origin from aquatic animals which are referred to in paragraph 2 and which are destined for Member States which have national measures against the diseases referred to in paragraph 1 of this Article.

5. Handling after entry into the Union of the aquatic animals referred to in paragraph 2 of this Article and products from those animals, shall comply with the conditions set out in Article 174.

PART VI

SPECIAL RULES FOR ENTRY OF CERTAIN COMMODITIES AS REFERRED TO IN ARTICLES 3 AND 5 FOR WHICH THE UNION IS NOT THE FINAL DESTINATION AND FOR ENTRY OF CERTAIN COMMODITIES ORIGINATING FROM AND RETURNING TO THE UNION

Article 176

Requirements for transit through the Union

1. Consignments of animals, germinal products and products of animal origin falling within the scope of this Regulation not originating from but transiting through the Union and intended for a destination outside the Union shall only be permitted to transit through the Union if, either:

- (a) they comply with all the relevant requirements for entry into the Union of the particular species and category of animals, germinal products or products of animal origin in question laid down in Parts I to V; or
- (b) they fall within the scope of specific conditions, specifically assigned by the Union in the list to the listed third country or territory or zone of origin and to the particular species and category of animals, germinal products and products of animal origin, to mitigate any potential animal health risk involved in such movements.

2. Consignments of animals, germinal products and products of animal origin falling within the scope of this Regulation originating and returning to the Union after transiting through a third country or territory or zone thereof shall only be permitted to re-enter the Union if they comply with all the relevant requirements for the particular category of animals, germinal products or products of animal origin in question for entry into the Union laid down in Parts I to V, unless they fall within the scope of either:

- (a) the additional requirements laid down in Articles 177 to 182;

or

- (b) specific conditions, specifically assigned by the Union in the list to the listed third country or territory or zone of transit and to the particular species and category of animals, germinal products and products of animal origin, to mitigate any potential animal health risk involved in such movements.

3. The specific conditions referred to in paragraph 1(b) and paragraph 2(b) shall be set out and assigned to the third country or territory of or zone thereof based on a risk assessment and taking into account the following:

- (a) the criteria laid down in Article 230 of Regulation (EU) 2016/429;
- (b) the particular species and category of animals, germinal products and products of animal origin intended for transit and the related animal health risks;
- (c) geographical constraints;
- (d) established trade routes;
- (e) other relevant factors.

*Article 177***Additional requirements for entry of registered horses originating from, and returning to the Union after temporary export to a third country or territory or zone thereof to participate in competitions, races or equestrian cultural events**

1. Consignments of registered horses temporarily exported from a Member State to third countries or territories or zones thereof listed for entry of equine animals into the Union shall be permitted to enter the Union provided they comply with the following additional requirements:
 - (a) they have been outside the Union for a period specified by the Commission for the different purposes, not exceeding 90 days;
 - (b) they have been kept in isolation in the third country or territory or zone thereof except during races, competitions or cultural events, and the related activities (including training, warm-up and presentation);
 - (c) they have been kept only in third countries or territories or zones thereof belonging to the same sanitary group to which the third country or territory of dispatch to the Union is assigned, in accordance with the specific requirements of Part B of Annex XI, and they were moved into the third country or territory or directly into the zone of dispatch under conditions at least as strict as if they were moved directly to the Union.
2. By way of derogation from paragraph 1(c), the entry into the Union of registered horses after temporary export to third countries or territories or zones thereof belonging to more than one sanitary group shall be authorised for registered horses which have participated exclusively in specified high level competitions or races.

*Article 178***Special requirements for entry of ungulates, poultry and aquatic animals originating from, and returning to the Union following a refusal of entry by a third country**

1. Consignments of ungulates, poultry and aquatic animals originating from and returning to the Union following a refusal of entry by the competent authority of a third country or territory shall only be permitted to re-enter the Union if the following requirements are fulfilled:
 - (a) the refusing third country or territory is a third country or territory or zone thereof listed for entry into the Union of the species and category of animals which are returning;
 - (b) the animals referred to in point (a) did not transit through a third country or territory or zone thereof other than those referred to in point (a);
 - (c) the animals are accompanied by the following documents:
 - (i) the original animal health certificate issued by the competent authority of the Member State, or its electronic equivalents submitted in IMSOC, or an authenticated copy of the official animal health certificate provided by the competent authority of the Member State of origin;
 - (ii) one of the following:
 - an official declaration of the competent authority or other public authority of the third country or territory, indicating the reason for the refusal and if applicable, confirming that the requirements of point (d) have been complied with,
 - or
 - in the case of sealed consignments with an intact original seal, a declaration by the operator responsible for the consignment confirming that transport has taken place in accordance with point d(ii) and where required point d(iii);
 - (iii) a declaration from the competent authority of the Member State of origin that it agrees to accept the consignment and indicating the place of destination for its return;
 - (d) where they have been unloaded in the third country or territory or zone thereof, the competent authority of the third country or territory shall certify the following:
 - (i) it authorised and supervised the unloading of the animals directly to facilities suitable for their isolation and temporary handling within the premises of the border control post of the third country or territory;

- (ii) effective measures were put in place to avoid direct and indirect contact between the animals of the consignment and any other animals;
- (iii) where necessary, effective protection from vectors of relevant animal diseases were provided for.

2. The transport to and arrival at the place of the destination of the consignment shall be monitored in accordance with Article 2 and 3 of Delegated Regulation (EU) 2019/1666.

Article 179

Special requirements for entry of animals other than ungulates, poultry and aquatic animals originating from, and returning to the Union following a refusal of entry by a third country or territory

1. Consignments of animals other than ungulates, poultry and aquatic animals originating from and returning to the Union following a refusal of entry by the competent authority of a third country or territory shall only be permitted to re-enter the Union if the animals of the consignment are accompanied by the following documents:

- (a) the original animal health certificate issued by the competent authority of the Member State of origin, or its electronic equivalents submitted in IMSOC, or an authenticated copy of the official animal health certificate provided by the competent authority of the Member State of origin;
- (b) one of the following:
 - (i) an official declaration of the competent authority or other public authority of the third country or territory, indicating the reason for refusal;or
 - (ii) in the case of sealed consignments or unopened containers, a declaration by the operator responsible for the consignment indicating the reason for refusal.
- (c) a declaration from the competent authority of the Member State of origin that it agrees to accept the consignment and indicating the place of destination for its return.

2. The transport to and arrival at the place of the destination of the consignment shall be monitored in accordance with Article 2 and 3 of Delegated Regulation (EU) 2019/1666.

Article 180

Special requirements for entry of germinal products and packaged products of animal origin, originating from, and returning to the Union following a refusal of entry by a third country or territory

1. Consignments of germinal products and packaged products of animal origin, originating from and returning to the Union following a refusal of entry by the competent authority of a third country or territory shall only be permitted to re-enter the Union if the following requirements are fulfilled:

- (a) if the germinal products remain in the original container and the packaging of the products of animal origin is intact;
- (b) the germinal products and the products of animal origin are accompanied by:
 - (i) the original animal health certificate issued by the competent authority of the Member State of the place of origin, or its electronic equivalent submitted in IMSOC, or an authenticated copy of the official animal health certificate provided by the competent authority of the Member State of origin;
 - (ii) one of the following documents indicating the reason for refusal and if applicable the place and date of unloading, storage and re-loading in the third country or territory thereof and confirming that the requirements of point (c) have been complied with:
 - a declaration of the competent authority or other public authority of the third country or territory, or
 - in the case of containers with an intact original seal, a declaration by the operator responsible for the consignment;
 - (iii) a declaration from the competent authority of a Member State that it agrees to accept the consignment and indicating the place of destination for its return;

- (c) where the germinal products or products of animal origin referred to in points (a) and (b) have been unloaded in the third country or territory thereof, the competent authority of the third country or territory shall certify the following:
 - (i) the germinal products or products of animal origin did not undergo any other handling except unloading, storage and re-loading;
 - (ii) effective measures were put in place to avoid the contamination of the container where the germinal products are placed or the packaging of products of animal origin with pathogens of listed diseases during the unloading, storage and re-loading.
2. The transport to and arrival at the place of the destination of the consignment shall be monitored in accordance with Article 2 and 3 of Delegated Regulation (EU) 2019/1666.

Article 181

Special requirements for entry of unpackaged or in bulk products of animal origin, originating from, and returning to the Union following a refusal of entry by a listed third country or territory

1. Consignments of unpackaged or in bulk products of animal origin originating from and returning to the Union following a refusal of entry by the competent authority of a listed third country or territory shall only be permitted to re-enter the Union if the following requirements are fulfilled:
- (a) the refusing third country or territory is listed for the entry into the Union of the particular species and category of products of animal origin which are being returned to the Union;
 - (b) the products of animal origin are accompanied by:
 - (i) the original animal health certificate issued by the competent authority of the Member State of origin, or its electronic equivalents submitted in IMSOC, or an authenticated copy of the official certificate provided by the competent authority of the Member State of origin;
 - (ii) one of the following:
 - an official declaration of the competent authority or other public authority of the third country or territory, indicating the reason for refusal and confirming that the seal on the vehicle or container of the consignment was only opened for official purposes and the products were handled only to the smallest extent necessary for those purposes and in particular without unloading them and the vehicle or container was immediately re-sealed afterwards, or
 - in the case of sealed consignments, a declaration by the operator responsible for the consignment indicating the reason for refusal;
 - (iii) a declaration from the competent authority of a Member State that it agrees to accept the consignment and indicating the place of destination for its return.
2. The transport to and arrival at the place of the destination of the consignment shall be monitored in accordance with Article 2 and 3 of Delegated Regulation (EU) 2019/1666.

Article 182

Special requirements for entry of unpackaged or in bulk products of animal origin, originating from, and returning to, the Union following a refusal of entry by a non-listed third country

1. Consignments of unpackaged or in bulk products of animal origin originating from and returning to the Union following a refusal of entry by the competent authority of a third country or territory which is not listed for entry into the Union of the particular species and category of products of animal origin which are being returned, shall only be permitted to re-enter the Union if the following requirements are fulfilled:
- (a) the consignment is sealed with an intact original seal;

- (b) the products of animal origin are accompanied by:
- (i) the original animal health certificate issued by the competent authority of the Member State of origin, or its electronic equivalents submitted in IMSOC, or an authenticated copy of the official animal health certificate provided by the competent authority of the Member State of origin;
 - (ii) one of the following:
 - an official declaration of the competent authority or other public authority of the third country or territory, indicating the reason for refusal, or
 - a declaration by the operator responsible for the consignment indicating the reason for refusal;
 - (iii) a declaration from the competent authority of a Member State that they agree to accept the consignment and indicating the place of destination for its return.
2. The transport to and arrival at the place of the destination of the consignment shall be monitored in accordance with Article 2 and 3 of Delegated Regulation (EU) 2019/1666.

PART VII

FINAL PROVISIONS

Article 183

Repeals

The following acts are repealed as from 21 April 2021:

- Commission Regulation (EU) No 206/2010,
- Commission Implementing Regulation (EU) No 139/2013,
- Commission Regulation (EU) No 605/2010,
- Commission Regulation (EC) No 798/2008,
- Commission Decision 2007/777/EC,
- Commission Regulation (EC) No 119/2009,
- Commission Regulation (EU) No 28/2012,
- Commission Implementing Regulation (EU) 2016/759.

Article 184

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 30 January 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

LIST OF DISEASES REQUIRED TO BE NOTIFIED AND REPORTED IN THE EXPORTING THIRD COUNTRY OR TERRITORY**1. TERRESTRIAL ANIMALS**

All the listed diseases referred to in Article 5 of Regulation (EU) 2016/429 and listed in Annex II thereto for the listed species of terrestrial animals in the Annex to Commission Implementing Regulation (EU) 2018/1882.

2. GERMINAL PRODUCTS**2.1. From ungulates**

- Foot and mouth disease
- Infection with *Brucella abortus*, *B. melitensis* and *B. suis*
- Infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*)
- Infection with bluetongue virus (serotypes 1-24)
- Infection with epizootic haemorrhagic disease virus
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Bovine viral diarrhoea
- Bovine genital campylobacteriosis
- Trichomonosis
- Enzootic bovine leukosis
- Ovine epididymitis (*Brucella ovis*)
- Infection with equine arteritis virus
- Equine infectious anemia
- Contagious equine metritis
- Classical swine fever
- Infection with Aujeszky's disease virus
- Infection with porcine reproductive and respiratory syndrome virus.

2.2. From poultry and captive birds

All the listed diseases referred to in Article 5 of Regulation (EU) 2016/429 and listed in Annex II thereto that are relevant for the listed species of poultry and captive birds in the Annex to Commission Implementing Regulation (EU) 2018/1882, from which germinal products authorised to enter the Union are obtained.

3. PRODUCTS OF ANIMAL ORIGIN FROM UNGULATES, POULTRY AND WILD GAME BIRDS**3.1. Fresh meat from ungulates**

- Foot and mouth disease
- Infection with rinderpest virus
- Infection with Rift Valley fever virus
- Sheep pox and goat pox

- Peste des petits ruminants
- Classical swine fever
- African swine fever

3.2. Fresh meat from poultry and wild game birds

- Highly pathogenic avian influenza
- Infection with Newcastle disease virus

3.3. Meat products from ungulates

- Foot and mouth disease
- Infection with rinderpest virus
- Classical swine fever
- African swine fever

3.4. Meat products from poultry and wild game birds

- Highly pathogenic avian influenza
- Infection with Newcastle disease virus

3.5. Milk, colostrum, dairy products and colostrum-based products

- Foot and mouth disease
- Infection with rinderpest virus

4. AQUATIC ANIMALS AND PRODUCTS OF ANIMAL ORIGIN FROM AQUATIC ANIMALS

- Epizootic haematopoietic necrosis
 - Viral haemorrhagic septicaemia
 - Infectious haematopoietic necrosis
 - Infection with highly polymorphic region (HPR) deleted infectious salmon anaemia virus
 - Koi herpes virus
 - Infection with *Mikrocytos mackini*
 - Infection with *Perkinsus marinus*
 - Infection with *Bonamia ostreae*
 - Infection with *Bonamia exitiosa*
 - Infection with *Marteilia refringens*
 - Infection with Taura syndrome virus
 - Infection with yellow head virus
 - Infection with white spot syndrome virus.
-

ANNEX II

MINIMUM INFORMATION FOR DISEASE SURVEILLANCE PROGRAMMES**(referred to in Article 10)**

The submission of a disease surveillance programme must include at least the following information:

- (a) a description of the epidemiological situation of the disease before the date the surveillance programme began to be implemented, and data on the epidemiological evolution of the disease;
 - (b) the targeted animal population, epidemiological units and zones of the surveillance programme;
 - (c) a description of:
 - (i) the organisation of the competent authority;
 - (ii) how the implementation of the surveillance programme is supervised;
 - (iii) the official controls to be applied during the implementation of the programme;
 - (iv) the role of all relevant operators, animal health professionals, veterinarians, animal health laboratories and other natural or legal person concerned;
 - (d) a description and demarcation of the geographical and administrative areas in which the surveillance programme is to be implemented;
 - (e) the indicators to measure the progress of the programme;
 - (f) the diagnostic methods to be used, the number of samples to be tested, and the frequency of testing and sampling patterns;
 - (g) the risk factors to be considered for the design of risk-based targeted surveillance.
-

ANNEX III

Table 1

Requirements as regards the residency periods for ungulates, honeybees and bumblebees before their entry into the Union

<i>Species and category of animals</i>	<i>Minimum residency period in the third country or territory of origin or zone thereof, as referred to Article 11(b)(i)</i>	<i>Minimum residency period in the establishment of origin, as referred to in Article 11(b)(ii)</i>	<i>Minimum period without contact with animals of a lower health status as referred to in Article 11(b)(iii)</i>
Bovine, ovine, caprine and porcine animals	6 months or since birth, if the animals are less than 6 months of age	40 days, or since birth, if the animals are less than 40 days of age	30 days, or since birth, if the animals are less than 30 days of age
Bovine, ovine, caprine and porcine animals intended for slaughter	3 months, or since birth if the animals are less than 3 months of age	40 days, or since birth, if the animals are less than 40 days of age	30 days, or since birth, if the animals are less than 30 days of age
Equine animals other than registered equine animals	3 months, or since birth if the animals are less than 3 months of age	30 days or since birth, if the animals are less than 30 days of age except for African horse sickness risk areas where the period shall be 40 days	15 days
Registered equine animals	40 days or since birth if the animals are less than 40 days of age	30 days or since birth, if the animals are less than 30 days of age, except for African horse sickness risk areas where the period shall be 40 days	15 days
Registered horses re-entering after temporary export for competition, races or cultural equestrian events	up to 30 days or up to 90 days in case of specific competitions, races or cultural equestrian events	Not established	During the entire period of temporary export
Ungulates other than bovine, ovine, caprine, porcine and equine animals	6 months or since birth, if the animals are less than 6 months of age	40 days, or since birth, if the animals are less than 40 days of age	6 months or since birth, if the animals are less than 6 months of age
Honeybees and bumblebees	Since hatching	Since hatching	Since hatching

Table 2

Requirements as regards the residency periods of poultry and captive birds before their entry into the Union

<i>Category of birds</i>	<i>The residency period applies to</i>	<i>Minimum residency period in the third country or territory of origin or zone thereof, as referred to Article 11(b)(i)</i>	<i>Minimum residency period in the establishment of origin, as referred to Article 11(b)(ii)</i>	<i>Minimum period without contact with animals of a lower health status as referred to in Article 11(b)(iii)</i>
Breeding poultry	AC	3 months or since hatching, if the animals are less than 3 months of age	6 weeks, or since hatching, if the animals are less than 6 weeks of age	6 weeks, or since hatching, if the animals are less than 6 weeks of age
Productive poultry for the production of meat and eggs for consumption	AC	3 months, or since hatching, if the animals are less than 3 months of age	6 weeks, or since hatching, if the animals are less than 6 weeks of age	6 week, or since hatching, if the animals are less than 6 weeks of age

<i>Category of birds</i>	<i>The residency period applies to</i>	<i>Minimum residency period in the third country or territory of origin or zone thereof, as referred to Article 11(b)(i)</i>	<i>Minimum residency period in the establishment of origin, as referred to Article 11(b)(ii)</i>	<i>Minimum period without contact with animals of a lower health status as referred to in Article 11(b)(iii)</i>
Productive poultry for restocking supplies of game birds	AC	6 weeks, or since hatching, if the animals are less than 6 weeks of age	30 days, or since hatching	30 days, or since hatching
Poultry intended for slaughter	AC	6 weeks, or since hatching, if the animals are less than 6 weeks of age	30 days, or since hatching	30 days, or since hatching
Day-old chicks	AC	Since hatching	Since hatching	Since hatching
	FO	3 months	6 weeks	—
Less than 20 breeding poultry, productive poultry and poultry intended for slaughter other than ratites	AC	3 months, or since hatching, if the animals are less than 3 months of age	3 weeks, or since hatching, if the animals are less than 3 weeks of age	3 weeks, or since hatching, if the animals are less than 3 weeks of age
Less than 20 day-old chicks other than ratites	AC	Since hatching	Since hatching	Since hatching
	FO	3 months	3 weeks	3 weeks prior to the date of collection of the eggs from which the day-old chicks have been hatched
Captive birds	AC	NA	3 weeks or since hatching	3 weeks, or since hatching, if the animals are less than 3 weeks of age

AC = Animals of the consignment

FO = Flock of origin

NA = not applicable

ANNEX IV

PART A

1. Minimum periods of disease freedom of the third country or territory of origin or zone thereof, as provided for in Article 22(1) for **ungulates other than equine animals**:

	1. Bovine animals	2. Ovine animals	3. Caprine animals	4. Porcine animals	5. Camelid animals	6. Cervid animals	7. Ungulates other than those referred to in columns 1, 2, 3, 4, 5, 6 (*)
Foot and mouth disease	24 months (**)	24 months (**)	24 months (**)	24 months (**)	24 months (**)	24 months (**)	24 months (**)
Infection with rinderpest virus	12 months	12 months	12 months	12 months	12 months	12 months	12 months
Infection with Rift Valley fever virus	12 months	12 months	12 months	NA	12 months	12 months	12 months
Infection with <i>Mycoplasma mycoides subsp. mycoides SC</i> (Contagious bovine pleuropneumonia)	12 months	NA	NA	NA	NA	NA	12 months
Infection with peste des petits ruminants virus	NA	12 months	12 months	NA	12 months	12 months	NA
Sheep pox and goat pox	NA	12 months	12 months	NA	NA	NA	NA
Contagious caprine pleuropneumonia	NA	12 months	12 months	NA	NA	NA	12 months
African swine fever	NA	NA	NA	12 months	NA	NA	NA
Classical swine fever	NA	NA	NA	12 months (**)	NA	NA	12 months
Infection with lumpy skin disease virus	12 months	NA	NA	NA	NA	NA	NA

(*) only applicable for listed species in accordance with the Annex to Commission Implementing Regulation (EU) 2018/1882

(**) or specific conditions are provided by the competent authority of the third country or territory in accordance with Part B as provided for in Article 22(3)

NA = not applicable

2. Minimum periods of disease freedom of the third country or territory of origin or zone thereof in accordance with Article 22(2)(a) for **equine animals**:

African horse sickness	24 months
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3. Minimum periods during which disease has not been reported in the third country or territory of origin or zone thereof in accordance with Article 22(2)(b) for **equine animals**:

Venezuelan equine encephalomyelitis	24 months
Infection with <i>Burkholderia mallei</i> (Glanders)	36 months (**)
Dourine	24 months (**)
Surra (<i>Trypanosoma evansi</i>)	24 months (**)

(**) or specific conditions are provided by the competent authority of the third country or territory in accordance with Part B as provided for in Article 22(3)

PART B

Specific conditions to be provided by the competent authority of the third country or territory where the third country or territory or zone thereof has been free from certain diseases for less than the period set out in the table in Part A of this Annex as referred to in Article 22(3):

Foot and mouth disease	Supplementary information to determine the date from which the third country or territory or zone thereof is considered to be free from foot and mouth disease.
Classical swine fever	<p>(a) supplementary information to determine the date from which the third country or territory or zone thereof is considered to be free from classical swine fever;</p> <p>(b) the animals intended for entry into the Union have reacted negatively to a test for the detection of classical swine fever, carried out within a period of 30 days prior to the date of dispatch to the Union.</p>
Infection with <i>Burkholderia mallei</i> (Glanders)	<p>(a) the disease not reported in the establishment of origin during a period of at least 6 months prior to the date of dispatch to the Union;</p> <p>(b) the Commission has recognised the surveillance programme carried out in breeding equine animals in the establishment of origin to demonstrate absence of infection during that period of 6 months.</p>
Dourine	<p>(a) the disease not reported in the establishment of origin for a period at least 6 months prior to the date of dispatch to the Union;</p> <p>(b) the Commission has recognised the surveillance programme carried out to demonstrate the absence of infection in the establishment of origin during that period of 6 months.</p>
Surra (<i>Trypanosoma evansi</i>)	<p>(a) the disease has not been reported in the establishment of origin for a period of at least the 6 months prior to the date of dispatch to the Union;</p> <p>(b) the Commission has recognised the surveillance programme carried out to demonstrate the absence of infection in the establishment of origin during that period of 6 months.</p>

PART C

1. Requirements as regards the absence of vaccination for the third country or territory of origin or zone thereof and for the **ungulates other than equine animals** as referred to in Article 22(4)(a):

	1. Bovine animals	2. Ovine animals	3. Caprine animals	4. Porcine animals	5. Camelid animals	6. Cervid animals	7. Ungulates others than those referred to in columns 1, 2, 3, 4, 5, 6 (*)
Foot and mouth disease	NV/NVA	NV/NVA	NV/NVA	NV/NVA	NV/NVA	NV/NVA	NV/NVA
Infection with rinderpest virus	NV/NVA	NV/NVA	NV/NVA	NV/NVA	NV/NVA	NV/NVA	NV/NVA
Rift Valley fever virus	NV/NVA	NV/NVA	NV/NVA	NA	NV/NVA	NV/NVA	NV/NVA
Infection with <i>Mycoplasma mycoides subsp. mycoides</i> SC (Contagious bovine pleuropneumonia)	NV/NVA	NA	NA	NA	NA	NA	NV/NVA
Infection with peste des petits ruminants virus	NA	NV/NVA	NV/NVA	NA	NV/NVA	NV/NVA	NA
Sheep pox and goat pox	NA	NV/NVA	NV/NVA	NA	NA	NA	NA
Contagious caprine pleuropneumonia	NA	NV/NVA	NV/NVA	NA	NA	NA	NV/NVA
Classical swine fever	NA	NA	NA	NV/NVA	NA	NA	NA
Infection with lumpy skin disease virus	NVA	NA	NA	NA	NA	NA	NA

(*) only applicable for listed species in accordance with the Annex to Commission Implementing Regulation (EU) 2018/1882

NV = for a period of at least 12 months prior to the date of dispatch to the Union, no vaccination has been carried out in the third country, territory or zone and no vaccinated animals entered into the third country territory or zone

NVA = the animals intended for the entry into the Union have not been vaccinated

NA = not applicable

2. Requirements as regards the absence of vaccination for the third country or territory of origin or zone thereof and for the **equine animals** as referred to in Article 22(4)(b):

African horse sickness	— No systematic vaccination has been carried out in in the third country or territory of origin or zone thereof during a period of at least 12 months prior to the date of dispatch to the Union and the equine animals have not been vaccinated at least in the last 40 days prior to dispatch to the Union
Venezuelan equine encephalomyelitis	— The equine animals have not been vaccinated at least in the last 60 days prior to dispatch to the Union

ANNEX V

REQUIREMENTS FOR ENTRY INTO THE UNION AS REGARDS THE DISEASE FREEDOM OF THE THIRD COUNTRY OR TERRITORY OF ORIGIN OR ZONE THEREOF FROM INFECTION WITH MYCOBACTERIUM TUBERCULOSIS COMPLEX (M. BOVIS, M. CAPRAE, M. TUBERCULOSIS) AND INFECTION WITH BRUCELLA ABORTUS, B. MELITENSIS AND B. SUIIS**1. INFECTION WITH MYCOBACTERIUM TUBERCULOSIS COMPLEX (M. BOVIS, M. CAPRAE AND M. TUBERCULOSIS) (AS REFERRED TO IN ARTICLE 22(5))****1.1. Bovine animals**

Where bovine animals do not originate from a third country or territory or zone thereof free of *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae*, *M. tuberculosis*) as regards bovine animals, they must comply with one of the following requirements:

- (a) they have been tested using one of the diagnostic methods provided for in Part 2 of Annex I to Delegated Regulation (EU) 2020/688 for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), with negative results, during the period of 30 days prior to the date of dispatch to the Union; or
- (b) they are less than 6 weeks old.

2. INFECTION WITH BRUCELLA ABORTUS, B. MELITENSIS AND B. SUIIS (AS REFERRED TO IN ARTICLE 22(6))**2.1. Bovine animals**

Where bovine animals do not originate from a third country or territory or zone thereof free of *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination as regards bovine animals, they must comply with one of the following requirements:

- (a) they have been tested using one of the diagnostic methods provided for in Part 1 of Annex I to Delegated Regulation (EU) 2020/688 for infection with *Brucella abortus*, *B. melitensis* and *B. suis*, with negative results, on a sample taken during the period of 30 days prior to the date of dispatch to the Union and, in the case of post-parturient females, the test has been carried out on a sample taken at least 30 days after parturition; or
- (b) they are less than 12 months old; or
- (c) they are castrated.

2.2. Ovine and caprine animals

Where ovine and caprine animals do not originate from a third country or territory or zone thereof free of *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination as regards ovine and caprine animals, they must comply with one of the following requirements:

- (a) they have been tested using one of the diagnostic methods provided for in Part 1 of Annex I to Delegated Regulation (EU) 2020/688 for infection with *Brucella abortus*, *B. melitensis* and *B. suis*, with negative results, on a sample taken during the period of 30 days prior to the date of dispatch to the Union and, in the case of post-parturient females, the test has been carried out on a sample taken at least 30 days after parturition; or
 - (b) they are less than 6 months old; or
 - (c) they are castrated.
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ANNEX VI

PART A

**SPECIFIC CONDITIONS FOR THE ENTRY INTO THE UNION OF UNGULATES AS REGARDS THE DISEASE
FREEDOM OF THE THIRD COUNTRY OR TERRITORY OF ORIGIN OR ZONE THEREOF FROM INFECTION
WITH BLUETONGUE VIRUS (SEROTYPES 1-24) FOR A PERIOD OF 2 YEARS**

(AS REFERRED TO IN ARTICLE 22(7))

Where ungulates of listed species do not originate from a third country or territory or zone thereof free from infection with bluetongue virus (serotypes 1-24), they must originate from a third country or territory or zone thereof which complies with at least one of the following requirements:

- (a) the animals have been kept in a third country or territory or zone thereof seasonally free from infection with bluetongue virus (serotypes 1-24) as defined in Delegated Regulation (EU) 2020/689:
 - (i) for a period of at least 60 days prior to the date of dispatch to the Union; or
 - (ii) for a period of at least 28 days prior to the date of dispatch to the Union, and have undergone a serological test, with negative results, carried out on samples collected at least 28 days following the date of the animal's entry into the third country or territory or zone thereof seasonally free from infection with bluetongue virus (serotypes 1-24);
or
 - (iii) for a period of at least 14 days prior to the date of dispatch to the Union, and have undergone a polymerase chain reaction (PCR) test, with negative results, carried out on samples collected at least 14 days following the date of the animal's entry into the third country or territory or zone thereof that is seasonally free of BTV;
- (b) the animals originate from a third country, territory or zone thereof with a surveillance system in place designed and implemented in accordance with Sections 1 and 2 of Chapter 1, Part II of Annex to Delegated Regulation (EU) 2020/689 and have been vaccinated against all the serotypes (1 to 24) of bluetongue virus reported during the preceding 2 years in that third country, territory or zone thereof, and the animals are still within the immunity period of time guaranteed in the specifications of the vaccine, and the animals comply with at least one of the following requirements:
 - (i) they have been vaccinated more than 60 days prior to the date of dispatch to the Union; or
 - (ii) they have been vaccinated with an inactivated vaccine and have undergone a PCR test, with negative results on samples collected at least 14 days after the onset of the immunity protection set in the specifications of the vaccine;
- (c) the animals originate from a third country, territory or zone thereof with a surveillance system in place designed and implemented in accordance with Sections 1 and 2 of Chapter 1, Part II of Annex to Delegated Regulation (EU) 2020/689 and the animals have undergone, with positive results, a serological test able to detect specific antibodies against all serotypes (1-24) bluetongue virus reported during the preceding 2 years in that third country or territory or zone thereof, and:
 - (i) the serological test must have been carried out on samples collected at least 60 days prior to the date of movement;

or

 - (ii) the serological test must have been carried out on samples collected at least 30 days prior to the date of movement and the animals were subjected to a PCR test, with negative results, carried out on samples collected not earlier than 14 days prior to the date of dispatch to the Union.

PART B**SPECIFIC CONDITIONS FOR THE ENTRY INTO THE UNION OF CONSIGNMENTS OF BOVINE ANIMALS AS REGARDS THE DISEASE FREEDOM OF THE THIRD COUNTRY OR TERRITORY OF ORIGIN OR ZONE THEREOF FOR ENZOOTIC BOVINE LEUKOSIS**

(AS REFERRED TO IN ARTICLE 22(8))

Where bovine animals do not originate from a third country or territory or zone thereof free of enzootic bovine leukosis, they must come from an establishment where that disease has not been reported during the period of 24 months prior to the date of dispatch to the Union, and:

- (a) if the animals are over the age of 24 months, they have been subjected to a laboratory examination for enzootic bovine leukosis using one of the diagnostic methods provided for in Part 4 of Annex I to Delegated Regulation (EU) 2020/688, carried out, with negative results either:
 - (a) on samples taken on two occasions at an interval of at least 4 months while the animals were kept in isolation from the other bovine animals of the same establishment; or
 - (b) on a sample taken during the last 30 days prior to their dispatch to the Union, and all bovine animals over 24 months kept in the establishment have been subjected to a laboratory examination for enzootic bovine leucosis with one of the diagnostic methods provided for in Part 4 of Annex I to Delegated Regulation (EU) 2020/688, carried out, with negative results, on samples taken on two occasions at an interval of not less than 4 months during the last 12 months prior to the date of dispatch to the Union;
 - (b) if the animals are less than 24 months of age, they were born to dams, which have been subjected to a laboratory examination for enzootic bovine leukosis using one of the diagnostic methods provided for in Part 4 of Annex I to Delegated Regulation (EU) 2020/688, carried out, with negative results, on samples taken on two occasions at an interval of not less than 4 months during the period of 12 months prior to the date of dispatch to the Union.
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ANNEX VII

**ADDITIONAL REQUIREMENTS FOR THE ENTRY INTO THE UNION OF UNGULATES AS REGARDS CERTAIN
CATEGORY C DISEASES**

(AS REFERRED TO IN ARTICLE 22(9))

1. INFECTIOUS BOVINE RHINOTRACHEITIS/INFECTIOUS PUSTULAR VULVOVAGINITIS**1.1. Bovine animals**

The animals must have not been vaccinated and they must have been kept in quarantine for a period of at least 30 days prior to the date of dispatch to the Union and have undergone a serological test for the detection of antibodies against whole BoHV-1. One of the diagnostic methods provided for in Part 5 of Annex I to Delegated Regulation (EU) 2020/688 must have been used, and a negative result obtained. In addition, the test must have been carried out on a sample collected in the establishment of origin within the period of 15 days prior to the date of dispatch for the Union.

1.2. Camelid and cervid animals

Camelid and cervid animals intended for entry into a Member State or zone thereof with disease-free status or with an approved eradication programme regarding infectious bovine rhinotracheitis/infectious pustular vulvovaginitis in bovine animals, must come from an establishment in which infectious bovine rhinotracheitis/infectious pustular vulvovaginitis has not been reported on animals of the same species as the animals of the consignment during the last 30 days prior to dispatch to the Union.

2. BOVINE VIRAL DIARRHOEA

The animals have not been vaccinated against bovine viral diarrhoea and must have been tested for bovine viral diarrhoea virus antigen or genome using one of the diagnostic methods provided for in Part 6 of Annex I to Delegated Regulation (EU) 2020/688, with negative results, and either:

- (a) the animals have been kept in an approved quarantine establishment for a period of at least 21 days prior to their departure and, in the case of pregnant dams, they have been subjected to a serological test for the detection of antibodies against bovine viral diarrhoea virus using one of the diagnostic methods provided for in Part 6 of Annex I to Delegated Regulation (EU) 2020/688, with negative results, carried out on samples taken not less than 21 days after commencement of the quarantine; or
- (b) the animals have been subjected to a serological test for the detection of antibodies against bovine viral diarrhoea virus using one of the diagnostic methods provided for in Part 6 of Annex I to Delegated Regulation (EU) 2020/688, with positive results, carried out on samples taken either prior to departure or, in the case of pregnant dams, before insemination preceding the current gestation.

3. INFECTION WITH AUJESZKY'S DISEASE VIRUS

The animals have not been vaccinated against infection with Aujeszky's disease virus and must have been:

- (a) kept in an approved quarantine establishment for a period of at least 30 days; and
 - (b) subjected to a serological test for the detection of antibodies against whole Aujeszky's disease virus with the diagnostic method provided for in Part 7 of Annex I to Delegated Regulation (EU) 2020/688, with a negative result, carried out on samples taken on two occasions at an interval of not less than 30 days, the last sample taken during the period of 15 days prior to the date of dispatch to the Union.
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ANNEX VIII

ANIMAL HEALTH REQUIREMENTS AS REGARDS THE ESTABLISHMENT OF ORIGIN OF UNGULATES

1. Minimum areas (radius) and periods (prior to dispatch to the Union) without reported disease in the area in and around the establishment of origin of the **ungulates other than equine animals**, as referred to in Article 23(1)(a)(i):

	1. Bovine animals	2. Ovine animals	3. Caprine animals	4. Porcine animals	5. Camelid animals	6. Cervid animals	7. Ungulates others than those referred to in columns 1, 2, 3, 4, 5, 6 (*)
Foot and mouth disease	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days
Infection with rinderpest virus	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days
Infection with Rift Valley fever virus	10 km/30 days	10 km/30 days	10 km/30 days	NA	10 km/30 days	10 km/30 days	10 km/30 days
Infection with <i>Mycoplasma mycoides subsp. mycoides SC</i> (Contagious bovine pleuropneumonia)	10 km/30 days	NA	NA	NA	NA	NA	10 km/30 days
Infection with peste des petits ruminants virus	NA	10 km/30 days	10 km/30 days	NA	10 km/30 days	10 km/30 days	NA
Sheep pox and goat pox	NA	10 km/30 days	10 km/30 days	NA	NA	NA	NA
Contagious caprine pleuropneumonia	NA	10 km/30 days	10 km/30 days	NA	NA	NA	10 km/30 days
African swine fever	NA	NA	NA	10 km/30 days	NA	NA	NA
Classical swine fever	NA	NA	NA	10 km/30 days	NA	NA	NA
Infection with lumpy skin disease virus	10 km/30 days	NA	NA	NA	NA	NA	NA
Infection with epizootic haemorrhagic disease virus	150 km/2 years (**)	150 km/2 years (**)	150 km/2 years (**)	NA	150 km/2 years (**)	150 km/2 years (**)	150 km/2 years (**)

(*) only applicable for listed species in accordance with the Annex to Commission Implementing Regulation (EU) 2018/1882

(**) not applicable if the animals originate from a third country, territory or zone thereof seasonally free of the disease in accordance with the relevant Chapter of the Terrestrial Animal Health Code of the World Animal Health Organisation (OIE)

NA = not applicable

2. Minimum periods without reported disease in the establishment of origin for **ungulates other than equine animals** as referred to in Article 23(1)(a)(i):

	1. Bovine animals	2. Ovine animals	3. Caprine animals	4. Porcine animals	5. Camelid animals	6. Cervid animals	7. Ungulates others than those referred to in columns 1, 2, 3, 4, 5, 6 (*)
<i>Burkholderia mallei</i> (Glanders)	NA	NA	6 months	NA	Same as equine animals (point (4))	NA	NA
Rabies	30 days						
Surra (<i>Trypanosoma evansi</i>)	30 days (**)	30 days (**)	30 days (**)	NA	30 days (**)	30 days (**)	30 days (**)
Anthrax	15 days						
Infection with Aujeszky's disease virus	NA						

(*) only applicable for listed species in accordance with the Annex to Commission Implementing Regulation (EU) 2018/1882

(**) if the disease was reported in the establishment of origin during the period of 2 years prior to the date of dispatch to the Union, following the last outbreak the affected establishment must have remained under restriction until:

(a) the infected animals were removed from the establishment;

(b) the remaining animals on the establishment underwent, with negative result, a test for surra (*Trypanosoma evansi*) as described in Part 3 of Annex I to Delegated Regulation (EU) 2020/688 carried out on samples taken at least 6 months after the infected animals were removed from the establishment.

NA = not applicable

3. Minimum areas (radius) and periods without a reported case or outbreak of equine infectious anaemia in the area in and around the establishment of origin of **equine animals** as referred to in Article 23(1)(a)(ii):

	Area	Period	Requirements to be complied with where there has been an outbreak in the establishment
Equine infectious anaemia	200 m	3 months	All the equine animals were isolated until they were subjected to a serological test for equine infectious anaemia carried out with negative results on two samples taken after the slaughter of the infected animal and 3 months apart

4. Minimum periods without a reported case or outbreak of certain diseases in the establishment of origin for **equine animals** as referred to in Article 23(1)(a)(ii):

	Period	Requirements to be complied with where there has been a previous outbreak in the establishment
Infection with <i>Burkholderia mallei</i> (Glanders)	6 months	<p>Where an infection was reported in the establishment during the period of 3 years prior to the date of dispatch to the Union, following the last outbreak the establishment remained under movement restrictions by the competent authority until:</p> <ul style="list-style-type: none">— the infected animals have been killed and destroyed, and— the remaining animals were subjected to a test carried out as described in point 3.1 of Chapter 2.5.1.1 of the OIE Terrestrial Manual (Version adopted 2015) with negative results on samples taken at least 6 months after the date on which the infected animals were killed and destroyed and the establishment cleaned and disinfected
Venezuelan equine encephalomyelitis	6 months	<p>If they come from an establishment situated in a third country, territory or zone thereof in which Venezuelan equine encephalomyelitis has been reported during the last 2 years prior to the date of dispatch to the Union, they comply with the conditions in point (i) and the conditions in either of points (ii) or (iii):</p> <p>(i) during the period of at least 21 days prior to departure they have remained clinically healthy and any animal referred to in point (ii) or (iii) which showed a rise in body temperature, taken daily, have been subjected to a diagnostic test for Venezuelan equine encephalomyelitis with the diagnostic method provided for in point (a) of Part 10(1) of Annex I of Delegated Regulation (EU) 2020/688, with negative results; and</p> <p>(ii) the animals were kept in quarantine for a period of at least 21 days protected from attacks by insect vector, and either</p> <ul style="list-style-type: none">— have been vaccinated against Venezuelan equine encephalomyelitis with a complete primary course and revaccinated according to manufacturer's recommendations not less than 60 days and not more than 12 months prior to the date of dispatch, or— have been subjected to a test for Venezuelan equine encephalomyelitis with the diagnostic method provided for in point (b) of Part 10(1) of Annex I of Delegated Regulation (EU) 2020/688, with negative results, carried out on a sample taken not less than 14 days after the date of entry into quarantine; <p>(iii) the animals have been subjected to</p> <ul style="list-style-type: none">— a test for Venezuelan equine encephalomyelitis with the diagnostic method provided for in point (b) of Part 10(1) of Annex I of Delegated Regulation (EU) 2020/688, without an increase in antibody titre, carried out on paired samples taken on two occasions with an interval of 21 days, the second of which was taken during a period of 10 days prior to the date of departure, and— a test for the detection of Venezuelan equine encephalomyelitis virus genome with the diagnostic method provided for in Part 10(2) of Annex I Delegated Regulation (EU) 2020/688, with negative result, carried out on a sample taken within 48 hours prior to departure, and the animals have been protected from attacks by insect vectors after sampling until departure.

	Period	Requirements to be complied with where there has been a previous outbreak in the establishment
Dourine	6 months	Where an infection was reported in the establishment during the period of 2 years prior to the date of dispatch to the Union, following the last outbreak the establishment remained under movement restriction by the competent authority until: <ul style="list-style-type: none"> — the infected animals have been killed and destroyed or slaughtered, or the infected entire male equine animals have been castrated, and — the remaining equine animals in the establishment, with the exception of the castrated male equine animals referred to in first indent kept apart from female equine animals, were subjected to a test for dourine with the diagnostic method provided for in Part 8 of Annex I of Delegated Regulation (EU) 2020/688 with negative results, carried out on samples taken at least 6 months after the measures described in the first indent have been completed.
Surra (<i>Trypanosoma evansi</i>)	6 months	Where infection was reported in the establishment during the period of 2 years prior to the date of dispatch to the Union, the establishment remained under movement restriction by the competent authority until: <ul style="list-style-type: none"> — the infected animals have been removed from the establishment, and — the remaining animals have undergone a test for surra (<i>Trypanosoma evansi</i>) using one of the diagnostic methods provided for in Part 3 of Annex I of Delegated Regulation (EU) 2020/688 with negative results, carried out on samples taken at least 6 months after the last infected animal has been removed from the establishment.
Equine anemia	90 days	Where an infection was reported in the establishment during the period of 12 months prior to the date of dispatch to the Union, following the last outbreak the establishment remained under movement restriction by the competent authority until: <ul style="list-style-type: none"> — the infected animals have been killed and destroyed or slaughtered, and — the remaining animals in the establishment have been subjected to a test for equine infectious anemia with the diagnostic method provided for in Part 9 of Annex I of Delegated Regulation (EU) 2020/688 with negative results, carried out on samples taken on two occasions with a minimum interval of 3 months after the measures described in the first indent have been completed and the establishment was cleaned and disinfected.
Rabies	30 days	—
Anthrax	15 days	—

ANNEX IX

1. INFECTION WITH MYCOBACTERIUM TUBERCULOSIS COMPLEX (M. BOVIS, M. CAPRAE AND M. TUBERCULOSIS) (AS REFERRED TO IN ARTICLE 23(2))

Species	Requirements as regards the establishment of origin
Bovine animals	Free as regards bovine animals
Ovine animals	In the establishment, infection with <i>Mycobacterium tuberculosis</i> complex (<i>M. bovis</i> , <i>M. caprae</i> and <i>M. tuberculosis</i>) has not been reported during the last 42 days prior to dispatch to the Union
Caprine animals	In the establishment, surveillance for infection with <i>Mycobacterium tuberculosis</i> complex (<i>M. bovis</i> , <i>M. caprae</i> and <i>M. tuberculosis</i>) has been carried out on animals of the same species as the animals of the consignment kept on the establishments in accordance with the procedures provided for in point 1 and 2 of Part 1 of Annex II to Delegated Regulation (EU) 2020/688 during at least the last 12 months prior to dispatch to the Union and during this period: (a) only animals of the same species as the animals of the consignment from establishments applying the measures provided in the paragraph have been introduced in the establishment; (b) in case infection with <i>Mycobacterium tuberculosis</i> complex (<i>M. bovis</i> , <i>M. caprae</i> and <i>M. tuberculosis</i>) has been reported in animals of the same species as the animals of the consignment kept on the establishment, measures were taken in accordance with Part 1(3) of Annex II to Delegated Regulation (EU) 2020/688.
Camelid animals	
Cervid animals	

2. INFECTION WITH BRUCELLA ABORTUS, B. MELITENSIS AND B. SUIIS (AS REFERRED TO IN ARTICLE 23(3))

Species	Requirements as regards the establishment of origin
Bovine animals	The establishment is free without vaccination as regards bovine animals
Ovine animals	The establishment is free without vaccination as regards ovine and caprine animals
Caprine animals	The establishment is free without vaccination as regards ovine and caprine animals
Porcine animals	In the establishment, infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i> has not been reported during the last 42 days prior to dispatch to the Union and during the last 12 months prior to dispatch to the Union: (a) biosecurity and risk mitigating measures, including housing conditions and feeding systems, have been applied in the establishment as necessary to prevent transmission of infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i> from wild animals of listed species to porcine animals kept on the establishment and only porcine animals from establishments applying equivalent biosecurity measures have been introduced; or (b) surveillance for infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i> has been carried out on the porcine animals kept on the establishment in accordance with Annex III to Delegated Regulation (EU) 2020/688, and during the same period: — only porcine animals from establishments applying the biosecurity measures or the surveillance measures provided for in points (a) or (b) have been introduced in the establishment, and — in case infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i> has been reported in porcine animals kept on the establishment, measures were taken in accordance with Part 1(3) of Annex II to Delegated Regulation (EU) 2020/688
Camelid animals	Infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i> in camelid animals has not been reported during the last 42 days prior to dispatch to the Union, and they have been subjected to a test for the detection of infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i> with one of the diagnostic methods provided for in Part 1 of Annex I to Delegated Regulation (EU) 2020/688, with negative results, carried out on a sample taken during the last 30 days prior to dispatch to the Union, and in the case of post-parturient females, taken at least 30 days after parturition
Cervid animals	Infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i> in cervid animals has not been reported during the last 42 days prior to dispatch to the Union

ANNEX X

SPECIFIC REQUIREMENTS FOR ENTRY INTO THE UNION OF CERTAIN SPECIES AND CATEGORIES OF UNGULATES AS REGARDS INFECTION WITH BRUCELLA AS REFERRED TO IN ARTICLE 24(5)**1. OVINE ANIMALS**

Uncastrated males of ovine animals, others than those intended for slaughter in the Union, must comply with the following requirements:

- (a) they have remained for a continuous period of at least 60 days in an establishment where infection with *Brucella ovis* (contagious epididymitis) has not been reported during the period of 12 months prior to the date of dispatch to the Union;
- (b) they have undergone a serological test for the detection of *Brucella ovis* (contagious epididymitis), with negative results, during the 30 days prior to the date of dispatch to the Union.

2. UNGULATES OF THE FAMILY TAYASSUIDAE

Ungulates of the family *Tayassuidae* must have undergone a test for the detection of *Brucella suis* using one of the diagnostic methods provided for in point 2 of Part 1 of Annex I of Delegated Regulation (EU) 2020/688, with negative results, during the period of 30 days prior to the date of dispatch to the Union.

ANNEX XI

SPECIFIC REQUIREMENTS FOR EQUINE ANIMALS AS REFERRED TO IN ARTICLE 24(6)

1. SANITARY GROUPS TO WHICH THIRD COUNTRIES, TERRITORIES OR ZONES THEREOF ARE ASSIGNED

Sanitary group	Diseases for which specific requirements are required
A	equine infectious anaemia
B	equine infectious anaemia, glanders, dourine
C	equine infectious anaemia, Venezuelan equine encephalomyelitis
D	equine infectious anaemia, glanders, dourine, Venezuelan equine encephalomyelitis, surra
E	equine infectious anaemia, glanders, dourine, African horse sickness, surra
F	equine infectious anaemia, dourine, African horse sickness
G	equine infectious anaemia, glanders, dourine, surra

2. SPECIFIC REQUIREMENTS

2.1. Specific requirements for African horse sickness

Equine animals must comply with the set of requirements laid down in one of the points set out below.

- (a) the animals have been kept in isolation in vector-protected facilities for a period of at least 30 days prior to dispatch to the Union and a serological and an agent identification test for African horse sickness were carried out with negative result in each case on a blood sample taken not less than 28 days after the date of introduction into the vector-protected facilities and within a period of 10 days prior to the date of dispatch;
- (b) the animals have been kept in isolation in vector-protected facilities for a period of at least 40 days prior to the date of dispatch to the Union and serological tests to detect antibodies against African horse sickness -virus were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the vector-protected facilities;
- (c) the animals have been kept in isolation in vector-protected facilities for a period of at least 14 days prior to dispatch and an agent identification test for African horse sickness virus was carried out with negative result on a blood sample taken not less than 14 days after the date of introduction into the vector-protected facilities and not more than 72 hours before the time of dispatch;
- (d) there is documented evidence that the animals have been vaccinated against African horse sickness with a complete primary course, and revaccinated according to manufacturer's instructions, with a licensed vaccine against all serotypes of the African horse sickness virus present in the source population at least 40 days prior to entry into the vector-protected facilities, and the animals have been kept in isolation in vector-protected facilities for a period of at least 40 days;
- (e) the animals have been kept in isolation in vector-protected facilities for a period of at least 30 days prior to the date of dispatch to the Union and underwent a serological test for the detection of antibodies against the African horse sickness virus, carried out by the same laboratory, on the same day, on blood samples taken during the isolation period in vector-protected facilities on two occasions with an interval of between 21 and 30 days. The second of these must have been taken within a period of 10 days prior to the date of dispatch, with negative results in each case or with a negative result in an agent identification test for African horse sickness virus on the second sample.

2.2. Specific requirements for Venezuelan equine encephalomyelitis

Equine animals must comply with at least one of the following requirements:

- (a) the animals have been vaccinated against Venezuelan equine encephalomyelitis with a complete primary course and revaccinated in accordance with the manufacturer's recommendations during a period of not less than 60 days and not more than 12 months prior to the date of dispatch to the Union and have been kept in vector-protected quarantine for a period of at least 21 days prior to the date of dispatch to the Union, and during that period they have remained clinically healthy, and their body temperature, taken daily, has remained within the normal physiological range.

Any other equine animal on the same establishment which showed a rise in body temperature, taken daily, was subjected to a blood test for virus isolation for Venezuelan equine encephalomyelitis with negative results;

- (b) the animals have not been vaccinated against Venezuelan equine encephalomyelitis and have been and were kept in vector-protected quarantine for a period of at least 21 days, and during that period they have remained clinically healthy, and their body temperature, taken daily, has remained within the normal physiological range. During quarantine the animals were subjected to a diagnostic test for Venezuelan equine encephalomyelitis, with negative results, conducted on a sample taken not less than 14 days after the date of entry of the animals into the vector-protected quarantine; the animals remained protected from vector insects until dispatch.

Any other equine animal on the same establishment that showed a rise in body temperature, taken daily, was subjected to a blood test for virus isolation for Venezuelan equine encephalomyelitis with negative results;

- (c) the animals have been subjected to a haemagglutination inhibition test for Venezuelan equine encephalomyelitis carried out by the same laboratory on the same day on samples taken on two occasions with an interval of 21 days, the second of which was taken during a period of 10 days prior to the date of dispatch, without an increase in antibody titre, and an RT-PCR (reverse transcription polymerase chain reaction) test for the detection of Venezuelan equine encephalomyelitis virus genome, carried out with negative result on a sample taken within 48 hours prior to dispatch, and have been protected from vector attacks from the moment of the RT-PCR sampling until loading for dispatch, by combined use of approved insect repellents and insecticides on the animals and disinsection of the stable and the means in which they are transported.

2.3. Specific requirements for infection with *Burkholderia mallei* (Glanders)

Equine animals must have undergone a complement fixation test for glanders, as described in point 3.1 of Chapter 2.5.11 of the OIE Terrestrial Manual (Version adopted 2015). The test must have been carried out, with negative results, at a serum dilution of 1 in 5 on a blood sample taken within a period of 30 days prior to the date of dispatch to the Union.

2.4. Specific requirements for dourine

Equine animals must have undergone a complement fixation test for dourine, as described in point 3.1 of Chapter 2.5.3 of the OIE Terrestrial Manual (Version adopted 2013). The test must have been carried out, with negative results, at a serum dilution of 1 in 5 on a blood sample taken within a period of 30 days prior to the date of dispatch to the Union. In addition, the tested animals must not have been used for breeding during the period of at least 30 days prior to and after the date the sample was taken.

2.5. Specific conditions for surra (*Trypanosoma evansi*)

Equine animals must have undergone a card agglutination test for trypanosomiasis (CATT), as described in point 2.3 of Chapter 2.1.21 of the OIE Terrestrial Manual (Version adopted 2012). The test must have been carried out, with negative results, at a serum dilution of 1 in 4 on a blood sample taken within a period of 30 days prior to the date of dispatch to the Union.

2.6. Specific conditions for equine infectious anaemia

Equine animals must have undergone an agar gel immunodiffusion test (AGID test) or to an enzyme-linked immunoassay (ELISA) for equine infectious anaemia, as described in points 2.1 and 2.2 of Chapter 2.5.6 of the OIE Terrestrial Manual (Version adopted 2013). The test must have been carried out, with negative results, on a blood sample taken within a period not exceeding 90 days prior to the date of dispatch to the Union.

ANNEX XII

UNGULATES INTENDED FOR CONFINED ESTABLISHMENTS

PART A

Minimum periods without reported disease in the confined establishment of origin of the **ungulates intended for confined establishments in the Union**:

	1. Bovine animals	2. Ovine animals	3. Caprine animals	4. Porcine animals	5. Camelid animals	6. Cervid animals	7. Ungulates others than those referred to in columns 1, 2, 3, 4, 5, 6 (*)
Foot and mouth disease	6 months	6 months	6 months	6 months	6 months	6 months	6 months
Infection with Rift Valley fever virus	6 months	6 months	6 months	NA	6 months	6 months	6 months
Infection with <i>Mycoplasma mycoides</i> subsp. <i>Mycoides</i> SC (Contagious bovine pleuropneumonia)	6 months	NA	NA	NA	NA	NA	6 months
Infection with peste des petits ruminants virus	NA	6 months	6 months	NA	6 months	6 months	NA
Sheep pox and goat pox	NA	6 months	6 months	NA	NA	NA	NA
Contagious caprine pleuropneumonia	NA	6 months	6 months	NA	NA	NA	6 months
African swine fever	NA	NA	NA	6 m	NA	NA	NA
Classical swine fever	NA	NA	NA	6 m	NA	NA	NA
Infection with lumpy skin disease virus	6 m	NA	NA	NA	NA	NA	NA
Infection with <i>Burkholderia mallei</i> (Glanders)	NA	NA	6 months	NA	6 months	NA	NA
Infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i>	6 months	6 months	6 months	6 months	6 months	6 months	6 months
Infection with <i>Mycobacterium tuberculosis</i> complex (<i>M. bovis</i> , <i>M. caprae</i> , <i>M. tuberculosis</i>)	6 months	6 months	6 months	6 months	6 months	6 months	6 months
Rabies	6 months	6 months	6 months	6 months	6 months	6 months	6 months
Surra (<i>Trypanosoma evansi</i>)	30 days	30 days	30 days	NA	180 days	30 days	30 days
Anthrax	30 days	30 days	30 days	30 days	30 days	30 days	30 days
Infection with bluetongue virus (Serotypes 1-24)	6 months	6 months	6 months	NA	6 months	6 months	6 months
Infection with Aujeszky's disease virus	NA	NA	NA	12 months	NA	NA	NA

(*) only applicable for listed species in accordance with the Annex to Commission Implementing Regulation (EU) 2018/1882

NA = not applicable

PART B

Minimum areas (radius) and periods without reported disease in the area around the confined establishment of origin of the **ungulates intended for confined establishments in the Union**:

	1. Bovine animals	2. Ovine animals	3. Caprine animals	4. Porcine animals	5. Camelid animals	6. Cervid animals	7. Ungulates others than those referred to in column 1, 2, 3, 4, 5, 6 (*)
Foot and mouth disease	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days	10 km/30 days
Infection with Rift Valley fever virus	150 km/30 days	150 km/30 days	150 km/30 days	NA	150 km/30 days	150 km/30 days	150 km/30 days
Infection with <i>Mycoplasmma mycoides</i> subsp. <i>Mycoides</i> SC (Contagious bovine pleuropneumonia)	10 km/30 days	NA	NA	NA	NA	NA	10 km/30 days
Infection with Peste des petits ruminants virus	NA	10 km/30 days	10 km/30 days	NA	10 km/30 days	10 km/30 days	NA
Sheep pox and goat pox	NA	10 km/30 days	10 km/30 days	NA	NA	NA	NA
Contagious caprine pleuropneumonia	NA	10 km/30 days	10 km/30 days	NA	NA	NA	10 km/30 days
African swine fever	NA	NA	NA	10 km/12 months	NA	NA	NA
Classical swine fever	NA	NA	NA	10 km/12 months	NA	NA	NA
Infection with lumpy skin disease virus	150 km/30 days	NA	NA	NA	NA	NA	NA
Infection with bluetongue virus (Serotypes 1-24)	150 km/30 days	150 km/30 days	150 km/30 days	NA	150 km/30 days	150 km/30 days	150 km/30 days
Infection with epizootic haemorrhagic disease virus	150 km/30 days	150 km/30 days	150 km/30 days	NA	150 km/30 days	150 km/30 days	150 km/30 days
Infection with Aujeszky's disease virus	NA	NA	NA	5 km/12 months (**)	NA	NA	NA

(*) only applicable for listed species in accordance with the Annex to Commission Implementing Regulation (EU) 2018/1882

(**) in addition, a virology and serology test must be carried out to rule out the presence of the disease 30 days prior to dispatch to the Union

NA = not applicable

PART C

Minimum periods of disease freedom of the third country or territory or zone thereof where the confined establishment of origin is located for **ungulates intended for confined establishments in the Union**:

	1. Bovine animals	2. Ovine animals	3. Caprine animals	4. Porcine animals	5. Camelid animals	6. Cervid animals	7. Ungulates others than those referred to in columns 1, 2, 3, 4, 5, 6 (*)
Foot and mouth disease	12 months (**)	12 months (**)	12 months (**)	12 m (**)	12 months (**)	12 months (**)	12 months (**)
Infection with rinderpest virus	12 months	12 months	12 months	12 months	12 months	12 months	12 months
Infection with Rift Valley fever virus	48 months (**)	48 months (**)	48 months (**)	NA	48 months (**)	48 months (**)	48 months (**)
African swine fever	NA	NA	NA	12 months (**)	NA	NA	NA
Classical swine fever	NA	NA	NA	12 months (**)	NA	NA	NA
Infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i>	12 months (**)	12 months (**)	12 months (**)	12 months (**)	12 months (**)	12 months (**)	12 months (**)
Infection with bluetongue virus (Serotypes 1-24)	24 months (**)	24 months (**)	24 months (**)	NA	24 months (**)	24 months (**)	24 months (**)
Infection with epizootic haemorrhagic disease virus	24 months (**)	24 months (**)	24 months (**)	NA	24 months (**)	24 months (**)	24 months (**)

(*) only applicable for listed species in accordance with the Annex to Commission Implementing Regulation (EU) 2018/1882

(**) or alternative guarantees are provided by the competent authority of the third country or territory according to Part D

NA = not applicable

PART D

Alternative guarantees to be provided by the competent authority of the third country or territory as regards certain listed diseases

Foot and mouth disease	<p>(a) the animals must have undergone a serological test for evidence of foot and mouth disease virus infection carried out in accordance with one of the prescribed tests for international trade laid down in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE Terrestrial Manual), with negative results, on samples taken within a period of 10 days prior to the date of dispatch to the Union; and</p> <p>(b) for <i>Bovidae</i>, <i>Cervidae</i> and <i>Elephas</i> spp.: a probang test for evidence of foot and mouth disease virus infection carried out in accordance with the procedures laid down in the OIE Terrestrial Manual, with negative results. The test must have been carried out:</p> <ul style="list-style-type: none"> (i) 10 days prior to the date of dispatch to the Union, for species other than African buffalo (<i>Syncerus caffer</i>); (ii) on two occasions 15 days at least apart, the second of which must have been taken during the period of 10 days prior to the date of dispatch to the Union, for African buffalo (<i>Syncerus caffer</i>).
Infection with Rift Valley fever virus	<p>(a) the animals must:</p> <ul style="list-style-type: none"> (i) have been kept in quarantine in a vector-protected facility in the approved confined establishment for a period of at least 30 days prior to the date of dispatch to the Union; (ii) have showed no disease symptoms of infection with Rift valley fever virus for a period of at least 30 days prior to the date of dispatch to the Union; (iii) have been protected from vectors when transported between the vector-protected facility referred to in point (i) and loading for dispatch to the Union; and <p>(b) the animals have undergone a virus neutralisation test with negative results for evidence of infection with Rift valley fever virus in accordance with the OIE Terrestrial Manual, carried out firstly on samples taken at the date of commencement of the quarantine period and secondly on samples taken at least 42 days from that date and during a period of 10 days prior to the dispatch to the Union.</p>
African swine fever	The animals have undergone a virology and serology test for the detection of African swine fever and classical swine fever in accordance with the test prescribed for international trade in the OIE Terrestrial Manual, carried out on samples taken during the period of 30 days prior to the date of dispatch to the Union.
Classical swine fever	
Infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i>	<p>The animals:</p> <ul style="list-style-type: none"> (a) have undergone a test as laid down and prescribed for international trade by the OIE Terrestrial Manual, on samples taken during the period of the 30 days prior to the date of dispatch to the Union; or (b) they are castrated males of any age.

Infection with bluetongue virus (Serotypes 1-24)	The animals must comply with the requirements set out in one of the following points:
Infections with epizootic haemorrhagic disease virus	<p>(a) they have been kept in quarantine in a vector-protected facility in the confined establishment for a period of at least 30 days prior to the date of dispatch to the Union and have undergone a serology test for infection with bluetongue virus (1-24) and infection with epizootic haemorrhagic disease virus carried out in accordance with the OIE Terrestrial Manual with negative results, carried out at least 28 days after the introduction of the animals into the confined establishment;</p> <p>(b) they have been kept in quarantine in a vector-protected facility in the approved confined establishment for a period of at least 30 days prior to the date of dispatch to the Union and have undergone a PCR test for infection with bluetongue virus (1-24) and infection with epizootic haemorrhagic disease virus in accordance with the OIE Terrestrial Manual, with negative results, carried out at least 14 days after the introduction into the confined establishment;</p> <p>(c) they come from a seasonally disease-free area and have undergone during that disease-free period a serology test for infection with bluetongue virus (1-24) and infection with epizootic haemorrhagic disease virus according to the OIE Terrestrial Manual, with negative results, carried out on samples taken at least 28 days after introduction of the animals into the confined establishment;</p> <p>(d) they come from a seasonally free area and have undergone during that period a PCR test for infection with bluetongue virus (1-24) and infection with epizootic haemorrhagic disease virus in accordance with the OIE Terrestrial Manual, with negative results, carried out on samples taken at least 14 days after the introduction of the animals into the approved confined establishment.</p>

PART E

Requirements as regards the absence of vaccination against certain diseases for the third country or territory of origin or zone thereof and for the **ungulates intended for confined establishments**:

	1. Bovine animals	2. Ovine animals	3. Caprine animals	4. Porcine animals	5. Camelid animals	6. Cervid animals	7. Ungulates others than those referred to in columns 1, 2, 3, 4, 5, 6 (*)
Foot and mouth disease	NVA	NVA	NVA	NVA	NVA	NVA	NVA
Infection with Rift Valley fever virus	NVA (**)	NVA (**)	NVA (**)	NA	NVA (**)	NVA (**)	NVA (**)
Classical swine fever	NA	NA	NA	NVA	NA	NA	NA
Infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i>	NVA (**)	NVA (**)	NVA (**)	NVA (**)	NVA (**)	NVA (**)	NVA (**)
Infection with Aujeszky's disease virus	NA	NA	NA	NVA	NA	NA	NA

(*) only applicable for listed species in accordance with Commission Implementing Regulation (EU) 2018/1882

(**) or alternative guarantees are provided by the competent authority of the third country or territory according to Part D of this Annex

NVA = the ungulates intended to the Union have not been vaccinated

NA = not applicable

PART F**Requirements for the vector-protected facility in confined establishments in third countries**

Where required in Part D of this Annex, the vector-protected facility in the confined establishments in third countries or territories must comply with the following requirements:

- (a) has appropriate physical barriers at entry and exit points;
 - (b) the openings of the vector-protected facility must be vector-screened with mesh of appropriate gauge, impregnated regularly with an approved insecticide according to the instructions of the manufacturer;
 - (c) vector surveillance and control must be carried out within and around the vector-protected facility;
 - (d) measures must be taken to limit or eliminate breeding sites for vectors in the vicinity of the vector-protected facility;
 - (e) standard operating procedures must be in place, including descriptions of back-up and alarm systems, for the operation of the vector-protected facility and for the transport of the animals from that structure to the place of loading for dispatch to the Union.
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ANNEX XIII

MINIMUM REQUIREMENTS FOR VACCINATION PROGRAMMES AND ADDITIONAL SURVEILLANCE CARRIED OUT IN A THIRD COUNTRY OR TERRITORY OR ZONE THEREOF VACCINATING AGAINST HIGHLY PATHOGENIC AVIAN INFLUENZA**1. MINIMUM REQUIREMENTS FOR VACCINATION PROGRAMMES CARRIED OUT IN A THIRD COUNTRY OR TERRITORY OR ZONE THEREOF**

Vaccination programmes against highly pathogenic avian influenza submitted by a third country or territory must include at least the following information:

- (1) objectives of the vaccination strategy, selected bird population(s) and area;
- (2) data on the epidemiological evolution of the disease, including previous outbreaks in poultry or wild birds;
- (3) description of the reasons for the decision to introduce the vaccination;
- (4) risk assessment based on:
 - highly pathogenic avian influenza outbreaks within that third country or territory or zone thereof,
 - highly pathogenic avian influenza outbreak in a neighbouring country,
 - other risk factors such as certain areas, type of poultry husbandry or categories of poultry or captive birds;
- (5) geographical area where vaccination is carried out;
- (6) number of establishments in vaccination area;
- (7) number of establishments where vaccination is carried out, if different from the number in point 6;
- (8) species and categories of poultry or captive birds in the geographical area where vaccination is carried out;
- (9) approximate number of poultry or captive birds in the establishments referred to in point 7;
- (10) summary of the vaccine characteristics, authorisation and quality control;
- (11) handling, storage, supply, distribution and sale of avian influenza vaccines on the national territory;
- (12) implementation of a Differentiating Infected from Vaccinated Animals (DIVA) strategy;
- (13) envisaged duration of vaccination campaign;
- (14) provisions and restrictions on movements of vaccinated poultry and poultry products derived from vaccinated poultry or vaccinated captive birds;
- (15) clinical and laboratory tests, such as efficacy and pre-movement testing, carried out in the establishments vaccinated or located in the vaccination area;
- (16) means of record keeping.

2. ADDITIONAL SURVEILLANCE IN THIRD COUNTRIES OR TERRITORIES OR ZONES THEREOF THAT CARRY OUT VACCINATION AGAINST HIGHLY PATHOGENIC AVIAN INFLUENZA

Where vaccination is carried out in a third country or territory or zone thereof, all establishments where vaccination against highly pathogenic avian influenza is carried out must be required to undergo laboratory testing and the following information must be submitted to the Commission, in addition to the information referred to in Annex II:

- (1) number of vaccinated establishments in the area per category;
 - (2) number of vaccinated establishments to be sampled per poultry category;
 - (3) use of sentinel birds (namely, the species and number of sentinel birds used per epidemiological unit);
 - (4) number of samples taken per establishment and/or epidemiological unit;
 - (5) data on vaccine efficacy.
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ANNEX XIV

ANIMAL HEALTH REQUIREMENTS FOR RATITES, HATCHING EGGS THEREOF AND FRESH MEAT OF RATITES ORIGINATING IN A THIRD COUNTRY OR TERRITORY OR ZONE THEREOF NOT FREE FROM INFECTION WITH NEWCASTLE DISEASE VIRUS

1. Breeding ratites, productive ratites and ratites intended for slaughter originating in a third country or territory or zone thereof not free from infection with Newcastle disease virus must:
 - (a) have been placed under official surveillance for a period of at least 21 days prior to the date of dispatch of the consignment for entry into the Union;
 - (b) have been kept in complete isolation during the period referred to in point (a), away from direct or indirect contact with other birds, in facilities approved by the competent authority of the third country or territory of origin for this purpose;
 - (c) have undergone a virus detection test for infection with Newcastle disease virus;
 - (d) come from flocks in which surveillance for infection with Newcastle disease virus was carried out under a statistically-based sampling plan which produced negative results for a period of at least 6 months immediately prior to the date of dispatch of the consignment for entry into the Union.
2. Day-old chicks of ratites and hatching eggs of ratites originating in a third country or territory or zone thereof not free from infection with Newcastle disease virus, must come from flocks:
 - (a) which were placed in isolation under official surveillance for a period of at least 30 days prior to the date of laying of the hatching eggs intended for entry into the Union or of the hatching eggs from which the day-old chicks destined for entry into the Union are derived;
 - (b) which underwent a virus detection test for infection with Newcastle disease virus;
 - (c) where surveillance for infection with Newcastle disease virus was carried out under a statistically-based sampling plan which produced negative results for a period of at least 6 months immediately prior to the date of dispatch of the consignment for entry to the Union;
 - (d) which were not in contact with poultry which do not fulfil the guarantees under points (a), (b) and (c) during the period of 30 days prior to the date of laying and during the laying of the hatching eggs intended for entry into the Union or of the hatching eggs from which the day-old chicks destined for entry into the Union are derived.
3. Fresh meat of ratites originating in a third country or territory or zone thereof not free from infection with Newcastle disease virus must:
 - (a) be de-boned and skinned;
 - (b) come from ratites which for a period of at least 3 months prior to the date of slaughter were kept on establishments:
 - (i) on which there was no outbreak of infection with Newcastle disease virus or highly pathogenic avian influenza during the 6 months prior to the date of slaughter;
 - (ii) around which there were no outbreaks of highly pathogenic avian influenza or infection with Newcastle disease virus for a period of at least 3 months prior to the date of slaughter within 10 km of the perimeter of the part of the establishment containing the ratites, including, where appropriate, the territory of a neighbouring Member State or third country;
 - (iii) on which surveillance for infection with Newcastle disease virus was carried out under a statistically-based sampling plan, which produced negative results for a period of at least 6 months prior to the date of slaughter;
 - (c) have undergone surveillance as referred to in point (b)(iii):
 - (i) by serology, in the case of ratites not vaccinated against infection with Newcastle disease virus;
 - (ii) by tracheal swabs of ratites, in the case of ratites vaccinated against infection with Newcastle disease virus;
 - (d) come from ratites which, if vaccinated against infection with Newcastle disease virus, were not vaccinated with vaccines that did not meet the specific criteria set out in Part 1 of Annex XV during the period of 30 days prior to the date of slaughter.

4. The virus detection testing provided for in paragraphs 1(c) and 2(b) must have been carried out:
 - (a) within 7 to 10 days of the date the ratites entered isolation;
 - (b) on cloacal swabs or faeces samples from each bird.
 5. The virus detection testing provided for in paragraphs 1(c) and 2(b) must have shown that no avian paramyxovirus type 1 isolates with an Intracerebral Pathogenicity Index (ICPI) of more than 0,4 were found. In addition, favourable results must have been available from all birds in the consignment before:
 - (a) breeding ratites, productive ratites or ratites intended for slaughter left the facilities referred in 1(b) for dispatch to the Union;
 - (b) day-old chicks left the hatchery for dispatch to the Union;
 - (c) hatching eggs were loaded for dispatch to the Union.
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ANNEX XV

CRITERIA FOR VACCINES AGAINST INFECTION WITH NEWCASTLE DISEASE VIRUS AND REQUIREMENTS FOR CONSIGNMENTS OF POULTRY, HATCHING EGGS AND FRESH MEAT OF POULTRY ORIGINATING FROM A THIRD COUNTRY OR TERRITORY OR ZONE THEREOF VACCINATING AGAINST INFECTION WITH NEWCASTLE DISEASE VIRUS**1. CRITERIA FOR VACCINES AGAINST INFECTION WITH NEWCASTLE DISEASE VIRUS****1.1. General criteria**

- (a) Vaccines must comply with the standards set out in the chapter on Newcastle disease in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE).
- (b) Vaccines must be registered by the competent authorities of the third country or territory of origin concerned before being allowed to be distributed and used. For such registration, the competent authorities of the third country or territory of origin concerned must rely on a complete file submitted by the applicant containing data on the efficacy and innocuity of the vaccine. In the case of imported vaccines, the competent authorities of the third country or territory of origin may rely on data checked by the competent authorities of the country where the vaccine is produced, insofar as these checks have been carried out in conformity with OIE standards.
- (c) In addition to the requirements set out in points (a) and (b), imports or the production and distribution of the vaccines must be controlled by the competent authorities of the third country or territory of origin concerned.
- (d) Before distribution of the vaccines is allowed, each batch of vaccines must be tested on innocuity, in particular regarding attenuation or inactivation and freedom from extraneous agents, and on efficacy. The testing is performed under the control of the competent authorities of the third country or territory of origin.

1.2. Specific criteria

Live attenuated vaccines against infection with Newcastle disease virus must be prepared from a Newcastle disease virus strain for which the master seed has been tested and shown to have an ICPI of either:

- (a) less than 0,4, if not less than 10^7 EID₅₀ are administered to each bird in the ICPI test;
- or
- (b) less than 0,5, if not less than 10^8 EID₅₀ are administered to each bird in the ICPI test.

2. ANIMAL HEALTH REQUIREMENTS FOR POULTRY AND HATCHING EGGS ORIGINATING FROM A THIRD COUNTRY OR TERRITORY OR ZONE THEREOF WHERE VACCINES USED AGAINST INFECTION WITH NEWCASTLE DISEASE VIRUS DO NOT MEET THE SPECIFIC CRITERIA SET OUT IN POINT 1

Poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1.2 must meet the requirements set out below:

- (a) poultry and the flocks of origin of hatching eggs must not have been vaccinated with such vaccines for a period of at least 12 months prior to the date the consignment is loaded for dispatch to the Union;
- (b) the flocks of origin of poultry and of hatching eggs must have undergone a virus isolation test for infection with Newcastle disease virus not earlier than 2 weeks prior to the date of loading of the consignment for dispatch to the Union or, in the case of hatching eggs, not earlier than 2 weeks prior to the date the eggs were collected. The test must have been carried out in an official laboratory on a random sample of cloacal swabs taken from at least 60 birds in each flock, and no avian paramyxoviruses with an ICPI of more than 0,4 have been found;
- (c) poultry and the flocks of origin of hatching eggs must have been kept in isolation under official surveillance on the establishment of origin during the two-week period referred to in point (b);

- (d) poultry and the flocks of origin of hatching eggs must not have been in contact with poultry not meeting the requirements set out in points (a) and (b):
 - (i) in the case of poultry, during the period of 60 days prior to the date the consignment was loaded for dispatch to the Union;
 - (ii) in the case of hatching eggs, during the period of 60 days prior to the date the eggs were collected;
- (e) day-old chicks and the hatching eggs from which the day-old chicks are derived must not have been in contact in the hatchery or during transport to the Union with poultry or hatching eggs not meeting the requirements set out in points (a) to (d).

3. ANIMAL HEALTH REQUIREMENTS FOR FRESH MEAT OF POULTRY ORIGINATING FROM A THIRD COUNTRY OR TERRITORY OR ZONE THEREOF WHERE VACCINES USED AGAINST INFECTION WITH NEWCASTLE DISEASE VIRUS DO NOT MEET THE SPECIFIC CRITERIA SET OUT IN POINT 1

Fresh meat of poultry originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1.2 must originate from poultry that meet the following health requirements:

- (a) the poultry have not been vaccinated with live attenuated vaccines prepared from an infection with Newcastle disease virus master seed showing a higher pathogenicity than lentogenic strains of the virus within the period of 30 days prior to the date of slaughter;
- (b) the poultry underwent a virus isolation test for infection with Newcastle disease virus, carried out in an official laboratory at the time of slaughter on a random sample of cloacal swabs from at least 60 birds in each flock concerned, and in which no avian paramyxoviruses with an ICPI of more than 0,4 were found;
- (c) the poultry have not been in contact during the period of 30 days prior to the date of slaughter with poultry that does not fulfil the conditions set out in points (a) and (b).

4. INFORMATION TO BE PROVIDED WHEN FLOCKS OF ORIGIN OF POULTRY, FLOCKS OF ORIGIN OF HATCHING EGGS AND HATCHING EGGS ARE VACCINATED AGAINST INFECTION WITH NEWCASTLE DISEASE VIRUS

Where the flocks of origin of poultry, the flocks of origin of hatching eggs or hatching eggs are vaccinated against infection with Newcastle disease virus, the following information must be provided for the consignment:

- (a) identification of the flock;
 - (b) age of the birds;
 - (c) date of vaccination;
 - (d) name and type of virus strain used;
 - (e) batch number of the vaccine;
 - (f) name of the vaccine;
 - (g) manufacturer of the vaccine.
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ANNEX XVI

**REQUIREMENTS AS REGARDS THE INFORMATION TO BE MENTIONED ON THE CONTAINERS OF POULTRY,
CAPTIVE BIRDS AND HATCHING EGGS**

1. Breeding poultry and productive poultry must be transported in containers which bear the following indications:
 - (a) the name and ISO code of the third country or territory of origin;
 - (b) the species of poultry concerned;
 - (c) the number of animals;
 - (d) the category and type of production for which they are intended;
 - (e) the name, address and approval number of the establishment of origin;
 - (f) the name of the Member State of destination.
2. Poultry intended for slaughter must be transported in containers which bear the following indications:
 - (a) the name and ISO code of the third country or territory of origin;
 - (b) the species of poultry concerned;
 - (c) the number of animals;
 - (d) the category and type of production for which they are intended;
 - (e) the name, address and registration number of the establishment of origin;
 - (f) the name of the Member State of destination.
3. Day-old chicks must be transported in containers which bear the following indications:
 - (a) the name and ISO code of the third country or territory of origin;
 - (b) the species of poultry concerned;
 - (c) the number of animals;
 - (d) the category and type of production for which they are intended;
 - (e) the name, address and approval number of the establishment of origin of the day-old chicks;
 - (f) the approval number of the establishment of origin of the flock of origin;
 - (g) the name of the Member State of destination.
4. Captive birds must be transported in containers which bear the following indications:
 - (a) the name and ISO code of the third country or territory of origin;
 - (b) the number of animals;
 - (c) the name, address and approval number of the establishment of origin;
 - (d) the specific identification number of the container;
 - (e) the name of the Member State of destination.
5. Hatching eggs of poultry must be transported in containers which bear the following indications:
 - (a) the word 'hatching';
 - (b) the name and ISO code of the third country or territory of origin;
 - (c) the species of poultry concerned;
 - (d) the number of eggs;

- (e) the category and type of production for which they are intended;
 - (f) the name, address and approval number of the establishment of origin of the eggs;
 - (g) the approval number of the establishment of origin of the flock of origin, if different from point (f);
 - (h) the name of the Member State of destination.
6. Specified pathogen-free eggs must be transported in containers which bear the following indications:
- (a) the wording 'SPF eggs for diagnostic, research or pharmaceutical use only';
 - (b) the name and ISO code of the third country or territory of origin;
 - (c) the number of eggs;
 - (d) the name, address and approval number of the establishment of origin;
 - (e) the name of the Member State of destination.
7. Hatching eggs of captive birds must be transported in containers which bear the following indications:
- (a) the name and ISO code of the third country or territory of origin;
 - (b) the number of eggs;
 - (c) the name, address and approval number of the establishment of origin;
 - (d) the specific identification number of the container;
 - (e) the name of the Member State of destination.
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ANNEX XVII

REQUIREMENTS FOR TESTING OF CONSIGNMENTS OF LESS THAN 20 HEADS OF POULTRY OTHER THAN RATITES AND LESS THAN 20 HATCHING EGGS THEREOF BEFORE THEIR ENTRY INTO THE UNION

Consignments of less than 20 heads of poultry other than ratites or less than 20 hatching eggs of poultry other than ratites must have been tested negative for the diseases referred to in point (e) of Article 49 and point (e)(ii) of Article 110 as follows:

- (a) in the case of breeding poultry, productive poultry and poultry intended for slaughter other than ratites, the animals must have been tested negative in serological and/or bacteriological tests within the period of 30 days prior to the date of loading of the consignment for dispatch to the Union;
 - (b) in the case of hatching eggs of poultry other than ratites and day-old chicks other than ratites, the flock of origin must have tested negative in serological tests and/or bacteriological tests within the period of 90 days prior to the date of loading of the consignment for dispatch to the Union at a level which gives 95 % confidence of detecting infection at 5 % prevalence;
 - (c) where the animals have been vaccinated against infection with any serotype of *Salmonella* or *Mycoplasma*, only bacteriological testing must be used, but the confirmation method must be capable of differentiating live vaccinal strains from field strains.
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ANNEX XVIII

SAMPLING AND TESTING OF POULTRY OTHER THAN RATITES AFTER THE ENTRY INTO THE UNION

1. The official veterinarian shall take samples for virological examination from breeding poultry other than ratites, productive poultry other than ratites and day-old chicks other than ratites which have entered into the Union from a third country or territory or zone thereof. The samples must be collected as follows:
 - (a) between the seventh and the fifteenth day following the date when the animals were placed in the establishments of destination in the Union, cloacal swabs must be taken at a level which gives a 95 % confidence of detecting infection at 5 % prevalence;
 - (b) testing of samples must be carried out for:
 - (i) highly pathogenic avian influenza;
 - (ii) infection with Newcastle disease virus.
 2. Samples may be pooled to a maximum of five samples from individual birds in each pool.
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ANNEX XIX

ANIMAL HEALTH REQUIREMENTS FOR GRANTING APPROVAL OF THE ESTABLISHMENT OF ORIGIN OF CAPTIVE BIRDS

1. The animal health requirements in relation to biosecurity measures, as referred to in Article 56, are as follows:
 - (a) only animals coming from other approved establishments may be introduced into the establishment;
 - (b) birds may be introduced into the establishment from sources other than approved establishments after approval for such introduction is given by the competent authority of the third country or territory, provided that such animals are isolated for at least 30 days from the date they were introduced into the establishment, in accordance with the instructions given by the competent authority of the third country or territory, before being added to the collection of birds in the establishment.
2. The animal health requirements in relation to the facilities and equipment on the establishment, as referred to in Article 56, are as follows:
 - (a) the establishment must be clearly demarcated and separated from its surroundings;
 - (b) the establishment must have adequate means for catching, confining and isolating animals and have available adequate approved quarantine facilities and approved procedures for animals coming from establishments that have not been approved;
 - (c) the establishment must either have suitable arrangements or on-site facilities and equipment for the appropriate disposal of the bodies of animals which die of a disease or are euthanised.
3. The animal health requirements in relation to record keeping, as referred to in Article 56, are as follows:
 - (a) the operator responsible for the establishment must keep up-to-date records indicating:
 - (i) the number and identity (namely the age, sex, species and individual identification number where practical) of the animals of each species present in the establishment;
 - (ii) the number and identity (namely the age, sex, species and individual identification number where practical) of animals arriving in the establishment or leaving it, together with information on their origin or destination, the transport from or to the establishment and the animal health status;
 - (iii) the results of blood tests or any other diagnostic procedures;
 - (iv) cases of disease and, where appropriate, the treatment administered;
 - (v) the results of the post-mortem examinations on animals that have died in the establishment, including still-born animals;
 - (vi) observations made during any isolation or quarantine period;
 - (b) the operator responsible for the establishment must keep the records referred to in point (a) following the date of approval, for a period of at least 10 years.
4. The animal health requirements in relation to personnel, as referred to in Article 56, are as follows:
 - (a) the person responsible for the establishment must have adequate ability and knowledge;
 - (b) the operator responsible for the establishment must secure, by contract or other legal instrument, the services of a veterinarian approved by and under the control of the competent authority of the third country or territory, who:
 - (i) ensures that appropriate disease surveillance and control measures in relation to the disease situation of the third country or territory concerned are approved by the competent authority and applied in the establishment; such measures must include the following:
 - an annual disease surveillance programme including appropriate zoonoses control of the animals,
 - clinical, laboratory and post-mortem testing of animals suspected to be affected by diseases,
 - vaccination of susceptible animals against diseases as appropriate, in conformity with the Terrestrial Animal Health Code and the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the OIE;

- (ii) ensures that any suspect deaths or the presence of any other symptoms indicative of highly pathogenic avian influenza, infection with Newcastle disease virus or avian chlamydiosis is notified without delay to the competent authority of the third country or territory;
 - (iii) ensures that animals entering the establishment have been isolated as necessary and in accordance with the requirements of paragraph 1(b) and with the instructions, if any, given by the competent authority of the third country or territory.
5. The animal health requirements in relation to health status, as referred to in Article 56, are as follows:
- (a) the establishment must be free from highly pathogenic avian influenza, infection with Newcastle disease virus and avian chlamydiosis; in order for the establishment to be declared free from those diseases, the competent authority of the third country or territory shall assess the records on the animal health status kept for a period of at least three years prior to the date of the application for approval and the results of the clinical and laboratory tests carried out on the animals therein. However, new establishments must only be approved based on the results of the clinical and laboratory tests carried out on the animals in such establishments;
 - (b) the operator responsible for the establishment must either have an arrangement with a laboratory to perform post-mortem examinations, or have one or more appropriate premises where such examinations may be performed by a competent person under the authority of a veterinarian approved for that purpose by the competent authority of the third country or territory.
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ANNEX XX

EXAMINATION, SAMPLING AND TESTING PROCEDURES OF CAPTIVE BIRDS FOR HIGHLY PATHOGENIC AVIAN INFLUENZA AND NEWCASTLE DISEASE

1. During quarantine either the sentinel birds, or if sentinel birds are not used, the captive birds, shall must undergo the following procedures:
 - (a) cases involving the use of sentinel birds:
 - (i) blood samples for serological examination must be taken from all sentinel birds within a period of not less than 21 days following the date of their entry into the quarantine and within a period of at least 3 days prior to the date of the end of the quarantine;
 - (ii) if sentinel birds show positive or inconclusive serological results for the samples referred to in point (i):
 - the imported birds must undergo a virological examination,
 - cloacal swabs (or faeces) and tracheal or oropharyngeal swabs must be taken from at least 60 birds, or from all birds if the consignment is less than 60 birds;
 - (b) cases not involving the use of sentinel birds:
 - imported birds must be examined virologically (i.e. serological testing is not appropriate),
 - tracheal or oropharyngeal or cloacal swabs (or faeces) must be taken from at least 60 birds, or from all birds if the consignment is less than 60 birds, during the period of the first 7 to 15 days of the quarantine.
2. In addition to the testing set out in point 1, the following samples must be taken for virological examination:
 - (a) cloacal swabs (or faeces) and tracheal or oropharyngeal swabs, if possible, from clinically ill birds or ill sentinel birds;
 - (b) from the intestinal contents, brain, trachea, lungs, liver, spleen, kidneys and other obviously affected organs as soon as possible following death, from:
 - (i) dead sentinel birds and all birds dead on arrival in quarantine and those which die during quarantine; or
 - (ii) in the case of high mortality in large consignments made of small birds, from at least 10 % of the dead birds.
3. For virological examination, pooling of samples up to a maximum of five samples of individual birds in one pool is allowed.

Faecal material must be pooled separately from other organ and tissue samples.

ANNEX XXI

SPECIFIC REQUIREMENTS AS REGARDS DOGS, CATS AND FERRETS INTENDED FOR ENTRY INTO THE UNION

1. ANTIBODY RABIES TITRATION TEST REQUIREMENTS:

- (a) must be carried out on a sample collected by a veterinarian authorised by the competent authority during the period commencing at least 30 days after the date of the primary vaccination, within a current valid vaccination series, and ending 3 months before the date of issue of the certificate;
- (b) must measure a titre of neutralising antibody to rabies virus equal to or greater than 0,5 IU/ml;
- (c) must be certified by an official report from the official laboratory as regards the result, and a copy of this report must be attached to the animal health certificate accompanying the animals to the Union;
- (d) does not have to be renewed on an animal which, following the antibody rabies titration test with satisfactory results, has been revaccinated against rabies within the period of validity of the primary vaccination referred to in point (a) and all subsequent valid vaccinations in the series.

2. TREATMENT AGAINST INFESTATION WITH *ECHINOCOCCUS MULTILOCULARIS*

Prior to entry into the Union, dogs must be treated against infestation with *Echinococcus multilocularis*, as follows:

- (a) the treatment must consist of an approved veterinary medicinal product which contains the appropriate dose of praziquantel or pharmacologically active substances which alone or in combination have proven to reduce the burden of mature and immature intestinal forms of *Echinococcus multilocularis* in the host species concerned;
 - (b) the product must be administered by a veterinarian within a period commencing not more than 48 hours and ending not less than 24 hours before the time of arrival in the Union;
 - (c) the following details of the treatment must be certified by the administering veterinarian in the animal health certificate referred to in Article 3(1)(c)(i):
 - (i) the transponder or tattoo alphanumeric code of the dog, cat or ferret;
 - (ii) the name of the product against infestation with *Echinococcus multilocularis*;
 - (iii) the name of the manufacturer of the product;
 - (iv) the date and time of treatment;
 - (v) the name, stamp and signature of the administering veterinarian.
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ANNEX XXII

REQUIREMENTS AS REGARDS THE RESIDENCY PERIODS OF HATCHING EGGS BEFORE THE ENTRY INTO THE UNION

<i>Category of hatching eggs</i>	<i>Minimum residency period applies to</i>	<i>Minimum residency period in the third country or territory of origin or zone thereof, as referred in Article 98(a)</i>	<i>Minimum residency period in the establishment of origin, as referred to in Article 98(b)</i>	<i>Minimum period without contact with poultry or hatching eggs of lower health status, captive birds or wild birds as referred to in Article 98(c)</i>
Hatching eggs of poultry	Flock of origin	3 months	6 weeks	6 weeks
Consignments of less than 20 hatching eggs of poultry other than ratites	Flock of origin	3 months	3 weeks	3 week

ANNEX XXIII

**REQUIREMENTS AS REGARDS THE RESIDENCY PERIOD BEFORE SLAUGHTER OR KILLING OF THE KEPT
UNGULATES OF ORIGIN OF THE FRESH MEAT**

1. The period during which the ungulates must have remained in the third country or territory of origin or zone thereof before the date of slaughter or killing, as referred to in Article 131(2)(a), must be either:
 - (a) at least 3 months prior that date; or
 - (b) less than 3 months prior to that date, if the ungulates are less than 3 months of age.
 2. Kept ungulates must have remained in their establishment of origin without having come into contact with ungulates of a lower health status, as referred to in Article 131(2)(b) and (c), for at least the 40 days prior to the date of slaughter or killing, where such animals:
 - (a) originate from a third country, territory or zone thereof which applies one or more of the specific conditions set out in Part B of Annex XXIV;
 - (b) are covered by the derogation provided for in Article 132.
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ANNEX XXIV

DISEASE FREEDOM IN THE THIRD COUNTRY OR TERRITORY OF ORIGIN OF THE PRODUCTS OF ANIMAL ORIGIN

PART A

Minimum periods (in months) of disease freedom of the third country or territory of origin or zone thereof in accordance with Article 133(1).

	1. Bovine animals	2. Ovine animals	3. Caprine animals	4. Porcine animals	5. Camelid animals	6. Cervid animals	7. Ungulates other than those referred to in columns 1, 2, 3, 4, 5, 6 (*)
Foot and mouth disease	12 m (**)	12 m (**)	12 m (**)	12 m (**)	12 m (**)	12 m (**)	12 m (**)
Infection with rinderpest virus	12 m	12 m	12 m	12 m	12 m	12 m	12 m
African swine fever	NA	NA	NA	12 m	NA	NA	NA
Classical swine fever	NA	NA	NA	12 m (**)	NA	NA	NA

(*) only applicable to listed species in accordance with Annex to Commission Implementing Regulation (EU) 2018/1882

(**) this period may be reduced where specific conditions, in accordance with Part B, are provided by the competent authority of the third country or territory

NA = not applicable

PART B

Specific conditions to be provided by the competent authority where the third country or territory or zone thereof has been free of the disease for a period of less than 12 months as provided for in the derogation laid down in Article 133(1):

Foot and mouth disease	Supplementary information to guarantee the determination of a date from which the third country or territory or zone thereof is considered free from the disease
Classical swine fever	

ANNEX XXV
VACCINATION IN THE THIRD COUNTRY OR TERRITORY OF ORIGIN OR ZONE THEREOF AND IN THE ESTABLISHMENT OF ORIGIN OF THE ANIMALS FROM WHICH THE FRESH MEAT IS OBTAINED

PART A

Animal health requirements regarding the absence of vaccination in the third country or territory of origin or zone thereof and in the establishment of origin of the ungulates from which the fresh meat is obtained:

	1. Bovine animals	2. Ovine animals	3. Caprine animals	4. Porcine animals	5. Camelid animals	6. Cervid animals	7. Ungulates other than those referred to in columns 1, 2, 3, 4, 5, 6 (*)
Foot and mouth disease	NV/NVE (**)	NV/NVE (**)	NV/NVE (**)	NV/NVE	NV/NVE (**)	NV/NVE (**)	NV/NVE (**)
Infection with rinderpest virus	NV/NVE (**)	NV/NVE (**)	NV/NVE (**)	NV/NVE	NV/NVE (**)	NV/NVE (**)	NV/NVE (**)
African swine fever	NA	NA	NA	NV/NVE	NA	NA	NA
Classical swine fever	NA	NA	NA	NV/NVE	NA	NA	NA

(*) only applicable for listed species in accordance with Annex to Commission Implementing Regulation (EU) 2018/1882
(**) or specific conditions, in accordance with Part B, are provided by the competent authority of the third country or territory

NV = for a period of at least 12 months prior to the date of dispatch to the Union: no vaccination has been carried out in the third country or territory or zone thereof and there have been no entries of vaccinated animals in the third country territory or zone

NVE = no vaccinated animals in the establishment of origin of the ungulates from which the fresh meat is obtained

NA = not applicable

PART B

Specific conditions to be provided by the competent authorities where vaccination against foot and mouth disease has been carried out in the third country or territory or zone thereof for a period of less than 12 months as referred to in Article 133(3)

1. FROM A THIRD COUNTRY, TERRITORY OR ZONE THEREOF WHICH IS FREE FROM FOOT AND MOUTH DISEASE AND WHERE VACCINATION AGAINST FOOT AND MOUTH DISEASE STRAINS A, O OR C IS PRACTISED

The competent authority of the third country or territory of origin must provide supplementary information to guarantee the absence of foot and mouth disease virus in fresh meat and compliance with the following requirements:

- (a) a vaccination programme against foot and mouth disease is carried out in kept bovine animals and controlled by the competent authority of the third country or territory of origin;
- (b) the fresh meat is obtained from either:
 - (i) bovine, ovine and caprine animals that originate from establishments in and around which, in an area with a 25 kilometres radius, foot and mouth disease or rinderpest have not been reported during the 60 days prior to the date of dispatch to the slaughterhouse;
 - or
 - (ii) kept ungulates of listed species other than bovine, ovine, caprine and porcine that originate from establishments in and around which in an area of 50 kilometres radius, foot and mouth disease or rinderpest have not been reported during the 90 days prior to the date of dispatch to the slaughterhouse;
 - or
 - (iii) wild ungulates that comply with the requirements laid down in Article 138;
- (c) the meat is de-boned fresh meat other than offal that was obtained from carcasses:
 - (i) in which the main accessible lymph nodes have been removed;
 - (ii) which have been submitted to maturation at a temperature above +2 °C for at least 24 hours before the bones were removed;
 - (iii) in which the pH value of the meat was below 6,0 when tested electronically in the middle of the *longissimus-dorsi* muscle after maturation and before de-boning.

2. FROM A THIRD COUNTRY, TERRITORY OR ZONE THEREOF WHICH IS FREE FROM FOOT AND MOUTH DISEASE AND WHERE VACCINATION AGAINST FOOT AND MOUTH DISEASE STRAINS A, O OR C IS PRACTISED AND IS SUBJECT TO ADDITIONAL SPECIFIC CONDITIONS

In addition to the requirements set out in point 1, the competent authority of the third country or territory must comply with additional specific conditions in relation to the vaccination programme which support the absence of foot and mouth disease virus in fresh meat from the zone.

3. FOOT AND MOUTH DISEASE-FREE ZONES WHERE VACCINATION IS NOT PRACTISED

3.1. Foot and mouth disease strains SAT or ASIA 1

Where fresh meat originates from a foot and mouth disease-free zone where vaccination is not practised, but that zone is in a third country or territory in which vaccination against foot and mouth disease (FMD) strains SAT or ASIA 1 is practised in other zones or where those strains are endemic in part(s) of the third country or territory or in the neighbouring Member State or third countries, the competent authorities of a third country or territory of origin of such meat must provide the necessary supplementary information to guarantee the absence of the foot and mouth disease virus in the fresh meat and to guarantee compliance with the following animal health requirements:

- (a) the fresh meat is obtained from either:
 - (i) kept animals of listed species that originate from establishments in and around which, in an area of 10 kilometres radius, foot and mouth disease or rinderpest have not been reported during the period of 12 months prior to the date of slaughter;
 - or
 - (ii) wild ungulates that comply with the requirements laid down in Article 138;
- (b) the meat is not authorised for export to the Union until 21 days have elapsed following the date of slaughter;
- (c) the meat is de-boned fresh meat other than offal, obtained from carcasses:
 - (i) in which the main accessible lymphnodes have been removed;
 - (ii) which have been submitted to maturation at a temperature above +2 °C for a period of at least 24 hours before the bones were removed.

3.2. Foot and mouth disease strains A, O or C

Where fresh meat originates in a foot and mouth free zone where vaccination against foot and mouth disease is not practised, but that zone is in a third country or territory in which vaccination against foot and mouth disease strains A, O or C is practised, and where the competent authorities of the third country or territory have provided additional guarantees on conditions specific for the third country or territory or zone and which support the absence of foot and mouth disease virus in the fresh meat from the zone, the competent authorities of the third country or territory of origin must provide the following supplementary information:

- (a) guarantees that the surveillance programme for foot and mouth disease applicable for the free zone, demonstrating the absence of foot and mouth disease, is carried out and controlled by the competent authorities of the third country or territory of origin;
 - (b) guarantees on the application of the animal health requirements set out in points (b) and (c) of Point 1.
-

ANNEX XXVI

RISK MITIGATING TREATMENTS FOR MEAT PRODUCTS**1. RISK MITIGATING TREATMENTS FOR MEAT PRODUCTS LISTED IN DESCENDING ORDER OF SEVERITY**

- B = Treatment in a hermetically sealed container to a F_0 value of three or more.
- C = A minimum temperature of 80 °C, which must be reached throughout the meat product during its processing.
- D = A minimum temperature of 70 °C, which must be reached throughout the meat or stomachs, bladders and intestines during the processing of meat products and treated stomachs, bladders and intestines, or for raw ham, a treatment consisting of natural fermentation and maturation of not less than nine months and resulting in the following characteristics:
- Aw value of not more than 0,93,
 - pH value of not more than 6,0.
- D1 = Thorough the cooking of meat, previously de-boned and defatted, subjected to heating so that an internal temperature of 70 °C or greater is maintained for a minimum period of 30 minutes.
- E = In the case of 'biltong'-type products, a treatment to achieve:
- Aw value of not more than 0,93,
 - pH value of not more than 6,0.
- F = A heat treatment ensuring that a core temperature of at least 65 °C is reached for a period of time as necessary to achieve a pasteurisation value (Pv) equal to or above 40.

2. RISK MITIGATING TREATMENTS FOR CASINGS

- Casing 1 = Salting with sodium chloride (NaCl), either dry or as saturated brine ($a_w < 0,80$), for a continuous period of 30 days or longer, at a temperature of 20 °C or above.
- Casing 2 = Salting with phosphate supplemented salt containing 86,5 % NaCl, 10,7 % Na_2HPO_4 and 2,8 % Na_3PO_4 (weight/weight/weight), either dry or as saturated brine ($a_w < 0,80$), for a continuous period of 30 days or longer, at a temperature of 20 °C or above.
- Casing 3 = Salting with NaCl for 30 days
- Casing 4 = Bleaching
- Casing 5 = Drying after scraping.
-

ANNEX XXVII

RISK MITIGATING TREATMENTS FOR MILK AND DAIRY PRODUCTS

	A	B
Species of origin of the milk and the dairy products	<i>Bos Taurus</i> , <i>Ovis aries</i> , <i>Capra hircus</i> , <i>Bubalus bubalis</i> and <i>Camelus dromedarius</i>	Other than <i>Bos Taurus</i> , <i>Ovis aries</i> , <i>Capra hircus</i> , <i>Bubalus bubalis</i> and <i>Camelus dromedarius</i>
Animal health status of the third country	1. Third countries not officially free of foot and mouth (FMD) for the preceding 12 months 2. Third countries where vaccination against FMD is practised	Any
Sterilisation process, to achieve an F_0 value equal to or greater than 3	Yes	Yes
Ultra-high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time	Yes	Yes
High temperature short time pasteurisation treatment (HTST) at 72 °C for 15 seconds applied twice to milk with a pH equal to or greater than 7,0 achieving, where applicable, a negative reaction to a alkaline phosphatase test, applied immediately after the heat treatment	Yes	No
HTST treatment of milk with a pH below 7,0	Yes	No
HTST treatment combined with another physical treatment by either: (i) lowering the pH below 6 for one hour; or (ii) additional heating equal to or greater than 72 °C, combined with desiccation	Yes	No
No: treatment not permitted		
Yes: acceptable treatment		

ANNEX XXVIII

RISK MITIGATION TREATMENTS FOR EGG PRODUCTS

1. TREATMENTS OF EGG PRODUCTS FOR THE INACTIVATION OF HIGHLY PATHOGENIC AVIAN INFLUENZA

The following treatments are suitable for the inactivation of highly pathogenic avian influenza in the following egg products:

Egg product	Treatment	
	Core temperature (in degrees Celsius (°C))	Duration of treatment (in seconds (s) or hours (hr))
Liquid egg white	55,6 °C	870 s
	56,7 °C	232 s
10 % salted yolk	62,2 °C	138 s
Dried egg white	67 °C	20 hr
	54,4 °C	513 hr
Whole eggs	60 °C	188 s
	completely cooked	
Whole egg blends	60 °C	188 s
	61,1 °C	94 s
	completely cooked	

2. TREATMENTS OF EGG PRODUCTS FOR THE INACTIVATION OF INFECTION WITH NEWCASTLE DISEASE VIRUS

The following treatments are suitable for the inactivation of infection with Newcastle disease virus in the following egg products:

Egg product	Treatment	
	Core temperature (in degrees Celsius (°C))	Duration of treatment (in seconds (s) or hours (hr))
Liquid egg white	55 °C	2 278 s
	57 °C	986 s
	59 °C	301 s
10 % salted yolk	55 °C	176 s
Dried egg white	57 °C	50,4 hr
Whole eggs	55 °C	2 521 s
	57 °C	1 596 s
	59 °C	674 s
	completely cooked	

ANNEX XXIX

**LIST OF SPECIES SUSCEPTIBLE TO DISEASES FOR WHICH MEMBER STATES HAVE NATIONAL MEASURES IN
ACCORDANCE WITH ARTICLE 226 OF REGULATION (EU) 2016/429**

Disease	Susceptible species
Spring viraemia of carp (SVC)	Bighead carp (<i>Aristichthys nobilis</i>), goldfish (<i>Carassius auratus</i>), crucian carp (<i>Carassius carassius</i>), grass carp (<i>Ctenopharyngodon idellus</i>), common carp and koi carp (<i>Cyprinus carpio</i>), silver carp (<i>Hypophthalmichthys molitrix</i>), sheatfish (<i>Silurus glanis</i>), tench (<i>Tinca tinca</i>), Orfe (<i>Leuciscus idus</i>)
Bacterial kidney disease (BKD)	Family: Salmonidae
Infectious pancreatic necrosis (IPN)	Brook trout (<i>Salvelinus fontinalis</i>), brown trout (<i>Salmo trutta</i>), Atlantic salmon (<i>Salmo salar</i>), (<i>Oncorhynchus</i> spp.) whitefish (<i>Coregonus lavaretus</i>)
Infection with salmonid alphavirus (SAV)	Atlantic salmon (<i>Salmo salar</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), brown trout (<i>Salmo trutta</i>)
Infection with <i>Gyrodactylus salaris</i> (GS)	Atlantic salmon (<i>Salmo salar</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), Arctic char (<i>Salvelinus alpinus</i>), North American brook trout (<i>Salvelinus fontinalis</i>), grayling (<i>Thymallus thymallus</i>), North American lake trout (<i>Salvelinus namaycush</i>), brown trout (<i>Salmo trutta</i>) Any species which have been in contact with a susceptible species are also regarded as susceptible
Ostreid herpes virus 1 μ var (OsHV-1 μ Var)	Pacific oyster (<i>Crassostrea gigas</i>)

ANNEX XXX

CONDITIONS UNDER WHICH SPECIES LISTED IN COLUMN 4 OF THE TABLE IN THE ANNEX TO COMMISSION IMPLEMENTING REGULATION (EU) 2018/1882 ARE REGARDED AS VECTORS

List of diseases	Vectors	Conditions under which the species of aquatic animals listed in column 4 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 are regarded as vectors
Epizootic haematopoietic necrosis	As listed in column 4 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882	Regarded as vectors of Epizootic haematopoietic necrosis under all conditions.
Viral haemorrhagic septicaemia		Regarded as vectors of Viral haemorrhagic septicaemia when in contact with species listed in column 3 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 through co-habitation or through water supply.
Infectious haematopoietic necrosis		Regarded as vectors of Infectious haematopoietic necrosis when in contact with species listed in column 3 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 through co-habitation or through water supply.
Infection with highly polymorphic region (HPR) deleted infectious salmon anaemia virus		No vector species listed for infection with highly polymorphic region (HPR) deleted infectious salmon anaemia virus.
Infection with <i>Mikrocytos mackini</i>		No vector species listed for infection with <i>Mikrocytos mackini</i> .
Infection with <i>Perkinsus marinus</i>		Regarded as vectors of <i>Perkinsus marinus</i> when in contact with species listed in column 3 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 through co-habitation or through water supply.
Infection with <i>Bonamia ostreae</i>		Regarded as vectors of <i>Bonamia ostreae</i> when in contact with species listed in column 3 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 through co-habitation or through water supply.
Infection with <i>Bonamia exitiosa</i>		Regarded as vectors of <i>Bonamia exitiosa</i> when in contact with species listed in column 3 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 through co-habitation or through water supply.
Infection with <i>Marteilia refringens</i>		Regarded as vectors of <i>Marteilia refringens</i> when in contact with species listed in column 3 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 through co-habitation or through water supply.
Infection with Taura syndrome virus		Regarded as vectors of Taura syndrome virus when in contact with species listed in column 3 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 through co-habitation or through water supply.
Infection with yellow head virus	As listed in column 4 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882	Regarded as vectors of yellow head virus when in contact with species listed in column 3 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 through co-habitation or through water supply.
Infection with white spot syndrome virus		Regarded as vectors of white spot syndrome virus when in contact with species listed in column 3 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 through co-habitation or through water supply.

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office of the European Union
L-2985 Luxembourg
LUXEMBOURG

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