

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, leptospire and mycoplasmas, and in accordance with Directive 90/429/EEC there is an obligation to add to porcine semen antibiotics which are effective against leptospire, 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

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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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