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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2019/624

of 8 February 2019

concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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) ⁽¹⁾, and in particular Article 18(7) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the official controls and other official activities performed by the competent authorities of the Member States in order to verify that matters such as food safety comply with Union legislation at all stages of the production, processing and distribution process. In particular, it provides for official controls to be performed on products of animal origin intended for human consumption in order to verify compliance with the requirements laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽²⁾, Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽³⁾, Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽⁴⁾ and Council Regulation (EC) No 1099/2009 ⁽⁵⁾.
- (2) Regulation (EU) 2017/625 repeals Regulation (EC) No 854/2004 of the European Parliament and of the Council ⁽⁶⁾ with effect from 14 December 2019. Regulation (EC) No 854/2004 currently lays down specific rules

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

⁽³⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

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

⁽⁵⁾ Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).

⁽⁶⁾ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

for the organisation of official controls on products of animal origin intended for human consumption in order to verify compliance with the requirements of Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 1069/2009. It also provides for the possibility to grant certain derogations from those requirements.

- (3) The rules laid down in this Regulation should ensure a continuation of the requirements currently laid down in Regulation (EC) No 854/2004, taking into account the experience gained since the date of adoption of that act, as well as new scientific evidence and notified national rules to ensure the continued use of traditional methods at any stage of food production, processing and distribution.
- (4) Regulation (EU) 2017/625 provides for delegated acts to be adopted, laying down the criteria and conditions for derogations from certain requirements of that Regulation, so that ante-mortem and post-mortem inspections can be performed under the responsibility of the official veterinarian, instead of being performed or supervised by the official veterinarian. These delegated acts should also lay down the criteria and conditions under which official controls may be performed by other staff designated by the competent authorities in cutting plants.
- (5) Ante-mortem inspection is essential for the protection of human health, animal health and animal welfare and therefore remains the responsibility of the official veterinarian. However, certain routine tasks within ante-mortem inspection in slaughterhouses might be carried out by the official auxiliary without compromising the achievement of the objectives of Regulation (EU) 2017/625, provided certain criteria and conditions are complied with.
- (6) In particular, if ante-mortem inspection has been carried out by the official veterinarian at the holding of provenance, more flexibility should be given to the ante-mortem inspection at arrival in the slaughterhouse which might be carried out under the responsibility of the official veterinarian. However, when no ante-mortem inspection took place at the holding of provenance, the delegation of tasks should only be allowed if the inspections are supervised by the official veterinarian, subject to certain criteria and conditions for species other than poultry and lagomorphs.
- (7) In the event of emergency slaughter, ante-mortem inspection cannot be carried out in the slaughterhouse. In order to avoid causing the animal unnecessary suffering by transporting it to a slaughterhouse, and to limit economic losses for operators and reduce food waste, criteria and conditions should be laid down permitting ante-mortem inspection to be performed outside the slaughterhouse in the event of an emergency slaughter. Animals subject to emergency slaughter may still be fit for human consumption subject to a favourable meat inspection. These inspections should provide maximal guarantees of the fitness for consumption when allowing emergency slaughter outside the slaughterhouse.
- (8) It might be more efficient to evaluate human health, animal health and animal welfare requirements by carrying out ante-mortem inspections at the holding of provenance instead of in the slaughterhouse. Derogations from ante-mortem inspections in the slaughterhouse should therefore be allowed in all species, subject to certain criteria.
- (9) While post-mortem inspections and auditing activities are essential to protect human health, animal health and animal welfare and should therefore remain the responsibility of the official veterinarian, certain tasks may be carried out by the official auxiliary provided sufficient guarantees are met for these objectives and if certain criteria and conditions are complied with. These criteria and conditions should allow, in particular, a continuation of current practices in the case of discontinuous slaughter in low-capacity slaughterhouses and low-capacity game-handling establishments.
- (10) Certain criteria and conditions need to be defined for derogating from the basic requirements on ante-mortem and post-mortem inspection in slaughterhouses and game-handling establishments. A threshold of production is a non-discriminatory criterion, focussing on the smallest establishments in accordance with Article 16(3)(a) of Regulation (EU) 2017/625. Since the structure of these establishments varies between Member States, this threshold should be based on the number of animals slaughtered or handled or on the demonstration that the threshold represents a limited and fixed percentage of the meat placed on the market. Regulation (EC) No 1099/2009 defines livestock units and lays down conversion rates to express the number of animals of a certain species in such livestock units. These provisions should be used to set thresholds and harmonise derogations from certain requirements based on the size of a slaughterhouse.
- (11) Certain tasks in cutting plants may be carried out by staff designated by the competent authorities without jeopardising the objectives of protecting human health, animal health and animal welfare if certain criteria and conditions are complied with.

- (12) Official controls on the production of bivalve molluscs are necessary to ensure compliance with the criteria and targets laid down in Union legislation. In accordance with Part A of Chapter II of Section VII of Annex III to Regulation (EC) No 853/2004, live bivalve molluscs are to be harvested from production areas classified by the competent authorities and from which they authorise the harvesting. Regulation (EU) 2017/625 provides for delegated acts to be adopted, laying down the criteria and conditions to determine, in relation to *Pectinidae*, marine gastropods and *Holothuroidea*, when production and relaying areas need not be classified.
- (13) The place where official controls are to be performed on the production of these *Pectinidae*, marine gastropods and *Holothuroidea* which are not filter feeders should also be established.
- (14) Regulation (EU) 2017/625 also provides for the possibility to lay down specific derogations for official controls in respect to *Rangifer tarandus tarandus* (reindeer), *Lagopus lagopus* and *Lagopus mutus* (grouse) in order to allow the continuation of longstanding local and traditional customs and practices.
- (15) In accordance with Article 17(3) of Regulation (EC) No 854/2004, Member States were allowed to adopt national measures to enable the continued use of traditional methods or to accommodate the needs of food business with a low throughput or that are situated in regions that are subject to special geographic constraints. On this basis, Sweden and Finland have notified national measures with specific derogations from certain requirements for official controls on the meat of reindeer and on the meat of grouse to the Commission and to the other Member States. Since Regulation (EU) 2017/625 no longer allows such adaptation by national measures, derogations should be laid down in this Regulation for official controls covering reindeer and grouse in order to allow the continuation of longstanding local and traditional customs and practices which do not affect the achievement of the objectives of Regulation (EU) 2017/625.
- (16) Regulation (EU) 2017/625 lays down specific minimum requirements for the staff designated by the competent authorities and for the official veterinarians and for official auxiliaries involved in official controls and certain other official activities. It also lays down minimum training requirements for slaughterhouse staff involved in official controls and certain other control activities.
- (17) Specific minimum requirements for official veterinarians, official auxiliaries and other staff designated by the competent authorities should be laid down in order to maintain high and adequate performance of their tasks and therefore ensure a high level of protection of consumers, animal health and animal welfare. These should include specific minimum training requirements. Sufficient flexibility should be provided to adapt the requirement to the tasks to be performed taking into account working experience.
- (18) In order to maintain high and adequate performance, appropriate minimum training requirements should also be laid down for slaughterhouse staff assisting in the performance of tasks related to the official controls and other official control activities laid down in the Regulation.
- (19) As Regulation (EU) 2017/625 repeals Regulation (EC) No 854/2004 with effect from 14 December 2019, this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down specific rules concerning the performance of the official controls referred to in Article 18(1) of Regulation (EU) 2017/625 carried out on products of animal origin.

Those specific rules cover:

- (a) criteria and conditions to determine
 - (i) when the ante-mortem inspection in certain slaughterhouses may be performed under the supervision or under the responsibility of an official veterinarian;
 - (ii) when the ante-mortem inspection may be performed outside the slaughterhouse in case of emergency slaughter;
 - (iii) when the ante-mortem inspections may be performed at the holding of provenance;

- (iv) the guarantees to be in place for the performance of post-mortem inspections and auditing activities under the responsibility of the official veterinarian as referred to in Article 18(2)(c) and (d) of Regulation (EU) 2017/625;
 - (v) derogations from Article 18(6) of Regulation (EU) 2017/625 regarding the classification of production and relaying areas in relation to *Pectinidae*, marine gastropods and *Holothuroidea*;
 - (vi) where the official controls in cutting plants may be performed by staff designated by the competent authorities for that purpose and who are appropriately trained;
- (b) the establishment of specific derogations in respect of *Rangifer tarandus tarandus*, *Lagopus lagopus* and *Lagopus mutus* in order to allow the continuation of longstanding local and traditional customs and practices;
 - (c) the establishment of specific minimum requirements, including training requirements for the official veterinarian, the official auxiliary and the staff designated by the competent authorities, to ensure adequate performance of the tasks described in Article 18 of Regulation (EU) 2017/625;
 - (d) the establishment of appropriate minimum training requirements for slaughterhouse staff who assist in performing the tasks described in Article 18(3) of Regulation (EU) 2017/625.

Article 2

Definitions

The following definitions shall apply for the purpose of this Regulation:

- (1) 'slaughterhouse' means slaughterhouse as defined in point 1.16 of Annex I of Regulation (EC) No 853/2004;
- (2) 'holding of provenance' means the holding where the animals were last reared. In the case of semi-domesticated cervids as defined in point 2(q) of Annex I to Regulation (EC) No 999/2001 of the European Parliament and of the Council ⁽⁷⁾, it includes round-ups intended to select animals for slaughter;
- (3) 'production area' means a production area as defined in point 2.5 of Annex I of Regulation (EC) No 853/2004;
- (4) 'relaying area' means a relaying area as defined in point 2.6 of Annex I of Regulation (EC) No 853/2004;
- (5) 'staff designated by the competent authorities' means a person other than the official auxiliary and the official veterinarian, who is qualified in accordance with this Regulation to act in such a capacity in cutting plants and to whom the competent authorities assign the performance of specific actions;
- (6) 'risk analysis' means risk analysis as defined in Article 3(10) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁸⁾;
- (7) 'cutting plant' means a cutting plant as defined in point 1.17 of Annex I of Regulation (EC) No 853/2004;
- (8) 'poultry' means poultry as defined in point 1.3 of Annex I of Regulation (EC) No 853/2004;
- (9) 'lagomorphs' means lagomorphs as defined in point 1.4 of Annex I of Regulation (EC) No 853/2004;
- (10) 'food business operator' means a food business operator as defined in Article 3(3) of Regulation (EC) No 178/2002;
- (11) 'domestic ungulates' means domestic ungulates as defined in point 1.2 of Annex I of Regulation (EC) No 853/2004;
- (12) 'meat' means meat as defined in point 1.1 of Annex I of Regulation (EC) No 853/2004;
- (13) 'farmed game' means farmed game as defined in point 1.6 of Annex I of Regulation (EC) No 853/2004;
- (14) 'final consumer' means a final consumer as defined in Article 3(18) of Regulation (EC) No 178/2002;
- (15) 'retail' means retail as defined in Article 3(7) of Regulation (EC) No 178/2002;

⁽⁷⁾ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

⁽⁸⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (16) 'establishment' means an establishment as defined in Article 2(1)(c) of Regulation (EC) No 852/2004;
- (17) 'Low-capacity slaughterhouse' means a slaughterhouse designated by the competent authorities on the basis of a risk analysis and in which slaughtering takes place only during part of the working day or takes place during the whole working day but not on each working day of the week;
- (18) 'Low-capacity game-handling establishment' means a game-handling establishment designated by the competent authorities on the basis of a risk analysis and in which game-handling takes place only during part of the working day or takes place during the whole working day but not on each working day of the week;
- (19) 'livestock unit' means a livestock unit as defined in Article 17(6) of Regulation (EC) No 1099/2009;
- (20) 'small wild game' means small wild game as defined in point 1.7 of Annex I of Regulation (EC) No 853/2004;
- (21) 'game-handling establishment' means a game-handling establishment as defined in point 1.18 of Annex I of Regulation (EC) No 853/2004;
- (22) 'dispatch centre' means a dispatch centre as defined in point 2.7 of Annex I of Regulation (EC) No 853/2004;
- (23) 'bivalve molluscs' means bivalve molluscs as defined in point 2.1 of Annex I of Regulation (EC) No 853/2004;
- (24) 'processing' means processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004;
- (25) 'viscera' means viscera as defined in point 1.12 of Annex I of Regulation (EC) No 853/2004;
- (26) 'primary production' means primary production as defined in Article 3(17) of Regulation (EC) No 178/2002;
- (27) 'milk production holding' means a milk production holding as defined in point 4.2 of Annex I of Regulation (EC) No 853/2004.

Article 3

Criteria and conditions establishing when ante-mortem inspections in certain slaughterhouses may be performed by an official auxiliary

1. By way of derogation from Article 18(2)(a) of Regulation (EU) 2017/625, ante-mortem inspections may be performed by an official auxiliary under the supervision of the official veterinarian on species other than poultry and lagomorphs, provided that the procedures applied in the slaughterhouse comply with the following criteria and conditions:
 - (a) the tasks within ante-mortem inspections are of a purely practical nature and only concern one or more of the following:
 - (i) verification that the food business operator complies with the requirements related to food chain information and to the animal's identity check;
 - (ii) the preselection of animals showing possible abnormalities as regards human health, animal health and animal welfare requirements;
 - (b) the official veterinarian is immediately informed by the official auxiliary performing the inspection when possible abnormalities are observed or suspected and the official veterinarian then carries out the ante-mortem inspection in person; and
 - (c) the official veterinarian regularly verifies that the official auxiliary is carrying out his/her tasks properly.
2. By way of derogation from Article 18(2)(a) of Regulation (EU) 2017/625, ante-mortem inspections may be performed on all species by an official auxiliary in a slaughterhouse under the responsibility of the official veterinarian, provided that the following criteria and conditions are met:
 - (a) an ante-mortem inspection has already been carried out by the official veterinarian at the holding of provenance in accordance with Article 5;
 - (b) the official veterinarian is immediately informed by the official auxiliary performing the inspection when possible abnormalities are observed or suspected and the official veterinarian then carries out the ante-mortem inspection in person;
and
 - (c) the official veterinarian regularly verifies that the official auxiliary is carrying out his/her tasks properly.

3. The derogations in paragraphs 1 and 2 shall not apply:
 - (a) to animals that undergo emergency slaughter as referred to in Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004;
 - (b) to animals suspected of having a disease or condition that may adversely affect human health;
 - (c) to bovine animals from herds that have not been declared officially free of tuberculosis or the officially free status of which has been suspended;
 - (d) to bovine animals from herds and to ovine and caprine animals from holdings that have not been declared officially free of brucellosis or the officially free status of which has been suspended;
 - (e) in the case of an outbreak of animal diseases to animals coming from a region as defined in Article 2 of Council Directive 64/432/EEC ⁽⁹⁾ in which animal health restrictions are applied in accordance with Union legislation;
 - (f) to animals subject to stricter controls due to the spread of emerging diseases or particular diseases listed by the World Organisation for Animal Health.

Article 4

Criteria and conditions establishing when ante-mortem inspections may be performed outside the slaughterhouse in the case of emergency slaughter

By way of derogation from Article 18(2)(a) of Regulation (EU) 2017/625, the official veterinarian may perform ante-mortem inspections outside the slaughterhouse in the case of emergency slaughter, only in the case of domestic ungulates and subject to compliance with the requirements for emergency slaughter laid down in points (1), (2) and (6) of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004.

A model health certificate as set out in Annex V to Commission Implementing Regulation (EU) 2019/628 ⁽¹⁰⁾ shall be issued for animals fit for slaughter. The health certificate shall accompany the animals to the slaughterhouse or be sent in advance in any format. Any observations relevant for subsequent meat inspection shall be recorded in the health certificate.

Article 5

General criteria and conditions laying down when ante-mortem inspections may be performed at the holding of provenance

1. By way of derogation from Article 18(2)(a) and (b) of Regulation (EU) 2017/625, the competent authority may allow ante-mortem inspections on animals intended for slaughter to be performed at the holding of provenance in accordance with the criteria and conditions laid down in paragraph 2 and Article 6.
2. The following criteria and conditions shall be applied for all species:
 - (a) checks on records or documentation at the holding of provenance, including verification of the food chain information, shall be carried out;
 - (b) individual examination of the animals shall be facilitated by the food business operator if required;
 - (c) ante-mortem inspections at the holding of provenance shall comprise a physical examination of the animals to determine whether:
 - (i) they have a disease or condition which may be transmitted to animals or humans through handling or consuming the meat of such animals, or whether they are behaving, individually or collectively, in a manner indicating that such a disease has occurred;
 - (ii) they show general behavioural disturbance, signs of disease or abnormalities which may make the meat of such animals unfit for human consumption;

⁽⁹⁾ Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977).

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards model certificates (see page 101 of this Official Journal).

- (iii) there is evidence or reason to suspect that the animals may contain chemical residues in excess of the levels laid down in Union legislation, or residues of forbidden substances;
 - (iv) they show signs indicating problems related to animal welfare, including excessive dirtiness;
 - (v) they are fit for transport.
- (d) the checks and ante-mortem inspection at the holding of provenance referred to in (a), (b) and (c) shall be carried out by an official veterinarian;
- (e) the animals fit for slaughter shall be properly identified and separated from other animals and sent to the slaughterhouse directly from the holding of provenance;
- (f) a health certificate as set out in Part I of Annex IV to Implementing Regulation (EU) 2019/628 shall be issued for animals fit for slaughter. The health certificate shall accompany the animals to the slaughterhouse or be sent in advance in any format. Any observations relevant for subsequent meat inspection shall be recorded in the health certificate.
3. At the slaughterhouse the following additional checks shall be carried out in accordance with Article 18(2)(a) and (b) of Regulation (EU) 2017/625 and Article 3 of this Regulation:
- (a) regular verification of the food business operators' obligation to ensure that the animals are identified properly;
 - (b) regular verification that animal welfare rules have been complied with during transport and at arrival in the slaughterhouse and whether there are signs of any condition which might adversely affect human or animal health.
4. In the event that the animals are not slaughtered within three days, or 28 days in cases referred to in Article 6(5), from the date of issue of the health certificate referred to in paragraph 2(f):
- (a) where the animals have not been dispatched from the holding of provenance to the slaughterhouse, an additional ante-mortem inspection shall be carried out and a new health certificate shall be issued;
 - (b) where the animals are already on their way to or are at the slaughterhouse, the slaughter may be authorised as soon as the reason for the delay has been assessed, provided that the animals undergo an additional ante-mortem inspection in accordance with Article 11 of Commission Implementing Regulation (EU) 2019/627 ⁽¹⁾.

Article 6

Species specific criteria and conditions laying down when ante-mortem inspections may be performed at the holding of provenance

1. The competent authorities shall apply the specific criteria and conditions laid down in this Article in the relevant cases of poultry and farmed game.
2. In the case of poultry reared for the production of 'foie gras' and of delayed eviscerated poultry slaughtered at the holding of provenance, the certificate completed in accordance with the model health certificate set out in Part II of Annex IV of Implementing Regulation (EU) 2019/628, shall accompany the uneviscerated carcasses to the slaughterhouse or cutting plant or be sent in advance in any format, instead of the certificate referred to in point 2(f) of Article 5.
3. In the case of farmed game slaughtered at the holding of provenance in accordance with point 3 of Section III of Annex III to Regulation (EC) No 853/2004, the certificate completed in accordance with the model health certificate set out in Part III of Annex IV to Implementing Regulation (EU) 2019/628 shall accompany the animals to the slaughterhouse or be sent in advance in any format, instead of the certificate referred to in point 2(f) of Article 5.
4. In the case of farmed game slaughtered at the holding of provenance in accordance with point 3(a) of Section III of Annex III to Regulation (EC) No 853/2004:
- (a) a certificate completed in accordance with the model health certificate set out in Part IV of Annex IV to Implementing Regulation (EU) 2019/628 shall accompany the animals to the slaughterhouse or be sent in advance in any format, instead of the certificate referred to in point 2(f) of Article 5;
 - (b) the official veterinarian shall regularly verify that those carrying out the slaughter and bleeding properly perform their tasks.

⁽¹⁾ Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (see page 51 of this Official Journal).

5. By way of derogation from Article 5(4), Member States may allow slaughter of farmed game until 28 days from the date of issue of the health certificate referred to in Article 5(2)(f) if:
- (a) only small quantities of the farmed game meat are directly supplied by the producer to the final consumer or to local retail establishments directly supplying to the final consumer; and
 - (b) not more than 50 animals are slaughtered per year and per holding of provenance.

Article 7

Criteria and conditions for the performance of post-mortem inspections under the responsibility of the official veterinarian, referred to in Article 18(2)(c) of Regulation (EU) 2017/625

(1) Post-mortem inspections referred to in Article 18(2)(c) of Regulation (EU) 2017/625 may be performed by an official auxiliary under the responsibility of the official veterinarian, subject to compliance with Chapter II of Annex II to this Regulation, when the following criteria and conditions are met:

- (a) the slaughter or game-handling activities are carried out in a low-capacity slaughterhouse or game-handling establishment which slaughters or handles:
 - (i) less than 1 000 livestock units per year; or
 - (ii) less than 150 000 poultry, lagomorphs and small wild game per year;
- (b) the competent authority may increase the thresholds laid down in point (a) ensuring that the derogation is applied in the smallest slaughterhouses and game handling establishments complying with the definition of low-capacity slaughterhouse or game-handling establishment and provided that the combined annual production of these establishments does not exceed 5 % of the total amount of fresh meat produced in a Member State:
 - (i) for the species concerned;
 - (ii) of all ungulates together;
 - (iii) of all poultry together; or,
 - (iv) of all birds and lagomorphs together;

in such case, the competent authorities shall notify this derogation and the evidence to support it in accordance with the procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council ⁽¹²⁾;
- (c) the establishment concerned has sufficient facilities to store meat with abnormalities separately from other meat until the official veterinarian can inspect the meat with abnormalities in person;
- (d) the official veterinarian is present in the establishment at least once a day, including regularly during slaughter activities;
- (e) the competent authority has put in place a procedure to assess on a regular basis the performance of official auxiliaries in these establishments, including:
 - (i) monitoring individual performance;
 - (ii) verifying documentation on inspection findings and comparing it with the corresponding carcasses;
 - (iii) checks of carcasses in the storage room;
- (f) a risk analysis has been carried out by the competent authority, taking at least account of the following elements:
 - (i) the number of animals slaughtered or handled per hour or per day;
 - (ii) the species and class of animals slaughtered or handled;
 - (iii) the throughput of the establishment;
 - (iv) the historical performance of slaughter or handling activities;
 - (v) the effectiveness of any additional measures in the food chain taken to guarantee the food safety of animals intended for slaughter;

⁽¹²⁾ Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

- (vi) the effectiveness of the hazard analysis and critical control point (HACCP)-based procedures;
- (vii) audit records;
- (viii) the competent authority's historical records of ante-mortem and post-mortem inspections.

(2) For the purpose of point (a) (i) of paragraph 1, the conversion rates laid down in Article 17(6) of Regulation (EC) No 1099/2009 shall be used. However in case of ovine and caprine animals and small (< 100 kg life weight) *Cervidae* a conversion rate of 0,05 livestock units, and in case of other large game a conversion rate of 0,2 livestock units shall be used.

Article 8

Performance of post-mortem inspections by the official veterinarian

Post-mortem inspection shall be performed by the official veterinarian in the following cases:

- (a) animals that undergo emergency slaughter as referred to in Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004;
- (b) animals suspected of having a disease or condition that may adversely affect human health;
- (c) bovine animals from herds that have not been declared officially free of tuberculosis;
- (d) bovine, ovine and caprine animals from herds that have not been declared officially free of brucellosis;
- (e) outbreak of animal diseases for which animal health rules are laid down in Union legislation. This concerns animals susceptible to the particular disease in question that come from the particular region as defined in Article 2(2)(p) of Directive 64/432/EEC;
- (f) when stricter controls are necessary to take account of emerging diseases or particular diseases listed by the World Organisation for Animal Health;
- (g) in case of derogation on the timing of post-mortem inspection in accordance with Article 13 of Implementing Regulation (EU) 2019/627.

Article 9

Criteria and conditions for the performance of auditing activities in slaughterhouses and game-handling establishments

The auditing activities referred to in Article 18(2)(d)(iii) of Regulation (EU) 2017/625 may be performed in slaughterhouses and game-handling establishments by official auxiliaries under the responsibility of the official veterinarian only as regards the collection of information on good hygiene practices and HACCP-based procedures, and subject to compliance with Chapter II of Annex II to this Regulation.

Article 10

Criteria and conditions for the performance of official controls including auditing activities in cutting plants

Official controls referred to in Article 18(2)(d), including auditing activities, in cutting plants may also be performed by other staff designated by the competent authorities, by way of derogation from the requirements laid down in Article 18(2)(d) of Regulation (EU) 2017/625, provided that the competent authorities regularly check the work of such staff. Performance of these activities is subject to compliance with Chapter III of Annex II to this Regulation.

Article 11

Official controls on *Pectinidae* and marine gastropods and *Holothuroidea*, which are not filter feeders, that are harvested from production areas which are not classified in accordance with Article 18(6) of Regulation (EU) 2017/625

By way of derogation from Article 18(6) of Regulation (EU) 2017/625, the classification of production and relaying areas is not required in relation to the harvesting of *Pectinidae*, marine gastropods and *Holothuroidea*, which are not filter feeders, when the competent authorities carry out official controls on such animals in fish auctions, dispatch centres and processing establishments.

Such official controls shall verify compliance with:

- (a) the health standards for live bivalve molluscs set out in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004;
- (b) the specific requirements for *Pectinidae* and marine gastropods and *Holothuroidea* which are not filter feeders, that are harvested outside the classified production areas, set out in Chapter IX of that Section.

Article 12

Specific derogations in respect of *Rangifer tarandus tarandus*, *Lagopus lagopus* and *Lagopus mutus*, as provided for in Article 18(7)(h) of Regulation (EU) 2017/625

1. In accordance with Article 18(7)(h) of Regulation (EU) 2017/625, the following specific derogations from the official control requirements for *Rangifer tarandus tarandus* (reindeer) that are laid down in Article 18 of that Regulation may be granted by Sweden and Finland in respect of the areas of those Member States listed in Annex I to this Regulation without affecting the achievement of the objectives of that Regulation:

- (a) by way of derogation from Article 18(1) of Regulation (EU) 2017/625, official controls shall not be required on meat derived from *Rangifer tarandus tarandus*, where it is directly supplied by the producer in small amounts to the final consumer or to local retail establishments directly supplying the final consumer;
- (b) by way of derogation from Article 18(2) of Regulation (EU) 2017/625, an ante-mortem inspection is not mandatory for stray reindeer slaughtered in single cases between 1 May and 30 September;
- (c) by way of derogation from Article 18(2)(c) and (3) of Regulation (EU) 2017/625, slaughterhouse staff who have received training appropriate to this task in accordance with Article 14 may inspect:
 - (i) abdominal viscera excluding liver and kidneys;
 - (ii) genital organs;
 - (iii) udder.

2. By way of derogation from Article 18(1) of Regulation (EU) 2017/625, official controls shall not be required on meat derived from *Lagopus lagopus* and *Lagopus mutus* (grouse), where they are killed by snaring in the Swedish counties of Norrbotten, Västerbotten and Jämtland and the Swedish municipality of Älvdalen in Dalarna county during the winter hunting season.

Article 13

Specific minimum requirements for the official veterinarian, the official auxiliary and the staff designated by the competent authorities

1. Official veterinarians performing tasks provided for in Article 18 of Regulation (EU) 2017/625 shall comply with the minimum specific requirements set out in Chapter I of Annex II to this Regulation.

By way of derogation from the rules laid down in points 1 to 6 of Chapter I of Annex II, Member States may lay down specific rules for:

- (a) official veterinarians working on a part-time basis who are responsible for inspecting small businesses or only carrying out official controls at primary production, in particular controls in milk production holdings and ante-mortem inspections outside slaughterhouses; and
- (b) veterinary students having successfully passed an exam on the subjects referred to in point 3 of Chapter I of Annex II and who are temporarily working at a slaughterhouse in the presence of an official veterinarian.

2. Veterinarians already appointed as official veterinarians before the date of application of this Regulation shall have adequate knowledge of the subjects referred to in point 3 of Chapter I of Annex II to this Regulation. Where necessary, the competent authority shall ensure that such knowledge is obtained through continuing training activities.

3. Official auxiliaries performing the tasks provided for in Article 18 of Regulation (EU) 2017/625 shall comply with the minimum specific requirements set out in Chapter II of Annex II to this Regulation.

4. Staff designated by the competent authorities performing the tasks provided for in Article 18 of Regulation (EU) 2017/625 shall comply with the minimum specific requirements set out in Chapter III of Annex II to this Regulation.

*Article 14***Minimum training requirements for slaughterhouse staff**

Slaughterhouse staff assisting in the performance of tasks related to official controls and other control activities in accordance with Article 18(3) of Regulation (EU) 2017/625 shall be trained to the satisfaction of the competent authorities. They shall also comply with the minimum training requirements set out in Chapter II of Annex II to this Regulation to the extent relevant for their assistance tasks.

*Article 15***Entry into force and applicability**

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 14 December 2019.

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

Done at Brussels, 8 February 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

SPECIFIC DEROGATIONS FOR THE INSPECTION OF MEAT DERIVED FROM REINDEER (RANGIFER TARANDUS TARANDUS)

The specific derogations referred to in Article 12(1) shall only apply in the following areas:

- (a) In Sweden:
- (i) the county of Norrbotten;
 - (ii) the county of Västerbotten;
 - (iii) the county of Jämtland;
 - (iv) the county of Västernorrland;
 - (v) the Älvdalen municipality in the county of Dalarna;
 - (vi) the municipalities of Nordanstig, Hudiksvall and Söderhamn in the county of Gävleborg.
- (b) In Finland, as they were allowed on 31 December 2014:
- (i) the county of Lapland except for the municipalities of Kemi, Keminmaa and Tornio;
 - (ii) the counties of North Ostrobothnia and Kainuu:
 - the municipalities of Kuusamo, Taivalkoski, Pudasjärvi, Suomussalmi and Hyrynsalmi;
 - in the municipality of Oulu: the area of the former Yli-Ii municipality and the area to the north of the River Kiiminkijoki in the former Ylikiminki municipality;
 - in the municipality of Ii: the area of the former Kuivaniemi municipality;
 - in the municipalities of Puolanka and Utajärvi: the areas to the north of the River Kiiminkijoki and regional road 891 (Hyrynsalmi-Puolanka).
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ANNEX II

**SPECIFIC MINIMUM REQUIREMENTS FOR THE OFFICIAL VETERINARIAN, THE OFFICIAL AUXILIARY
AND THE STAFF DESIGNATED BY THE COMPETENT AUTHORITIES**

CHAPTER I

OFFICIAL VETERINARIANS

1. The competent authorities may appoint as an official veterinarian only veterinarians who have passed a test meeting the requirements set out in point 3.
2. The competent authorities must make arrangements for the test for candidates applying to be appointed as an official veterinarian.
3. The test must demonstrate knowledge of the following subjects, specifically targeted to the tasks of official veterinarian and to the extent necessary depending on the veterinarian's background and qualifications while avoiding any duplication of tests on the knowledge and skills required for veterinary surgeon in accordance with Article 38(3) of Directive 2005/36/EC of the European Parliament and of the Council ⁽¹⁾:
 - (a) national and Union legislation on human health, food safety, animal health, animal welfare and pharmaceutical substances;
 - (b) principles of the common agricultural policy, market measures, export refunds and fraud detection, including the global context: World Trade Organisation sanitary and phytosanitary agreement, Codex Alimentarius, the World Organisation for Animal Health;
 - (c) essentials of food processing and food technology;
 - (d) principles, concepts and methods of good manufacturing practice and quality management;
 - (e) pre-harvest quality management (good farming practices);
 - (f) promotion and use of food hygiene, food-related safety (good hygiene practices);
 - (g) principles, concepts and methods of risk analysis;
 - (h) principles, concepts and methods of HACCP, use of HACCP throughout the food production food chain;
 - (i) auditing and verification of compliance with the requirements referred to in points a) to h);
 - (j) prevention and control of food-borne hazards to human health;
 - (k) population dynamics of infection and intoxication;
 - (l) diagnostic epidemiology;
 - (m) monitoring and surveillance systems;
 - (n) principles and diagnostic applications of modern testing methods;
 - (o) information and communication technology when relevant as working tools;
 - (p) data-handling and applications of biostatistics;
 - (q) investigations of outbreaks of food-borne diseases in humans;
 - (r) relevant aspects concerning transmissible spongiform encephalopathies (TSEs);
 - (s) animal welfare at the level of production, transport and slaughter;
 - (t) environmental issues related to food production (including waste management);
 - (u) precautionary principle and consumer concerns;
 - (v) principles of training personnel working in the production chain;

⁽¹⁾ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).

- (w) health rules as regards animal by-products and derived products;
- (x) fraud aspects.

Candidates may acquire the required knowledge as part of their basic veterinary training, or through training undertaken or professional experience acquired after qualifying as veterinarians.

If the competent authorities are satisfied that a candidate has acquired all the required knowledge as part of a university degree, or through continuing education resulting in a postgraduate qualification, professional experience or other qualifications, it shall waive the requirement for a test. If the candidate has partly acquired the required knowledge, the competent authorities shall arrange for tests different from those referred to in point 2 to take account of candidates' background.

4. The official veterinarian must have aptitude for multidisciplinary cooperation.
5. Each official veterinarian must undergo practical training for a probationary period of at least 200 hours before starting to work independently. Relevant training during veterinary studies may be included in the probationary period. During this period the probationer is to work under the supervision of existing official veterinarians in slaughterhouses, cutting plants and on holdings. The training must concern the auditing of Good Hygiene Practices and procedures based on the HACCP principles in particular.
6. The official veterinarian must keep up-to-date and keep abreast of new developments through regular continuing education activities and professional literature in the areas referred to in point 3. The official veterinarian must, wherever possible, undertake annual continuing education activities.
7. Mutual recognition of the tests for official veterinarians between Member States must apply, when professionals move cross-border or wish to establish themselves in another Member State. In such case the tests must be limited to subjects, essential for human health and animal health protection in the Member States of employment, but not covered by the tests in the Member State of origin.

CHAPTER II

OFFICIAL AUXILIARY

1. Only people who have undergone training and passed a test in accordance with the requirements set out in point 5 are allowed to carry out the tasks of an official auxiliary.
2. The competent authorities shall make arrangements for the tests referred to in point 1. To be eligible for these tests, candidates must prove that they have received:
 - (a) at least 500 hours of training, including at least 400 hours of practical training, covering the areas referred to in point 5; and
 - (b) any additional training required to enable official auxiliaries to undertake their duties competently.
3. The practical training referred to in point 2(a) must take place in slaughterhouses, game-handling establishments and/or cutting plants under the supervision of an official veterinarian.
4. Training and tests must concern principally red meat or poultry meat. However, people who undergo training for one of these two categories and pass the test must only be required to undergo abridged training to pass the test for the other category. The training and tests must cover wild game, farmed game and lagomorphs, where appropriate.
5. Training for official auxiliaries must cover, and tests must confirm knowledge of, the following subjects:
 - (a) in relation to holdings:
 - (i) theoretical part:
 - background related to the farming industry organisation, production methods, international trade standards for animals;
 - good livestock husbandry practices;

- basic knowledge of diseases, in particular zoonoses by viruses, bacteria and parasites;
 - monitoring for disease, use of medicines and vaccines, residue testing;
 - hygiene and health inspection;
 - animal welfare on the farm and during transport;
 - environmental requirements — in buildings, on farms and in general;
 - relevant laws, regulations and administrative provisions;
 - consumer concerns and quality control;
- (ii) practical part:
- visits to holdings of different types and using different rearing methods;
 - visits to production establishments;
 - observation of the loading and unloading of animals;
 - laboratory demonstrations;
 - veterinary checks;
 - documentation;
- (b) in relation to slaughterhouses, game-handling establishments and cutting plants:
- (i) theoretical part:
- background related to meat industry organisation, production methods, international trade standards for food and slaughter and cutting technology;
 - basic knowledge of hygiene and good hygienic practices, and in particular industrial hygiene, slaughter, cutting and storage hygiene, hygiene at work;
 - basic knowledge of HACCP and the audit of HACCP-based procedures;
 - animal welfare on unloading after transport and at the slaughterhouse;
 - basic knowledge of the anatomy and physiology of slaughtered animals;
 - basic knowledge of the pathology of slaughtered animals;
 - basic knowledge of the pathological anatomy of slaughtered animals;
 - relevant knowledge concerning TSEs and other important zoonoses and zoonotic agents, as well as important animal diseases;
 - knowledge of methods and procedures for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat;
 - basic knowledge of microbiology;
 - ante-mortem inspection;
 - sampling and analysis for *Trichinella*;
 - post-mortem inspection;
 - administrative tasks;
 - knowledge of the relevant laws, regulations and administrative provisions;
 - sampling procedure;
 - fraud aspects;
- (ii) practical part:
- animal identification;
 - age checks;

- inspection and assessment of slaughtered animals;
 - ante-mortem inspection at the slaughterhouse;
 - post-mortem inspection in a slaughterhouse or game-handling establishment;
 - sampling and analysis for *Trichinella*;
 - identification of animal species by examining typical parts of the animal;
 - identifying and commenting on parts of slaughtered animals in which changes have occurred;
 - hygiene control, including the audit of the good hygiene practices and the HACCP-based procedures;
 - recording the results of ante-mortem inspections;
 - sampling;
 - traceability of meat;
 - documentation such as evaluation of food chain information and record reading.
6. The competent authorities may decide to reduce training and tests as regards:
 - (a) the theoretical part if the official auxiliary demonstrates sufficient education on specific bullet points laid down in point 5(a)(i) or (b)(i) of this Chapter;
 - (b) the practical part if the official auxiliary demonstrates sufficient working experience on specific bullet points laid down in point 5(a)(ii) or (b)(ii) of this Chapter.
 7. The official auxiliary must have aptitude for multidisciplinary cooperation.
 8. Official auxiliaries must keep up-to-date and abreast of new developments through regular continuing education activities and professional literature. The official auxiliary must, wherever possible, undertake annual continuing training activities.
 9. If official auxiliaries carry out only sampling and analysis in connection with examinations for *Trichinella* and microbiological criteria, the competent authorities are only required to ensure that they receive training appropriate to these tasks.
 10. Mutual recognition of the tests for official auxiliaries between Member States must apply, when professionals move cross-border or wish to establish themselves in another Member State. In such case the tests must be limited to subjects, essential for human health and animal health protection in the Member States of employment, but not covered by the tests in the Member State of origin.

CHAPTER III

STAFF DESIGNATED BY THE COMPETENT AUTHORITIES

1. The competent authorities may only appoint staff who have undergone training and passed a test in accordance with the requirements set out in point 5 of this Chapter.
2. The competent authorities must make arrangements for the test referred to in point 1. To be eligible for this test, candidates must prove that they have received:
 - (a) at least 500 hours of training including at least 400 hours of practical training covering the areas referred to in point 5; and
 - (b) any additional training required to enable staff designated by the competent authorities to undertake their duties competently.
3. The practical training referred to in point 2(a) must take place in cutting plants, under the supervision of an official veterinarian.
4. Training and tests must concern principally red meat or poultry meat. However, people who undergo training for one of these two categories and pass the test must only be required to undergo abridged training to pass the test for the other category. The training and tests must cover wild game, farmed game and lagomorphs, where appropriate.

5. Training for staff designated by the competent authorities must include, and tests must confirm knowledge of, the following subjects in relation to cutting plants:
 - (i) theoretical part:
 - background related to meat industry organisation, production methods, international trade standards for food and cutting technology;
 - thorough knowledge of hygiene and good hygienic practices, and in particular industrial hygiene, cutting and storage hygiene, hygiene at work;
 - thorough knowledge of HACCP and the audit of HACCP-based procedures;
 - relevant knowledge concerning TSEs and other important zoonoses and zoonotic agents;
 - knowledge of methods and procedures for the preparation, wrapping, packaging and transport of fresh meat;
 - basic knowledge of microbiology;
 - administrative tasks;
 - knowledge of the relevant laws, regulations and administrative provisions;
 - sampling procedure;
 - fraud aspects;
 - (ii) practical part:
 - inspection and assessment of slaughtered animals;
 - hygiene control, including the audit of the good hygiene practices and the HACCP-based procedures;
 - sampling;
 - traceability of meat;
 - documentation.
 6. The competent authorities may decide to reduce training and tests as regards:
 - (a) the theoretical part if the staff designated by the competent authorities demonstrates sufficient education on specific bullet points laid down in point 5(i) of this Chapter;
 - (b) the practical part if the staff designated by the competent authorities demonstrates sufficient working experience on specific bullet points laid down in point 5(ii) of this Chapter.
 7. The staff designated by the competent authorities must have an aptitude for multidisciplinary cooperation.
 8. Staff designated by the competent authorities must keep up-to-date and abreast of new developments through regular continuing education activities and professional literature. The staff designated by the competent authorities must, wherever possible, undertake annual continuing training activities.
 9. Mutual recognition of the tests for other staff designated by competent authorities between Member States must apply, when professionals move cross-border or wish to establish themselves in another Member State. In such case the tests must be limited to subjects, essential for human health and animal health protection in the Member States of employment, but not covered by the tests in the Member State of origin.
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COMMISSION DELEGATED REGULATION (EU) 2019/625**of 4 March 2019****supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to 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) ⁽¹⁾, and in particular Article 126(1) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States, including for the establishment of requirements to be fulfilled for the entry into the Union of consignments of animals and goods from third countries or regions thereof and official controls performed on such consignments that are intended for human consumption in order to ensure that they comply with Union legislation in the area of food and food safety.
- (2) Regulation (EU) 2017/625 provides a legal basis for delegated acts to be adopted in order to supplement the conditions laid down in that Regulation for the entry into Union of certain animals and goods. These additional requirements include guarantees concerning the verification of compliance with:
 - the measures to monitor substances and groups of residues in animals and goods intended for human consumption in accordance with Council Directive 96/23/EC ⁽²⁾;
 - the rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in live animals and products of animal origin in accordance with Regulation (EC) No 999/2001 of the European Parliament and of the Council ⁽³⁾;
 - the general principles and requirements governing food in general and food safety in particular at Union and national level in accordance with Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁴⁾;
 - the general rules for food business operators on the hygiene of foodstuffs in accordance with Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽⁵⁾;

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

⁽³⁾ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

⁽⁴⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

⁽⁵⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

- the specific rules on the hygiene of food of animal origin for food business operators in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽⁶⁾;
 - the specific rules on official controls and for action taken by the competent authorities in relation to production of products of animal origin intended for human consumption in accordance with Commission Delegated Regulation (EU) 2019/624 ⁽⁷⁾ and Commission Implementing Regulation (EU) 2019/627 ⁽⁸⁾.
- (3) Regulation (EC) No 854/2004 of the European Parliament and of the Council ⁽⁹⁾ laid down specific conditions for the entry into the Union of products of animal origin intended for human consumption, while Regulation (EC) No 882/2004 of the European Parliament and of the Council ⁽¹⁰⁾ laid down the general conditions for the entry into the Union of food. Regulation (EU) 2017/625 lays down rules in areas currently covered by those two Regulations and it repeals them and replaces them with effect from 14 December 2019.
- (4) The requirements laid down in this Regulation should ensure a continuation of the requirements laid down in Regulations (EC) No 854/2004 and (EC) No 882/2004 to ensure a high level of protection of health and in order to avoid a disruption of the entry into the Union of consignments of certain animals and goods intended for human consumption. At the same time the experience gained in the application of the rules laid down in those two Regulations should be taken into account using a risk-based approach.
- (5) Regulation (EC) No 853/2004 lays down requirements for food business operators importing products of animal origin into the Union. Accordingly, the additional requirements laid down in this Regulation for official controls should be consistent with those already laid down in Regulation (EC) No 853/2004.
- (6) Commission Regulation (EU) 2017/185 ⁽¹¹⁾ provides for derogations from Regulation (EC) No 854/2004 concerning public health requirements for imports of certain products of animal origin (such as insects and reptile meat) and food containing both products of plant origin and processed products of animal origin (composite products) until 31 December 2020. In order to ensure a high level of protection of health, requirements for the entry into the Union of such products should also be laid down before the expiry of the transitional measures in order to verify compliance with Union rules covering these products.
- (7) Insects are increasingly produced for human consumption. It should be ensured that imported insects comply with Union requirements for food and food safety. The additional requirements laid down in this Regulation for the entry into the Union of consignments of products of animal origin should therefore also apply to insects. Insects may also be subject to authorisation as novel food in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council ⁽¹²⁾.
- (8) On 18 October 2007, the European Food Safety Authority adopted an Opinion on the public health risks involved in the human consumption of reptile meat ⁽¹³⁾. A number of hazards such as *Salmonella* and *Trichinella* were identified. Requirements for the entry into the Union should include verification of compliance with Union requirements to reduce the risk from these hazards in consignments of reptile meat.

⁽⁶⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

⁽⁷⁾ Commission Delegated Regulation (EU) 2019/624, of 8 February 2018 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (see page 1 of this Official Journal).

⁽⁸⁾ Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (see page 51 of this Official Journal).

⁽⁹⁾ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

⁽¹⁰⁾ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

⁽¹¹⁾ Commission Regulation (EU) 2017/185 of 2 February 2017 laying down transitional measures for the application of certain provisions of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and the Council (OJ L 29, 3.2.2017, p. 21).

⁽¹²⁾ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

⁽¹³⁾ <http://www.efsa.europa.eu/en/efsajournal/pub/578>

- (9) The composition of composite products affects the physico-chemical characteristics of such foods, leading to different risks. For this reason, only consignments of composite products which comply with applicable requirements, notably on the origin of the processed products of animal origin that compose such foods, the origin of the food itself, or the guarantees that accompany the consignments of composite products, should be authorised for entry into the Union. For composite products that pose a low risk to human health, this Regulation should provide for derogations from checks at the border control posts.
- (10) When laying down requirements for the entry into the Union of consignments of certain animals and good intended for human consumption, reference should be made to the Combined Nomenclature codes in accordance with Council Regulation (EEC) No 2658/87 ⁽¹⁴⁾ to clearly identify these goods and animals.
- (11) Consignments of certain animals and goods intended for human consumption should only be allowed to enter the Union, based on a risk analysis, when the third countries or regions thereof from which these animals and goods originate, can ensure compliance with the requirements on the safety of these animals and goods intended for human consumption and are duly listed in Commission Implementing Regulation (EU) 2019/626 ⁽¹⁵⁾.
- (12) In addition to the requirements in Article 127(3) of Regulation (EU) 2017/625, specific requirements should be laid down for certain animals and goods intended for human consumption in order to provide guarantees as regards the efficiencies of official controls on food safety in third countries or regions thereof. Third countries or regions thereof should only appear on lists after evidence and guarantees have been provided that the animals and goods concerned from the third countries or regions thereof comply with Union requirements for the safety of food, or with requirements recognised to be equivalent thereto, laid down in Directive 96/23/EC, Regulations (EC) No 999/2001, (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EU) 2017/625, and Delegated Regulation (EU) 2019/624 and Implementing Regulation (EU) 2019/627.
- (13) Consignments of certain goods intended for human consumption should only be allowed to enter the Union where those goods are dispatched from, and obtained or prepared in, establishments which appear on lists drawn up and kept up to date in accordance with Article 127(3)(e) of Regulation (EU) 2017/625. In addition, in order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, it is appropriate to provide that when drawing up and updating the lists of such establishments referred to in Article 127(3)(e) of Regulation (EU) 2017/625, the third country should give guarantees in addition those referred to in Article 127(3)(e)(i) and (iv) of Regulation (EU) 2017/625.
- (14) The Commission should make the lists of establishments provided for in Article 127 of Regulation (EU) 2017/625 available to the public to ensure transparency for food business operators and consumers as regards which establishments such goods may enter the Union for placing on the market. With a view to ensure the effectiveness of these requirements, Member States should allow the entry of consignments of such goods provided that the official certificates which are required to accompany such consignments pursuant to the applicable Union rules are issued by the competent authorities of the third country starting with the date of publication by the Commission of the lists.
- (15) Such requirements concerning establishments should not be established in relation to goods intended for transit, since they represent a low risk from a food safety perspective and there is no placing on the market of animals and goods within the Union. In addition, such requirements should not be established for establishments carrying out only primary production activities, transport operations, storage of products of animal origin not requiring temperature-controlled storage conditions or production of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids referred to in Section XVI of Annex III to Regulation (EC) No 853/2004.

⁽¹⁴⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

⁽¹⁵⁾ Commission Implementing Regulation (EU) 2019/626 of 5 March 2019 concerning lists of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption and amending Implementing Regulation (EU) 2016/759 as regards these lists (see page 31 of this Official Journal).

- (16) Commission Regulation (EU) No 210/2013 ⁽¹⁶⁾ requires establishments producing sprouts to be approved by the competent authorities in accordance with Article 6 of Regulation (EC) No 852/2004. In order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, sprouts should only be allowed entry to the Union if they are produced in establishments, which appear on lists drawn-up and updated in accordance with this Regulation.
- (17) In order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, products from establishments manufacturing fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen, should only be allowed entry into the Union if these establishments appear on lists drawn-up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission. In addition, the raw materials these products are manufactured from, should come from establishments (slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products) appearing on lists drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission.
- (18) Consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods should only be allowed entry into the Union from production areas in third countries or regions thereof that appear on lists drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission, in order to ensure compliance with the applicable specific requirements for these products laid down in Regulation (EC) No 853/2004 and Implementing Regulation (EU) 2019/627, or with rules recognised to be at least equivalent thereto. The publication of those lists should ensure transparency for food business operators and consumers as regards from which production areas live bivalve molluscs, echinoderms, tunicates and marine gastropods may enter the Union.
- (19) Consignments of fishery products should only be allowed entry into the Union when the consignments are dispatched from, obtained or prepared in an on-land establishment, reefer, factory or freezer vessels flying the flag of a third country that appears on lists drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission, in order to ensure compliance with Union requirements, in particular with the specific requirements for fishery products laid down in Regulation (EC) No 853/2004 and Implementing Regulation (EU) 2019/627, or with rules recognised to be at least equivalent thereto. The publication of such lists should ensure transparency for food business operators and consumers as regards the vessels from which fishery products may enter the Union.
- (20) The conditions for entry into the Union of products of animal origin laid down in Regulation (EC) No 853/2004 do not apply to composite products. However, that Regulation requires the food business operators importing composite products to ensure that the processed products of animal origin contained in such foods satisfy the requirements laid down in that Regulation.
- (21) The risk related to the composite products depends on the type of ingredients and on their storage conditions. Requirements concerning the consignments of composite products should therefore be laid down in order to ensure that those composite products presenting a risk be exported from countries which are authorised to export to the Union pursuant to Commission Decision 2007/777/EC ⁽¹⁷⁾, Commission Decision 2006/766/EC ⁽¹⁸⁾, Commission Regulation (EC) No 798/2008 ⁽¹⁹⁾, Commission Regulation (EU) No 605/2010 ⁽²⁰⁾ and Commission Decision 2011/163/EU ⁽²¹⁾.

⁽¹⁶⁾ Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council (OJ L 68, 12.3.2013, p. 24).

⁽¹⁷⁾ Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC (OJ L 312, 30.11.2007, p. 49).

⁽¹⁸⁾ Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted (OJ L 320, 18.11.2006, p. 53).

⁽¹⁹⁾ Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

⁽²⁰⁾ Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk, dairy products, colostrum and colostrum-based products intended for human consumption (OJ L 175, 10.7.2010, p. 1).

⁽²¹⁾ Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

- (22) Based on the number of notifications received in the Rapid Alert System for Food and Feed established by Regulation (EC) No 178/2002, consignments of certain animals and goods placed on the market for human consumption present an enhanced risk for non-compliance with Union requirements on food safety. Consignments of such animals and goods placed on the market for human consumption should therefore be subject to the individual certification of each consignment for entry into the Union for placing on the market. Certification of compliance with Union requirements may also contribute to reminding food business operators and the competent authorities of third countries or regions thereof of the applicable Union requirements. In the case of transit, the use of the current dedicated transit certificates with animal health attestation should remain.
- (23) As Regulation (EU) 2017/625 applies with effect from 14 December 2019, this Regulation should also apply from that date. Transitional measures providing derogations from Regulations (EC) No 853/2004 and (EC) No 854/2004, concerning public health requirements for the imports of composite products have been laid down in Regulation (EU) 2017/185 and will be extended until 20 April 2021 in accordance with Commission Regulation (EU) 2019/759 ⁽²²⁾. The import requirements laid down in this Regulation should therefore apply from 20 April 2021 for composite products in order to ensure a smooth transition,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation supplements Regulation (EU) 2017/625 as regards the requirements for the entry in the Union of consignments of certain animals and goods intended for human consumption from third countries or regions thereof in order to ensure that they comply with the applicable requirements established by the rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625 or with requirements recognised to be at least equivalent thereto.
2. The requirements referred to in paragraph 1 cover:
 - (a) the identification of animals and goods subject to the following requirements for entry into the Union:
 - (i) the requirement that those animals and goods shall come from a third country or region thereof listed in accordance with Article 126(2)(a) of Regulation (EU) 2017/625;
 - (ii) the requirement that those animals and goods be dispatched from, and obtained or prepared in, establishments which comply with applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto, and which appear on lists drawn-up and updated in accordance with Article 127(3)(e)(ii) and (iii) of Regulation (EU) 2017/625;
 - (iii) the requirement that each consignment of animals and goods be accompanied by an official certificate, or official attestation or any other evidence of compliance with the rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625, such as a private attestation, in accordance with Article 126(2)(c) of Regulation (EU) 2017/625;
 - (b) requirements for the entry into the Union of certain animals and goods from a third country or region thereof, listed in accordance with Article 127(2) of Regulation (EU) 2017/625;
 - (c) requirements that consignments of certain goods from third countries be dispatched from, and obtained or prepared in, establishments which comply with the applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto, and which appear on lists drawn-up and updated in accordance with Article 127(3)(e)(ii) and (iii) of Regulation (EU) 2017/625;
 - (d) requirements for the entry into the Union for placing on the market of the specific following commodities in addition to the requirements laid down in accordance with Article 126 of Regulation (EU) 2017/625:
 - (i) fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen;

⁽²²⁾ Commission Regulation (EU) 2019/759 of 13 May 2019 laying down transitional measures for the application of public health requirements of imports of food containing both products of plant origin and processed products of animal origin (composite products) (OJ L 125, 14.5.2019, p. 11).

- (ii) live bivalve molluscs, echinoderms, tunicates and marine gastropods;
 - (iii) fishery products;
 - (iv) composite products;
- (e) additional requirements for the official certificates, official attestations and private attestations that shall accompany certain animals and goods for entry into the Union.
3. This Regulation shall not apply to:
- (a) Animals and goods not intended for human consumption, however when the destination of the animals and goods has not been decided at entry into the Union, this Regulation applies;
 - (b) Animals and goods intended for human consumption only for transit through the Union without being placed on the market.

Article 2

Definitions

For the purpose of this Regulation, the following definitions shall apply:

- (1) 'equivalent' means equivalent as defined in Article 2(1)(e) of Regulation (EC) No 852/2004;
- (2) 'placing on the market' means placing on the market as defined in point (8) of Article 3 of Regulation (EC) No 178/2002;
- (3) 'establishment' means an establishment as defined in Article 2(1)(c) of Regulation (EC) No 852/2004;
- (4) 'private attestation' means an attestation signed by the importing food business operator;
- (5) 'fresh meat' means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;
- (6) 'minced meat' means minced meat as defined in point 1.13 of Annex I to Regulation (EC) No 853/2004;
- (7) 'meat preparations' means meat preparations as defined in point 1.15 of Annex I to Regulation (EC) No 853/2004;
- (8) 'meat products' means meat products as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004;
- (9) 'mechanically separated meat' means mechanically separated meat as defined in point 1.14 of Annex I to Regulation (EC) No 853/2004;
- (10) 'gelatine' means gelatine as defined in point 7.7 of Annex I to Regulation (EC) No 853/2004;
- (11) 'collagen' means collagen as defined in point 7.8 of Annex I to Regulation (EC) No 853/2004;
- (12) 'bivalve molluscs' means bivalve molluscs as defined in point 2.1 of Annex I to Regulation (EC) No 853/2004;
- (13) 'fishery products' means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;
- (14) 'composite product' means food containing both products of plant origin and processed products of animal origin;
- (15) 'reptiles' means animals belonging to the species *Alligator mississippiensis*, *Crocodylus johnstoni*, *Crocodylus niloticus*, *Crocodylus porosus*, *Timon Lepidus*, *Python reticulatus*, *Python molurus bivittatus* or *Pelodiscus sinensis*;
- (16) 'reptile meat' means the edible parts, either unprocessed or processed, derived from farmed reptiles, which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 and listed in Commission Implementing Regulation (EU) 2017/2470 ⁽²³⁾;

⁽²³⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel food (OJ L 351, 30.12.2017, p. 72).

- (17) 'insects' means food consisting of, isolated from or produced from insects or their parts including any life stadia of insects intended for human consumption which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 and listed in Implementing Regulation (EU) 2017/2470;
- (18) 'sprouts' means sprouts as defined in point (a) of Article 2 of Commission Implementing Regulation (EU) No 208/2013 ⁽²⁴⁾;
- (19) 'primary production' means primary production as defined in point (17) of Article 3 of Regulation (EC) No 178/2002;
- (20) 'slaughterhouse' means a slaughterhouse as defined in point 1.16 of Annex I to Regulation (EC) No 853/2004;
- (21) 'game-handling establishment' means a game-handling establishment as defined in point 1.18 of Annex I to Regulation (EC) No 853/2004;
- (22) 'cutting plant' means a cutting plant as defined in point 1.17 of Annex I to Regulation (EC) No 853/2004;
- (23) 'production area' means a production area as defined in point 2.5 of Annex I to Regulation (EC) No 853/2004;
- (24) 'factory vessel' means a factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;
- (25) 'freezer vessel' means a freezer vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;
- (26) 'reefer vessel' means a vessel equipped to store and transport palletized or loose cargo (bulk) goods in temperature controlled holds or chambers;
- (27) 'food business operator' means a food business operator as defined in point (3) of Article 3 of Regulation (EC) No 178/2002.

Article 3

Animals and goods which are required to come from third countries or regions thereof included in the list referred to in Article 126(2)(a) of Regulation (EU) 2017/625

Consignments of the following animals and goods intended for human consumption shall enter the Union only from a third country or region thereof included in the list for those animals and goods laid down in Articles 3 to 22 of Implementing Regulation (EU) 2019/626:

- (a) products of animal origin, including reptile meat and dead whole insects, parts of insects or processed insects, for which Combined Nomenclature codes ('CN codes') have been laid down in Chapters 2 to 5, 15 and 16, and Harmonised System codes ('HS codes') under headings 1702, 1806, 2102, 2103, 2105, 2106, 2202, 2301, 2822, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110 and 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87, when these products are intended for human consumption;
- (b) live insects referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87.

Article 4

Additional requirements for entry into the Union of certain animals and goods from a third country or region thereof

In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, the Commission shall only decide on the inclusion of third countries or regions thereof in the list referred to in Article 126(2)(a) of that Regulation if the following requirements are recognised by the Commission as being at least equivalent to the relevant requirements in the Union for animals and goods referred to in Article 3:

- (a) the legislation of the third country on:
- (i) the production of food of animal origin;

⁽²⁴⁾ Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 16).

- (ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;
 - (iii) the preparation and use of feed, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;
- (b) the hygiene conditions of production, manufacture, handling, storage and dispatch currently applied to products of animal origin destined for the Union;
 - (c) any experience of marketing of the products of animal origin from the third country and the results of any official controls on entry in the Union;
 - (d) when available, the results of controls carried out by the Commission in the third country related to other animals and goods for which the third country is already listed in accordance with Article 127(2) of Regulation (EU) 2017/625, in particular the results of the assessment of the competent authorities in the third country audited, and the action that the competent authorities have taken in the light of any recommendations addressed to them following such audits by the Commission;
 - (e) the existence, implementation and communication of a zoonoses control programme approved by the Commission when applicable;
 - (f) the existence, implementation and communication of a residues control programme approved by the Commission when applicable, in accordance with Directive 96/23/EC.

Article 5

Requirements for entry into the Union of certain goods from a third country in relation to establishments

1. Consignments of the following goods shall only enter the Union where those consignments are dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and kept up-to-date in accordance with Article 127(3)(e)(ii) and (iii) of Regulation (EU) 2017/625:

- (a) products of animal origin for which requirements are laid down in Annex III to Regulation (EC) No 853/2004, and for which CN codes have been laid down in Chapters 2 to 5, 15 and 16, and HS codes under headings 2102, 2103, 2105, 2106, 2202, 2301, 2822, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103 and 4110 of Part Two of Annex I to Regulation (EEC) No 2658/87;
- (b) sprouts referred to by the following HS codes: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90 or 1214 90 of Part Two of Annex I to Regulation (EEC) No 2658/87.

2. Establishments referred to in paragraph 1 of this Article may be placed on the lists referred to in Article 127(3)(e) of Regulation (EU) 2017/625 only if, in addition to the guarantees laid down in Article 127(3)(e)(ii) and (iv) of Regulation (EU) 2017/625, the third country gives the following guarantees:

- (a) such establishments, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, comply with applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, in particular those of Regulation (EC) No 853/2004, or with requirements recognised to be at least equivalent thereto;
- (b) the establishment, where appropriate, only handles raw materials of animal origin that come from third countries with an approved residues monitoring plan for that product category in accordance with Directive 96/23/EC or from Member States;
- (c) it has real powers to stop the establishments from exporting to the Union in the event that the establishments fail to meet the relevant Union requirements or requirements recognised to be at least equivalent thereto.

3. The Commission shall provide the Member States with any new and updated lists that it receives from the competent authorities of the third country in accordance with Article 127(3)(e)(iii) of Regulation (EU) 2017/625 and shall publish such lists on its website.

4. Member States shall allow the entry into the Union of the consignments referred to in paragraph 1 provided that the official certificates which are required to accompany such consignments pursuant to the applicable Union rules are issued by the competent authorities of the third country starting with the date of publication by the Commission of the lists referred to in paragraph 1.

*Article 6***Establishments not subject to the requirements of Article 5(1)**

The requirements laid down in Article 5 shall not apply to establishments that only carry out the following activities:

- (a) primary production;
- (b) transport operations;
- (c) storage of products of animal origin not requiring temperature-controlled storage conditions;
- (d) production of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids referred to in Section XVI of Annex III to Regulation (EC) No 853/2004 and referred to by the CN codes under the heading of 2833, ex 3913, 2930, ex 2932, 3507 or 3503 of Part Two of Annex I to Regulation (EEC) No 2658/87.

*Article 7***Requirements for consignments of fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen**

Consignments of the following products of animal origin shall only enter the Union if they have been manufactured from raw materials obtained in slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products, appearing on lists of establishments drawn up and kept up-to-date in accordance with Article 127(3)(e) of Regulation (EU) 2017/625:

- (a) fresh meat;
- (b) minced meat;
- (c) meat preparations;
- (d) meat products and mechanically separated meat;
- (e) raw materials intended for the production of gelatine and collagen referred to respectively in point 4(a) of Chapter I of Section XIV and in point 4(a) of Chapter I of section XV of Annex III to Regulation (EC) No 853/2004.

*Article 8***Requirements for consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods**

1. Notwithstanding Article 6, consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods for which CN codes have been laid down in heading 0307 of Part Two of Annex I to Regulation (EEC) No 2658/87 shall enter the Union only from production areas in third countries that appear on lists drawn up by the competent authorities of the third country in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and published by the Commission.

2. The following products may enter the Union from production areas which have not been classified by the competent authorities in the third country in accordance with Article 18(6) of Regulation (EU) 2017/625:

- (a) *Pectinidae*, except where data from official monitoring programmes as established by Article 57 of Implementing Regulation (EU) 2019/627 enable the competent authorities to classify fishing grounds as set out in point (2) of Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004;
- (b) marine gastropods that are not filter feeders and *Holothuroidea* that are not filter feeders.

*Article 9***Listing of production areas**

1. Before the lists referred to in Article 8(1) are drawn up by the competent authorities of the third country, particular account shall be taken of the guarantees that the competent authorities of the third country can give concerning compliance with the requirements of Article 52 of Implementing Regulation (EU) 2019/627 on the classification and control of production areas.

The Commission shall carry out an on-the-spot control visit before such lists are drawn up.

2. Once lists referred to in Article 8(1) are drawn up, and when the competent authorities of the third country offer sufficient guarantees on the management and controls of production areas under their responsibility, the on-the-spot Commission control visit need not to be carried out prior to the addition of a new production area to an existing list established in accordance with Article 5.

*Article 10***Special requirements for fishery products**

Consignments of fishery products for which CN codes have been laid down in headings 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 1504, 1516, 1603, 1604, 1605 or 2106 of Part Two of Annex I to Regulation (EEC) No 2658/87, shall enter the Union for placing on the market only if they have been obtained or prepared, at any stage of their production, in an on-land establishment, a factory or freezer vessel or stored in a cold-store or a reefer vessel that appears on a list drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and published by the Commission.

Article 11

1. A vessel may be included on the lists of establishments referred to in Article 127(3)(e)(ii) of Regulation (EU) 2017/625 provided that the competent authorities of the third country the flag of which the vessel is flying and the competent authorities of another third country to which the competent authorities of the third country the flag of which the vessel is flying have delegated responsibility for the inspection of the vessel concerned, provide the Commission with a joint communication stating that all four of the following requirements are met:

- (a) both third countries appear on the list of third countries or regions thereof, drawn up in accordance with Article 127(3) of Regulation (EU) 2017/625, from which entry into the Union of fishery products is permitted;
- (b) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in the third country to which the third country the flag of which the vessel is flying has delegated responsibility for the inspection of the vessels concerned;
- (c) the delegated competent authorities have inspected the vessel and have declared that it complies with the applicable Union requirements;
- (d) the delegated competent authorities have declared that they will regularly inspect the vessel to ensure that it continues to comply with the applicable Union requirements.

2. A vessel may be included on the lists of establishments referred to in Article 127(3) of Regulation (EU) 2017/625 on the basis of a joint communication from the competent authorities of the third country the flag of which the vessel is flying and from the competent authorities of a Member State, to which the competent authorities of the third country the flag of which the vessel is flying have delegated responsibility for the inspection of the vessel concerned, if all three of the following requirements are met:

- (a) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in that Member State;
- (b) the competent authorities of that Member State have inspected the vessel and have declared that it complies with the applicable Union requirements;
- (c) the competent authorities of that Member State have declared that they will regularly inspect the vessel to ensure that it continues to comply with the applicable Union requirements.

3. When consignments of fishery products enter the Union directly from a reefer, factory or a freezer vessel flying the flag of a third country, the official certificate referred to in Article 13(3) of Commission Implementing Regulation (EU) 2019/628 ⁽²⁵⁾ may be signed by the captain.

Article 12

Requirements for consignments of composite products

1. Consignments of composite products referred to by the HS codes under headings 1601, 1602, 1603, 1604, 1605, 1901, 1902, 1905, 2004, 2005, 2103, 2104, 2105, 2106 of Part Two of Annex I to Regulation (EEC) No 2658/87 shall enter the Union for placing on the market only if each processed product of animal origin contained in the composite products was either produced in establishments that are located in third countries or regions thereof and authorised to export those processed products of animal origin to the Union in accordance with Article 5 or in establishments located in Member States.
2. Pending the establishment by the Commission of a specific list of third countries or regions thereof authorised to export composite products to the Union, consignments of composite products from third countries or regions thereof may enter into the Union, subject to compliance with the following rules:
 - (a) composite products referred to in paragraph 1 that need to be transported or stored under controlled temperatures shall originate from third countries or regions thereof authorised to export each processed product of animal origin contained in the final product to the Union, pursuant to Commission Decision 2007/777/EC, Commission Regulation (EU) No 605/2010, Commission Decision 2006/766/EC, Commission Regulation (EC) No 798/2008 and Decision 2011/163/EU;
 - (b) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures containing any quantity of processed meat shall originate from third countries or regions thereof authorised to export to the Union the meat products contained in the composite product pursuant to Commission Decision 2007/777/EC and Commission Decision 2011/163/EU;
 - (c) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures and which contain processed products of animal origin other than processed meat, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 shall originate from third countries or regions thereof authorised to export meat products, dairy products, colostrum-based products, fishery products or egg products to the Union on the basis of the Union animal and public health requirements and which are listed at least for one of these products of animal origin pursuant to Commission Decision 2007/777/EC, Commission Regulation (EU) No 605/2010, Commission Decision 2006/766/EC and Commission Regulation (EC) No 798/2008, and in the annex to Commission Decision 2011/163/EU on the basis of a residues control plan approved in accordance with Directive 96/23/EC.

Article 13

Official certificates

1. Each consignment of the following products shall enter the Union only where the consignment is accompanied by an official certificate:
 - (a) products of animal origin for which CN codes have been laid down in Chapters 2 to 5, 15 and 16, and HS codes under headings 1506, 1521, 1601, 1602, 1603, 1604, 1605, 2102, 2103, 2105, 2106, 2202, 2301, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110 and 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87, when these products are intended for human consumption;
 - (b) live insects referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;
 - (c) sprouts and seeds intended for the production of sprouts and referred to by the following HS codes: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90, 0713 10, 0713 33, 0712 34, 0712 35, 0713 39, 0713 40, 0712 50, 0712 60, 0713 90, 0910 99, 1201 10, 1201 90, 1207 50, 1207 99, 1209 10, 1209 21, 1209 91 or 1214 90 of Part Two of Annex I to Regulation (EEC) No 2658/87.

⁽²⁵⁾ Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (see page 101 of this Official Journal).

2. The official certificates referred to in paragraph 1 shall certify that the products comply with:
 - (a) the requirements laid down in Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 or provisions recognised to be equivalent to those requirements;
 - (b) any specific requirements for entry into the Union set out in this Regulation.
3. The official certificates referred to in paragraph 1 may include details required in accordance with other Union legislation on public and animal health matters.
4. The official certificate for sprouts and seeds intended for the production of sprouts referred to in paragraph 1(c), shall accompany the consignment until it reaches its destination as indicated in the official certificate. In the case of splitting of the consignment, a copy of the official certificate shall accompany each part of the consignment.

Article 14

Private attestation

1. A private attestation, prepared and signed by the importing food business operator, shall accompany the consignments of composite products as referred to in Article 12(2)(c) confirming that the consignments comply with the applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625.
2. By way of derogation to paragraph 1, for the products exempted from official controls at border control posts, in accordance with Article 48(h) of Regulation (EU) 2017/625, the private attestation shall accompany the products at the time of the placing on the market.
3. The private attestation referred to in paragraph 1 shall ensure the traceability of the consignment and shall include:
 - (a) information regarding the consignor and consignee of the imported goods;
 - (b) the list of products of plant origin and processed products of animal origin contained in the composite products, indicated in descending order of weight, as recorded at the time of their use in the manufacture of the composite product;
 - (c) the approval number of the establishment(s) manufacturing the processed products of animal origin contained in the composite product, as provided for in Article 4(2) of Regulation (EC) No 853/2004 and indicated by the importing food business operator.
4. The private attestation referred to in paragraph 1 shall attest that:
 - (a) the third country or region thereof producing the composite product is listed at least for one of the following category of product of animal origin:
 - (i) meat products;
 - (ii) dairy products or colostrum-based products;
 - (iii) fishery products;
 - (iv) egg products;
 - (b) the establishment producing the composite products fulfils hygiene standards, recognised to be equivalent to those required by Regulation (EC) No 852/2004;
 - (c) the composite product does not need to be stored or transported under controlled temperature;
 - (d) the processed products of animal origin contained in the composite product originate from third countries or regions thereof authorised to export each processed product of animal origin to the Union, or from the Union, and are sourced from listed establishment(s);
 - (e) the processed products of animal origin used in the composite product have undergone at least the treatment provided for those products pursuant to Commission Decision 2007/777/EC and Commission Regulation (EU) No 605/2010 with a brief description of any processes undergone and temperatures applied to the product.

*Article 15***Entry into force**

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 14 December 2019. However, the requirements laid down in Article 12, and Article (14)(1) and (2) shall apply from 21 April 2021.

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

Done at Brussels, 4 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2019/626**of 5 March 2019****concerning lists of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption, amending Implementing Regulation (EU) 2016/759 as regards these lists****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to 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) ⁽¹⁾, and in particular Article 127(2) thereof,

After consulting the Standing Committee on Plants, Animals, Food and Feed,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for official controls and other control activities performed by the competent authorities of the Member States in order to verify compliance with Union legislation in the area of, among others, food safety at all stages of the production, processing and distribution process. In particular, it provides that certain animals and goods are only to enter the Union from of a third country or region thereof which appears on a list drawn up by the Commission for that purpose.
- (2) Commission Delegated Regulation (EU) 2019/625 ⁽²⁾ supplements Regulation (EU) 2017/625 as regards the conditions for the entry into the Union of consignments of certain animals and goods intended for human consumption from third countries or regions thereof in order to ensure that they comply with the relevant requirements established in the rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625 (food safety) or with requirements recognised to be at least equivalent. Those conditions include the identification of the animals and goods intended for human consumption to which the requirement to come from a third country or region thereof listed in accordance with Article 126(2)(a) of Regulation (EU) 2017/625 applies.
- (3) Lists of third countries or regions thereof for the entry into the Union of consignments of certain animals and goods intended for human consumption are established to ensure compliance with food safety requirements in accordance with Article 11(1) of Regulation (EC) No 854/2004 of the European Parliament and of the Council ⁽³⁾, which will be repealed by 14 December 2019 by Regulation (EU) 2017/625, and with animal health requirements in accordance with Article 8(1) of Council Directive 2002/99/EC ⁽⁴⁾. When compliance with both human and animal health requirements was deemed necessary, common lists covering both aspects were

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (see page 18 of this Official Journal).

⁽³⁾ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

⁽⁴⁾ Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).

laid down by Commission Implementing Regulation (EU) 2016/759 ⁽⁵⁾, Commission Regulation (EU) No 206/2010 ⁽⁶⁾, Commission Regulation (EC) No 119/2009 ⁽⁷⁾, Commission Decision 2007/777/EC ⁽⁸⁾, Commission Decision 2003/779/EC ⁽⁹⁾ and Commission Regulation (EU) No 605/2010 ⁽¹⁰⁾.

- (4) Additional lists of third countries or regions thereof from which the entry into the Union of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products is permitted, based on public health considerations, are established in Commission Decision 2006/766/EC ⁽¹¹⁾, adopted under Article 11(1) of Regulation (EC) No 854/2004.
- (5) Since Regulation (EC) No 854/2004 is repealed by Regulation (EU) 2017/625 with effect from 14 December 2019 and in order to have one single legal act compiling all third countries or regions thereof required to be listed to enter certain animals and goods on the Union market from food and food safety perspective, it is appropriate to lay down lists for those animals and goods in this Regulation.
- (6) Since discussions within the context of the implementation of Regulation (EU) 2016/429 of the European Parliament and of the Council ⁽¹²⁾ are ongoing on the requirements for the listing of third countries or regions thereof for the entry into the Union of certain products of animal origin for animal health reasons, it is also appropriate to provide lists for these products of animal origin by laying down cross-references to the existing lists for animal health reasons in order to avoid duplication of lists. These lists have been drawn up on the basis of Regulation (EC) No 854/2004 and Directive 2002/99/EC at the request of the third countries concerned. In order to be on these lists, the competent authorities of the third countries provided appropriate guarantees, in particular as regards compliance or equivalence with Union food law and the organisation of the third country's competent authorities. The re-assessment of compliance with these conditions in accordance with Regulation (EU) 2017/625 is therefore not necessary.
- (7) It is appropriate to maintain common lists for the purpose of Regulation (EU) 2017/625 related to food and food safety with the existing lists, laid down for animal health reasons and to keep a coordinated approach by only listing third countries and regions thereof if a residue control programme has been approved in accordance with Council Directive 96/23/EC ⁽¹³⁾, when applicable.
- (8) Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽¹⁴⁾ lays down requirements for food business operators importing products of animal origin and composite products. In particular, it provides that food business operators importing products of animal origin from third countries or regions thereof are to ensure that the third country of dispatch appears on a list of third countries from which imports of such products are permitted.

⁽⁵⁾ Commission Implementing Regulation (EU) 2016/759 of 28 April 2016 drawing up lists of third countries, parts of third countries and territories from which Member States are to authorise the introduction into the Union of certain products of animal origin intended for human consumption, laying down certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC (OJ L 126, 14.5.2016, p. 13).

⁽⁶⁾ Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).

⁽⁷⁾ Commission Regulation (EC) No 119/2009 of 9 February 2009 laying down a list of third countries or parts thereof, for import into, or transit through, the Community of meat and wild leporidae, of certain wild land mammals and farmed rabbits and the veterinary certification requirements (OJ L 39, 10.2.2009, p. 12).

⁽⁸⁾ Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC (OJ L 312, 30.11.2007, p. 49).

⁽⁹⁾ Commission Decision 2003/779/EC of 31 October 2003 laying down animal health requirements and the veterinary certification for the import of animal casings from third countries (OJ L 285, 1.11.2003, p. 38).

⁽¹⁰⁾ Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk, dairy products, colostrum and colostrum-based products intended for human consumption (OJ L 175, 10.7.2010, p. 1).

⁽¹¹⁾ Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted (OJ L 320, 18.11.2006, p. 53).

⁽¹²⁾ 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') (OJ L 84, 31.3.2016, p. 1).

⁽¹³⁾ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

⁽¹⁴⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

- (9) Transitional measures providing for derogations from the import conditions laid down in Regulation (EC) No 853/2004 and applying to certain products of animal origin are provided for in Commission Regulation (EU) 2017/185 ⁽¹⁵⁾, and apply until 31 December 2020.
- (10) Additional lists of third countries or regions thereof must therefore be established at the latest before the transitional measures laid down in Regulation (EU) 2017/185 expire to avoid an interruption of the entry into the Union of consignments of those products of animal origin. Lists should be established in particular for rendered animal fats and greaves, reptile meat, insects and casings.
- (11) Food consisting of, isolated from or produced from insects or their parts, including live insects, are subject to novel food authorisation in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council ⁽¹⁶⁾. It is appropriate to establish a list for these groups of products.
- (12) It is necessary to establish before the end of the transitional measures provided for in Regulation (EU) 2017/185, a list of products of animal origin other than those for which specific lists have been laid down in this Regulation to avoid jeopardising the entry into the Union of currently imported products of animal origin, which are essential for European food business operators.
- (13) The transitional measures laid down in Regulation (EU) 2017/185 for certain products of animal origin and composite products were introduced because they represent a low risk for human health because of the very low quantities consumed or because the manufacturing of the products largely excludes human health risk. It is therefore disproportionate to request all evidence and guarantees from third countries in accordance with Article 127(3) of Regulation (EU) 2017/625 and Article 4 of Delegated Regulation (EU) 2019/625.
- (14) Lists should be laid down in this Regulation and deleted from Implementing Regulation (EU) 2016/759 and Decision 2006/766/EC. Regulation (EU) 2016/759 should therefore be amended accordingly and Decision 2006/766/EC should be repealed.
- (15) As Regulation (EU) 2017/625 applies with effect from 14 December 2019, this Regulation should also apply from that date.
- (16) Lists of third countries or regions thereof allowed, on the basis of their animal health status, for the entry into the Union of consignments of casings will only be established as from 21 April 2021 in accordance with Regulation (EU) 2016/429. It is appropriate that the list of third countries or regions thereof allowed for the entry into the Union of consignments of casings for human consumption applies only from the same date on. Transitional measures providing derogations concerning public health requirements for the entry into the Union of consignments of casings should therefore be extended until 20 April 2021.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation concerns the lists of third countries or regions thereof from which consignments of certain animals and goods intended for human consumption shall be authorised for entry into the Union from food safety perspective in accordance with Article 126(2)(a) of Regulation (EU) 2017/625.

⁽¹⁵⁾ Commission Regulation (EU) 2017/185 of 2 February 2017 laying down transitional measures for the application of certain provisions of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council (OJ L 29, 3.2.2017, p. 21).

⁽¹⁶⁾ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

*Article 2***Definitions**

For the purpose of this Regulation, the following definitions shall apply:

- (1) 'fresh meat' means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;
- (2) 'meat preparations' means meat preparations as defined in point 1.15 of Annex I to Regulation (EC) No 853/2004;
- (3) 'meat' means meat as defined in point 1.1 of Annex I to Regulation (EC) No 853/2004;
- (4) 'poultry' means poultry as defined in point 1.3 of Annex I to Regulation (EC) No 853/2004;
- (5) 'wild game' means wild game as defined in point 1.5 of Annex I to Regulation (EC) No 853/2004;
- (6) 'eggs' means eggs as defined in point 5.1 of Annex I to Regulation (EC) No 853/2004;
- (7) 'egg products' means egg products as defined in point 7.3 of Annex I to Regulation (EC) No 853/2004;
- (8) 'meat products' means meat products as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004;
- (9) 'treated stomachs, bladders and intestines' means treated stomachs, bladders and intestines as defined in point 7.9 of Annex I to Regulation (EC) No 853/2004;
- (10) 'bivalve molluscs' means bivalve molluscs as defined in point 2.1 of Annex I to Regulation (EC) No 853/2004;
- (11) 'fishery products' means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;
- (12) 'raw milk' means raw milk as defined in point 4.1 of Annex I to Regulation (EC) No 853/2004;
- (13) 'dairy products' means dairy products as defined in point 7.2. of Annex I to Regulation (EC) No 853/2004;
- (14) 'colostrum' means colostrum as defined in point 1 of Section IX of Annex III of Regulation (EC) No 853/2004;
- (15) 'colostrum-based products' means colostrum-based products as defined in points 2 of Section IX of Annex III of Regulation (EC) No 853/2004;
- (16) 'frogs' legs' means frogs' legs as defined in point 6.1 of Annex I to Regulation (EC) No 853/2004;
- (17) 'snails' means snails as defined in point 6.2 of Annex I to Regulation (EC) No 853/2004;
- (18) 'rendered animal fat' means rendered animal fat defined in point 7.5 of Annex I to Regulation (EC) No 853/2004;
- (19) 'greaves' means greaves as defined in point 7.6 of Annex I to Regulation (EC) No 853/2004;
- (20) 'gelatine' means gelatine as defined in point 7.7 of Annex I to Regulation (EC) No 853/2004;
- (21) 'collagen' means collagen as defined in point 7.8 of Annex I to Regulation (EC) No 853/2004;
- (22) 'honey' means honey as defined in point 1 of Part IX of Annex II of Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽¹⁷⁾;
- (23) 'apiculture products' means apiculture products as defined in point 2 of Part IX of Annex II of Regulation (EU) No 1308/2013;
- (24) 'reptile meat' means reptile meat as defined in point (16) of Article 2 of Regulation (EU) 2019/625;
- (25) 'insects' means insects as defined in point (17) of Article 2 of Regulation (EU) 2019/625.

⁽¹⁷⁾ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

*Article 3***List of third countries or regions thereof authorised for the entry into the Union of fresh meat and meat preparations of ungulates**

Consignments of fresh meat and meat preparations of ungulates intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the import into the Union in accordance with point (a) of Article 14 of Regulation (EU) No 206/2010.

*Article 4***List of third countries or regions thereof authorised for the entry into the Union of meat of poultry, ratites and wild game birds, meat preparations of poultry, eggs and egg products**

Consignments of meat of poultry, ratites and wild game birds, meat preparations of poultry, eggs and egg products intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the import into the Union in accordance with Article 3 of Commission Regulation (EC) No 798/2008 ⁽¹⁸⁾.

*Article 5***List of third countries or regions thereof authorised for the entry into the Union of meat of wild leporidae, of wild land mammals other than ungulates and leporidae, and of farmed rabbits**

Consignments of meat of wild leporidae, of wild land mammals other than ungulates and leporidae, and of farmed rabbits intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the import into the Union in accordance with Article 3 of Regulation (EC) No 119/2009.

*Article 6***List of third countries or regions thereof authorised for the entry into the Union of meat products and treated stomachs, bladders and intestines other than casings**

Consignments of meat products and treated stomachs, bladders and intestines, others than casings, intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the import into the Union in accordance with point (b) of Article 3 of Decision 2007/777/EC.

However, consignments of biltong/jerky and pasteurised meat products intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the import into the Union in accordance with Part 3 of Annex II of Decision 2007/777/EC.

*Article 7***Third countries or regions thereof authorised for the entry into the Union of casings**

Consignments of casings intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the import into the Union in accordance with Article 1 of Decision 2003/779/EC.

⁽¹⁸⁾ Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

*Article 8***List of third countries or regions thereof authorised for the entry into the Union of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods**

Consignments of live chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption shall only be authorised for the entry into the Union if they come from third countries or regions thereof that are listed in Annex I. Nevertheless, entry into the Union of adductor muscles of pectinidae other than aquaculture animals, completely separated from the viscera and gonads, shall also be permitted from third countries not appearing on such a list.

*Article 9***List of third countries or regions thereof authorised for the entry into the Union of fishery products others than those referred to in Article 8**

Consignments of fishery products others than those referred to in Article 8, intended for human consumption shall only be authorised for the entry into the Union if they come from third countries or regions thereof that are listed in Annex II.

*Article 10***List of third countries or regions thereof authorised for the entry into the Union of consignments of raw milk, colostrum, dairy products and colostrum-based products**

Consignments of raw milk, colostrum, dairy products and colostrum-based products intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the import into the Union in accordance with Article 2 of Regulation (EU) No 605/2010.

*Article 11***List of third countries or regions thereof authorised for the entry into the Union of frogs' legs**

Consignments of frogs' legs intended for human consumption shall only be authorised for the entry into the Union if they come from third countries or regions thereof that are listed in Annex III.

*Article 12***List of third countries or regions thereof authorised for the entry into the Union of snails, prepared in accordance with Section XI to Annex III to Regulation (EC) No 853/2004**

Consignments of snails, prepared in accordance with Section XI of Annex III to Regulation (EC) No 853/2004 intended for human consumption shall only be authorised for the entry into the Union if they come from third countries or regions thereof that are listed in Annex III to this Regulation.

*Article 13***List of third countries or regions thereof authorised for the entry into the Union of rendered animal fats and greaves**

Consignments of rendered animal fats and greaves intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the import of meat products into the Union in accordance with point (b)(i) of Article 3 of Decision 2007/777/EC.

*Article 14***List of third countries or regions thereof authorised for the entry into the Union of gelatine and collagen**

1. Consignments of gelatine and collagen derived from bovine, ovine, caprine and porcine and equine animals, intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the import of consignments of fresh meat of the specific ungulates into the Union in accordance with point (a) of Article 14 of Regulation (EU) No 206/2010, or from the South Korea, Malaysia, Pakistan or Taiwan.
2. Consignments of gelatine and collagen derived from poultry intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof listed in column 1 of the table in Part 1 of Annex I to Regulation (EC) No 798/2008 for which imports of poultry meat of the respective species are authorised as specified in that part of that Annex or from Taiwan.
3. Consignments of gelatine and collagen derived from fishery products intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof that are listed in Annex II.
4. Consignments of gelatine and collagen derived from leporidae and from wild land mammals others than ungulates intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof listed in column 1 of the table in Part 1 of Annex I to Regulation (EC) No 119/2009.

*Article 15***List of third countries or regions thereof authorised for the entry into the Union of raw materials for the production of gelatine and collagen**

1. Consignments of raw materials for the production of gelatine and collagen derived from bovine, ovine, caprine and porcine and equine animals intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the import of consignments of fresh meat of the specific ungulates into the Union in accordance with point (a) of Article 14 of Regulation (EU) No 206/2010.
2. Consignments of raw materials for the production of gelatine and collagen derived from poultry intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof listed in Part 1 of Annex I to Regulation (EC) No 798/2008 for which imports of poultry meat of the respective species are authorised as specified in that part of that Annex.
3. Consignments of raw materials for the production of gelatine and collagen derived from fishery products intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof that are listed in Annex II.
4. Consignments of raw materials for the production of gelatine and collagen derived from leporidae and from wild land mammals others than ungulates intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof listed in column 1 of the table in Part 1 of Annex I to Regulation (EC) No 119/2009.

*Article 16***List of third countries or regions thereof authorised for the entry into the Union of treated raw materials for the production of gelatine and collagen**

1. Consignments of treated raw materials for the production of gelatine and collagen derived from bovine, ovine, caprine and porcine and equine animals intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries listed in column 1 of the table in Part 1 of Annex II to Regulation (EU) No 206/2010, or from the South Korea, Malaysia, Pakistan or Taiwan.

2. Consignments of treated raw materials for the production of gelatine and collagen derived from poultry intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries listed in column 1 the table in of Part 1 of Annex I to Regulation (EC) No 798/2008 or from Taiwan.
3. Consignments of treated raw materials for the production of gelatine and collagen derived from fishery products intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof that are listed in Annex II.
4. Consignments of treated raw materials for the production of gelatine and collagen derived from leporidae and from wild land mammals others than ungulates, intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries or regions thereof listed in column 1 of the table in Part 1 of Annex I to Regulation (EC) No 119/2009.
5. Consignments of treated raw materials for the production of gelatine and collagen referred to in point 4(b)(iii) of Chapter I of Section XIV of Annex III to Regulation (EC) No 853/2004, shall only be authorised for the entry into the Union if they come from the third countries or regions thereof authorised for the entry of raw materials derived from those commodities in accordance with Article 15 of this Regulation.

Article 17

List of third countries authorised for the entry into the Union of honey and other apiculture products

Consignments of honey and other apiculture products intended for human consumption shall only be authorised for the entry into the Union if they come from the third countries listed in the 'Country' column in the Annex to Commission Decision 2011/163/EU ⁽¹⁹⁾ and marked with an 'X' in the 'Honey' column in that Annex.

Article 18

List of third countries or regions thereof authorised for the entry into the Union of certain highly refined products

Consignments of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids intended for human consumption shall only be authorised for the entry into the Union if they come from the following third countries or regions thereof:

1. in the case of raw materials derived from ungulates, third countries listed in column 1 of the table in Part 1 of Annex II to Regulation (EU) No 206/2010, or from South Korea, Malaysia, Pakistan or Taiwan;
2. in the case of raw materials derived from fishery products, all third countries or regions thereof that are listed in Annex II;
3. in the case of raw materials derived from poultry, third countries and or territories listed in column 1 of the table in Part 1 of Annex I to Regulation (EC) No 798/2008.

Article 19

List of third countries authorised for the entry into the Union of reptile meat

Consignments of reptile meat intended for human consumption shall only be authorised for the entry into the Union if they come from Switzerland ⁽²⁰⁾, Botswana, Vietnam, South Africa or Zimbabwe.

⁽¹⁹⁾ Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

⁽²⁰⁾ In accordance with the Agreement of 21 June 1999 between the European Community and the Swiss Confederation on trade in agricultural products (OJ L 114, 30.4.2002, p. 132).

*Article 20***Third countries or regions thereof authorised for the entry into the Union of insects**

Consignments of insects intended for human consumption shall be authorised for the entry into the Union only if such foods are originated in and consigned from a third country or region thereof, from which insects have been authorised in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council and listed in Commission Implementing Regulation (EU) 2017/2470 ⁽²¹⁾.

*Article 21***List of third countries or regions thereof authorised for the entry into the Union of other products of animal origin**

Consignments of products of animal origin other than those referred to in Articles 3 to 20 intended for human consumption shall only be authorised for the entry into the Union if they come from the following third countries or regions thereof:

1. if derived from ungulates, the third countries listed in column 1 of the table in Part 1 of Annex II to Regulation (EU) No 206/2010, or from the South Korea, Malaysia, Pakistan or Taiwan;
2. if derived from poultry, the third countries listed in the column 1 of the table in Part 1 of Annex I to Regulation (EC) No 798/2008 or from Taiwan;
3. if derived from fishery products, the third countries or regions thereof listed in Annex II;
4. if derived from leporidae and from wild land mammals other than ungulates, the third countries or regions thereof listed in column 1 of the table in Part 1 of Annex I to Regulation (EC) No 119/2009;
5. if derived from different species, the third countries or regions thereof listed in points 1 to 4 of this Article for each product of animal origin.

*Article 22***Amendment to Implementing Regulation (EU) 2016/759**

Implementing Regulation (EU) 2016/759 is amended as follows:

1. Article 1 is deleted;
2. Annex I is deleted.

*Article 23***Repeal**

Decision 2006/766/EC is repealed. References to Decision 2006/766/EC shall be construed as references to this Regulation and read in accordance with the correlation table set out in Annex IV to this Regulation.

*Article 24***Transitional provisions**

Until 20 April 2021, Member States shall continue to allow the entry on their territory of consignments of casings referred to in Article 7 from third countries or regions thereof authorised for the import of such consignments into the Union in accordance with Article 1 of Decision 2003/779/EC.

⁽²¹⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

*Article 25***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 14 December 2019.

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

Done at Brussels, 5 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

LIST OF THIRD COUNTRIES OR REGIONS THEREOF FROM WHICH ENTRY INTO THE UNION ARE PERMITTED OF LIVE, CHILLED, FROZEN OR PROCESSED BIVALVE MOLLUSCS, ECHINODERMS, TUNICATES AND MARINE GASTROPODS FOR HUMAN CONSUMPTION ⁽¹⁾

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	REMARKS
AU	Australia	
CA	Canada	
CH	Switzerland ⁽²⁾	
CL	Chile	
GL	Greenland	
JM	Jamaica	Only marine gastropods
JP	Japan	Only frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods
KR	South Korea	Only frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods
MA	Morocco	Processed bivalve molluscs belonging to the species <i>Acanthocardia tuberculatum</i> must be accompanied by: (a) an additional health attestation in accordance with the model set out in Part B of Appendix V of Annex VI to Commission Regulation (EC) No 2074/2005 (OJ L 338, 22.12.2005, p. 27); and (b) the analytical results of the test demonstrating that the molluscs do not contain a paralytic shellfish poison (PSP) level detectable by the bioassay method.
NZ	New Zealand	
PE	Peru	Only eviscerated Pectinidae (scallops) of aquaculture origin
TH	Thailand	Only frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods
TN	Tunisia	
TR	Turkey	
US	United States of America	Washington State and Massachusetts
UY	Uruguay	
VN	Vietnam	Only frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods

⁽¹⁾ Including those covered by the definition of fishery products in point 3.1, of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council (OJ L 139, 30.4.2004, p. 55).

⁽²⁾ In accordance with the Agreement of 21 June 1999 between the European Community and the Swiss Confederation on trade in agricultural products (OJ L 114, 30.4.2002, p. 132).

ANNEX II

LIST OF THIRD COUNTRIES OR REGIONS THEREOF FROM WHICH ENTRY INTO THE UNION ARE PERMITTED OF FISHERY PRODUCTS, OTHER THAN THOSE COVERED BY ANNEX I

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	RESTRICTIONS
AE	United Arab Emirates	
AG	Antigua and Barbuda	Only live lobsters
AL	Albania	
AM	Armenia	Only live wild crayfish, heat processed non-farmed crayfish and frozen non-farmed crayfish
AO	Angola	
AR	Argentina	
AU	Australia	
AZ	Azerbaijan	Only caviar
BA	Bosnia and Herzegovina	
BD	Bangladesh	
BJ	Benin	
BN	Brunei	Only aquaculture products
BR	Brazil	
BQ	Bonaire, Sint Eustatius, Saba	
BS	The Bahamas	
BY	Belarus	
BZ	Belize	
CA	Canada	
CG	Congo	Only fishery products caught, gutted (where appropriate), frozen and packed in their final packaging at sea
CH	Switzerland ⁽¹⁾	
CI	Cote d'Ivoire	
CL	Chile	
CN	China	
CO	Colombia	
CR	Costa Rica	
CU	Cuba	
CV	Cape Verde	

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	RESTRICTIONS
CW	Curaçao	
DZ	Algeria	
EC	Ecuador	
EG	Egypt	
ER	Eritrea	
FJ	Fiji	
FK	Falkland Islands	
GA	Gabon	
GD	Grenada	
GE	Georgia	
GH	Ghana	
GL	Greenland	
GM	Gambia	
GN	Guinea	Only fish that has not undergone any preparation or processing operation other than heading, gutting, chilling or freezing. The reduced frequency of physical checks, provided for by Commission Decision 94/360/EC (OJ L 158, 25.6.1994, p. 41), shall not be applied.
GT	Guatemala	
GY	Guyana	
HK	Hong Kong	
HN	Honduras	
ID	Indonesia	
IL	Israel	
IN	India	
IR	Iran	
JM	Jamaica	
JP	Japan	
KE	Kenya	
KI	Republic of Kiribati	
KR	South Korea	
KZ	Kazakhstan	

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	RESTRICTIONS
LK	Sri Lanka	
MA	Morocco	
MD	Republic of Moldova	Only caviar
ME	Montenegro	
MG	Madagascar	
MK	North Macedonia	
MM	Myanmar	
MR	Mauretania	
MU	Mauritius	
MV	Maldives	
MX	Mexico	
MY	Malaysia	
MZ	Mozambique	
NA	Namibia	
NC	New Caledonia	
NG	Nigeria	
NI	Nicaragua	
NZ	New Zealand	
OM	Oman	
PA	Panama	
PE	Peru	
PF	French Polynesia	
PG	Papua New Guinea	
PH	Philippines	
PM	Saint Pierre and Miquelon	
PK	Pakistan	
RS	Serbia Not including Kosovo as defined by the United Nations Security Council Resolution 1244 of 10 June 1999	
RU	Russia	

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	RESTRICTIONS
SA	Saudi Arabia	
SB	Solomon Islands	
SC	Seychelles	
SG	Singapore	
SH	Saint Helena Not including the islands of Tristan da Cunha and Ascension	
	Tristan da Cunha Not including the islands of Saint Helena and Ascension	Only lobsters (fresh or frozen)
SN	Senegal	
SR	Suriname	
SV	El Salvador	
SX	Sint Maarten	
TG	Togo	
TH	Thailand	
TN	Tunisia	
TR	Turkey	
TW	Taiwan	
TZ	Tanzania	
UA	Ukraine	
UG	Uganda	
US	United States of America	
UY	Uruguay	
VE	Venezuela	
VN	Vietnam	
YE	Yemen	
ZA	South Africa	
ZW	Zimbabwe	

(¹) In accordance with the Agreement of 21 June 1999 between the European Community and the Swiss Confederation on trade in agricultural products (OJ L 114, 30.4.2002, p. 132).

ANNEX III

LIST OF THIRD COUNTRIES OR REGIONS THEREOF FROM WHICH ENTRY INTO THE UNION ARE PERMITTED OF FROGS' LEGS AND SNAILS, PREPARED IN ACCORDANCE WITH SECTION XI TO ANNEX III TO REGULATION (EC) NO 853/2004 INTENDED FOR HUMAN CONSUMPTION

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	RESTRICTIONS
AE	United Arab Emirates	
AL	Albania	
AO	Angola	
AR	Argentina	
AU	Australia	
AZ	Azerbaijan	
BA	Bosnia and Herzegovina	
BD	Bangladesh	
BJ	Benin	
BR	Brazil	
BQ	Bonaire, Sint Eustatius, Saba	
BS	The Bahamas	
BY	Belarus	
BZ	Belize	
CA	Canada	
CH	Switzerland (1)	
CI	Cote d'Ivoire	
CL	Chile	
CN	China	
CO	Colombia	
CR	Costa Rica	
CU	Cuba	
CV	Cape Verde	
CW	Curaçao	
DZ	Algeria	
EC	Ecuador	
EG	Egypt	

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	RESTRICTIONS
ER	Eritrea	
FJ	Fiji	
FK	Falkland Islands	
GA	Gabon	
GD	Grenada	
GE	Georgia	
GH	Ghana	
GL	Greenland	
GM	Gambia	
GT	Guatemala	
GY	Guyana	
HK	Hong Kong	
HN	Honduras	
ID	Indonesia	
IL	Israel	
IN	India	
IR	Iran	
JM	Jamaica	
JP	Japan	
KE	Kenya	
KI	Republic of Kiribati	
KR	South Korea	
KZ	Kazakhstan	
LK	Sri Lanka	
MA	Morocco	
MD	Republic of Moldova	Only snails
ME	Montenegro	
MG	Madagascar	
MK	North Macedonia	
MM	Myanmar	
MR	Mauretania	

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	RESTRICTIONS
MU	Mauritius	
MV	Maldives	
MX	Mexico	
MY	Malaysia	
MZ	Mozambique	
NA	Namibia	
NC	New Caledonia	
NG	Nigeria	
NI	Nicaragua	
NZ	New Zealand	
OM	Oman	
PA	Panama	
PE	Peru	
PF	French Polynesia	
PG	Papua New Guinea	
PH	Philippines	
PM	Saint Pierre and Miquelon	
PK	Pakistan	
RS	Serbia Not including Kosovo as defined by the United Nations Security Council Resolution 1244 of 10 June 1999	
RU	Russia	
SA	Saudi Arabia	
SB	Solomon Islands	
SC	Seychelles	
SG	Singapore	
SH	Saint Helena Not including the islands of Tristan da Cunha and Ascension	
SN	Senegal	
SR	Suriname	
SV	El Salvador	

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	RESTRICTIONS
SX	Sint Maarten	
SY	Syria	Only snails
TG	Togo	
TH	Thailand	
TN	Tunisia	
TR	Turkey	
TW	Taiwan	
TZ	Tanzania	
UA	Ukraine	
UG	Uganda	
US	United States of America	
UY	Uruguay	
VE	Venezuela	
VN	Vietnam	
YE	Yemen	
ZA	South Africa	
ZW	Zimbabwe	

(¹) In accordance with the Agreement of 21 June 1999 between the European Community and the Swiss Confederation on trade in agricultural products (OJ L 114, 30.4.2002, p. 132).

ANNEX IV

CORRELATION TABLE REFERRED TO IN ARTICLE 23

Decision 2006/766/EC	This Regulation
Article 1	Article 8
Article 2	Article 9
Article 3	—
Article 4	—
Annex I	Annex I
Annex II	Annex II

COMMISSION IMPLEMENTING REGULATION (EU) 2019/627**of 15 March 2019****laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to 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) 1107/2009, (EU) 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) ⁽¹⁾, and in particular Article 18(8) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the official controls and other official activities performed by the competent authorities of the Member States to verify compliance with Union legislation, inter alia, in the area of food safety at all stages of production, processing and distribution. In particular, it provides for official controls in relation to products of animal origin intended for human consumption. In addition, it repeals Regulation (EC) No 854/2004 of the European Parliament and of the Council ⁽²⁾ with effect from 14 December 2019. That Regulation currently lays down specific rules for official controls on products of animal origin intended for human consumption, including requirements on uniform practical arrangements for the performance of the controls.
- (2) The rules laid down in this Regulation should ensure a continuation of the requirements to ensure the verification of food business operators' compliance with the rules for the safe handling of products of animal origin, in particular as laid down in:
 - Council Directive 96/23/EC ⁽³⁾ as regards measures to monitor certain substances and residues;
 - Regulation (EC) No 999/2001 of the European Parliament and of the Council ⁽⁴⁾ as regards controls on transmissible spongiform encephalopathies;
 - Council Directive 2002/99/EC ⁽⁵⁾ as regards animal health rules on products of animal origin;
 - Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁶⁾ as regards the general principles and requirements of food law;

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

⁽³⁾ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

⁽⁴⁾ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

⁽⁵⁾ Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).

⁽⁶⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- Directive 2003/99/EC of the European Parliament and of the Council ⁽⁷⁾ as regards the monitoring of zoonoses and zoonotic agents;
- Commission Decision 2003/467/EC ⁽⁸⁾ as regards control of tuberculosis, brucellosis and enzootic-bovine-leukosis;
- Regulation (EC) No 2160/2003 of the European Parliament and of the Council ⁽⁹⁾ as regards Salmonella controls;
- Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽¹⁰⁾ as regards the hygiene of foodstuffs;
- Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽¹¹⁾ as regards the specific hygiene rules for food of animal origin;
- Council Regulation (EC) No 1/2005 ⁽¹²⁾ as regards the protection of animals during transport and related operations;
- Commission Regulation (EC) No 2073/2005 ⁽¹³⁾ as regards microbiological criteria in foodstuffs;
- Commission Regulations (EC) No 1881/2006 ⁽¹⁴⁾ and (EC) No 124/2009 ⁽¹⁵⁾ as regards maximum levels for certain contaminants in foodstuffs;
- Council Directive 2007/43/EC ⁽¹⁶⁾ as regards the protection of chickens;
- Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽¹⁷⁾ as regards health rules on animal by-products;
- Council Regulation (EC) No 1099/2009 ⁽¹⁸⁾ as regards the protection of animals at the time of killing;
- Directive 2010/63/EU of the European Parliament and of the Council ⁽¹⁹⁾ as regards the protection of animals used for scientific purposes;
- Commission Implementing Regulation (EU) No 636/2014 ⁽²⁰⁾ as regards trade in unskinned large wild game;

⁽⁷⁾ Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).

⁽⁸⁾ Commission Decision 2003/467/EC of 23 June 2003 establishing the official tuberculosis, brucellosis and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds (OJ L 156, 25.6.2003, p. 74).

⁽⁹⁾ Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

⁽¹⁰⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

⁽¹¹⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

⁽¹²⁾ Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).

⁽¹³⁾ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

⁽¹⁴⁾ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

⁽¹⁵⁾ Commission Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed (OJ L 40, 11.2.2009, p. 7).

⁽¹⁶⁾ Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production (OJ L 182, 12.7.2007, p. 19).

⁽¹⁷⁾ 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).

⁽¹⁸⁾ Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).

⁽¹⁹⁾ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

⁽²⁰⁾ Commission Implementing Regulation (EU) No 636/2014 of 13 June 2014 on a model certificate for the trade of unskinned large wild game (OJ L 175, 14.6.2014, p. 16).

- Commission Implementing Regulation (EU) 2015/1375 ⁽²¹⁾ as regards official controls for *Trichinella*; and
- Regulation (EU) 2016/429 of the European Parliament and of the Council ⁽²²⁾ as regards animal health rules.
- (3) The practical arrangements for the performance of official controls on products of animal origin should be considered where a minimum level of official controls is necessary to respond to recognised uniform hazards and risks that might be posed by products of animal origin, covering all aspects that are important for protecting human health and, where appropriate, animal health and animal welfare. They should be based on the most recent relevant information available and scientific evidence from opinions of the European Food Safety Authority (EFSA).
- (4) On 31 August 2011, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (swine) ⁽²³⁾. The recommendations of that opinion were taken into account in the requirements for pig meat inspections laid down in Regulation (EC) No 854/2004 and should be maintained in the requirements laid down in this Regulation.
- (5) On 23 May 2012, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (poultry) ⁽²⁴⁾. That opinion identifies *Campylobacter* spp. and *Salmonella* spp. as the main hazards to be covered in poultry meat inspections through an integrated food safety assurance system, achievable through improved food chain information (FCI) and risk-based interventions.
- (6) On 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (bovine animals) ⁽²⁵⁾. That opinion identifies *Salmonella* spp. and pathogenic verocytotoxin-producing *Escherichia coli* (*E. coli*) as the most relevant hazards for meat inspections in bovine animals. It recommends the omission of palpation and incision during the post-mortem inspection of animals subjected to routine slaughter, since it may reduce spreading and cross-contamination with the high-priority biological hazards. However, palpations and incisions during post-mortem inspection, necessary to survey the occurrence of tuberculosis and *Taenia saginata* (tapeworm) cysticercosis, should be maintained.
- (7) Also on 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat from sheep and goats ⁽²⁶⁾. That opinion identifies pathogenic verocytotoxin-producing *E. coli* as the most relevant hazard for meat inspections in sheep and goats. It also recommends omitting palpation and incisions to the extent possible from the post-mortem inspection of sheep and goats subject to routine slaughter. However, palpation and incisions for the surveillance of tuberculosis and fascioliasis should be maintained in older animals for reasons of animal and human health surveillance.
- (8) Also on 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (solipeds) ⁽²⁷⁾. That opinion recommends the use of visual-only inspection in solipeds, which may have a significant favourable effect on the microbiological status of soliped carcase meat. Such inspection is considered unlikely to affect the overall surveillance of animal diseases.
- (9) Also on 6 June 2013, EFSA adopted a scientific opinion on the meat inspection of farmed game. That opinion recommends omitting palpation and incision unless abnormalities are detected, while at the same time underlining that such omission might have consequences for the overall surveillance of tuberculosis.
- (10) The recommendations set out in these EFSA opinions should be taken into account when laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption. The possible impact on trade with third countries should also be taken into account. At the same time, a smooth transition from the current requirements, as laid down in Regulation (EC) No 854/2004, should be ensured.

⁽²¹⁾ Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for *Trichinella* in meat (OJ L 212, 11.8.2015, p. 7).

⁽²²⁾ 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) (OJ L 84, 31.3.2016, p. 1).

⁽²³⁾ EFSA Journal 2011;9(10):2351

⁽²⁴⁾ EFSA Journal 2012;10(6):2741.

⁽²⁵⁾ EFSA Journal 2013;11(6):3266.

⁽²⁶⁾ EFSA Journal 2013;11(6):3265.

⁽²⁷⁾ EFSA Journal 2013;11(6):3263.

- (11) These practical arrangements should apply to official controls on products of animal origin laid down in Article 18 of Regulation (EU) 2017/625 and in Commission Delegated Regulation (EU) 2019/624 ⁽²⁸⁾. These practical arrangements for the performance of official controls should be uniform and facilitate the application of the requirements for a minimum level of official controls, taking into account the size of small businesses as laid down in Article 16 of Regulation (EU) 2017/625 by the use of a threshold in a non-discriminatory way.
- (12) Since the structure of slaughterhouses and game-handling establishments differs across Member States, a threshold should be based on the number of animals slaughtered or handled, or on the demonstration that it represents a limited and fixed percentage of the meat placed on the market. Article 17(6) of Regulation (EC) No 1099/2009 defines livestock units and lays down conversion rates to express the number of animals of a certain species in such livestock units. These provisions should be used to set thresholds and harmonise derogations from certain requirements based on the size of a slaughterhouse to the extent possible.
- (13) Specific requirements for auditing by the competent authorities should also be maintained to ensure the uniform practical verification of compliance with Union requirements on products of animal origin. Auditing is of particular interest for the verification of general and specific hygiene requirements and the application of procedures based on hazard analysis and critical control points (HACCP).
- (14) Verification of compliance with the requirements on identification marking in Section I of Annex II to Regulation (EC) No 853/2004, as currently laid down in Regulation (EC) No 854/2004, should be maintained to allow tracing back the animals.
- (15) Ante-mortem and post-mortem inspections are essential to verify compliance with requirements on human and animal health and animal welfare. In order to ensure at least the same level of human and animal health and animal welfare protection as provided by Regulation (EC) No 854/2004 and fair trade in an open market, it is necessary to lay down uniform practical requirements for such inspections, including cases where official controls are performed under the responsibility of the official veterinarian. As regards official controls on fresh meat, these inspections should be supplemented by appropriate documentary checks, controls on the safe disposal of specified risk material, as defined in Article 3(1)(g) of Regulation (EC) No 999/2001, and other animal by-products, and laboratory testing where appropriate.
- (16) It is important to identify cases of suspected and established non-compliance where competent authorities must take measures with respect to certain products of animal origin. Non-compliance with good hygiene practices should also result in corrective action by competent authorities.
- (17) The health mark defined in point 51 in Article 3 of Regulation (EU) 2017/625 covers meat of certain species and attests that the meat is fit for human consumption. Technical requirements of the health mark and practical arrangements for its application should be laid down in a specific and uniform way in order to indicate the fitness of the meat for human consumption and to prevent any trade disruption.
- (18) Commission Regulation (EC) No 2074/2005 ⁽²⁹⁾ lays down, inter alia, implementing measures for the organisation of official controls under Regulation (EC) No 854/2004 as regards recognised testing methods for marine biotoxins in live bivalve molluscs, testing methods for raw milk and heat-treated milk, official controls in fishery products and the inspection of meat. It is appropriate to merge all implementing measures for the organisation of official controls and include the ones from Regulation (EC) No 2074/2005 in this Regulation. They should be deleted in Regulation (EC) No 2074/2005.
- (19) The current conditions for the classification and monitoring of classified production and relaying areas for live bivalve molluscs have proven to be effective and ensure a high level of consumer protection. They should therefore be maintained.

⁽²⁸⁾ Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (see page 1 of this Official Journal).

⁽²⁹⁾ Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ L 338, 22.12.2005, p. 27).

- (20) A reference method for the analysis of *E. coli* in live bivalve molluscs, as currently laid down in Regulation (EC) No 854/2004, should be maintained.
- (21) The limits for marine biotoxins are laid down in Regulation (EC) No 853/2004. In particular, point 2 in Chapter V of Section VII of Annex III to that Regulation provides that live bivalve molluscs must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the limits established in that Chapter.
- (22) Specific requirements for the performance of official controls and the uniform minimum frequency for such controls on raw milk and dairy products should be laid down to ensure a high level of consumer protection and fair competition between food business operators.
- (23) Specific requirements for the performance of official controls and the uniform minimum frequency for such controls on fishery products should be laid down to ensure a high level of consumer protection and fair competition between food business operators. Those controls should include at least regular checks on the hygiene conditions of landing and first sale, regular inspections of vessels and establishments, including fish auctions and wholesale markets, and checks on storage and transport. Specific requirements for the control of vessels should also be established.
- (24) Those controls should also include practical arrangements as regards organoleptic examinations, freshness indicators, controls on histamine, residues and contaminants, microbiological checks. Special attention should be paid to the controls of parasites and on poisonous fishery products. Fishery products not meeting those hygiene requirements should be declared as unfit for human consumption.
- (25) Special requirements concerning the official controls on fishery products caught by vessels flying the flag of Member States entering the Union after being transferred in a third country with or without storage should also be established.
- (26) There is an increasing interest in the production and placing on the market of reptile meat. In order to ensure the safety of reptile meat, it is relevant to introduce specific official controls at slaughter in addition to the existing general hygiene rules laid down in Regulation (EC) No 852/2004 and the *Trichinella* controls laid down in Implementing Regulation (EU) 2015/1375.
- (27) Regulation (EC) No 2074/2005 should be amended accordingly.
- (28) As Regulation (EU) 2017/625 repeals Regulation (EC) No 854/2004 with effect from 14 December 2019, this Regulation should also apply from that date.
- (29) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

TITLE I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

This Regulation lays down uniform practical arrangements for the performance of official controls and actions in relation to the production of products of animal origin intended for human consumption. These official controls and actions shall be performed by the competent authorities taking into account the requirements of Article 18(2), (3) and (5) of Regulation (EU) 2017/625 and Delegated Regulation (EU) 2019/624.

The specific rules cover:

- (a) specific requirements and uniform minimum frequency of official controls on any product of animal origin, as regards audits and identification marking;
- (b) specific requirements and uniform minimum frequency of official controls on fresh meat, including specific requirements for audits and specific tasks as regards controls on fresh meat;

- (c) measures to be taken in cases of non-compliance of fresh meat with Union requirements for the protection of human health and animal health and welfare;
- (d) technical requirements and practical arrangements as regards the health mark referred to in Article 5 of Regulation (EC) No 853/2004;
- (e) specific requirements and uniform minimum frequency of official controls on milk, colostrum, dairy products and colostrum-based products;
- (f) conditions for the classification and monitoring of classified production and relaying areas for live bivalve molluscs, including decisions to be taken after monitoring classified production and relaying areas;
- (g) specific requirements and uniform minimum frequency of official controls on fishery products.

Article 2

Definitions

The following definitions shall apply for the purpose of this Regulation:

- (1) 'fresh meat' means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;
- (2) 'colostrum' means colostrum as defined in point 1 of Section IX of Annex III of Regulation (EC) No 853/2004;
- (3) 'dairy products' means dairy products as defined in point 7.2. of Annex I to Regulation (EC) No 853/2004;
- (4) 'colostrum-based products' means colostrum-based products as defined in point 2 of Section IX of Annex III of Regulation (EC) No 853/2004;
- (5) 'production area' means a production area as defined in point 2.5 of Annex I of Regulation (EC) No 853/2004;
- (6) 'relaying area' means relaying area as defined in point 2.6 of Annex I of Regulation (EC) No 853/2004;
- (7) 'bivalve molluscs' means bivalve molluscs as defined in point 2.1 of Annex I of Regulation (EC) No 853/2004;
- (8) 'fishery products' means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;
- (9) 'establishment' means an establishment as defined in Article 2(1)(c) of Regulation (EC) No 852/2004;
- (10) 'food business operator' means a food business operator as defined in Article 3(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽³⁰⁾;
- (11) 'microbiological criterion' means microbiological criterion as defined in Article 2(b) of Regulation (EC) No 2073/2005;
- (12) 'slaughterhouse' means slaughterhouse as defined in point 1.16 of Annex I of Regulation (EC) No 853/2004;
- (13) 'traceability' means traceability as defined in Article 3(15) of Regulation (EC) No 178/2002;
- (14) 'specified risk material' means specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;
- (15) 'contamination' means contamination as defined in Article 2(1)(f) of Regulation (EC) No 852/2004;
- (16) 'holding of provenance' means a holding of provenance as defined in point 2 of Article 2 of Delegated Regulation (EU) 2019/624;
- (17) 'primary production' means primary production as defined in Article 3(17) of Regulation (EC) No 178/2002;

⁽³⁰⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (18) 'domestic ungulates' means domestic ungulates as defined in point 1.2 of Annex I of Regulation (EC) No 853/2004;
- (19) 'game-handling establishment' means a game-handling establishment as defined in point 1.18 of Annex I of Regulation (EC) No 853/2004;
- (20) 'large wild game' means large wild game as defined in point 1.8 of Annex I to Regulation (EC) No 853/2004;
- (21) 'flock' means a flock as defined in Article 2(3)(b) of Regulation (EC) No 2160/2003;
- (22) 'lagomorphs' means lagomorphs as defined in point 1.4 of Annex I of Regulation (EC) No 853/2004;
- (23) 'carcase' means a carcase as defined in point 1.9 of Annex I to Regulation (EC) No 853/2004;
- (24) 'offal' means offal as defined in point 1.11 of Annex I to Regulation (EC) No 853/2004;
- (25) 'low-capacity slaughterhouse' means a low-capacity slaughterhouse as defined in Article 2(17) of Delegated Regulation (EU) 2019/624;
- (26) 'low-capacity game-handling establishment' means a game-handling establishment as defined in Article 2(18) of Delegated Regulation (EU) 2019/624;
- (27) 'livestock unit' means a livestock unit as defined in Article 17(6) of Regulation (EC) No 1099/2009;
- (28) 'small wild game' means small wild game as defined in point 1.7 of Annex I of Regulation (EC) No 853/2004;
- (29) 'poultry' means poultry as defined in point 1.3 of Annex I of Regulation (EC) No 853/2004;
- (30) 'cutting plant' means a cutting plant as defined in point 1.17 of Annex I of Regulation (EC) No 853/2004;
- (31) 'viscera' means viscera as defined in point 1.12 of Annex I of Regulation (EC) No 853/2004;
- (32) 'meat' means meat as defined in point 1.1 of Annex I of Regulation (EC) No 853/2004;
- (33) 'farmed game' means farmed game as defined in point 1.6 of Annex I of Regulation (EC) No 853/2004;
- (34) 'wild game' means wild game as defined in point 1.5 of Annex I to Regulation (EC) No 853/2004;
- (35) 'milk production holding' means a milk production holding as defined in point 4.2 of Annex I of Regulation (EC) No 853/2004;
- (36) 'raw milk' means raw milk as defined in point 4.1 of Annex I to Regulation (EC) No 853/2004;
- (37) 'purification centre' means a purification centre as defined in point 2.8 of Annex I to Regulation (EC) No 853/2004;
- (38) 'marine biotoxins' means marine biotoxins as defined in point 2.2 of Annex I to Regulation (EC) No 853/2004;
- (39) 'stages of production, processing and distribution' means stages of production, processing and distribution as defined in Article 3(16) of Regulation (EC) No 178/2002;
- (40) 'dispatch centre' means a dispatch centre as defined in point 2.7 of Annex I of Regulation (EC) No 853/2004;
- (41) 'placing on the market' means placing on the market as defined in Article 3(8) of Regulation (EC) No 178/2002;
- (42) 'factory vessel' means factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;
- (43) 'freezer vessel' means freezer vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;
- (44) 'reptiles' means reptiles as defined in point 15 of Article 2 of Commission Delegated Regulation (EU) 2019/625 ⁽³¹⁾;

⁽³¹⁾ Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (see page 18 of this Official Journal).

- (45) 'reptile meat' means reptile meat as defined in point 16 of Article 2 of Delegated Regulation (EU) 2019/625;
- (46) 'fresh fishery products' means fresh fishery products as defined in point 3.5 of Annex I to Regulation (EC) No 853/2004;
- (47) 'prepared fishery products' means prepared fishery products as defined in point 3.6 of Annex I to Regulation (EC) No 853/2004;
- (48) 'processed fishery products' means processed fishery products as defined in point 7.4 of Annex I to Regulation (EC) No 853/2004.

TITLE II

**SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND THE UNIFORM
MINIMUM FREQUENCY FOR OFFICIAL CONTROLS ON PRODUCTS OF ANIMAL ORIGIN**

CHAPTER I

***Specific requirements for audits by the competent authorities in establishments handling products of
animal origin***

Article 3

Requirements subject to auditing

1. When auditing good hygiene practices in establishments, the competent authorities shall verify that food business operators handling products of animal origin apply procedures continuously and properly concerning at least the following:
- (a) the design and maintenance of premises and equipment;
 - (b) pre-operational, operational and post-operational hygiene;
 - (c) personal hygiene;
 - (d) training in hygiene and in work procedures;
 - (e) pest control;
 - (f) water quality;
 - (g) temperature control;
 - (h) controls on animals or food entering and leaving the establishment, and any accompanying documentation.
2. When auditing procedures based on hazard analysis and critical control points (HACCP), as laid down in Article 5 of Regulation (EC) No 852/2004, the competent authorities shall verify that food business operators handling products of animal origin apply such procedures continuously and properly.
3. They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin:
- (a) comply with Article 3 of Regulation (EC) No 2073/2005 as regards microbiological criteria;
 - (b) comply with Union legislation on:
 - the monitoring of chemical residues, in accordance with Council Directive 96/23/EC and Commission Decision 97/747/EC ⁽³²⁾;
 - maximum residue limits for pharmacologically active substances, in accordance with Commission Regulation (EU) No 37/2010 ⁽³³⁾ and Commission Implementing Regulation (EU) 2018/470 ⁽³⁴⁾;

⁽³²⁾ Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products (OJ L 303, 6.11.1997, p. 12).

⁽³³⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

⁽³⁴⁾ Commission Implementing Regulation (EU) 2018/470 of 21 March 2018 on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC (OJ L 79, 22.3.2018, p. 16).

- prohibited and unauthorised substances, in accordance with Commission Regulation (EU) No 37/2010, Council Directive 96/22/EC ⁽³⁵⁾, Commission Decision 2005/34/EC ⁽³⁶⁾;
 - contaminants, in accordance with Regulations (EC) No 1881/2006 and (EC) No 124/2009 setting maximum levels for certain contaminants in food;
 - pesticide residues, in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽³⁷⁾;
- (c) do not contain physical hazards, such as foreign bodies.
4. Where a food business operator uses procedures set out in guides to the application of HACCP-based principles, in accordance with Article 5(5) of Regulation (EC) No 852/2004, the audit shall cover the correct use of those guides.
5. When carrying out auditing tasks, the competent authorities shall take special care:
- (a) to determine whether staff and staff activities in the establishment at all stages of the production process comply with the requirements, as regards hygienic practices and HACCP laid down in Article 3 of Regulation (EC) No 2073/2005, Articles 4 and 5 of Regulation (EC) No 852/2004 and Article 3(1) of Regulation (EC) No 853/2004. To complement the audit, the competent authorities may carry out performance tests, in order to ascertain that staff are sufficiently skilled;
 - (b) to verify the food business operator's relevant records;
 - (c) to take samples for laboratory analysis where necessary;
 - (d) to document elements taken into account and the findings of the audit.

Article 4

Nature and frequency of auditing

1. The nature and frequency of auditing tasks in respect of individual establishments shall depend on the assessed risk. To this end, the competent authorities shall regularly assess:
- (a) human and, where appropriate, animal health risks;
 - (b) in the case of slaughterhouses, animal welfare aspects;
 - (c) the type and throughput of the processes carried out;
 - (d) the food business operator's past record as regards compliance with food law.
2. Where food business operators in the food chain take additional measures to guarantee food safety by implementing integrated systems, private control systems or independent third-party certification, or by other means, and where these measures are documented and animals covered by such schemes are clearly identifiable, the competent authorities may take such measures into account when carrying out audits to review good hygiene practices and the HACCP-based procedures.

CHAPTER II

Specific requirements for identification marking

Article 5

Compliance with the requirements of Regulation (EC) No 853/2004 concerning the application of identification marks shall be verified in all establishments approved in accordance with that Regulation, in addition to verification of compliance with other traceability requirements in accordance with Article 18 of Regulation (EC) No 178/2002.

⁽³⁵⁾ Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of β -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p. 3).

⁽³⁶⁾ Commission Decision 2005/34/EC of 11 January 2005 laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries (OJ L 16, 20.1.2005, p. 61).

⁽³⁷⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

CHAPTER III

Scientific and technological developments

Article 6

The Member States shall inform the Commission and other Member States on scientific and technological developments, as referred to in Article 16(2)(b) of Regulation (EU) 2017/625 for consideration and further action as appropriate.

TITLE III

SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND THE UNIFORM MINIMUM FREQUENCY FOR OFFICIAL CONTROLS ON FRESH MEAT

CHAPTER I

Audits

Article 7

Additional requirements for audits in establishments handling fresh meat

1. In addition to the requirements for audits laid down in Articles 3 and 4, the competent authorities shall, when carrying out an audit in establishments handling fresh meat, verify continuous compliance with food business operators' own procedures concerning the collection, transport, storage and handling of fresh meat, and the use or disposal of animal by-products, including specified risk material, for which they are responsible.
2. In the course of audits in slaughterhouses, the competent authorities shall verify the evaluation of food chain information, as laid down in Section III of Annex II to Regulation (EC) No 853/2004.
3. When carrying out audits of HACCP-based procedures, the competent authorities shall check that due regard is given to the procedures set out in Section II of Annex II to Regulation (EC) No 853/2004 and that the food business operators' procedures guarantee, to the extent possible, that fresh meat:
 - (a) does not contain pathological abnormalities or changes;
 - (b) does not bear
 - (i) faecal contamination; or,
 - (ii) any other contamination considered to pose an unacceptable human health risk;
 - (c) complies with the microbiological criteria in Article 3 of Regulation (EC) No 2073/2005;
 - (d) does not contain specified risk material, in accordance with the requirements in Regulation (EC) No 999/2001.

CHAPTER II

Official controls on fresh meat

Article 8

Relevance of audit results

When carrying out official controls in accordance with this Chapter, the official veterinarian shall take into account the results of the audits carried out in accordance with Chapter I. Where appropriate, the official veterinarian shall target official controls to deficiencies detected during previous audits.

Section 1

Checks of documents

Article 9

Obligations of the competent authorities as regards checks of documents

1. The competent authorities shall inform the food business operator of the holding of provenance of the minimum elements of food chain information to be supplied to the slaughterhouse operator in accordance with Section III of Annex II to Regulation (EC) No 853/2004.

2. The competent authorities shall perform the necessary checks of documents to verify that:
 - (a) the food chain information is consistently and effectively communicated between the food business operator who raised or kept the animals before dispatch and the slaughterhouse operator;
 - (b) the food chain information is valid and reliable;
 - (c) feedback of relevant information to the holding of provenance, if applicable, is provided in accordance with Article 39(5).
3. Where animals are dispatched for slaughter to another Member State, the competent authorities at the holding of provenance and the place of slaughter shall cooperate to ensure that the food chain information provided by the food business operator of the holding of provenance is easily accessible to the slaughterhouse operator receiving it.

Article 10

Obligations of the official veterinarian as regards checks of documents

1. The official veterinarian shall verify the results of the checks and evaluations of food chain information provided by the slaughterhouse operator in accordance with Section III of Annex II to Regulation (EC) No 853/2004. The official veterinarian shall take those checks and evaluations into account when carrying out ante-mortem and post-mortem inspections, together with any other relevant information from the records of the animals' holding of provenance.
2. When carrying out ante-mortem and post-mortem inspections, the official veterinarian shall take into account official certificates provided for in accordance with Article 29 of Commission Implementing Regulation (EU) 2019/628 ⁽³⁸⁾, and any declarations by veterinarians carrying out official controls or other checks at the level of primary production.
3. In the case of the emergency slaughter of domestic ungulates outside the slaughterhouse, the official veterinarian at the slaughterhouse shall examine the certification provided for in accordance with Article 29 of Implementing Regulation (EU) 2019/628 and issued by the official veterinarian who carried out the ante-mortem inspection in accordance with point 6 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004 and any other relevant information provided by the food business operator.
4. In the case of large wild game, the official veterinarian at the game-handling establishment shall examine and take into account the declaration accompanying the body of the animal, as issued by a trained person in accordance with point 4(a) of Chapter II of Section IV of Annex III to Regulation (EC) No 853/2004.

Section 2

Ante-mortem inspection

Article 11

Requirements as regards ante-mortem inspection at the slaughterhouse

1. All animals shall be subjected to ante-mortem inspection before slaughter. However, inspection can be limited to a representative sample of birds from each flock and a representative sample of lagomorphs from each holding of provenance of lagomorphs.
2. Ante-mortem inspection shall take place within 24 hours of arrival of the animals at the slaughterhouse and less than 24 hours before slaughter. The official veterinarian may require an additional ante-mortem inspection at any other time.
3. Ante-mortem inspections shall determine whether, as regards the particular animal inspected, there is any sign:
 - (a) that the health and welfare of the animal has been compromised;

⁽³⁸⁾ Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (see page 101 of this Official Journal).

- (b) of any condition, abnormalities or disease that make the fresh meat unfit for human consumption or that might adversely affect animal health, paying particular attention to the detection of zoonotic diseases and animal diseases for which animal health rules are laid down in Regulation (EU) 2016/429;
 - (c) of the use of prohibited or unauthorised substances, misuse of veterinary medicinal products or the presence of chemical residues or contaminants.
4. Ante-mortem inspection shall include verification of food business operators' compliance with their obligation to ensure that animals have a clean hide, skin or fleece, so as to avoid any unacceptable risk of contamination of the fresh meat during slaughter.
5. The official veterinarian shall carry out a clinical inspection of all animals that the food business operator or an official auxiliary may have put aside for a more thorough ante-mortem inspection.
6. Where the ante-mortem inspection is carried out at the holding of provenance in accordance with Article 5 of Delegated Regulation (EU) 2019/624, the official veterinarian at the slaughterhouse shall carry out ante-mortem inspection only when and to the extent specified.

Section 3

Post-mortem inspection

Article 12

Requirements for post-mortem inspection

1. Subject to the derogation stipulated in Point 4 of Chapter II of Section IV to Annex III of Regulation (EC) No 853/2004, carcasses and accompanying offals, shall be subjected to post-mortem inspection:
- (a) without delay after slaughter, or
 - (b) as soon as possible after arrival at the game-handling establishment.
2. The competent authorities may require the food business operator to provide special technical facilities and sufficient space to check offal.
3. The competent authorities shall:
- (a) check all external surfaces, including those of body cavities of carcasses, as well as offal;
 - (b) pay particular attention to the detection of zoonotic diseases and animal diseases for which animal health rules are laid down in Regulation (EU) 2016/429.
4. The speed of the slaughter line and the number of inspection staff present shall be such as to allow for proper inspection.

Article 13

Derogation on the timing of post-mortem inspection

1. By way of derogation from Article 12(1), the competent authorities may allow that, when neither the official veterinarian nor the official auxiliary are present in the game-handling establishment or slaughterhouse during slaughter and dressing, the post-mortem inspection is delayed by a maximum period of 24 hours from slaughter or arrival in the game-handling establishment, provided that:
- (a) the animals concerned are slaughtered in a low-capacity slaughterhouse or handled in a low-capacity game-handling establishment that slaughters or handles:
 - (i) fewer than 1 000 livestock units per year; or
 - (ii) fewer than 150 000 poultry, lagomorphs and small wild game per year;
 - (b) sufficient facilities exist within an establishment to store the fresh meat and offal so that they can be examined;
 - (c) the post-mortem inspection is carried out by the official veterinarian.

2. The competent authorities may increase the thresholds laid down in point (a) (i) and (ii) of paragraph 1 ensuring that the derogation is applied in the smallest slaughterhouses and game-handling establishments complying with the definition of low-capacity slaughterhouse or low-capacity game-handling establishment and provided that the combined annual production of these establishments does not exceed 5 % of the total amount of fresh meat produced in a Member State:

- (a) for the species concerned;
- (b) or for all ungulates together;
- (c) of all poultry together; or,
- (d) of all birds and lagomorphs together.

In such case, the competent authorities shall notify this derogation and the evidence to support it in accordance with the procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council ⁽³⁹⁾;

3. For the purpose of point (a) (i) of paragraph 1, the conversion rates laid down in Article 17(6) of Regulation (EC) No 1099/2009 shall be used. However in case of ovine and caprine animals and small (< 100 kg live weight) *Cervidae* a conversion rate of 0,05 livestock units, and in case of other large game a conversion rate of 0,2 livestock units shall be used.

Article 14

Additional examination requirements for post-mortem inspection

1. Additional examinations, such as palpation and incision of parts of the carcass and offal, and laboratory tests, shall be carried out if needed to:

- (a) reach a definitive diagnosis of a suspected hazard; or
- (b) detect the presence of:
 - (i) an animal disease for which animal health rules are laid down in Regulation (EU) 2016/429;
 - (ii) chemical residues or contaminants as referred to in Directive 96/23/EC and Decision 97/747/EC, especially:
 - chemical residues in excess of the levels laid down in Regulations (EU) No 37/2010 and (EC) No 396/2005;
 - contaminants exceeding the maximum levels laid down in Regulations (EC) No 1881/2006 and (EC) No 124/2009; or
 - residues of substances that are prohibited or unauthorised in accordance with Regulation (EU) No 37/2010 or Directive 96/22/EC;
 - (iii) non-compliance with the microbiological criteria referred to in Article 3(1)(b) of Regulation (EC) No 2073/2005 or the possible presence of other microbiological hazards that would make the fresh meat unfit for human consumption;
 - (iv) other factors that might require the fresh meat to be declared unfit for human consumption or restrictions to be placed on its use.

2. During the post-mortem inspection, precautions shall be taken to ensure that contamination of fresh meat by actions such as palpation, cutting or incision is kept to a minimum.

Article 15

Requirements for post-mortem inspection of domestic solipeds, bovine animals over eight months old and domestic swine more than five weeks old, and large wild game

1. The requirements in this Article shall apply in addition to the requirements in Articles 12 and 14.

⁽³⁹⁾ Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

2. The official veterinarian shall require that carcasses of domestic solipeds, bovine animals over eight months old and domestic swine more than five weeks old are submitted for post-mortem inspection split lengthways into half carcasses down the spinal column.
3. If the post-mortem inspection so necessitates, the official veterinarian may require any head or any carcass to be split lengthways. However, to take account of particular eating habits, technological developments or specific sanitary situations, the official veterinarian may authorise the submission for post-mortem inspection of carcasses of domestic solipeds, bovine animals more than eight months old and domestic swine more than five weeks old that are not split in half.
4. In low-capacity slaughterhouses or low-capacity game-handling establishments handling fewer than 1 000 livestock units per year, the official veterinarian may, for sanitary reasons, authorise the cutting into quarter carcasses of adult domestic solipeds, adult bovine animals and adult large wild game before post-mortem inspection.

Article 16

Additional requirements for post-mortem inspection in cases of emergency slaughter

In the event of emergency slaughter, the carcass shall be subjected to post-mortem inspection as soon as possible in accordance with Articles 12, 13, 14 and 15 before it is released for human consumption.

Article 17

Practical arrangements for post-mortem inspection of domestic bovine animals, domestic sheep and goats, domestic solipeds and domestic swine

Where the post-mortem inspection is performed by an official veterinarian, under the supervision of the official veterinarian or, where sufficient guarantees are in place, under the responsibility of the official veterinarian in accordance with Article 18(2)(c) of Regulation (EU) 2017/625 and Article 7 of Delegated Regulation (EU) 2019/624, the competent authorities shall ensure that the practical arrangements laid down in the following Articles 18 to 24 are complied with in the cases of domestic bovine animals, domestic sheep and goats, domestic solipeds and domestic swine in addition to the requirements laid down in Articles 12, 14 and 15.

Article 18

Young bovine animals

1. Carcasses and offal of the following bovine animals shall undergo the post-mortem inspection procedures laid down in paragraph 2:
 - (a) animals under eight months old; and,
 - (b) animals under 20 months old if reared without access to pasture land during their whole life in an officially tuberculosis-free Member State or region of a Member State in accordance with Article 1 of Decision 2003/467/EC.
2. The post-mortem inspection procedures shall include at least a visual inspection of the following:
 - (a) the head and throat; together with palpation and examination of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*), however, in order to ensure the surveillance of the officially tuberculosis free status, Member States may decide to carry out further investigations; inspection of the mouth and fauces;
 - (b) the lungs, trachea and oesophagus; palpation of the lungs; palpation and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);
 - (c) the pericardium and heart;
 - (d) the diaphragm;
 - (e) the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*);

- (f) the gastro-intestinal tract, the mesentery and gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);
- (g) the spleen;
- (h) the kidneys;
- (i) the pleura and peritoneum;
- (j) the umbilical region and the joints of young animals.

3. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

- (a) incision of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*); palpation of the tongue;
- (b) incision of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*); lengthwise opening of the trachea and the main branches of the bronchi; the lungs shall be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;
- (c) lengthways incision of the heart so as to open the ventricles and cut through the interventricular septum;
- (d) incision of the gastric and mesenteric lymph nodes;
- (e) palpation of the spleen;
- (f) incision of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (g) palpation of the umbilical region and the joints. The umbilical region shall be incised and the joints opened; the synovial fluid must be examined.

Article 19

Other bovine animals

1. Carcasses and offal of bovine animals other than those referred to in Article 18(1) shall undergo the following post-mortem inspection procedures:

- (a) a visual inspection of the head and throat; incision and examination of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*); examination of the external masseters, in which two incisions shall be made parallel to the mandible, and the internal masseters (internal pterygoid muscles), which shall be incised along one plane. The tongue shall be freed to permit a detailed visual inspection of the mouth and the fauces;
- (b) an inspection of the trachea and oesophagus; visual inspection and palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);
- (c) a visual inspection of the pericardium and heart, the latter being incised lengthways so as to open the ventricles and cut through the interventricular septum;
- (d) a visual inspection of the diaphragm;
- (e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*);
- (f) a visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); palpation of the gastric and mesenteric lymph nodes;
- (g) a visual inspection of the spleen;
- (h) a visual inspection of the kidneys;
- (i) a visual inspection of the pleura and the peritoneum;
- (j) a visual inspection of the genital organs (except for the penis, if already discarded);
- (k) a visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*).

2. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

- (a) an incision and examination of the sub-maxillary and parotid lymph nodes (*Lnn. mandibulares* and *parotidei*); palpation of the tongue and the fauces;
- (b) an incision of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes*, *eparteriales* and *mediastinales*); lengthwise opening of the trachea and the main branches of the bronchi; the lungs shall be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;
- (c) a palpation of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts;
- (d) an incision of the gastric and mesenteric lymph nodes;
- (e) a palpation of the spleen;
- (f) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (g) a palpation and incision of the udder and its lymph nodes (*Lnn. supramammarii*) in cows. Each half of the udder shall be opened by a long, deep incision as far as the lactiferous sinuses (*sinus lactiferes*) and the lymph nodes of the udder shall be incised, except where the udder is excluded from human consumption.

Article 20

Young domestic sheep and goats and sheep with no eruption of permanent incisors

1. Carcases and offal of sheep not having any permanent incisor erupted or less than 12 months of age, and goats less than six months of age, shall undergo the following post-mortem inspection procedures:

- (a) a visual inspection of the head, including the throat, mouth, tongue and parotid and retropharyngeal lymph nodes. These examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;
- (b) a visual inspection of the lungs, trachea and oesophagus and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes*, *eparteriales* and *mediastinales*);
- (c) a visual inspection of the pericardium and heart;
- (d) a visual inspection of the diaphragm;
- (e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*);
- (f) a visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici*, *mesenterici*, *craniales* and *caudales*);
- (g) a visual inspection of the spleen;
- (h) a visual inspection of the kidneys;
- (i) a visual inspection of the pleura and peritoneum;
- (j) a visual inspection of the umbilical region and joints.

2. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

- (a) a palpation of the throat, mouth, tongue and parotid lymph nodes. Unless animal-health rules provide otherwise, these examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;
- (b) a palpation of the lungs; incision of the lungs, trachea, oesophagus, bronchial and mediastinal lymph nodes;

- (c) an incision of the heart;
- (d) a palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;
- (e) a palpation of the spleen;
- (f) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (g) a palpation of the umbilical region and joints; the umbilical region shall be incised and the joints opened; the synovial fluid shall be examined.

Article 21

Other domestic sheep and goats

1. Carcasses and offal of sheep having a permanent incisor erupted or 12 months of age or more, and goats six months of age or more, shall undergo the following post-mortem inspection procedures:

- (a) a visual inspection of the head, including the throat, mouth, tongue and parotid lymph nodes and palpation of the retropharyngeal lymph nodes. These examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;
- (b) a visual inspection of the lungs, trachea and oesophagus; palpation of the lungs, the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*);
- (c) a visual inspection of the pericardium and heart;
- (d) a visual inspection of the diaphragm;
- (e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;
- (f) a visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*);
- (g) a visual inspection of the spleen;
- (h) a visual inspection of the kidneys;
- (i) a visual inspection of the pleura and peritoneum;
- (j) a visual inspection of the genital organs (except for the penis, if already discarded);
- (k) a visual inspection of the udder and its lymph nodes.

2. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcass and offal when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

- (a) a palpation of the throat, mouth, tongue and parotid lymph nodes. Unless animal-health rules provide otherwise, these examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;
- (b) an incision of the lungs, trachea, oesophagus and the bronchial and mediastinal lymph nodes;
- (c) an incision of the heart;
- (d) a palpation of the spleen;
- (e) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*).

Article 22

Domestic solipeds

1. Carcasses and offal of domestic solipeds shall undergo the following post-mortem inspection procedures:

- (a) a visual inspection of the head and, after freeing the tongue, the throat; the tongue shall be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually examined;

- (b) a visual inspection of the lungs, trachea, oesophagus and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);
- (c) a visual inspection of the pericardium and the heart;
- (d) a visual inspection of the diaphragm;
- (e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn portales*);
- (f) a visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);
- (g) a visual inspection of the spleen;
- (h) a visual inspection of the kidneys;
- (i) a visual inspection of the pleura and peritoneum;
- (j) a visual inspection of the genital organs of stallions (except for the penis, if already discarded) and mares;
- (k) a visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*);
- (l) a visual inspection of the umbilical region and joints of young animals;
- (m) examination of the muscles and lymph nodes (*Lnn. subrhomboidei*) of the shoulders beneath the scapular cartilage after loosening the attachment of one shoulder, in the case grey horses, in order to inspect for melanosis and melanomata. The kidneys shall be exposed.

2. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

- (a) a palpation and incision of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn. retropharyngiales, mandibulares* and *parotidei*); palpation of the tongue;
- (b) a palpation of the lungs; palpation and incision of the bronchial and mediastinal lymph nodes. The trachea and the main branches of the bronchi shall be opened lengthwise and the lungs shall be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;
- (c) an incision of the heart lengthwise, so as to open the ventricles and cut through the interventricular septum;
- (d) a palpation and incision of the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*);
- (e) an incision of the gastric and mesenteric lymph nodes;
- (f) a palpation of the spleen;
- (g) a palpation of the kidneys and incision of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (h) an incision of the supramammary lymph nodes;
- (i) a palpation of the umbilical region and joints of young animals. In cases of doubt, the umbilical region shall be incised and the joints opened; the synovial fluid must be examined;
- (j) an incision through the entire kidney in grey horses.

Article 23

Domestic swine

1. Carcases and offal of domestic swine shall undergo the following post-mortem inspection procedures:

- (a) a visual inspection of the head and throat;
- (b) a visual inspection of the mouth, fauces and tongue;
- (c) a visual inspection of the lungs, trachea and oesophagus;
- (d) a visual inspection of the pericardium and heart;

- (e) a visual inspection of the diaphragm;
- (f) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);
- (g) a visual inspection of the spleen; visual inspection of the kidneys; visual inspection of the pleura and peritoneum;
- (h) a visual inspection of the genital organs (except for the penis, if already discarded);
- (i) a visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*);
- (j) a visual inspection of the umbilical region and joints of young animals.

2. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcass and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

- (a) an incision and examination of the submaxillary lymph nodes (*Lnn. mandibulares*);
- (b) a palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*). The trachea and the main branches of the bronchi shall be opened lengthwise and the lungs shall be incised in their posterior third, perpendicular to their main axes; those incisions are not necessary where the lungs are excluded from human consumption;
- (c) an incision of the heart lengthwise so as to open the ventricles and cut through the interventricular septum;
- (d) a palpation of the liver and its lymph nodes;
- (e) a palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;
- (f) a palpation of the spleen;
- (g) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (h) an incision of the supramammary lymph nodes;
- (i) a palpation of the umbilical region and joints of young animals and, if necessary, incision of the umbilical region and opening of the joints.

Article 24

Indications of a possible risks to human health, animal health or animal welfare in domestic bovine animals, domestic sheep and goats, domestic solipeds and domestic swine

The official veterinarian shall proceed with the additional post-mortem inspection procedures referred to in Articles 18(3), 19(2), 20(2), 21(2), 22(2) and 23(2) using incision and palpation of the carcass and offal, where, in his/her opinion, one of the following indicates a possible risk to human health, animal health or animal welfare:

- (a) the checks and analysis of the checks of documents carried out in accordance with Articles 9 and 10;
- (b) the findings of the ante-mortem inspection carried out in accordance with Article 11;
- (c) the results of the verifications of compliance with animal welfare rules carried out in accordance with Article 38;
- (d) the findings of post-mortem inspection carried out in accordance with Articles 12 to 24;
- (e) additional epidemiological data or other data from the holding of provenance of the animals.

Article 25

Practical arrangements for post-mortem inspection of poultry

1. All poultry shall undergo post-mortem inspection which may include the assistance of slaughterhouse staff in accordance with Article 18(3) of Regulation (EU) 2017/625. The official veterinarian or official auxiliary, in accordance with Article 18(2)(c) of that Regulation shall personally carry out the following checks:

- (a) daily inspection of the viscera and body cavities of a representative sample of each flock;

- (b) a detailed inspection of a random sample of parts of birds or entire birds declared unfit for human consumption following post-mortem inspection from each flock;
 - (c) any further investigations necessary where there is reason to suspect that the meat from the birds concerned could be unfit for human consumption.
2. By way of derogation from paragraph 1, the competent authorities may decide that only a representative sample of poultry from each flock undergoes post-mortem inspection if:
- (a) food business operators have a system in place to the satisfaction of the official veterinarian, that allows the detection and the separation of birds with abnormalities, contamination or defects;
 - (b) the slaughterhouse has a longstanding history of compliance with the requirements as regards:
 - (i) general and specific requirements in accordance with Article 4 of Regulation (EC) No 852/2004, including the microbiological criteria applicable to Point 1.28 and 2.1.5 of Annex I to Regulation (EC) No 2073/2005;
 - (ii) procedures based on the HACCP principles in accordance with Article 5 of Regulation (EC) No 852/2004; and
 - (iii) specific hygiene rules in accordance with Article 5 and Section II of Annex III to Regulation (EC) No 853/2004;
 - (c) no abnormalities that may indicate a serious problem for human or animal health that may indicate the need for measures laid down in Articles 40 to 44, have been found during ante-mortem inspection or verification of food chain information.
3. In case of poultry reared for the production of *foie gras* and delayed eviscerated poultry obtained at the holding of provenance in accordance with Points 8 and 9 of Chapter VI to Section II of Annex III to Regulation (EC) No 853/2004, post-mortem inspection shall take place at the cutting plant where such carcasses are transported directly from the holding of provenance.

Article 26

Practical arrangements for post-mortem inspection of farmed lagomorphs

The practical arrangements for post-mortem inspection in poultry in accordance with Article 25, shall apply to farmed lagomorphs. The provisions applicable to a single poultry flock in Article 25 shall apply to farmed lagomorphs slaughtered the same day from a single holding of provenance.

Article 27

Practical arrangements for post-mortem inspection of farmed game

1. The following post-mortem inspection procedures shall apply to farmed game:
- (a) in the case of small (< 100 kg) *Cervidae*, the post-mortem procedures for ovine animals laid down in Article 21, however in the case of reindeer the post-mortem procedures for ovine animals laid down in Article 20 shall be used and the tongue may be used for human consumption without inspection of the head;
 - (b) in the case of game of the family *Suidae*, the post-mortem procedures for domestic swine laid down in Article 23;
 - (c) in the case of large game of the family *Cervidae* and other large game, not covered by paragraph (a) and in the case of large game of the family *Suidae* not covered by paragraph (b), the post-mortem procedures for bovine animals laid down in Article 19;
 - (d) in the case of ratites, the post-mortem procedures for poultry laid down in Article 25(1).
2. Where the animals have been slaughtered outside the slaughterhouse, the official veterinarian at the slaughterhouse shall verify the certificate.

Article 28

Practical arrangements for post-mortem inspection of wild game

1. The official veterinarian shall verify that a health certificate conforming to the specimen set out in the Annex to Regulation (EU) No 636/2014, or the declaration(s) in accordance with point 8(b) of Chapter II of Section IV of Annex III to Regulation (EC) No 853/2004, accompanies unskinned large wild game transported to the game-handling establishment from the territory of another Member State. The official veterinarian shall take into account the content of that certificate or declaration(s).
2. During post-mortem inspection, the official veterinarian shall carry out:
 - (a) a visual inspection of the carcass, its cavities and, where appropriate, organs with a view to:
 - (i) detecting any abnormalities not resulting from the hunting process. For this purpose, the diagnosis may be based on any information that the trained person has provided concerning the behaviour of the animal before killing;
 - (ii) checking that death was not due to reasons other than hunting;
 - (b) an investigation of organoleptic abnormalities;
 - (c) palpation and incisions of organs, where appropriate;
 - (d) where there are serious grounds for suspecting the presence of residues or contaminants, an analysis by sampling of residues not resulting from the hunting process, including environmental contaminants. Where a more extensive inspection is made on the basis of such suspicions, the veterinarian shall wait until that inspection has been concluded before assessing all the wild game killed during a specific hunt, or those parts suspected of showing the same abnormalities;
 - (e) examination for characteristics indicating that the meat presents a health risk, including:
 - (i) abnormal behaviour or disturbance of the general condition of the live animal, as reported by the hunter;
 - (ii) the generalised presence of tumours or abscesses affecting different internal organs or muscles;
 - (iii) arthritis, orchitis, pathological changes in the liver or the spleen, inflammation of the intestines or the umbilical region;
 - (iv) the presence of foreign bodies not resulting from the hunting process in the body cavities, stomach, intestines or urine, where the pleura or peritoneum are discoloured (when relevant viscera are present);
 - (v) the presence of parasites;
 - (vi) formation of a significant amount of gas in the gastro-intestinal tract with discolouring of the internal organs (when these viscera are present);
 - (vii) significant abnormalities of colour, consistency or odour of muscle tissue or organs;
 - (viii) aged open fractures;
 - (ix) emaciation and/or general or localised oedema;
 - (x) recent pleural or peritoneal adhesions;
 - (xi) other obvious extensive changes, such as putrefaction.
3. Where the official veterinarian so requires, the vertebral column and the head shall be split lengthwise.
4. In the case of small wild game not eviscerated immediately after killing, the official veterinarian shall carry out a post-mortem inspection on a representative sample of animals from the same source. Where inspection reveals a disease transmissible to humans or any of the characteristics listed in point (e) in paragraph 2, the official veterinarian shall carry out more checks on the entire batch to determine whether it shall be declared unfit for human consumption or whether each carcass shall be inspected individually.
5. The official veterinarian may perform any further cuts and inspections of the relevant parts of the animals that are necessary to reach a final diagnosis. If an assessment cannot be made on the basis of the practical arrangements in paragraph 2, additional investigations shall be carried out in a laboratory.

6. In addition to the cases provided for in Article 45, meat presenting during post-mortem inspection any of the characteristics listed in point (e) in paragraph 2 shall be declared unfit for human consumption.

Section 4

Official controls on specific hazards and laboratory testing

Article 29

Practical arrangements for official controls for transmissible spongiform encephalopathies (TSEs)

1. In addition to the requirements of Regulation (EC) No 999/2001 concerning the official controls to be carried out in relation to TSEs, the official veterinarian shall check the removal, separation and, where appropriate, marking of specified risk material also in accordance with the rules laid down in Article 8(1) of that Regulation and in Article 12 of Regulation (EC) No 1069/2009 on animal by-products.
2. The official veterinarian shall ensure that the food business operator takes all necessary measures to avoid contaminating meat with specified risk material during slaughter, including stunning. This includes the removal of specified risk material.

Article 30

Practical arrangements for official controls for cysticercosis during post-mortem inspection in domestic bovine animals and *Suidae*

1. The post-mortem inspection procedures described in Articles 18, 19 and 23 shall be the minimum requirements for the examination for cysticercosis in bovine animals and *Suidae* (domestic swine, farmed game and wild game). In the case of bovine animals referred to in Article 19, the competent authorities may decide that incision of the masseters at post-mortem inspection is not compulsory if:
 - (a) a specific serological test is used;
 - (b) the animals have been raised on a holding of provenance officially certified to be free of cysticercosis; or,
 - (c) the prevalence of the source population or in a well-defined subpopulation is below one in a million, has been demonstrated with 95 % certainty or no cases have been detected in all slaughtered animals in the past five years (or two years where supported and justified by the competent authorities' risk analysis) based on data from reporting carried out in accordance with Article 9(1) of Directive 2003/99/EC.
2. Meat infected with cysticerci shall be declared unfit for human consumption. However, where the animal is not generally infected with cysticercus, the parts not infected may be declared fit for human consumption after having undergone a cold treatment.

Article 31

Practical arrangements for official controls for *Trichinella* during post-mortem inspection

1. Carcasses of *Suidae*, solipeds and other species susceptible to *Trichinella* shall be examined for *Trichinella* in accordance with Regulation (EU) 2015/1375 unless one of the derogations set out in Article 3 of that Regulation applies.
2. Meat from animals infected with trichinae shall be declared unfit for human consumption.

Article 32

Practical arrangements for official controls for glanders during post-mortem inspection of solipeds

1. Fresh meat of solipeds shall be placed on the market only if it was produced from solipeds kept for at least 90 days prior to the date of slaughter in a Member State or in a third country or region thereof from which it is authorised to bring solipeds into the Union.

2. In the case of solipeds originating from a Member State or third country or region thereof not meeting the World Organisation for Animal Health criteria for a glanders-free country, solipeds shall be inspected for glanders by a careful examination of the mucous membranes of the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum.
3. Meat produced from solipeds in which glanders has been diagnosed shall be declared unfit for human consumption.

Article 33

Practical arrangements for official controls for tuberculosis during post-mortem inspection

1. Where animals have reacted positively or inconclusively to tuberculin, or there are other grounds for suspecting infection, they shall be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcasses, the slaughter line and staff present in the slaughterhouse.
2. All meat from animals in which post-mortem inspection has revealed localised lesions similar to tuberculoid lesions in a number of organs or a number of areas of the carcass shall be declared unfit for human consumption. However, where a tuberculoid lesion has been found in the lymph nodes of only one organ or part of the carcass, only the affected organ or part of the carcass and the associated lymph nodes shall be declared unfit for human consumption.

Article 34

Practical arrangements for official controls for brucellosis during post-mortem inspection

1. Where animals have reacted positively or inconclusively to a brucellosis test, or there are other grounds for suspecting infection, they shall be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcasses, the slaughter line and staff present in the slaughterhouse.
2. Meat from animals in which post-mortem inspection has revealed lesions indicating acute brucellosis shall be declared unfit for human consumption. In the case of animals reacting positively or inconclusively to a brucellosis test, the udder, genital tract and blood shall be declared unfit for human consumption even if no such lesion is found.

Article 35

Practical arrangements for official controls for *Salmonella*

1. The competent authorities shall verify the correct implementation by food business operators of points 2.1.3, 2.1.4 and 2.1.5 of Chapter 2 of Annex I of Regulation (EC) No 2073/2005 by applying one or more of the following measures:
 - (a) official sampling using the same method and sampling area as food business operators. At least 49 random samples⁽⁴⁰⁾ shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation;
 - (b) collecting all information on the total number and the number of *Salmonella*-positive samples taken by food business operators in accordance with Article 5 of Regulation (EC) No 2073/2005, in the framework of points 2.1.3, 2.1.4 and 2.1.5 of Chapter 2 of Annex I thereto;
 - (c) collecting all information on the total number and the number of *Salmonella*-positive samples taken in the framework of national control programmes in Member States or regions of Member States for which special guarantees have been approved in accordance with Article 8 of Regulation (EC) No 853/2004 as regards ruminant, equine, swine and poultry production.
2. Where the food business operator fails on several occasions to comply with the process hygiene criterion, the competent authorities shall require it to submit an action plan and shall strictly supervise its outcome.

⁽⁴⁰⁾ If all are negative, 95 % statistical certainty is provided that the prevalence is below 6 %.

3. The total number and the number of *Salmonella*-positive samples, differentiating between samples taken under points (a), (b) and (c) in paragraph 1, when applied, shall be reported in accordance with Article 9(1) of Directive 2003/99/EC.

Article 36

Practical arrangements for official controls for *Campylobacter*

1. The competent authorities shall verify the correct implementation by food business operators of point 2.1.9 (process hygiene criterion for *Campylobacter* on carcasses of broilers) of Chapter 2 of Annex I of Regulation (EC) No 2073/2005 by applying the following measures:

- (a) official sampling using the same method and sampling area as food business operators. At least 49 random samples shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation; or
- (b) collecting all information on the total number and the number of *Campylobacter* samples with more than 1 000 cfu/g taken by food business operators in accordance with Article 5 of Regulation (EC) No 2073/2005, in the framework of point 2.1.9 of Chapter 2 of Annex I thereto.

2. Where the food business operator fails on several occasions to comply with the process hygiene criterion, the competent authorities shall require it to submit an action plan and shall strictly supervise its outcome.

3. The total number and the number of *Campylobacter* samples with more than 1 000 cfu/g, differentiating between samples taken under points (a) and (b) in paragraph 1, when applied, shall be reported in accordance with Article 9(1) of Directive 2003/99/EC.

Article 37

Specific requirements as regards laboratory tests

1. When performing laboratory tests in accordance with Article 18(2)(d)(ii) and (iv) of Regulation (EU) 2017/625, the official veterinarian shall ensure that, when sampling takes place, samples are appropriately identified and handled and sent to the appropriate laboratory in the framework of:

- (a) the monitoring and control of zoonoses and zoonotic agents;
- (b) the annual programme for the monitoring of TSEs in accordance with Article 6 of Regulation (EC) No 999/2001;
- (c) the detection of pharmacologically active substances or products either prohibited or unauthorised, and controls for regulated pharmacologically active substances, pesticides, feed additives and contaminants exceeding applicable maximum Union limits, in particular in the framework of the national plans for the detection of residues or substances referred to in Article 110(2) of Regulation (EU) 2017/625 and in Article 5 of Directive 96/23/EC;
- (d) the detection of animal diseases for which animal health rules are laid down in Regulation (EU) 2016/429.

2. The official veterinarian shall ensure that any additional laboratory testing deemed necessary for the fulfilment the obligations under Article 18(2) of Regulation (EU) 2017/625 takes place as required.

Section 5

Official controls on animal welfare

Article 38

Official controls on animal welfare at transport and slaughter

The official veterinarian shall verify compliance with the rules concerning the protection of animals during transport in accordance with Regulation (EC) No 1/2005 and at the time of slaughter in accordance with Regulation (EC) No 1099/2009 and national rules on animal welfare.

CHAPTER III

Communication of inspection results and measures to be taken by competent authorities in cases of specific non-compliance with requirements for fresh meat and for animal welfare

Article 39

Measures concerning the communication of the results of official controls

1. The official veterinarian shall record and evaluate the results of official controls carried out in accordance with Articles 7 to Article 38.
2. The following actions shall be taken by the official veterinarian where inspections reveal the presence of any disease or condition that might affect human or animal health, or compromise animal welfare:
 - (a) the official veterinarian shall inform the slaughterhouse operator;
 - (b) where the problem referred to in this paragraph arose during primary production and relates to human health, animal health, animal welfare or residues of veterinary medicinal products, unauthorised or prohibited substances, pesticide residues, feed additives or contaminants, the official veterinarian shall inform:
 - (i) the veterinarian attending the holding of provenance;
 - (ii) the official veterinarian who carried out any ante-mortem inspection at the holding of provenance, where different from (i);
 - (iii) the food business operator responsible for the holding of provenance (provided that such information would not prejudice subsequent legal proceedings); and,
 - (iv) the competent authorities responsible for supervising the holding of provenance or the hunting area;
 - (c) where the animals concerned were raised in another country, the official veterinarian shall ensure that the country's competent authorities are informed.
3. The competent authorities shall enter the results of official controls in relevant databases, at least where the collection of such information is required under Article 4 of Directive 2003/99/EC, Article 8 of Council Directive 64/432/EEC ⁽⁴¹⁾ and Annex III to Directive 2007/43/EC.
4. Where the official veterinarian, while carrying out ante-mortem or post-mortem inspection or any other official control, suspects the presence of an animal disease for which animal health rules are laid down in Regulation (EU) 2016/429, he/she shall notify the competent authorities. The official veterinarian and competent authorities, within their respective areas of competence, shall take all necessary measures and precautions to prevent the possible spread of the disease agent.
5. The official veterinarian may use the model document in Annex I for the purpose of communicating the relevant results of ante-mortem and post-mortem inspections to the holding of provenance where the animals were kept before slaughter.
6. Where the animals were kept on a holding of provenance in another Member State, the competent authorities of the Member State in which they were slaughtered shall communicate the relevant results of ante-mortem and post-mortem inspections to the competent authorities in the Member State of provenance. They shall use the model document in Annex I in the official languages of both Member States involved or in a language agreed between both Member States.

Article 40

Measures in cases of non-compliance with requirements for food chain information

1. The official veterinarian shall ensure that animals are not slaughtered unless the slaughterhouse operator has been provided with, checked and evaluated relevant food chain information in accordance with Article 9(2)(a) and (b).

⁽⁴¹⁾ Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 121, 29.7.1964, p. 1977).

2. By way of derogation from paragraph 1, the official veterinarian may allow animals to undergo slaughter in the slaughterhouse if the relevant food chain information is not available. In such cases, the information shall be supplied before the meat is declared fit for human consumption and carcasses and related offal shall be stored separately from other meat pending that declaration.

3. Where relevant food chain information is not available within 24 hours of an animal's arrival at the slaughterhouse, the official veterinarian shall declare all meat from the animal unfit for human consumption. If the animal has not yet been slaughtered, it shall be killed separately from other animals taking all necessary precautions to safeguard animal and human health.

Article 41

Measures in cases of non-compliance recorded in food chain information

1. The official veterinarian shall verify that the slaughterhouse operator does not accept animals for slaughter when the food chain information or any other accompanying records, documentation or information shows that:

- (a) the animals come from a holding of provenance or an area subject to a movement prohibition or other restriction for reasons of animal or human health;
- (b) rules on the use of veterinary medicinal products have not been complied with, animals have been treated with prohibited or unauthorised substances, or the legal limits for chemical residues or contaminants have not been complied with; or
- (c) any other condition which might adversely affect human or animal health is present.

2. If the animals are already present at the slaughterhouse, they shall be killed separately and declared unfit for human consumption, taking precautions to safeguard animal and human health. Where the official veterinarian considers it necessary, official controls shall be carried out on the holding of provenance.

Article 42

Measures in cases of misleading food chain information

1. The competent authorities shall take appropriate action if they discover that the accompanying records, documentation or other information do not correspond to the true situation of the holding of provenance or the true condition of the animals, or aim deliberately to mislead the official veterinarian.

2. They shall take action against the food business operator responsible for the holding of provenance of the animals, or any other person involved, including the slaughterhouse operator. In particular, this action may consist of extra controls. The food business operator responsible for the holding of provenance or any other person involved shall bear the costs of such extra controls.

Article 43

Measures in cases of non-compliance with requirements for live animals

1. The official veterinarian shall verify the food business operator's compliance with its duty under point 3 in Chapter IV of Section I of Annex III to Regulation (EC) No 853/2004 to ensure that animals accepted for slaughter for human consumption are properly identified. The official veterinarian shall ensure that animals whose identity is not ascertainable are killed separately and declared unfit for human consumption. Where the official veterinarian considers it necessary, official controls shall be carried out on the holding of provenance.

2. The official veterinarian shall ensure that animals subject to an unacceptable risk of contamination of the meat during slaughter, as laid down in Article 11(4), are not slaughtered for human consumption unless they are cleaned beforehand.

3. The official veterinarian shall ensure that animals with a disease or condition that may be transmitted to animals or humans handling or eating the meat and, in general, animals showing clinical signs of systemic disease or emaciation, or any other condition rendering meat unfit for human consumption, are not slaughtered for human consumption. Such animals shall be killed separately under such conditions that other animals or carcasses cannot be contaminated, and declared unfit for human consumption.

4. The official veterinarian shall defer the slaughter of animals suspected of having a disease or condition that may adversely affect human or animal health. Such animals shall undergo detailed ante-mortem examination by the official veterinarian in order to make a diagnosis. In addition, the official veterinarian may decide that sampling and laboratory examinations must take place to supplement post-mortem inspection. If necessary to avoid contamination of other meat, the animals shall be slaughtered separately or at the end of normal slaughtering, taking all other necessary precautions.

5. The official veterinarian shall ensure that animals that might contain residues of prohibited or unauthorised pharmacologically active substances or residues of authorised pharmacologically active substances, pesticides or contaminants in excess of the levels laid down in accordance with Union legislation, are dealt with in accordance with Articles 16 to 19 of Directive 96/23/EC.

6. The official veterinarian shall impose the conditions under which animals shall be dealt with under a specific scheme for the eradication or control of a specific disease, such as brucellosis or tuberculosis, or zoonotic agents such as salmonella, under his/her direct supervision. The competent authorities shall determine the conditions under which such animals may be slaughtered. These conditions shall be designed to minimise the contamination of other animals and the meat of other animals.

As a rule, animals that are presented to a slaughterhouse for slaughter shall be slaughtered there. However, in exceptional circumstances, such as a serious breakdown of the slaughter facilities, the official veterinarian may allow direct movements to another slaughterhouse.

Where non-compliance which results in a risk to animal or human health, or animal welfare, is detected during ante-mortem inspection at the holding of provenance, the official veterinarian shall not allow the animals to be transported to the slaughterhouse and the relevant measures regarding the communication of inspection results in accordance with Article 39(2)(b)(i) and (iii) shall apply.

Article 44

Measures in cases of non-compliance with requirements for animal welfare

1. In cases of non-compliance with the rules concerning the protection of animals at the time of slaughter or killing laid down in Articles 3 to 9 and Articles 14 to 17, 19 and 22 of Council Regulation (EC) No 1099/2009, the official veterinarian shall verify that the food business operator immediately takes the necessary corrective measures and prevents recurrence.

2. The official veterinarian shall take a proportionate and stepped approach to enforcement action, ranging from issuing directions to slowing down and stopping production, depending on the nature and gravity of the problem.

3. Where appropriate, the official veterinarian shall inform other competent authorities of welfare problems.

4. Where the official veterinarian discovers non-compliance with the rules concerning the protection of animals during transport laid down in Regulation (EC) No 1/2005, he/she shall take the requisite measures in accordance with the relevant Union legislation.

5. Where an official auxiliary carries out checks on animal welfare and those checks identify non-compliance with the rules on the protection of animals, he/she shall immediately inform the official veterinarian. If necessary in urgent cases, he/she shall take the necessary measures referred to in paragraphs 1 to 4 pending the arrival of the official veterinarian.

Article 45

Measures in cases of non-compliance with requirements for fresh meat

The official veterinarian shall declare fresh meat unfit for human consumption if it:

- (a) derives from animals that have not undergone ante-mortem inspection in accordance with Article 18(2)(a) or (b) of Regulation (EU) 2017/625, except for wild game and stray reindeer referred to in Article 12(1)(b) of Delegated Regulation (EU) 2019/624;

- (b) derives from animals whose offal has not undergone post-mortem inspection in accordance with Article 18(2)(c) of Regulation (EU) 2017/625, except in case of viscera of large wild game that do not need to accompany the body to a game-handling establishment in accordance with point 4 of Chapter II of Section IV in Annex III of Regulation (EC) No 853/2004;
- (c) derives from animals that are dead before slaughter, stillborn, unborn or slaughtered under the age of seven days;
- (d) results from the trimming of sticking points;
- (e) derives from animals affected by animal diseases for which animal health rules are laid down in the Union legislation listed in Annex I to Directive 2002/99/EC, except if it is obtained in conformity with the specific requirements provided for in that Directive; this exception shall not apply if otherwise provided for in the requirements on the official controls of tuberculosis and brucellosis provided for in Articles 33 and 34 of this Regulation;
- (f) derives from animals affected by a generalised disease, such as generalised septicaemia, pyaemia, toxaemia or viraemia;
- (g) is not in conformity with the food safety criteria laid down in Chapter I of Annex I to Regulation (EC) No 2073/2005 for determining whether food may be placed on the market;
- (h) exhibits parasitic infestation, unless otherwise provided for in the requirements on the official controls for cysticercosis provided for in Article 30;
- (i) contains chemical residues or contaminants in excess of the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005, (EC) No 1881/2006 and (EC) No 124/2009 or residues of substances that are prohibited or unauthorised under Regulation (EU) No 37/2010 or Directive 96/22/EC;
- (j) consists of the liver and kidneys of animals more than two years old from regions where implementation of plans approved in accordance with Article 5 of Directive 96/23/EC has revealed the generalised presence of heavy metals in the environment;
- (k) has been treated illegally with decontaminating substances;
- (l) has been treated illegally with ionising radiation, including UV-radiation;
- (m) contains foreign bodies, except, in the case of wild game, material used to hunt the animal;
- (n) exceeds maximum permitted radioactivity levels laid down under Union legislation or, in the absence of Union legislation, under national rules;
- (o) indicates pathological or organoleptic changes, in particular a pronounced sexual odour or insufficient bleeding (except for wild game);
- (p) derives from emaciated animals;
- (q) contains specified risk material unless removal is allowed in another establishment in accordance with Point 4.3 of Annex V to Regulation (EC) No 999/2001 and the fresh meat remains under the control of the competent authorities;
- (r) shows soiling, faecal or other contamination;
- (s) consists of blood that may constitute a risk to human or animal health owing to the health status of any animal from which it derives or contamination arising during the slaughter process;
- (t) in the opinion of the official veterinarian, after examination of all the relevant information, may constitute a risk to human or animal health or is for any other reason not suitable for human consumption;
- (u) gives rise to specific hazards in accordance with Articles 29 to 36.

*Article 46***Measures in cases of non-compliance with requirements on good hygiene practices**

1. The competent authorities may instruct the food business operator to take immediate corrective action, including a reduction in the speed of slaughter, where this is considered necessary by the official present in the following cases:
 - (a) where contamination is detected on external surfaces of a carcass or its cavities and the food business operator does not take appropriate action to rectify the situation; or
 - (b) if the competent authorities consider that good hygiene practices are jeopardised.
2. In such cases, the competent authorities shall increase the intensity of inspection until such time as they are satisfied that the food business operator has regained control of the process.

*CHAPTER IV***Restrictions***Article 47***Restrictions for certain fresh meat**

The official veterinarian may impose requirements concerning the use of fresh meat derived from animals:

- (a) that have undergone emergency slaughter outside the slaughterhouse; or
- (b) from flocks where a treatment of the meat is applied in accordance with Part E of Annex II to Regulation (EC) No 2160/2003 before the meat is placed on the market.

*CHAPTER V***Health marking of meat fit for human consumption after ante-mortem and post-mortem inspection***Article 48***Technical requirements of the health mark and practical arrangements for its application**

1. The official veterinarian shall supervise health marking and the marks used.
2. The official veterinarian shall ensure, in particular, that:
 - (a) the health mark is applied only to domestic ungulates and farmed game mammals other than lagomorphs, having undergone ante-mortem and post-mortem inspection, and large wild game having undergone post mortem inspection, in accordance with Article 18(2)(a), (b) and (c) of Regulation (EU) 2017/625, where there are no grounds for declaring the meat unfit for human consumption. However, the mark may be applied before the results of any examination for *Trichinella* and/or TSE testing are available, provided that the competent authorities introduced a system in place in the slaughterhouse or game-handling establishment ensuring that all parts of the animal can be traced, and no parts of the examined animals bearing the mark leave the slaughterhouse or game-handling establishment until a negative result has been obtained except when provided for in accordance with Article 2(3) of Regulation (EU) 2015/1375;
 - (b) the health mark is applied on the external surface of the carcass, by stamping in ink or hot branding, in such a manner that, if carcasses are cut in the slaughterhouse into half carcasses or quarters, or half carcasses are cut into three pieces, each piece bears a health mark.
3. The competent authorities shall ensure that the practical arrangements for the health mark are applied in accordance with Annex II.
4. The competent authorities shall ensure that meat from unskinned wild game does not bear a health mark until, after skinning in a game-handling establishment, it has undergone post-mortem inspection and been declared fit for human consumption.

TITLE IV

SPECIFIC REQUIREMENTS AND UNIFORM MINIMUM FREQUENCY OF OFFICIAL CONTROLS WITH RESPECT TO RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS, AS NECESSARY TO RESPOND TO RECOGNISED UNIFORM HAZARDS AND RISKS*Article 49***Control of milk and colostrum production holdings**

1. The official veterinarian shall verify that the health requirements for raw milk and colostrum production as laid down in Part I of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 are complied with. In particular, the official veterinarian shall verify:
 - (a) the health status of the animals;
 - (b) the absence of the use of prohibited or unauthorised pharmacologically active substances; and
 - (c) that the possible presence of residues of authorised pharmacologically active substances, pesticides or contaminants does not exceed the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005 or (EC) No 1881/2006.
2. The official controls referred to in paragraph 1 may take place at the occasion of veterinary checks carried out pursuant to Union provisions on animal or human health or animal welfare.
3. If there are grounds for suspecting that the health requirements referred to in paragraph 1 are not being complied with, the official veterinarian shall check the general health status of the animals.
4. Milk and colostrum production holdings shall undergo official controls by the competent authorities to verify that hygiene requirements laid down in Part II of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 are being complied with. These controls may involve inspections and the monitoring of controls carried out by professional organisations. If it is demonstrated that the hygiene is inadequate, the competent authorities shall verify that appropriate steps are taken to correct the situation.

*Article 50***Control of milk and colostrum**

1. In the case of raw milk and colostrum, the competent authorities shall monitor the checks carried out in accordance with Part III of Chapter I, Section IX of Annex III to Regulation (EC) No 853/2004. When testing is used, the competent authorities shall use the analytical methods set out in Annex III to this Regulation to check compliance with the limits laid down for raw milk and colostrum in Part III of Chapter I, Section IX of Annex III to Regulation (EC) No 853/2004.
2. If the food business operator of the production holding has not corrected the situation within three months of the first notification to the competent authorities of non-compliance with the plate count and/or somatic cell count criteria for raw milk and colostrum, the competent authorities shall verify that:
 - (a) delivery of raw milk and colostrum from the production holding is suspended, or
 - (b) the raw milk and colostrum is subjected to requirements concerning its treatment and use necessary to protect human health in accordance with a specific authorisation of, or general instructions from the competent authorities.This suspension or these requirements shall remain in place by the competent authorities until the food business operator has proved that the raw milk and colostrum again comply with the criteria.
3. The competent authorities shall use the analytical methods set out in Annex III of this Regulation to verify appropriate application of a pasteurisation process to dairy products as referred to in Part II of Chapter II, Section IX of Annex III to Regulation (EC) No 853/2004.

TITLE V

SPECIFIC REQUIREMENTS FOR OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AND RELAYING AREAS*Article 51***Exclusion**

This Title applies to live bivalve molluscs. It also applies to live echinoderms, live tunicates and live marine gastropods. This Title does not apply to live marine gastropods and live *Holothuroidea* that are not filter feeders.

*Article 52***Classification of production and relaying areas for live bivalve molluscs**

1. The competent authorities shall fix the location and boundaries of the production and relaying areas that they classify in accordance with Article 18(6) of Regulation (EU) 2017/625. They may, where appropriate, do so in cooperation with the food business operator.
2. The competent authorities shall classify production and relaying areas from which they authorise the harvesting of live bivalve molluscs as Class A, Class B and Class C areas according to the level of faecal contamination. They may, where appropriate, do so in cooperation with the food business operator.
3. In order to classify production and relaying areas, the competent authorities shall fix a review period for sampling data from each production and relaying area in order to determine compliance with the standards referred to in Articles 53, 54 and 55.

CHAPTER I

Specific requirements for the classification of production and relaying areas for live bivalve molluscs*Article 53***Requirements for Class A areas**

1. The competent authorities may classify as Class A areas those from which live bivalve molluscs may be collected for direct human consumption.
2. Live bivalve molluscs placed on the market from such areas shall meet the health standards for live bivalve molluscs set out in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004.
3. Samples of live bivalve molluscs from Class A areas shall not exceed, in 80 % of samples collected during the review period, 230 *E. coli* per 100 g of flesh and intravalvular liquid.
4. The remaining 20 % of samples shall not exceed 700 *E. coli* per 100 g of flesh and intravalvular liquid.
5. When evaluating the results for the fixed review period for maintenance of a Class A area, the competent authorities may, on the basis of a risk assessment based on an investigation, decide to disregard an anomalous result exceeding the level of 700 *E. coli* per 100 g of flesh and intravalvular liquid.

*Article 54***Requirements for Class B areas**

1. The competent authorities may classify as Class B areas those from which live bivalve molluscs may be collected and placed on the market for human consumption only after treatment in a purification centre or after relaying so as to meet the health standards referred to in Article 53.
2. Live bivalve molluscs from Class B areas shall not exceed, in 90 % of the samples, 4 600 *E. coli* per 100 g of flesh and intravalvular liquid.

3. The remaining 10 % of samples shall not exceed 46 000 *E. coli* per 100 g of flesh and intravalvular liquid.

Article 55

Requirements for Class C areas

1. The competent authorities may classify as Class C areas those from which live bivalve molluscs may be collected and placed on the market only after relaying over a long period so as to meet the health standards referred to in Article 53.
2. Live bivalve molluscs from Class C areas shall not exceed 46 000 *E. coli* per 100 g of flesh and intravalvular liquid.

Article 56

Sanitary survey requirements

1. Before classifying a production or relaying area, the competent authorities shall carry out a sanitary survey that includes:
 - (a) an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;
 - (b) an examination of the quantities of organic pollutants released during the different periods of the year, according to the seasonal variations of human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc.;
 - (c) determination of the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area.
2. The competent authorities shall carry out a sanitary survey fulfilling the requirements set out in paragraph 1 in all classified production and relaying areas, unless carried out previously.
3. The competent authorities may be assisted by other official bodies or food business operators under conditions established by the competent authorities in relation to the performance of this survey.

Article 57

Monitoring programme

The competent authorities shall establish a monitoring programme for live bivalve mollusc production areas that is based on an examination of the sanitary survey referred to in Article 56. The number of samples, geographical distribution of sampling points and sampling frequency for the programme shall ensure that the results of the analysis are representative of the area in question.

Article 58

The competent authorities shall establish a procedure to ensure that the sanitary survey referred to in Article 56 and the monitoring programme referred to in Article 57 are representative of the area considered.

CHAPTER II

Conditions for the monitoring of classified production and relaying areas for live bivalve molluscs

Article 59

Monitoring of classified production and relaying areas

The competent authorities shall periodically monitor production and relaying areas classified in accordance with Article 18(6) of Regulation (EU) 2017/625 in order to check:

- (a) that there is no malpractice with regard to the origin, provenance and destination of live bivalve molluscs;

- (b) the microbiological quality of live bivalve molluscs in relation to the classified production and relaying areas;
- (c) for the presence of toxin-producing plankton in production and relaying waters and marine biotoxins in live bivalve molluscs;
- (d) for the presence of chemical contaminants in live bivalve molluscs.

Article 60

Recognised methods for the detection of marine biotoxins in live bivalve molluscs

1. The competent authorities shall use the analytical methods laid down in Annex V to check compliance with the limits laid down in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 and, where appropriate, to verify compliance by food business operators. Food business operators shall use these methods where appropriate.
2. In accordance with Article 4 of Directive 2010/63/EU, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used where possible, instead of a procedure as defined in Article 3(1) of that Directive.
3. In accordance with Article 4 of Directive 2010/63/EU, elements of replacement, refinement and reduction must be taken into account when biological methods are used.

Article 61

Sampling plans

1. For the purposes of the checks provided for in points (b), (c) and (d) of Article 59, the competent authorities shall draw up sampling plans providing for such checks to take place at regular intervals, or on a case-by-case basis if harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency shall ensure that the results of the analysis are representative of the classified production and relaying area concerned.
2. Sampling plans to check the microbiological quality of live bivalve molluscs shall take particular account of:
 - (a) the likely variation in faecal contamination;
 - (b) the parameters referred to in Article 56(1).
3. Sampling plans to check for the presence of toxin-producing plankton in the water in classified production and relaying areas and for marine biotoxins in live bivalve molluscs shall take particular account of possible variations in the presence of plankton containing marine biotoxins. Sampling shall comprise:
 - (a) periodic sampling to detect changes in the composition of plankton containing toxins and their geographical distribution. Results suggesting an accumulation of toxins in live bivalve mollusc flesh shall be followed by intensive sampling;
 - (b) periodic toxicity tests using live bivalve molluscs from the affected area most susceptible to contamination.
4. The sampling frequency for toxin analysis in live bivalve molluscs shall be weekly during harvesting periods, except when:
 - (a) the sampling frequency may be reduced in specific classified relaying or production areas, or for specific types of live bivalve mollusc, if a risk assessment of toxins or phytoplankton occurrence suggests a very low risk of toxic episodes;
 - (b) the sampling frequency shall be increased where such an assessment suggests that weekly sampling would not be sufficient.
5. The risk assessment referred to in paragraph 4 shall be reviewed periodically in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.

6. Where knowledge of toxin accumulation rates is available for a group of species growing in the same classified production or relaying area, the species with the highest rate may be used as an indicator species. This will allow the exploitation of all species in the group if toxin levels in the indicator species are below the regulatory limits. Where toxin levels in the indicator species are above the regulatory limits, the harvesting of the other species may be allowed only if further analysis of the other species shows toxin levels below the limits.
7. With regard to the monitoring of plankton, the samples shall be representative of the water column in the classified production or relaying area and provide information on the presence of toxic species and on population trends. If any changes in toxic populations that may lead to toxin accumulation are detected, the sampling frequency for live bivalve molluscs shall be increased or precautionary closures of the areas established until results of toxin analysis are obtained.
8. Sampling plans to check for the presence of chemical contaminants shall enable the detection of any overshooting of the levels laid down in Regulation (EC) No 1881/2006.

CHAPTER III

Management of classified production and relaying areas after monitoring

Article 62

Decisions following monitoring

1. Where the results of the monitoring provided for in Article 59 indicate that the health standards for live bivalve molluscs are not met or that there may otherwise be a risk to human health, the competent authorities shall close the classified production or relaying area concerned, preventing the harvesting of live bivalve molluscs. However, they may reclassify a production or relaying area as being of Class B or C if it meets the relevant criteria set out in Articles 54 and 55 and presents no other risk to human health.
2. Where the results of microbiological monitoring show that the health standards for live bivalve molluscs referred to in Article 53 not met, competent authorities may, on the basis of a risk assessment, and only on a temporary and non-recurring basis, permit continued harvesting without closure or reclassification subject to the following conditions:
 - (a) the classified production area concerned and all approved establishments receiving live bivalve molluscs from it are under the official control of the same competent authorities;
 - (b) the live bivalve molluscs concerned are subjected to appropriate restrictive measures such as purification, relaying or processing.
3. The accompanying registration document, as referred to in Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004, shall include all the information concerning the application of paragraph 2.
4. The competent authorities shall establish the conditions under which paragraph 2 can be availed of in order to ensure, for the production area concerned, maintenance of the compliance with the criteria established in Article 53.

Article 63

Re-opening of production areas

1. The competent authorities may re-open a closed production or relaying area only if the health standards for live bivalve molluscs comply once again with the relevant requirements of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 and present no other risk to human health.
2. Where the competent authorities have closed a production or relaying area because of the presence of plankton or levels of toxins in live bivalve molluscs that exceed the regulatory limit for marine biotoxins laid down in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004, they may re-open it only if at least two consecutive analytical results separated by at least 48 hours are below the regulatory limit.
3. When deciding whether to re-open a production or relaying area, the competent authorities may take account of information on phytoplankton trends.

4. Where there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authorities may decide to re-open an area with results below the regulatory limit in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 obtained from a single sampling.

Article 64

Control system

1. The competent authorities shall set up a control system to ensure that products of animal origin harmful to human health are not placed on the market. The control system shall comprise laboratory tests to verify food business operators' compliance with the requirements for the end product, including live bivalve molluscs and any products derived from them, at all stages of production, processing and distribution.
2. This control system shall verify, where applicable, that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.

Article 65

Decision by the competent authorities

1. The competent authorities shall act promptly where a production area must be closed or reclassified, or may be re-opened, or where live bivalve molluscs are subject to the application of measures as referred to in Article 62(2).
2. When deciding on the classification, reclassification, opening or closure of production areas in accordance with Articles 52, 62 and 63, competent authorities may take into account the results of checks carried out by food business operators or organisations representing food business operators, only if the laboratory carrying out the analysis is designated by the competent authorities, and the sampling and analysis are performed in accordance with a protocol agreed upon jointly by the competent authorities and food business operators or organisation concerned.

CHAPTER IV

Other requirements

Article 66

Recording and exchange of information

The competent authorities shall:

- (a) establish and keep up to date a list of classified production and relaying areas, with details of their location, and boundaries, as well as the Class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of Article 52. This list shall be communicated to interested parties affected by this Regulation, such as producers, gatherers and operators of purification centres and dispatch centres;
- (b) immediately inform the interested parties such as producers, gatherers and operators of purification centres and dispatch centres, of any change to the location, boundaries or Class of a production area, of its temporary or final closure, or of the application of measures as referred to in Article 60(2).

TITLE VI

SPECIFIC REQUIREMENTS AND UNIFORM MINIMUM FREQUENCY OF OFFICIAL CONTROLS WITH RESPECT TO FISHERY PRODUCTS

Article 67

Official controls on production and placing on the market

Official controls on the production and placing on the market of fishery products shall include verification of compliance with the requirements set out in Section VIII of Annex III to Regulation (EC) No 853/2004, in particular:

- (a) a regular check on the hygiene conditions of landing and first sale;

- (b) regular inspections of vessels and establishments on land, including fish auctions and wholesale markets, in particular to check:
 - (i) whether the conditions for approval are still fulfilled;
 - (ii) whether the fishery products are handled correctly;
 - (iii) compliance with hygiene and temperature requirements;
 - (iv) the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene;
- (c) checks on storage and transport conditions.

Article 68

Site of official controls

1. The competent authorities shall carry out official controls on vessels when these call at a port in a Member State. These controls shall concern all vessels landing fishery products at EU ports, irrespective of flag.
2. Flag state competent authorities may carry out official controls on vessels under their flag while the vessel is at sea or in a port in another Member State or a third country.

Article 69

Approval of factory, freezer or reefer vessels

1. Where a factory, freezer or reefer vessel flying the flag of a Member State is inspected with a view to granting approval of the vessel, the competent authorities of the flag Member State shall carry out official controls in accordance with Article 148 of Regulation (EU) 2017/625, particularly the time limits referred to in Article 148(4). If necessary, they may inspect the vessel while it is at sea or in a port in another Member State or a third country.
2. Where the competent authorities of the flag Member State have granted the vessel conditional approval in accordance with Article 148 of Regulation (EU) 2017/625, they may authorise the competent authorities of another Member State, or of a third country to carry out follow-up controls with a view to granting full approval, prolonging conditional approval or keeping approval under review, provided that, in the case of a third country, such country appears on a list of third countries from which imports of fishery products are permitted pursuant to Article 127 of Regulation (EU) 2017/625. If necessary, these competent authorities may inspect the vessel while it is at sea or in a port in another Member State or third country.
3. Where the competent authorities of a Member State authorise the competent authorities of another Member State or of a third country to carry out controls on their behalf in accordance with this Article, the two competent authorities shall agree on the conditions governing such controls. These conditions shall ensure, in particular, that the competent authorities of the flag Member State receive reports on the results of the controls and on any suspected non-compliance without delay, so as to enable them to take the necessary measures.

Article 70

Official controls of fishery products

Official controls of fishery products shall include at least the practical arrangements laid down in Annex VI as regards:

- (a) organoleptic examinations;
- (b) freshness indicators;
- (c) histamine;
- (d) residues and contaminants;
- (e) microbiological checks;
- (f) parasites;
- (g) poisonous fishery products.

*Article 71***Decisions after controls**

The competent authorities shall declare fishery products unfit for human consumption if:

- (a) official controls carried out in accordance with Article 70 reveal they are not in compliance with organoleptic, chemical, physical or microbiological requirements or requirements for parasites as established in Section VII of Annex III of Regulation (EC) No 853/2004 and/or Regulation (EC) No 2073/2005;
- (b) they contain in their edible parts chemical residues or contaminants in excess of the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005, (EC) No 1881/2006, or residues of substances that are prohibited or unauthorised in accordance with Regulation (EU) No 37/2010 or Directive 96/22/EC, or are not in compliance with any other relevant Union legislation on pharmacologically active substances;
- (c) they derive from:
 - (i) poisonous fish;
 - (ii) fishery products not complying with the requirements on marine biotoxins;
 - (iii) live bivalve molluscs, echinoderms, tunicates or marine gastropods containing marine biotoxins in total quantities exceeding the limits referred to in Regulation (EC) No 853/2004; or
- (d) the competent authorities consider that they may constitute a risk to human or animal health or are for any other reason not suitable for human consumption.

*Article 72***Requirements concerning the official controls on fishery products caught by vessels flying the flag of Member States entering the Union after being transferred in third countries with or without storage**

1. Fishery products intended for human consumption caught by vessels flying the flag of a Member State, unloaded, with or without storage, in third countries listed as provided for in Article 126(2)(a) of Regulation (EU) 2017/625 before entering the Union by a different means of transportation, shall be accompanied by a health certificate issued by the competent authorities of that third country and completed in accordance with the model health certificate set out in Chapter B of Part II to Annex III to Implementing Regulation (EU) 2019/628.
2. If the fishery products referred to in paragraph 1 are unloaded and transported to a storage facility located in the third country referred to in that paragraph, that storage facility shall appear in a list as provided for in Article 5 of Delegated Regulation (EU) 2019/625.
3. If the fishery products referred to in paragraph 1 are loaded in a vessel flying the flag of a third country, that third country shall be listed as provided for in Article 3 of Delegated Regulation (EU) 2019/625 and the vessel shall appear in a list as provided for in Article 5 of Delegated Regulation (EU) 2019/625.
4. Container vessels used to transport containerised fishery products are excluded from this requirement.

TITLE VII

SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND UNIFORM MINIMUM FREQUENCY FOR OFFICIAL CONTROLS ON REPTILE MEAT*Article 73***Ante-mortem and post-mortem inspection of reptiles**

Article 11 shall apply to the ante-mortem inspection of reptiles.

Articles 12, 13 and 14 shall apply to the post-mortem inspection of reptiles. For the purpose of Article 13 (a)(i), a reptile will be considered as 0,5 livestock units.

TITLE VIII

FINAL PROVISIONS

Article 74

Amendments to Regulation (EC) No 2074/2005

Regulation (EC) No 2074/2005 is amended as follows:

1. Articles 5, 6b and 6c are deleted.
2. In Annex I, Section II and the Appendix are deleted.
3. In Annex II, Section II is deleted.
4. Annexes III and V are deleted.
5. Annex VIa is deleted.
6. Annex VIb and its Appendix are deleted.

Article 75

Entry in force and application

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 14 December 2019.

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

Done at Brussels, 15 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

**MODEL DOCUMENT FOR COMMUNICATION WITH THE HOLDING OF PROVENANCE IN ACCORDANCE
WITH ARTICLE 39(5)**

1. Identification details

1.1. Holding of provenance (owner or manager)

Name/number

Full address

Telephone number

Electronic address if available

1.2. Identification numbers of [please specify]
or attach list

Total number of animals (by species)

Identification problems (if any)

1.3. Herd/flock/cage identification number (if
applicable)

1.4. Animal species

1.5. Reference number of health certificate (if
applicable)

2. Ante-mortem findings

2.1. Welfare

Number of animals affected

Type/class/age

Observations

2.2. Animals were delivered dirty

2.3. Clinical findings of disease

Number of animals affected

Type/class/age

Observations

Date of inspection

2.4. Laboratory results ⁽¹⁾

⁽¹⁾ Microbiological, chemical, serological, etc. (include results as attached).

3. Post-mortem findings

3.1. Macroscopic findings

Number of animals affected

Type/class/age

Organ or site of animal(s) affected

Date of slaughter

3.2. Disease (codes may be used ^(?))

Number of animals affected

Type/class/age

Organ or site of the animal(s) affected

Partially or totally condemned carcase (give reason)

Date of slaughter

3.3. Laboratory results ^(?)**3.4. Other results****3.5. Welfare findings**

4. Additional information

5. Contact details of slaughterhouse (approval number)

Name

Full address

Telephone number

Electronic address if available

6. Official veterinarian (print name)

Signature and stamp

7. Date

8. Number of pages attached to this form:

^(?) The competent authorities may introduce the following codes: code A for OIE-listed diseases; codes B100 and B200 for welfare issues and C100 to C290 for decisions concerning meat. The coding system can, if necessary, include further subdivisions (e.g. C141 for a mild generalised disease, C142 for a more severe disease, etc.). If codes are used, they must be readily available to the food business operator with a suitable explanation of their meaning.

^(?) Microbiological, chemical, serological, etc. (include results as attached).

ANNEX II

PRACTICAL ARRANGEMENTS FOR THE HEALTH MARK IN ACCORDANCE WITH ARTICLE 48

1. The health mark must be an oval mark at least 6,5 cm wide by 4,5 cm high bearing the following information in perfectly legible characters:
 - (a) the name of the country in which the establishment is located, which may be written out in full in capitals or shown as a two-letter code in accordance with the relevant ISO code. In the case of Member States, however, these codes are BE, BG, CZ, DK, DE, EE, IE, GR, ES, FR, HR, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, RO, SI, SK, FI, SE and UK;
 - (b) the approval number of the slaughterhouse; and
 - (c) (when the mark is applied in an establishment located in the Union) the abbreviation CE, EC, EF, EG, EK, EO, EY, ES, EÜ, EB, EZ, KE or WE. Those abbreviations must not appear on marks applied on meat imported into the Union from slaughterhouses located outside the Union.
 2. Letters must be at least 0,8 cm high and figures at least 1 cm high. The dimensions of the characters and the mark may be reduced for the health marking of lamb, kids and piglets.
 3. The ink used for health marking must be authorised in accordance with Union rules on the use of colouring substances in foodstuffs.
 4. The health mark may also include an indication of the official veterinarian who carried out the health inspection of the meat.
-

ANNEX III

TESTING METHODS FOR RAW MILK AND HEAT-TREATED COW'S MILK IN ACCORDANCE WITH ARTICLE 50

CHAPTER I

DETERMINATION OF PLATE COUNT AND SOMATIC CELL COUNT

A. When verifying compliance with the criteria laid down in Part III of Section IX, Chapter I of Annex III to Regulation (EC) No 853/2004, the following standards must be applied as reference methods:

1. EN ISO 4833-1 for the plate count at 30 °C;
2. EN ISO 13366-1 for the somatic cell count.

B. The use of alternative analytical methods is acceptable:

1. for the plate count at 30 °C, where the methods are validated against the reference method mentioned in point 1 of Part A in accordance with the protocol set out in standard EN ISO 16140-2, supplemented by standard EN ISO 16297 for the specific case of plate count in raw milk.

In particular, the conversion relationship between an alternative method and the reference method mentioned in point 1 of Part A is established according to standard EN ISO 21187.

2. for the somatic cell count, where the methods are validated against the reference method mentioned in point 2 of Part A in accordance with the protocol set out in standard ISO 8196-3 and operated in accordance with standard EN ISO 13366-2 or other similar internationally accepted protocols.

CHAPTER II

DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN COW'S MILK

A. To determine alkaline phosphatase activity in pasteurised cow's milk, standard EN ISO 11816-1 must be applied as the reference method.

B. The alkaline phosphatase activity in pasteurised cow's milk is expressed as milli units of enzyme activity per litre (mU/l). A unit of alkaline phosphatase activity is the amount of alkaline phosphatase enzyme that catalyses the transformation of 1 micromole of substrate per minute.

C. An alkaline phosphatase test is considered to give a negative result if the measured activity in cow's milk is not higher than 350 mU/l.

D. The use of alternative analytical methods is acceptable where they are validated against the reference methods mentioned in Part A in accordance with internationally accepted protocols and rules of good laboratory practices.

ANNEX IV

REFERENCE TESTING METHOD FOR ANALYSIS OF E. COLI IN LIVE BIVALVE MOLLUSCS FOR CLASSIFICATION OF PRODUCTION AND RELAYING AREAS IN ACCORDANCE WITH ARTICLE 52(2)

The reference method for analysis of E. coli in live bivalve molluscs shall be the detection and 'most probable number' (MPN) technique specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in ISO 16140.

ANNEX V

RECOGNISED METHODS FOR THE DETECTION OF MARINE BIOTOXINS IN ACCORDANCE WITH ARTICLE 60

CHAPTER I

PARALYTIC SHELLFISH POISON DETECTION METHOD

- A. The paralytic shellfish poisoning (PSP) toxins content of the whole body or any part edible separately of bivalve molluscs shall be determined using AOAC official method OMA 2005.06, as published in *AOAC International Journal* 88(6), 1714-1732 (Lawrence method), the mouse bioassay or any other internationally recognised validated method.
- B. If the results are challenged, the reference method shall be AOAC official method OMA 2005.06 as referred in Part A.

CHAPTER II

AMNESIC SHELLFISH POISON DETECTION METHOD

- A. The amnesic shellfish poisoning (ASP) toxins content of the entire body or any part edible separately of bivalve molluscs shall be determined using the high-performance liquid chromatography with ultraviolet detection (HPLC/UV) method or any other internationally recognised validated method.
- B. However, for screening purposes, AOAC official method 2006.02, as published in *AOAC International Journal* 90, 1011-1027 (ASP enzyme-linked immunosorbent assay (ELISA) method), or any other internationally recognised validated method may also be used.
- C. If the results are challenged, the reference method shall be the HPLC/UV method.

CHAPTER III

LIPOPHILIC TOXIN DETECTION METHODS

- A. The reference method for the detection of marine toxins as referred to in points (c), (d) and (e) in Chapter V(2) of Section VII of Annex III to Regulation (EC) No 853/2004 shall be the EU reference laboratory liquid chromatography-mass spectrometry/mass spectrometry (EURL LC-MS/MS) method. This method shall determine at least the following compounds:
- (a) okadaic acid group toxins: OA, DTX1 and DTX2, including their esters (DTX3);
 - (b) pectenotoxins group toxins: PTX1 and PTX2;
 - (c) yessotoxins group toxins: YTX, 45 OH YTX, homo YTX and 45 OH homo YTX;
 - (d) azaspiracids group toxins: AZA 1, AZA 2 and AZA 3.

If new analogues of the above toxins appear, for which a toxicity equivalent factor (TEF) has been established, they shall be included in the analysis.

Total toxicity equivalence shall be calculated using TEFs as recommended by the European Food Safety Authority (EFSA) in Journal (2008) 589, 1-62 or any updated EFSA advice.

- B. Methods other than those referred to in Part A, such as the LC-MS method, HPLC with appropriate detection, immunoassays and functional assays, such as the phosphatase inhibition assay, may be used as alternatives to, or as well as, the EURL LC-MS/MS method, provided that:
- (a) either alone or combined they can detect at least the analogues identified in Part A; more appropriate criteria shall be defined where necessary;

- (b) they meet the method performance criteria stipulated by the EURL LC-MS/MS method. Such methods must be intra-laboratory validated and successfully tested under a recognised proficiency test scheme. The European Reference Laboratory for marine biotoxins shall support activities toward inter-laboratory validation of the technique to allow for formal standardisation;
- (c) their implementation provides an equivalent level of public health protection.

CHAPTER IV

DETECTION OF NEW OR EMERGING MARINE TOXINS

Chemical methods, alternative methods with appropriate detection, or the mouse bioassay can be used during the periodic monitoring of production areas and relaying areas for detecting new or emerging marine toxins on the basis of the national control programmes elaborated by the Member States.

ANNEX VI

PRACTICAL ARRANGEMENTS FOR OFFICIAL CONTROLS ON FISHERY PRODUCTS IN ACCORDANCE WITH ARTICLE 70

CHAPTER I

GENERAL PROVISIONS**A. Organoleptic examinations**

Random organoleptic controls shall be carried out at all stages of production, processing and distribution. One aim of the controls is to verify compliance with the freshness criteria established in accordance with this Regulation. In particular, this includes verifying, at all stages of production, processing and distribution, that fishery products at least meet the baselines of freshness criteria established in accordance with Council Regulation (EC) No 2406/96 ⁽¹⁾.

B. Freshness indicators

When the organoleptic examination gives rise to any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N) in accordance with the technical arrangements in Chapter II.

The competent authorities shall use the criteria laid down in this Regulation.

When the organoleptic examination gives cause to suspect the presence of other conditions that may affect human health, appropriate samples shall be taken for verification purposes.

C. Histamine

Random testing for histamine shall be carried out to verify compliance with the permitted levels laid down in Regulation (EC) No 2073/2005.

D. Residues and contaminants

Monitoring arrangements shall be established in accordance with Directive 96/23/EC and Decision 97/747/EC to control compliance with the EU legislation on:

- maximum residue limits for pharmacologically active substances, in accordance with Regulations (EU) No 37/2010 and (EU) No 2018/470;
- prohibited and non-authorised substances, in accordance with Regulation (EU) No 37/2010, Directive 96/22/EC and Decision 2005/34/EC;
- contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food; and
- pesticide residues, in accordance with Regulation (EC) No 396/2005.

E. Microbiological checks

Where necessary, microbiological controls shall be performed in accordance with the relevant rules and criteria laid down in Regulation (EC) No 2073/2005.

F. Parasites

Risk-based testing shall take place to verify compliance with Part D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 and Section I of Annex II to Regulation (EC) No 2074/2005.

⁽¹⁾ Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products (OJ L 334, 23.12.1996, p. 1).

G. Poisonous fishery products

Controls shall take place to ensure that:

1. fishery products derived from poisonous fish of the following families are not placed on the market: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*;
2. fresh, prepared, frozen and processed fishery products belonging to the family *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may be placed on the market only in wrapped/package form and are appropriately labelled to inform the consumer about preparation/cooking methods and the risk related to the presence of substances with adverse gastrointestinal effects. The scientific names of the fishery products and the common names shall appear on the label;
3. fishery products containing biotoxins such as ciguatera or other toxins dangerous to human health are not placed on the market. However, fishery products derived from live bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII of Annex III to Regulation (EC) No 853/2004 and comply with the standards laid down in point 2 of Chapter V of that Section.

CHAPTER II

CONTROLS ON TOTAL VOLATILE BASIC NITROGEN (TVB-N)

A. TVB-N limit values for certain categories of fishery products and analysis methods to be used

1. Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:
 - (a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Part B of this Chapter;
 - (b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Part B of this Chapter;
 - (c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Part B of this Chapter;
 - (d) 60 mg of nitrogen/100 g of whole fishery product used directly for the preparation of fish oil for human consumption, as referred to in the second paragraph of point 1 of Chapter IV.B of Section VIII of Annex III to Regulation (EC) No 853/2004; however, where the raw material complies with points (a), (b) and (c) of the first paragraph of that point, Member States may set limits at a higher level for certain species pending the establishment of specific Union legislation.

The reference method to be used for checking the TVB-N limits involves distilling an extract deproteinised by perchloric acid as set out in Part C below.

2. Distillation as referred to in point 1 shall be performed using apparatus which complies with the diagram in Part D below.
3. The routine methods that may be used to check the TVB-N limit are as follows:
 - (a) microdiffusion method described by Conway and Byrne (1933);
 - (b) direct distillation method described by Antonacopoulos (1968);
 - (c) distillation of an extract deproteinised by trichloroacetic acid (Codex Alimentarius Committee on Fish and Fishery Products, 1968).
4. The sample shall consist of about 100 g of flesh, taken from at least three different points and mixed together by grinding.

Member States shall recommend that official laboratories use, as a matter of routine, the methods referred to above. Where the results are dubious or in the event of dispute regarding the results of analysis performed by one of the routine methods, only the reference method may be used to check the results.

B. Species categories for which TVB-N limit values are fixed

TVB-N limit values are fixed for the following species categories:

1. *Sebastes spp.*, *Helicolenus dactylopterus*, *Sebastichthys capensis*;
2. species belonging to the *Pleuronectidae* family (with the exception of halibut: *Hippoglossus spp.*);
3. *Salmo salar*, species belonging to the *Merlucciidae* family, species belonging to the *Gadidae* family.

C. Reference procedure for determining the concentration of TVB-N in fish and fishery products

1. Purpose and area of application

This method describes a reference procedure for identifying the nitrogen concentration of TVB-N in fish and fishery products. The procedure is applicable at TVB-N concentrations of 5 mg/100 g to at least 100 mg/100 g.

2. Definitions

'TVB-N concentration' means the nitrogen content of volatile nitrogenous bases as determined by the reference procedure described.

'Solution' means an aqueous solution as follows:

- (a) perchloric acid solution = 6 g/100 ml;
- (b) sodium hydroxide solution = 20 g/100 ml;
- (c) hydrochloric acid standard solution 0,05 mol/l (0,05 N). When using an automatic distillation apparatus, titration must take place with a hydrochloric acid standard solution of 0,01 mol/l (0,01 N);
- (d) boric acid solution = 3 g/100 ml;
- (e) silicone anti-foaming agent;
- (f) phenolphthalein solution = 1 g/100 ml 95 % ethanol;
- (g) indicator solution (Tashiro mixed indicator) = 2 g methyl-red and 1 g methylene-blue dissolved in 1 000 ml 95 % ethanol.

3. Brief description

The volatile nitrogenous bases are extracted from a sample using a solution of 0,6 mol/l perchloric acid. After alkalisation, the extract undergoes steam distillation and the volatile base components are absorbed by an acid receiver. The TVB-N concentration is determined by titration of the absorbed bases. The concentration is expressed in mg/100 g.

4. Chemicals

Unless otherwise indicated, reagent-grade chemicals shall be used. The water used shall be either distilled or demineralised and of at least the same purity.

5. The following instruments and accessories shall be used:

- (a) a meat grinder to produce a sufficiently homogenous fish mince;
- (b) high-speed blender with a speed of 8 000 to 45 000 revolutions/min;
- (c) fluted filter, diameter 150 mm, quick-filtering;
- (d) burette, 5 ml, graduated to 0,01 ml;
- (e) apparatus for steam distillation. The apparatus must be able to regulate various amounts of steam and produce a constant amount of steam over a given period of time. It must ensure that, during the addition of alkalisating substances, the resulting free bases cannot escape.

6. Execution of the reference procedure

When working with perchloric acid, which is strongly corrosive, necessary caution and preventive measures shall be taken. The samples shall be prepared as soon as possible after their arrival, in accordance with the following instructions:

(a) Preparing the sample

The sample to be analysed is ground carefully using a meat grinder as described in point 5(a). An amount of $10 \text{ g} \pm 0,1 \text{ g}$ of the ground sample is weighed out into a suitable container. This is mixed with 90,0 ml perchloric acid solution, homogenised for two minutes with a blender as described in point 5(b), and then filtered.

The extract thereby obtained can be kept for at least seven days at a temperature of between approximately $2 \text{ }^\circ\text{C}$ and $6 \text{ }^\circ\text{C}$;

(b) Steam distillation

50,0 ml of the extract obtained in accordance with point (a) is put into an apparatus for steam distillation as described in point 5(e). For a later check on the extract's alkalisation, several drops of phenolphthalein solution are added. After adding a few drops of silicone anti-foaming agent, 6,5 ml of sodium hydroxide solution is added to the extract and steam distillation begins immediately.

The steam distillation is regulated so that around 100 ml of distillate is produced in 10 minutes. The distillation outflow tube is submerged in a receiver with 100 ml boric acid solution, to which three to five drops of the indicator solution have been added. After exactly 10 minutes, distillation is ended. The distillation outflow tube is removed from the receiver and washed out with water. The volatile bases contained in the receiver solution are determined by titration with hydrochloric acid standard solution.

The pH of the end point must be $5,0 \pm 0,1$;

(c) Titration

Duplicate analyses are required. The applied method is correct if the difference between the duplicates is not greater than 2 mg/100 g;

(d) Blank

A blind test is carried out as described in point (b). Instead of the extract, 50,0 ml perchloric acid solution is used.

7. Calculation of TVB-N concentration

By titration of the receiver solution with hydrochloric acid standard solution, the TVB-N concentration is calculated using the following equation:

$$\text{TVB-N (expressed in mg/100 g sample)} = \frac{(V_1 - V_0) \times 0,14 \times 2 \times 100}{M}$$

where:

V1 = volume of 0,01 mol hydrochloric acid standard solution in ml for sample;

V0 = volume of 0,01 mol hydrochloric acid standard solution in ml for blank;

M = mass of sample in g.

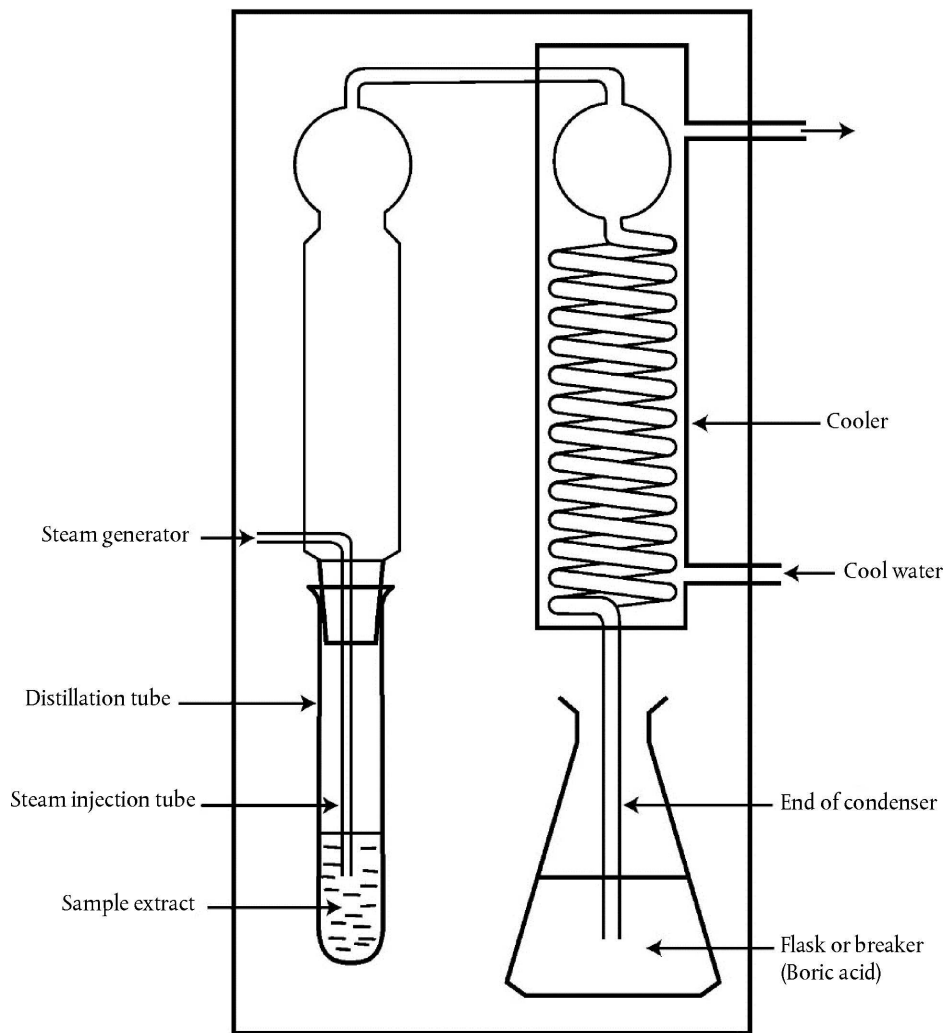
In addition, the following is required:

(a) duplicate analyses. The applied method is correct if the difference between duplicates is not greater than 2 mg/100 g;

(b) equipment check. The equipment is checked by distilling solutions of NH_4Cl equivalent to 50 mg TVB-N/100 g;

(c) standard deviations. The standard deviation for repeatability $S_r = 1,20 \text{ mg/100 g}$ and the standard deviation for reproducibility $S_R = 2,50 \text{ mg/100 g}$ are calculated.

D. TVB-N steam distillation apparatus



COMMISSION IMPLEMENTING REGULATION (EU) 2019/628**of 8 April 2019****concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to 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) ⁽¹⁾, and in particular points (a), (c) and (e) of the first paragraph of Articles 90 and 126(3) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for official controls and other control activities performed by the competent authorities of the Member States in order to verify compliance with Union legislation in the area of, among others, food safety at all stages of the production, processing and distribution process. In particular, it provides for official certification when considered appropriate to ensure compliance with EU rules on animals and goods.
- (2) Point (a) of the first paragraph of Article 90 of Regulation (EU) 2017/625 empowers the Commission to adopt, by means of implementing acts, rules concerning model official certificates and rules for the issuance of such certificates, where requirements are not laid down in the rules referred to in Article 1(2) of that Regulation.
- (3) Consignments of animals and goods shall be accompanied by an official certificate issued either on paper or in electronic form. Therefore, it is appropriate to establish common requirements as regards issuance of official certificates in both cases in addition to the requirements laid down in Chapter VII of Title II of Regulation (EU) 2017/625.
- (4) Model certificates are included in the electronic system Traces, set up by Commission Decision 2003/623/EC ⁽²⁾, to facilitate and accelerate administrative procedures at Union borders and to enable electronic communication between the competent authorities which helps preventing possible fraudulent or deceptive practices in respect of the official certificates.
- (5) Since 2003, computer technology has evolved considerably and the Traces system has been modified to improve the quality, processing and secure exchange of data. As a result, the format of the model certificates and the notes on their completion laid down in this Regulation should be adapted to the Traces system, for example by reflecting the use of multiple Combined Nomenclature (CN) codes or providing traceability for triangular trade, where the country of dispatch is not the country of origin of the consignment.
- (6) In accordance with Article 133(4) of Regulation (EU) 2017/625, the Traces system is to be integrated into the Information Management System for Official Controls (IMSOC). The model health certificates laid down in this Regulation should therefore be adapted to IMSOC.
- (7) Point (c) of the first paragraph of Article 90 of Regulation (EU) 2017/625 empowers the Commission to lay down by means of implementing acts rules concerning the procedures to be followed for the issuance of replacement certificates.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Commission Decision 2003/623/EC of 19 August 2003 concerning the development of an integrated computerised veterinary system known as Traces (OJ L 216, 28.8.2003, p. 58).

- (8) To avoid misuse and abuse, it is important to define the cases where a replacement certificate may be issued and the requirements that need to be met by such certificates. In particular, these cases should be limited to obvious administrative errors, such as transposed numbers in the container number or seal number, spelling errors in addresses or in product descriptions.
- (9) Article 126(2)(c) of Regulation (EU) 2017/625 establishes the requirement that consignments of certain animals and goods are to be accompanied by an official certificate, an official attestation or any other evidence that the consignment complies with the applicable rules referred to in Article 1(2) of that Regulation.
- (10) Commission Delegated Regulation (EU) 2019/625 ⁽³⁾ provides for a list of goods and animals intended for human consumption, in particular products of animal origin, live insects and sprouts and seeds intended for the production of sprouts, that need to be accompanied by an official certificate upon the entry into the Union if intended for placing on the market. To facilitate official controls upon the entry into the Union, model official certificates should be laid down for such goods and animals intended for human consumption in accordance with Point (a) of the first paragraph of Article 90 and Article 126(3) of Regulation (EU) 2017/625.
- (11) Model certificates required for public health reasons are currently laid down in various legal acts. It is appropriate to consolidate these model certificates in one single legal act by making cross-references to them.
- (12) With respect to certification of certain products of animal origin for animal health reasons, common model certificates are used. The requirements for certification for animal health reasons should be revised by 21 April 2021, which is the date of application of Regulation (EU) 2016/429 of the European Parliament and of the Council ⁽⁴⁾. The common model certificates should be maintained until that revision.
- (13) For reasons of harmonisation and clarity, model certificates currently laid down in Commission Regulation (EC) No 2074/2005 ⁽⁵⁾, Commission Regulation (EU) No 211/2013 ⁽⁶⁾ and Commission Implementing Regulation (EU) 2016/759 ⁽⁷⁾ should be incorporated into this Regulation. As a result, Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 should be amended accordingly and Regulation (EU) No 211/2013 should be repealed.
- (14) To facilitate the verification of compliance with EU requirements, it seems appropriate to introduce additional new model health certificates for the entry of rendered animal fats and greaves, insects and reptile meat intended for placing on the market. Such model certificates also make it easier for competent authorities in third countries to understand EU requirements and therefore facilitate the entry of animal fats and greaves, insects and reptile meat into the Union.
- (15) Point (e) of the first paragraph of Article 90 of Regulation (EU) 2017/625 empowers the Commission to adopt, by means of implementing acts, rules concerning the format of documents that are to accompany animals or goods after official controls have been performed. In accordance with Article 5 of Commission Delegated Regulation (EU) 2019/624 ⁽⁸⁾, such health certificates are to accompany animals to the slaughterhouse after ante-mortem inspection has been carried at the holding of provenance. The format of such certificates should therefore be laid down in this Regulation.

⁽³⁾ Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (see page 18 of this Official Journal).

⁽⁴⁾ 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') (OJ L 84, 31.3.2016, p. 1).

⁽⁵⁾ Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ L 338, 22.12.2005, p. 27).

⁽⁶⁾ Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 26).

⁽⁷⁾ Commission Implementing Regulation (EU) 2016/759 of 28 April 2016 drawing up lists of third countries, parts of third countries and territories from which Member States are to authorise the introduction into the Union of certain products of animal origin intended for human consumption, laying down certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC (OJ L 126, 14.5.2016, p. 13).

⁽⁸⁾ Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (see page 1 of this Official Journal).

- (16) In the case of emergency slaughter outside the slaughterhouse, it is appropriate for reasons of harmonisation and clarity, to lay down a model certificate in this Regulation for the declaration to be issued by the (official) veterinarian in accordance with point 6 of Chapter VI of Section I of Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽⁹⁾.
- (17) As Regulation (EU) 2017/625 applies with effect from 14 December 2019, this Regulation should also apply from that date.
- (18) It is appropriate to introduce a transitional period to take into account the consignments of animals and goods shipped and certified, if required, before the date of application of this Regulation.
- (19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation lays down:
- (a) rules for the uniform application of Articles 88 and 89 of Regulation (EU) 2017/625 as regards the signature and issuance of official certificates and the guarantees of reliability for official certificates, in order to comply with the requirements of Article 126(2)(c) of that Regulation;
 - (b) requirements for model official certificates which are not submitted in IMSOC;
 - (c) requirements for model official certificates which are submitted in IMSOC;
 - (d) requirements for replacement certificates.
2. This Regulation also sets out:
- (a) model official certificates for the entry into the Union of animals, products of animal origin, composite products, germinal products and animal by-products and notes for its completion;
 - (b) specific model official certificates for the entry into the Union of the following animals and goods intended for human consumption and placing on the market:
 - (i) products of animal origin for which such certificate is required in accordance with Article 13 of Delegated Regulation (EU) 2019/625;
 - (ii) live insects;
 - (iii) sprouts and seeds intended for the production of sprouts;
 - (c) model official certificates in the case of ante-mortem inspection at the holding of provenance or in the case of emergency slaughter outside the slaughterhouse.

Article 2

Definitions

For the purpose of this Regulation, the following definitions shall apply:

- (1) 'placing on the market' means placing on the market as defined in point (8) of Article 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽¹⁰⁾;

⁽⁹⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

⁽¹⁰⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (2) 'sprouts' means sprouts as defined in point (a) of Article 2 of Commission Implementing Regulation (EU) No 208/2013 ⁽¹⁾;
- (3) 'slaughterhouse' means a slaughterhouse as defined in point 1.16 of Annex I to Regulation (EC) No 853/2004;
- (4) 'fresh meat' means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;
- (5) 'meat' means meat as defined in point 1.1 of Annex I to Regulation (EC) No 853/2004;
- (6) 'poultry' means poultry as defined in point 1.3 of Annex I to Regulation (EC) No 853/2004;
- (7) 'wild game' means wild game as defined in point 1.5 of Annex I to Regulation (EC) No 853/2004;
- (8) 'eggs' means eggs as defined in point 5.1 of Annex I to Regulation (EC) No 853/2004;
- (9) 'egg products' means egg products as defined in point 7.3 of Annex I to Regulation (EC) No 853/2004;
- (10) 'meat preparations' means meat preparations as defined in point 1.15 of Annex I to Regulation (EC) No 853/2004;
- (11) 'meat products' means meat products as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004;
- (12) 'treated stomachs, bladders and intestines' means treated stomachs, bladders and intestines as defined in point 7.9 of Annex I to Regulation (EC) No 853/2004;
- (13) 'bivalve molluscs' means bivalve molluscs as defined in point 2.1 of Annex I to Regulation (EC) No 853/2004;
- (14) 'fishery products' means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;
- (15) 'raw milk' means raw milk as defined in point 4.1 of Annex I to Regulation (EC) No 853/2004;
- (16) 'dairy products' means dairy products as defined in point 7.2. of Annex I to Regulation (EC) No 853/2004;
- (17) 'colostrum' means colostrum as defined in point 1 of Section IX of Annex III of Regulation (EC) No 853/2004;
- (18) 'colostrum-based products' means colostrum-based products as defined in points 2 of Section IX of Annex III of Regulation (EC) No 853/2004;
- (19) 'frogs' legs' means frogs' legs as defined in point 6.1 of Annex I to Regulation (EC) No 853/2004;
- (20) 'snails' means snails as defined in point 6.2 of Annex I to Regulation (EC) No 853/2004;
- (21) 'rendered animal fat' means rendered animal fat defined in point 7.5 of Annex I to Regulation (EC) No 853/2004;
- (22) 'greaves' means greaves as defined in point 7.6 of Annex I to Regulation (EC) No 853/2004;
- (23) 'gelatine' means gelatine as defined in point 7.7 of Annex I to Regulation (EC) No 853/2004;
- (24) 'collagen' means collagen as defined in point 7.8 of Annex I to Regulation (EC) No 853/2004;
- (25) 'honey' means honey as defined in point 1 of Part IX of Annex II to Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽²⁾;

⁽¹⁾ Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 16).

⁽²⁾ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

- (26) 'apiculture products' means apiculture products as defined in point 2 of Part IX of Annex II to Regulation (EU) No 1308/2013;
- (27) 'reptile meat' means reptile meat as defined in point (16) of Article 2 of Delegated Regulation (EU) 2019/625;
- (28) 'insects' means insects as defined in point (17) of Article 2 of Delegated Regulation (EU) 2019/625;
- (29) 'reefer vessel' means a reefer vessel as defined in point (26) of Article 2 of Delegated Regulation (EU) 2019/625;
- (30) 'freezer vessel' means a freezer vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;
- (31) 'factory vessel' means a factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;
- (32) 'production area' means a production area as defined in point 2.5 of Annex I to Regulation (EC) No 853/2004;
- (33) 'dispatch centre' means a dispatch centre as defined in point 2.7 of Annex I to Regulation (EC) No 853/2004;
- (34) 'mechanically separated meat' means mechanically separated meat as defined in point 1.14 of Annex I to Regulation (EC) No 853/2004;
- (35) 'game-handling establishment' means a game-handling establishment as defined in point 1.18 of Annex I to Regulation (EC) No 853/2004;
- (36) 'cutting plant' means a cutting plant as defined in point 1.17 of Annex I to Regulation (EC) No 853/2004;
- (37) 'farmed game' means farmed game as defined in point 1.6 of Annex I to Regulation (EC) No 853/2004.

Article 3

Requirements for model official certificates not submitted in IMSOC

The model official certificates for those animals, products of animal origin, composite products, germinal products, animal by-products, sprouts and seeds intended for the production of sprouts originating from third countries or regions thereof which are required by Union legislation for the entry into the Union and are not submitted in IMSOC, shall meet the following requirements:

- (1) In addition to the signature of the certifying officer, the certificate shall bear an official stamp. The colour of signature shall be different to the colour of the printing. This requirement also applies to stamps other than those embossed or watermarked.
- (2) Where the model certificate contains statements, the statements which are not relevant shall be crossed out, initialed and stamped by the certifying officer, or completely removed from the certificate.
- (3) The certificate shall consist of:
 - (a) a single sheet of paper; or
 - (b) several sheets of paper where all sheets are indivisible and constitute an integral whole; or
 - (c) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence.
- (4) Where the certificate consists of a sequence of pages, each page shall indicate the unique code as referred to in Article 89(1)(a) of Regulation (EU) 2017/625 and bear the signature of the certifying officer and the official stamp.
- (5) The certificate shall be issued before the consignment to which it relates leaves the control of the competent authorities of the third country issuing the certificate.

*Article 4***Requirements for model official certificates submitted in IMSOC**

1. The model official certificates for the entry into the Union of animals, products of animal origin, composite products, germinal products and animal by-products originating from third countries or regions thereof, submitted in IMSOC, shall be based on the model official certificate laid down in Annex I.
2. Part II of the model official certificates referred to in paragraph 1 shall include the specific health guarantees and the information as required in Part II of the relevant model official certificates for those animals, products of animal origin, composite products, germinal products and animal by-products originating from third countries or regions thereof which are required by Union legislation for the entry into the Union.
3. The official certificate shall be submitted in IMSOC before the consignment to which it relates leaves the control of the competent authorities of the third country issuing the certificate.
4. The requirements laid down in this Article shall not affect the nature, content and format of the official certificates or attestations referred to in Article 73(2)(b) and (c) and Article 129(2)(a) of Regulation (EU) 2017/625.

*Article 5***Replacement certificates**

1. Competent authorities may issue a replacement certificate only in the case of administrative errors in the initial certificate or where the initial certificate has been damaged or lost.
2. The replacement certificate shall not modify information in the initial certificate concerning the identification, traceability and health guarantees of consignments.
3. In addition, the replacement certificate shall:
 - (a) make clear reference to the unique code referred to in Article 89(1)(a) of Regulation (EU) 2017/625 and the date of issue of the initial certificate, and clearly state that it replaces the initial certificate;
 - (b) have a new certificate number different to that of the initial certificate;
 - (c) carry the date when it was issued, as opposed to the date of issue of the initial certificate; and
 - (d) be presented in its original to the competent authorities, except in the case of electronic replacement certificates submitted in IMSOC.

*Article 6***Notes on the completion of model official certificates**

The model official certificates referred to in Articles 12, 13 and 15 to 27 shall be completed on the basis of the notes set out in Annex II.

*Article 7***Model official certificates for the entry into the Union for placing on the market of fresh meat of ungulates**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificates 'BOV', 'OVI', 'POR', 'EQU', 'RUF', 'RUW', 'SUF', 'SUW' and 'EQW' set out in Part 2 of Annex II to Commission Regulation (EU) No 206/2010 ⁽¹³⁾ shall be used for the entry into the Union for placing on the market of fresh meat of ungulates.

⁽¹³⁾ Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).

*Article 8***Model official certificates for the entry into the Union for placing on the market of meat of poultry, ratites and wild game birds, eggs and egg products**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificates 'POU', 'POU-MI/MSM', 'RAT', 'RAT-MI/MSM', 'WGM', 'WGM-MI/MSM', 'E' and 'EP' set out in Part 2 of Annex I to Commission Regulation (EC) No 798/2008 ⁽¹⁴⁾ shall be used for the entry into the Union for placing on the market of meat of poultry, ratites and wild game birds, egg and egg products.

*Article 9***Model official certificates for the entry into the Union for placing on the market of meat of wild leporidae, of certain wild land mammals and of farmed rabbits**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificates 'WL', 'WM' and 'RM' set out in Annex II to Commission Regulation (EC) No 119/2009 ⁽¹⁵⁾ shall be used for the entry into the Union for placing on the market of meat of wild leporidae, of certain wild land mammals and of farmed rabbits.

*Article 10***Model official certificate for the entry into the Union for placing on the market of meat preparations**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Annex II to Commission Decision 2000/572/EC ⁽¹⁶⁾ shall be used for the entry into the Union for placing on the market of meat preparations.

*Article 11***Model official certificates for the entry into the Union for placing on the market of certain meat products and treated stomachs, bladders and intestines**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Annex III to Commission Decision 2007/777/EC ⁽¹⁷⁾ shall be used for the entry into the Union for placing on the market of certain meat products and treated stomachs, bladders and intestines. However, in the case of the entry into the Union for placing on the market of casings, the animal health certificate set out in Annex I A to Commission Decision 2003/779/EC ⁽¹⁸⁾ shall be used.

*Article 12***Model official certificates for the entry into the Union for placing on the market of live bivalve molluscs, echinoderms, tunicates and marine gastropods**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Chapter A of Part I of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of live bivalve molluscs, echinoderms, tunicates and marine gastropods. In the

⁽¹⁴⁾ Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

⁽¹⁵⁾ Commission Regulation (EC) No 119/2009 of 9 February 2009 laying down a list of third countries or parts thereof, for imports into, or transit through, the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements (OJ L 39, 10.2.2009, p. 12).

⁽¹⁶⁾ Commission Decision 2000/572/EC of 8 September 2000 laying down the animal and public health and veterinary certification conditions for imports of meat preparations into the Community from third countries (OJ L 240, 23.9.2000, p. 19).

⁽¹⁷⁾ Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC (OJ L 312, 30.11.2007, p. 49).

⁽¹⁸⁾ Commission Decision 2003/779/EC of 31 October 2003 laying down animal health requirements and veterinary certification for the import of animal casings from third countries (OJ L 285, 1.11.2003, p. 38).

case of the entry into the Union and placing on the market of processed bivalve molluscs belonging to the species *Acanthocardia tuberculatum*, the model official certification set out in Chapter B of Part I of Annex III to this Regulation shall be added to the certificate referred to in the first sentence.

Article 13

Model official certificates for the entry into the Union for placing on the market of fishery products

1. To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Chapter A of Part II of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of fishery products.
2. In the case of fishery products caught by vessels flying the flag of a Member State and transferred in third countries with or without storage, the model certificate set out in Chapter B of Part II of Annex III to this Regulation shall be used.
3. To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate to be signed by the captain, set out in Chapter C of Part II to Annex III to this Regulation shall be used when fishery products are imported directly from a reefer, freezer or factory vessel as provided for in Article 11(3) of Delegated Regulation (EU) 2019/625.

Article 14

Model official certificates for the entry into the Union for placing on the market of raw milk, colostrum, dairy products and colostrum-based products

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificates 'Milk-RM', 'Milk-RMP', 'Milk-HTB', 'Milk-HTC' and 'Colostrum-C/CPB' set out in Part 2 of Annex II to Commission Regulation (EU) No 605/2010 ⁽¹⁹⁾ shall be used for the entry into the Union for placing on the market of raw milk, colostrum, dairy products and colostrum-based products.

Article 15

Model official certificate for the entry into the Union for placing on the market of chilled, frozen or prepared frogs' legs intended for human consumption

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out Part III of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of chilled, frozen or prepared frogs' legs intended for human consumption.

Article 16

Model official certificate for the entry into the Union for placing on the market of chilled, frozen, shelled, cooked, prepared or preserved snails intended for human consumption

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part IV of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of chilled, frozen, shelled, cooked, prepared or preserved snails intended for human consumption.

⁽¹⁹⁾ Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk, dairy products, colostrum and colostrum-based products intended for human consumption (OJ L 175, 10.7.2010, p. 1).

*Article 17***Model official certificate for the entry into the Union for placing on the market of rendered animal fats and greaves intended for human consumption**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part V of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of rendered animal fats and greaves intended for human consumption.

*Article 18***Model official certificate for the entry into the Union for placing on the market of gelatine intended for human consumption**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part VI of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of gelatine intended for human consumption.

*Article 19***Model official certificate for the entry into the Union for placing on the market of collagen intended for human consumption**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part VII of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of collagen intended for human consumption.

*Article 20***Model official certificate for the entry into the Union for placing on the market of raw materials for the production of gelatine and collagen intended for human consumption**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part VIII of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of raw materials for the production of gelatine and collagen intended for human consumption.

*Article 21***Model official certificate for the entry into the Union for placing on the market of treated raw materials for the production of gelatine and collagen intended for human consumption**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part IX of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of treated raw materials for the production of gelatine and collagen intended for human consumption.

*Article 22***Model official certificate for the entry into the Union for placing on the market of honey and other apiculture products intended for human consumption**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part X of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of honey and other apiculture products intended for human consumption.

*Article 23***Model official certificate for the entry into the Union for placing on the market of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids intended for human consumption**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part XI of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids intended for human consumption.

*Article 24***Model official certificate for the entry into the Union for placing on the market of reptile meat intended for human consumption**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part XII of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of reptile meat intended for human consumption.

*Article 25***Model official certificate for the entry into the Union for placing on the market of insects intended for human consumption**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part XIII of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of insects intended for human consumption.

*Article 26***Model official certificate for the entry into the Union for placing on the market of other products of animal origin intended for human consumption and not covered by Articles 7 to 25**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part XIV of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of other products of animal origin intended for human consumption and not covered by Articles 7 to 25 of this Regulation.

*Article 27***Model official certificate for the entry into the Union for placing on the market of sprouts and seeds intended for the production of sprouts**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out in Part XV of Annex III to this Regulation shall be used for the entry into the Union for placing on the market of sprouts and seeds intended for the production of sprouts.

*Article 28***Model official certificates in case of ante-mortem inspection at the holding of provenance**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificates set out in Annex IV to this Regulation shall be used in the case of ante-mortem inspection at the holding of provenance in accordance with Articles 5 and 6 of Delegated Regulation (EU) 2019/624.

*Article 29***Model official certificate in case of emergency slaughter outside the slaughterhouse**

To meet the certification requirements laid down in Articles 88, 89 and Article 126(2)(c) of Regulation (EU) 2017/625, the model official certificate set out Annex V to this Regulation shall be used in the case of emergency slaughter outside the slaughterhouse in accordance with Article 4 of Delegated Regulation (EU) 2019/624.

*Article 30***Amendments to Regulation (EC) No 2074/2005**

Regulation (EC) No 2074/2005 is amended as follows:

- (1) Article 6 is deleted;
- (2) Annex VI is deleted.

*Article 31***Amendments to Implementing Regulation (EU) 2016/759**

Implementing Regulation (EU) 2016/759 is amended as follows:

- (1) Article 2 is deleted;
- (2) Annex II is deleted.

*Article 32***Repeal**

Regulation (EU) No 211/2013 is repealed. References to Regulation (EU) No 211/2013 shall be construed as references to this Regulation and read in accordance with the correlation table set out in Annex VI to this Regulation.

*Article 33***Transitional provisions**

Consignments of products of animal origin accompanied by the relevant certificates issued in accordance with Regulation (EC) No 2074/2005, Regulation (EU) No 211/2013 and Implementing Regulation (EU) 2016/759 may be accepted for the entry into the Union until 13 March 2020 provided that the certificate was signed before 14 December 2019.

Until 13 March 2020, consignments of rendered animal fats and greaves may enter the Union when using the certificate for meat products set out in Annex III to Decision 2007/777/EC and consignments of reptile meat, insects and other products of animal origin referred to in Article 26 may enter the Union without certificate set out in Annex III of this Regulation.

*Article 34***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 14 December 2019.

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

Done at Brussels, 8 April 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

MODEL OFFICIAL CERTIFICATES FOR THE ENTRY INTO THE UNION OF ANIMALS, PRODUCTS OF ANIMAL ORIGIN, COMPOSITE PRODUCTS, GERMINAL PRODUCTS AND ANIMAL BY-PRODUCTS

COUNTRY				Official certificate to the EU				
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name			I.2. Certificate reference No		I.2.a IMSOC reference No		
	Address			I.3. Central Competent Authority				
	Tel. No			I.4. Local Competent Authority				
	I.5. Consignee/Importer Name			I.6. Operator responsible for the consignment Name				
	Address			Address				
	Postal code			Postal code				
	Tel. No							
	I.7. Country of origin	ISO	I.8. Region of origin	Code	I.9. Country of destination	ISO	I.10. Region of destination	Code
	I.11. Place of dispatch Name Address		Approval No		I.12. Place of destination Name Address			
	I.13. Place of loading			I.14. Date and time of departure				
I.15. Means of transport				I.16. Entry BCP				
Aeroplane <input type="checkbox"/>	Vessel <input type="checkbox"/>	Other <input type="checkbox"/>		I.17. Accompanying documents Type No				
Road vehicle <input type="checkbox"/>	Railway <input type="checkbox"/>							
Identification:								
I.18. Transport conditions								
Ambient <input type="checkbox"/>	Chilled <input type="checkbox"/>	Frozen <input type="checkbox"/>						
I.19. Container No/Seal No								

COUNTRY

Official certificate to the EU

I.20. Goods certified as								
Canning industry	<input type="checkbox"/>	Fattening	<input type="checkbox"/>	Technical use	<input type="checkbox"/>	Trade samples	<input type="checkbox"/>	
Animal feedingstuff	<input type="checkbox"/>	Quarantine	<input type="checkbox"/>	Pharmaceutical use	<input type="checkbox"/>	Circus/exhibition	<input type="checkbox"/>	
Human consumption	<input type="checkbox"/>	Further process	<input type="checkbox"/>	Approved body	<input type="checkbox"/>	Pets	<input type="checkbox"/>	
Breeding/production	<input type="checkbox"/>	Slaughter	<input type="checkbox"/>	Relaying	<input type="checkbox"/>	Other	<input type="checkbox"/>	
Game restocking	<input type="checkbox"/>	Artificial reproduction	<input type="checkbox"/>	Registered equidae	<input type="checkbox"/>			
I.21. For transit			<input type="checkbox"/>	I.22. For internal market				<input type="checkbox"/>
Third country			ISO	Definitive import				<input type="checkbox"/>
				Re-entry				<input type="checkbox"/>
				Temporary admission				<input type="checkbox"/>
I.23. Total number of packages		I.24. Quantity						
		Total number		Total net weight (Kg)		Total gross weight (Kg)		
I.25. Description of goods								
No		Code and CN title						
Species (scientific name)		Breed/Category		Identification system		Identification No		
Age		Sex		Quantity		Test		
Species (Scientific name)		Nature of commodity				Treatment type		
Zone		Abattoir		Manufacturing plant		Cold store		
Final consumer		Number of packages		Net weight		Batch No		
<input type="checkbox"/>						Type of packaging		
Stamp				Signature				

COUNTRY

Certificate model (**)

Part II: Certification	II. Health information (*)	II.a. Certificate reference No	II.b. IMSOC reference No						
<p>Certifying officer</p> <table> <tr> <td>Name (in capital letters)</td> <td>Qualification and title</td> </tr> <tr> <td>Date</td> <td>Signature</td> </tr> <tr> <td>Stamp</td> <td></td> </tr> </table>				Name (in capital letters)	Qualification and title	Date	Signature	Stamp	
Name (in capital letters)	Qualification and title								
Date	Signature								
Stamp									

(*) Specify sanitary requirement to be completed

(**) To be replaced by the specific title of each model of certificate

ANNEX II

NOTES ON THE COMPLETION OF THE MODEL OFFICIAL CERTIFICATES FOR THE ENTRY INTO THE UNION OF ANIMALS, PRODUCTS OF ANIMAL ORIGIN, COMPOSITE PRODUCTS, GERMINAL PRODUCTS, AND ANIMAL BY-PRODUCTS**General**

To positively select any option, please tick or mark the relevant box with a cross (X).

Whenever mentioned, 'ISO' means the international standard two-letter code for a country, in accordance with the international standard ISO 3166 alpha-2 ⁽¹⁾.

Only one of the options may be selected in boxes I.15, I.18, I.20 and I.22.

If the consignee, the entry border control post (BCP) or the transport details (that is to say, the means and date) change after the certificate has been issued, the operator responsible for the consignment must advise the competent authority of the Member State of entry. Such a change shall not result in a request for a replacement certificate.

Part I: Details of the dispatched consignment

Country: The name of the third country issuing the certificate.

Box I.1. Consignor/Exporter: the name and address (street, city and region, province or state, as appropriate) of the natural or legal person dispatching the consignment that must be located in the third country, except for the re-entry of consignments originating from the European Union.

Box I.2. Certificate reference No: the unique mandatory code assigned by the competent authority of the third country in accordance with its own classification. This box is compulsory for all certificates not submitted in IMSOC.

Box I.2.a IMSOC reference No: the unique reference code automatically assigned by IMSOC, if the certificate is registered in IMSOC. This box must not be completed if the certificate is not submitted in IMSOC.

Box I.3. Central competent authority: name of the central authority in the third country issuing the certificate.

Box I.4. Local competent authority: if applicable, the name of the local authority in the third country issuing the certificate.

Box I.5. Consignee/Importer: name and address of the natural or legal person to whom the consignment is intended in the Member State or third country of destination in the case of transit. However, this information is not compulsory for consignments in transit through the European Union.

Box I.6. Operator responsible for the consignment:

The name and address of the person in the European Union in charge of the consignment when presented to the BCP and who makes the necessary declarations to the competent authorities either as the importer or on behalf of the importer.

For products in transit through the European Union: the name and address are compulsory.

For certain animals: the name and address are compulsory if required by the relevant European Union legislation.

For animals and products for the placing on the market: the name and address are optional.

Box I.7. Country of origin:

For products: the name and ISO code of the country where the goods were produced, manufactured and packaged (labelled with the identification mark).

⁽¹⁾ List of country names and code elements under: http://www.iso.org/iso/country_codes/iso-3166-1_decoding_table.htm

For animals: the country of residence during the required period as set out in the relevant European Union health certificate. For registered horses re-entering the European Union, the country of origin means the country from which they were last consigned.

In the case of trade involving more than one third country (triangular trade), a separate certificate must be completed for each country of origin.

Box I.8. Region of origin: if applicable, for animals or products affected by the regionalisation measures in accordance with European Union legislation. The code of approved regions, zones or compartments must be stated as defined in the relevant European Union legislation.

Box I.9. Country of destination: the name and ISO code of the European Union country of destination of the animals or products.

If the products are in transit, the name and ISO code of the third country of destination is required.

Box I.10. Region of destination: see box I.8.

Box I.11. Place of dispatch: the name, address and approval number, if required by the European Union legislation, of the holdings or establishments from which the animals or the products come from.

For animals: a holding or any other officially monitored agricultural, industrial or commercial establishment, including zoos, amusement parks, wildlife and hunting reserves, where animals are regularly kept or bred.

For germinal products: semen collection or storage centres, or embryo collection or production teams.

For other products: any unit of a company in the food or animal by-product sector. Only the establishment shipping the products is to be named. In the case of trade involving more than one third country (triangular trade), the place of dispatch is the last third-country establishment of the export chain from which the final consignment is transported to the European Union.

Box I.12. Place of destination:

Except in the case of storage of products in transit, this information is optional.

For the placing on the market: the place where the animals or products are sent for final unloading. Give the name, address and approval number of the holdings or establishments of the place of destination, if applicable.

For storage of products in transit: the name, address and approval number of the warehouse in a free zone, the customs warehouse or the ship supplier.

Box I.13. Place of loading:

For animals: the name of the city or the place where the animals are loaded and if they are assembled beforehand, the details of the official assembly centre.

For products: the name of the city and category (for example, establishment, holding, port or airport) of the final place where the products are to be loaded in the means of transport for the journey to the European Union. In the case of a container, state where it is to be placed aboard the final means of transport to the European Union. In the case of a ferry, indicate the place where the truck embarked.

Box I.14. Date and time of departure:

For animals: the date and time at which the animals are scheduled to leave in their means of transport (aeroplane, vessel, railway or road vehicle).

For products: the date when the means of transport departs (aeroplane, vessel, railway or road vehicle).

Box I.15. Means of transport: means of transport leaving the country of dispatch.

Mode of transport: aeroplane, vessel, railway, road vehicle or other. 'Other' means modes of transport not covered by Council Regulation (EC) No 1/2005 ⁽²⁾.

⁽²⁾ Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).

Identification of the means of transport: for aeroplanes the flight number, for vessels the ship name(s), for railways the train identity and wagon number, for road transports the registration number plate with trailer number plate if applicable.

In the case of a ferry, state the identification of the road vehicle, the registration number plate with trailer number plate if applicable, and the name of the scheduled ferry.

Box I.16. Entry BCP: state the name of the BCP and its identification code assigned by IMSOC.

Box I.17. Accompanying documents:

The type and reference number of document must be stated when a consignment is accompanied by the other documents such as CITES permit, permit for invasive alien species (IAS) or a commercial document (for example, the airway bill number, the bill of lading number or the commercial number of the train or road vehicle)

Box I.18. Transport conditions: category of required temperature during the transport of products (ambient, chilled, frozen). Only one category may be selected.

Box I.19. Container No/Seal No: if applicable, the corresponding numbers.

The container number must be provided if the goods are transported in closed containers.

Only the official seal number must be stated. An official seal applies if a seal is affixed to the container, truck or rail wagon under the supervision of the competent authority issuing the certificate.

Box I.20. Goods certified as: state the purpose for the placing on the market of the animals or intended use for products as specified in the relevant European Union health certificate.

Animal feedingstuffs: concerns only animal by-products intended for animal feed as referred to in Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽³⁾.

Approved body: movement of animals to an approved body, an institute or a centre in accordance with Council Directive 92/65/EEC ⁽⁴⁾.

Artificial reproduction: concerns only germinal products.

Breeding/production: for breeding and production animals, including aquaculture animals intended for farming.

Canning industry: concerns, for example, tuna intended for the canning industry.

Circus/exhibition: for registered circus and exhibition animals and aquatic animals for aquariums or similar businesses not for further sale.

Fattening: concerns ovine and caprine animals only.

Further process: concerns only products which have to be further processed before being placed on the market.

Game restocking: concerns only game for the purpose of rebuilding stocks.

Human consumption: concerns only products intended for human consumption for which a health or veterinary certificate is required by European Union legislation.

Other: intended for purposes not listed elsewhere in this classification, including aquatic animals intended for put-and-take fisheries.

⁽³⁾ 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).

⁽⁴⁾ 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).

Pets: commercial movements into the Union of dogs, cats, ferrets and birds. For ornamental aquatic animals intended for pet shops or similar businesses for further sale.

Pharmaceutical use: animal by-products unfit for human or animal consumption, as referred to in Regulation (EC) No 1069/2009.

Quarantine: refers to Commission Implementing Regulation (EU) No 139/2013⁽⁵⁾ for birds other than poultry, to Directive 92/65/EEC for carnivores, primates and bats, and to Council Directive 2006/88/EC⁽⁶⁾ for aquaculture animals.

Registered equidae: in accordance with Council Directive 2009/156/EC⁽⁷⁾.

Relaying: concerns only aquaculture animals.

Slaughter: for animals destined directly or via an assembly centre to a slaughterhouse.

Technical use: animal by-products unfit for human or animal consumption, as referred to in Regulation (EC) No 1069/2009.

Trade samples: as defined in point 39 of Annex I to Commission Regulation (EU) No 142/2011⁽⁸⁾.

Box I.21. For transit: only for the transit of animals or products through the European Union from one third country to another third country or from one part of a third country to another part of the same third country. State the name and ISO code of the third country of destination.

Box I.22. For internal market: for all consignments destined to the European Union market.

Definitive import: this option must only be used for consignments intended to be placed under the customs procedure 'release for free circulation' in the European Union.

For certain animals (for example, registered equidae) only one of the following options must be selected:

Re-entry: this option must only be used for animals authorised for re-entry, such as registered horses for racing, competition and cultural events re-entering the European Union after their temporary export.

Temporary admission: this option must only be used for the entry of animals authorised for temporary entry into the European Union, such as registered horses for a period of less than 90 days.

Box I.23. Total number of packages: the number of boxes, cages or stalls, in which the animals are being transported, the number of cryogenic containers for germinal products or the number of packages for products. In the case of bulk consignments, this box is optional.

Box I.24. Quantity:

For animals: the total number of heads or straws expressed as units.

For germinal products: the total number of straws expressed as units.

For products and aquatic animals, except ornamental fish: the total gross and net weight in kilograms.

Total net weight: this is defined as the mass of the goods themselves without immediate containers or any packaging.

Total gross weight: overall weight in kilograms. This is defined as the aggregate mass of the products and of the immediate containers and all their packaging, but excluding transport containers and other transport equipment.

⁽⁵⁾ Commission Implementing Regulation (EU) No 139/2013 of 7 January 2013 laying down animal health conditions for imports of certain birds into the Union and the quarantine conditions thereof (OJ L 47, 20.2.2013, p. 1).

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

⁽⁷⁾ Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae (OJ L 192, 23.7.2010, p. 1).

⁽⁸⁾ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

Box I.25. Description of goods: State the relevant Harmonised System code (HS code) and the title defined by the World Customs Organisation as referred to in Council Regulation (EEC) No 2658/87⁽⁹⁾. This customs description shall be supplemented, if necessary, by additional information required to classify the animals or the products in veterinary terms. In addition, state any specific requirements relating to the animals or to the nature/processing of the products as defined in the relevant European Union model health or veterinary certificate.

Zone: for animals or products affected by the setting up of approved zones or compartments in accordance with European Union legislation. The zones or production areas (for example, in the case of bivalve molluscs) must be indicated as published in the European Union lists of approved establishments.

For animals: the species, breed or category, identification method, identification number, age, sex, quantity or net weight, and test.

For germinal products: collection or production date, approval number of the centre or team, identification of the straw, and quantity. In addition, as regards donor animals, the species, breed or category, and identification.

For products: the species, types of products, type of treatment, approval number of establishments together with ISO country code (slaughter house, processing plant, cold store), number of packages, type of packaging, batch number, net weight, and final consumer (i.e. products are packed for final consumer).

Species: the scientific name or as defined in accordance with European Union legislation.

Type of packaging: identify the type of packaging according to the definition given in Recommendation No 21⁽¹⁰⁾ of UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business).

Part II: Certification

This part must be completed by an official veterinarian or an official inspector.

Box II. Health information: please complete this part in accordance with the specific European Union health requirements relating to the animal species or to the nature of the products and as defined in the equivalence agreements with certain third countries or in other European Union legislation, such as that for certification.

Where there are no animal or public health attestations for the consignment, then the whole of this section shall be deleted or invalidated or not be present at all in accordance with the footnotes for Part II of the specific European Union health certificates.

Box II.a. Certificate reference No: same reference code as in box I.2.

Box II.b. IMSOC reference No: same reference code as in box I.2.a.

Certifying officer: Official veterinarian or official inspector as defined by the relevant European Union legislation: the name in capital letters, qualification and title, where applicable, identification number and original stamp of the competent authority and date of signature.

⁽⁹⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

⁽¹⁰⁾ Last version: Revision 9 Annexes V and VI as published on: <http://www.unece.org/tradewelcome/un-centre-for-trade-facilitation-and-e-business-uncefact/outputs/cefactrecommendationsrec-index/list-of-trade-facilitation-recommendations-n-21-to-24.html>

ANNEX III

MODEL OFFICIAL CERTIFICATES FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF ANIMALS AND GOODS INTENDED FOR HUMAN CONSUMPTION

PART I

CHAPTER A: MODEL OFFICIAL CERTIFICATE FOR THE ENTRY IN THE UNION FOR PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS, ECHINODERMS, TUNICATES AND MARINE GASTROPODS

COUNTRY				Official certificate to the EU				
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name			I.2. Certificate reference No		I.2.a IMSOC reference No		
	Address			I.3. Central Competent Authority				
	Tel. No			I.4. Local Competent Authority				
	I.5. Consignee/Importer Name			I.6. Operator responsible for the consignment Name				
	Address			Address				
	Postal code			Postal code				
	Tel. No							
	I.7. Country of origin	ISO	I.8. Region of origin	Code	I.9. Country of destination	ISO	I.10. Region of destination	Code
	I.11. Place of dispatch Name Address		Approval No		I.12. Place of destination Name Address			
	I.13. Place of loading			I.14. Date and time of departure				
I.15. Means of transport				I.16. Entry BCP				
Aeroplane	<input type="checkbox"/>	Vessel	<input type="checkbox"/>	Other <input type="checkbox"/>				
Road vehicle	<input type="checkbox"/>	Railway	<input type="checkbox"/>					
Identification:				I.17. Accompanying documents				
				Type No				
I.18. Transport conditions								
Ambient	<input type="checkbox"/>	Chilled	<input type="checkbox"/>	Frozen <input type="checkbox"/>				
I.19. Container No/Seal No								

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods No Code and CN title				
Species (Scientific name) Final consumer Number of packages <input type="checkbox"/>		Nature of commodity Cutting plant/manufacturing plant Net weight Batch No		Treatment type Cold store Type of packaging

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

COUNTRY

II.	Health information	II.a. Certificate reference number	II.b.
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II.1 (1) Public health attestation for live bivalve molluscs, echinoderms, tunicates and marine gastropods

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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) and certify that the (4) [live bivalve molluscs] (4) [live echinoderms] (4) [live tunicates] (4) [live marine gastropods] described above were produced in accordance with those requirements, in particular that they:

- come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Article 5 of Regulation (EC) No 852/2004;
- have been harvested, where necessary relayed and transported in accordance with Section VII, Chapters I and II of Annex III to Regulation (EC) No 853/2004;
- were handled, where necessary purified, and packaged in compliance with Section VII, Chapters III and IV of Annex III to Regulation (EC) No 853/2004;
- satisfy the health standards laid down in Section VII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1);
- have been packaged, stored and transported in compliance with Section VII, Chapters VI and VIII of Annex III to Regulation (EC) No 853/2004;
- have been marked and labelled in accordance with Section I of Annex II and Section VII, Chapter VII of Annex III to Regulation (EC) No 853/2004;
- in the case of *Pectinidae*, marine gastropods and *Holothuroidea* that are not filter feeders harvested outside classified production areas, comply with the specific requirements laid down in Section VII, Chapter IX of Annex III to Regulation (EC) No 853/2004;
- have satisfactorily undergone the official controls laid down in Articles 42 to 58 of Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51) and Article 7 of Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1); and
- fulfil the guarantees covering live animals and products thereof, if of aquaculture origin, provided by the residue plans submitted in accordance with Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10), and in particular Article 29 thereof.

II.2 (2) (4) Animal health attestation for live bivalve molluscs of aquaculture origin

II.2.1 (3) (4) [Requirements for species susceptible to *Bonamia exitiosa*, *Perkinsus marinus* and *Mikrocytos mackini*

I, the undersigned official inspector, hereby certify that the live bivalve molluscs referred to in Part I of this certificate:

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

COUNTRY

II. Health information	II.a. Certificate reference number	II.b.
<p>(⁵) originate from a country/territory, zone or compartment declared free from (⁴) [<i>Bonamia exitiosa</i>] (⁴) [<i>Perkinsus marinus</i>] (⁴) [<i>Mikrocytos mackini</i>] in accordance with Chapter VII of Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14) or the relevant OIE Standard by the competent authority of my country,</p> <ul style="list-style-type: none"> — where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services, and — all introduction of species susceptible to the relevant diseases come from an area declared free of the disease.] 		
<p>II.2.2 (³) (⁴) [Requirements for species susceptible to <i>Marteilia refringens</i> and <i>Bonamia ostreae</i> intended for a Member State, zone or compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease</p> <p>I, the undersigned official inspector, hereby certify that the live bivalve molluscs referred to above:</p> <p>(⁶) originate from a country/territory, zone or compartment declared free from (⁴) [<i>Marteilia refringens</i>] (⁴) [<i>Bonamia ostreae</i>] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,</p> <ul style="list-style-type: none"> (i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services, and (ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease.] 		
<p>II.2.3 Transport and labelling requirements</p> <p>I, the undersigned official inspector, hereby certify that:</p> <p>II.2.3.1 the live bivalve molluscs referred to above are placed under conditions, including with a water quality, that do not alter their health status,</p> <p>II.2.3.2 the transport container or well boat prior to loading is clean and disinfected or previously unused; and</p> <p>II.2.3.3 the consignment is identified by a legible label on the exterior of the micro container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.11 of Part I of this certificate, and the following statement:</p> <p>'Live bivalve molluscs intended for human consumption in the Union'.</p>		
<p>Notes</p> <p>See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101)</p>		
<p>Part I:</p> <ul style="list-style-type: none"> — Box reference I.8: Region of origin: indicate the production area. 		
<p>Part II:</p> <ul style="list-style-type: none"> (¹) Part II.1 <u>does not</u> apply to countries with special public health certification requirements laid down in Equivalence Agreements or other Union legislation. (²) Part II.2 does not apply to: <ul style="list-style-type: none"> (a) non-viable molluscs, which means molluscs no longer able to survive as living animals if returned to the environment from which they were obtained, (b) live bivalve molluscs placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004, 		

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

COUNTRY

II. Health information	II.a. Certificate reference number	II.b.
<p>(c) live bivalve molluscs destined for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level,</p> <p>(d) live bivalve molluscs which are intended for further processing before human consumption without temporary storage at the place of processing and packed and labelled for that purpose in accordance with Regulation (EC) No 853/2004.</p> <p>(³) Part II.2.1 and II.2.2 <u>only</u> apply to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Annex IV to Directive 2006/88/EC.</p> <p>(⁴) Keep as appropriate.</p> <p>(⁵) For consignments of species susceptible to <i>Bonamia exitiosa</i>, <i>Perkinsus marinus</i> and <i>Mikrocytos mackini</i> this statement must be kept for the consignment to be authorised into any part of the Union.</p> <p>(⁶) To be authorised into a Member State, zone or compartment (boxes I.9 and I.10 of Part I of the certificate) declared free from <i>Marteilia refringens</i> or <i>Bonamia ostreae</i> or with a surveillance or eradication programme established in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farms and mollusc farming areas in the Union are accessible at http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm.</p> <p>— The colour of the stamp and signature must be different to that of the other particulars in the certificate.</p>		
<p>Official inspector</p> <p>Name (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Qualification and title:</p> <p>Signature:</p>		

**CHAPTER B: ADDITIONAL MODEL OFFICIAL CERTIFICATION FOR PROCESSED BIVALVE MOLLUSCS
BELONGING TO THE SPECIES ACANTHOCARDIA TUBERCULATUM**

The official inspector hereby certifies that the processed bivalve molluscs of the species *Acanthocardia tuberculatum*, certified in the health certificate reference No:

1. were harvested in production areas clearly identified, monitored and authorised by the competent authority in accordance with Article 12 of Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18) and where the paralytic shellfish poisoning (PSP) level in the edible parts of these molluscs is lower than 300 µg for 100g;

2. were transported in containers or vehicles sealed by the competent authority, directly to the establishment:

.....
.....

(name and official approval number of the establishment, authorised specially by the
competent authority to carry out their treatment);

3. were accompanied while being transported to this establishment by a document issued by the competent authority which authorises the transport, attesting to the nature and quantity of the product, area of origin and establishment of destination;

4. were subjected to the heat treatment outlined in the Annex to Commission Decision 96/77/EC of 18 January 1996 establishing the conditions for the harvesting and processing of certain bivalve molluscs coming from areas where the paralytic shellfish poison level exceeds the limits laid down by Council Directive 91/495/EEC (OJ L 15, 20.1.1996, p. 46); and

5. do not contain a PSP level detectable by the bioassay method, as demonstrated by the attached analytical report(s) of the test carried out on each lot included in the consignment covered by this certification.

The official inspector hereby certifies that the competent authority has verified that the 'own health' checks carried out in the establishment referred to in point 2 are specifically applied to the heat treatment referred to in point 4.

The undersigned official inspector hereby declares that he/she is aware of the provisions of Decision 96/77/EC and that the attached analytical report(s) correspond(s) to the test carried out on the products after processing.

Official inspector

Name (in capitals):

Qualification and title:

Date:

Signature:

Stamp:

PART II

CHAPTER A: MODEL OFFICIAL CERTIFICATE FOR THE ENTRY IN THE UNION FOR PLACING ON THE MARKET OF FISHERY PRODUCTS

COUNTRY				Official certificate to the EU			
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name			I.2. Certificate reference No		I.2.a IMSOC reference No	
	Address			I.3. Central Competent Authority			
	Tel. No			I.4. Local Competent Authority			
	I.5. Consignee/Importer Name			I.6. Operator responsible for the consignment Name			
	Address			Address			
	Postal code			Postal code			
	Tel. No						
	I.7. Country of origin	ISO	I.8. Region of origin	Code	I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No		I.12. Place of destination Name Address		
	I.13. Place of loading				I.14. Date and time of departure		
I.15. Means of transport				I.16. Entry BCP			
Aeroplane <input type="checkbox"/>	Vessel <input type="checkbox"/>	Other <input type="checkbox"/>		I.17. Accompanying documents Type No			
Road vehicle <input type="checkbox"/>	Railway <input type="checkbox"/>						
Identification:							
I.18. Transport conditions							
Ambient <input type="checkbox"/>	Chilled <input type="checkbox"/>	Frozen <input type="checkbox"/>					
I.19. Container No/Seal No							

COUNTRY

Official certificate to the EU

I.20. Goods certified as Canning industry <input type="checkbox"/>				
Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods				
No	Code and CN title			
Species (Scientific name)	Nature of commodity Vessel/manufacturing plant		Treatment type Cold store	
Final consumer <input type="checkbox"/>	Number of packages	Net weight	Batch No Type of packaging	

COUNTRY

Fishery products

II. Health information

II.a. Certificate reference number

II.b.

Part II: Certification

II.1. (1) Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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) and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:

- come from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;
- have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004;
- satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1);
- have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII of Annex III to Regulation (EC) No 853/2004;
- have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004;
- fulfil the guarantees covering live animals and products thereof, if of aquaculture origin, provided by the residue plans submitted in accordance with Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10), and in particular Article 29 thereof; and
- have satisfactorily undergone the official controls laid down in Articles 59 to 65 of Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

II.2 (2) (4) Animal health attestation for fish and crustaceans of aquaculture origin**II.2.1 (3) (4) [Requirements for species susceptible to epizootic haematopoietic necrosis (EHN), taura syndrome and yellowhead disease]**

I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:

(5) originate from a country/territory, zone or compartment declared free from (4) [EHN] (4) [taura syndrome] (4) [yellowhead disease] in accordance with Chapter VII of Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14) or the relevant OIE Standard by the competent authority of my country,

- (i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,
- (ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and

COUNTRY

Fishery products

II. Health information	II.a. Certificate reference number	II.b.
(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases.]		
II.2.2 ⁽³⁾ ⁽⁴⁾ [Requirements for species susceptible to viral haemorrhagic septicaemia (VHS), infectious haematopoietic necrosis (IHN), infectious salmon anaemia (ISA), koi herpes virus (KHV) and white spot disease intended for a Member State, zone or compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease]		
I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:		
⁽⁶⁾ originate from a country/territory, zone or compartment declared free from ⁽⁴⁾ [VHS] ⁽⁴⁾ [IHN] ⁽⁴⁾ [ISA] ⁽⁴⁾ [KHV] ⁽⁴⁾ [White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,		
(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,		
(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and		
(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases.]		
II.2.3 Transport and labelling requirements		
I, the undersigned official inspector, hereby certify that:		
II.2.3.1 the aquaculture animals referred to above are placed under conditions in which the water quality does not alter their health status;		
II.2.3.2. prior to loading the transport container or well boat is clean and disinfected or previously unused; and		
II.2.3.3. the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.11 of Part I of this certificate, and the following statement:		
⁽⁴⁾ [Fish] ⁽⁴⁾ [Crustaceans] intended for human consumption in the Union'.		
Notes		
See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101)		
Part I:		
— Box reference I.8: Region of origin: For frozen or processed bivalve molluscs, indicate the production area.		
— Box reference I.20: Tick 'Canning industry' for whole fish initially frozen in brine at – 9 °C or at a temperature higher than – 18 °C and intended for canning in accordance with the requirements of Section VIII, Chapter I; point II(7) of annex III to Regulation (EC) No 853/2004. Tick 'Human consumption' for the other cases.		
— Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) using headings such as: 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 0511, 1504, 1516, 1518, 1603, 1604, 1605 or 2106.		
— Box reference I.25: <i>Nature of commodity:</i> specify whether aquaculture or wild origin.		
<i>Treatment type:</i> specify whether live, chilled, frozen or processed.		
<i>Manufacturing plant:</i> includes factory vessel, freezer vessel, reefer vessels, cold		
store and processing plant.		
Part II:		
⁽¹⁾ Part II.1 of this certificate <u>does not</u> apply to countries with special public health certification requirements laid down in equivalence agreements or other EU legislation.		

COUNTRY

Fishery products

II. Health information	II.a. Certificate reference number	II.b.
<p>(²) Part II.2 of this certificate <u>does not</u> apply to:</p> <p>(a) non-viable crustaceans, meaning crustaceans that cannot survive as living animals if returned to the environment from which they were obtained,</p> <p>(b) fish which are slaughtered and eviscerated before dispatch,</p> <p>(c) aquaculture animals and products thereof, which are placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004,</p> <p>(d) crustaceans destined for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system that inactivates the pathogens in question, or where the effluent undergoes other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level, and</p> <p>(e) crustaceans which are intended for further processing before human consumption without temporary storage at the place of processing and packed and labelled for that purpose in accordance with Regulation (EC) No 853/2004.</p> <p>(³) Parts II.2.1 and II.2.2 of this certificate <u>only</u> apply to species susceptible to one or more of the diseases referred to in the heading of the point concerned. Susceptible species are listed in Annex IV to Directive 2006/88/EC.</p> <p>(⁴) Keep as appropriate.</p> <p>(⁵) For consignments of species susceptible to EHN, taura syndrome and/or yellowhead disease this statement must be kept for the consignment to be authorised into any part of the EU.</p> <p>(⁶) In order to be authorised into a Member State, zone or compartment (boxes I.9 and I.10 of Part I of the certificate) declared free from VHS, IHN, ISA, KHV or white spot disease or with a surveillance or eradication programme drawn up in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farm and mollusc farming area in the Union are accessible at http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm.</p> <p>— The colour of the stamp and signature must be different to that of the other particulars in the certificate.</p>		
<p>Official inspector</p> <p>Name (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Qualification and title:</p> <p>Signature:</p>		

**CHAPTER B: MODEL OF OFFICIAL CERTIFICATE FOR FISHERY PRODUCTS CAUGHT BY VESSELS FLYING
THE FLAG OF A MEMBER STATE AND TRANSFERRED IN THIRD COUNTRIES WITH OR WITHOUT
STORAGE**

COUNTRY				Official certificate to the EU			
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No			I.2. Certificate reference No	I.2.a IMSOC reference No		
				I.3. Central Competent Authority			
				I.4. Local Competent Authority			
				I.5. Consignee/Importer Name Address Postal code Tel. No			I.6. Operator responsible for the consignment Name Address Postal code
	I.7. Country of origin	ISO	I.8. Region of origin	Code	I.9. Country of destination	ISO	I.10.
	I.11. Place of dispatch Name Address		Approval No		I.12. Place of destination Name Address		
	I.13. Place of loading			I.14. Date and time of departure			
	I.15. Means of transport Aeroplane <input type="checkbox"/> Vessel <input type="checkbox"/> Other <input type="checkbox"/> Road vehicle <input type="checkbox"/> Railway <input type="checkbox"/> Identification:			I.16. Entry BCP			I.17. Accompanying documents Type No
	I.18. Transport conditions Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>						
	I.19. Container No/Seal No						

COUNTRY

Official certificate to the EU

I.20. Goods certified as Canning industry <input type="checkbox"/>				
Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods				
No	Code and CN title			
Species (Scientific name)	Nature of commodity		Treatment type	
Zone	Vessel//manufacturing plant		Cold store	
Final consumer	Number of packages	Net weight	Batch No	Type of packaging
<input type="checkbox"/>				

COUNTRY

Fishery products transferred in third countries

II. Health information

II.a. Certificate reference number

II.b.

II.1. Public health attestation

I, the undersigned official inspector, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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) and certify that the fishery products described above:

- have been landed and unloaded hygienically from the approved/registered vessel(s) (indicate approval/registration number(s) and name of the flag Member State(s)) in compliance with the relevant requirements laid down in Chapter II of Section VIII, of Annex III to Regulation (EC) No 853/2004;
- if applicable, have been stored in approved cold store(s) (indicate approval number(s)) in compliance with the relevant requirements of Chapter VII of Section VIII of Annex III to Regulation (EC) No 853/2004;
- if applicable, have been loaded hygienically on the approved vessel(s) (indicate approval number(s)) of the Member State(s) or third country(ies) and the name of the flag Member State(s) or third country(ies) in compliance with the relevant requirements laid down in Chapter I and VIII of Section VIII of Annex III to Regulation (EC) No 853/2004;
- if applicable, have been loaded in a container (indicate container number) or in a truck (indicate registration number plate of truck and of trailer) or in an aeroplane (indicate the flight number) in compliance with the requirements laid down in Chapter VIII of Section VIII of Annex III to Regulation (EC) No 853/2004; and
- are accompanied by the print out(s) (**) of the fishing logbook(s) or relevant parts thereof. (**)

(**) Electronic format is also accepted.

Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101)

Part I:

- Box reference I.11: Place of dispatch: State the name, address and approval number of the cold store in the third country of dispatch or, if the product was not in cold storage, state the name and approval or registration number of the Member State flagged vessel of origin.
- Box reference I.15: State the means of transport leaving the third country of dispatch. In the case of freezer/reefer vessels, state the name of the vessel, approval number and flag State; in the case of a fishing vessel state the registration number and flag State. If the means of transport are containers, trucks or aeroplanes the same indications provided for in the fourth indent of Part II.1 must be stated.
- Box reference I.20: Tick 'Canning industry' for whole fish initially frozen in brine at – 9 °C or at a temperature higher than – 18 °C and intended for canning in accordance with the requirements of Section VIII, Chapter I; point II(7) of annex III to Regulation (EC) No 853/2004. Tick 'Human consumption' for the other cases.

COUNTRY

Fishery products transferred in third countries

II. Health information	II.a. Certificate reference number	II.b.						
<p>— Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) using headings such as: 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 0511, 1504, 1516, 1518, 1603, 1604, 1605 or 2106.</p> <p>— Box reference I.25: Treatment type: specify whether chilled, frozen or processed.</p> <p>(* includes fishing vessel, factory vessel, freezer and reefer vessel as applicable.</p>								
<p>Official inspector</p> <table><tr><td data-bbox="229 703 480 734">Name (in capital letters):</td><td data-bbox="865 703 1086 734">Qualification and title:</td></tr><tr><td data-bbox="229 757 288 788">Date:</td><td data-bbox="865 757 971 788">Signature:</td></tr><tr><td data-bbox="229 810 308 842">Stamp:</td><td></td></tr></table>			Name (in capital letters):	Qualification and title:	Date:	Signature:	Stamp:	
Name (in capital letters):	Qualification and title:							
Date:	Signature:							
Stamp:								

**CHAPTER C: MODEL OF OFFICIAL CERTIFICATE TO BE SIGNED BY THE CAPTAIN ACCOMPANYING
FROZEN FISHERY PRODUCTS WHEN ENTERING THE UNION FOR PLACING ON THE MARKET DIRECTLY
FROM A FREEZER, REEFER OR FACTORY VESSEL**

COUNTRY				Official certificate to the EU				
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name			I.2. Certificate reference No		I.2.a IMSOC reference No		
	Address			I.3.				
	Tel. No			I.4.				
	I.5. Consignee/Importer Name			I.6. Operator responsible for the consignment Name				
	Address			Address				
	Postal code			Postal code				
	Tel. No							
	I.7. Country of origin	ISO	I.8. Region of origin	Code	I.9. Country of destination	ISO	I.10.	
	I.11 Place of dispatch Name Address		Approval No		I.12. Place of destination Name Address			
	I.13.			I.14. Date and time of departure				
I.15.			I.16. Entry BCP					
			I.17. Accompanying documents Type No					
I.18.								
I.19.								

COUNTRY

Official certificate to the EU

I.20. Goods certified as Canning industry <input type="checkbox"/>				
Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods				
No	Code and CN title			
Species (Scientific name)				
Final consumer <input type="checkbox"/>	Number of packages	Net weight	Batch No	Type of packaging

COUNTRY

Fishery products

I.(bis) Other information

Fishing area(s):

IMO/Lloyd's number (if issued) or call sign of the vessel:

Fishing period:

Start date: .../.../.....

Stop date: .../.../.....

II. Health attestation

II.a. Certificate reference number

II.b.

II.1 Public health attestation

I, undersigned, declare that:

- I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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) and certify that the fishery products described above were produced in accordance with those requirements, in particular that the vessel appears on the list of vessels from which imports to the Union are permitted (being 'EU-listed');
- the vessel has a programme based on the hazard analysis and critical control points (HACCP) principles to control hazards in accordance with Article 5 of Regulation (EC) No 852/2004;
- the fishery products have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004. Viscera and parts that may pose a danger to public health have been removed as quickly as possible and kept apart from products intended for human consumption;
- the fishery products satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and, where appropriate, the criteria laid down in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1);
- the fishery products have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII of Annex III to Regulation (EC) No 853/2004;
- the fishery products have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004;
- the fishery products fulfil the guarantees covering live animals and products thereof, if of aquaculture origin, provided by the residue plans submitted in accordance with Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10), and in particular Article 29 thereof; and
- frozen fishery products have been kept at a temperature of not more than – 18 °C in all parts of the product, except whole fish initially frozen in brine intended for the manufacture of canned food which may be kept at a temperature of not more than – 9 °C.

COUNTRY

Fishery products

II. Health attestation	II.a. Certificate reference number	II.b.
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Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

Part I:

- Box reference I.2: A unique document number according to your own classification.
 - Box reference I.5: The name and address (street, town and post code) of the physical or legal person to whom the consignment is imported directly to in the Member State of destination.
 - Box reference I.7: The country whose flag is being flown by the vessel issuing this document.
 - Box reference I.11: The name of the vessel and approval number as listed in accordance with Article 10 of Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18) from which the fishery products are directly imported.
 - Box reference I.20: Tick 'Canning industry' for whole fish initially frozen in brine at – 9 °C or at a temperature higher than – 18 °C and intended for canning in accordance with the requirements of Section VIII, Chapter I; point II(7) of annex III to Regulation (EC) No 853/2004. Tick 'Human consumption' for the other cases.
 - Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) using headings such as: 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 0511, 1504, 1516, 1518, 1603, 1604, 1605 or 2106.
 - Box reference I.25: Treatment type: specify whether chilled, frozen or processed.
- (* includes fishing vessel, factory vessel, freezer and reefer vessel as applicable.

Captain of the vessel

Name (in capital letters):

Date:

Signature:

Stamp:

PART III

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
CHILLED, FROZEN OR PREPARED FROGS' LEGS INTENDED FOR HUMAN CONSUMPTION**

COUNTRY				Official certificate to the EU		
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No			I.2. Certificate reference No	I.2.a IMSOC reference No	
				I.3. Central Competent Authority		
				I.4. Local Competent Authority		
	I.5. Consignee/Importer Name Address Postal code Tel. No			I.6. Operator responsible for the consignment Name Address Postal code		
	I.7. Country of origin	ISO	I.8.	I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No	I.12. Place of destination Name Address		
	I.13. Place of loading			I.14. Date and time of departure		
	I.15. Means of transport Aeroplane <input type="checkbox"/> Road vehicle <input type="checkbox"/> Identification:		Vessel <input type="checkbox"/> Railway <input type="checkbox"/>	Other <input type="checkbox"/>	I.16. Entry BCP	
	I.18. Transport conditions Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>		I.17. Accompanying documents Type No			
	I.19. Container No/Seal No					

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods No Code and CN title				
Species (Scientific name) Final consumer Number of packages <input type="checkbox"/>		Manufacturing plant Net weight Batch No		Treatment type Cold store Type of packaging

Model FRG

COUNTRY

Chilled, frozen or prepared frogs' legs intended for human consumption

II. Health information

II.a. Certificate reference No

II.b.

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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), and

I certify that the frogs' legs described above were produced in accordance with these requirements, in particular that they:

- come from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;
- have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004; and
- originate from frogs that have been bled, prepared and, where appropriate, chilled, frozen or processed, packaged and stored in a hygienic manner in accordance with the requirements of Section XI of Annex III to Regulation (EC) No 853/2004.

Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

Part I:

- Box reference I.25: Insert the appropriate CN code(s) such as: 0208 90 70, 0210 99 39 or 1602 90 99.
- Box reference I.25: *Treatment type*: fresh, treated.

Part II:

- The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official inspector

Name (in capital letters):

Qualification and title:

Date:

Signature:

Stamp:

Part II: Certification

PART IV

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
CHILLED, FROZEN, SHELLED, COOKED, PREPARED OR PRESERVED SNAILS INTENDED FOR HUMAN
CONSUMPTION**

COUNTRY				Official certificate to the EU		
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No			I.2. Certificate reference No	I.2.a IMSOC reference No	
				I.3. Central Competent Authority		
				I.4. Local Competent Authority		
	I.5. Consignee/Importer Name Address Postal code Tel. No			I.6. Operator responsible for the consignment Name Address Postal code		
	I.7. Country of origin	ISO	I.8.	I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No	I.12. Place of destination Name Address		
I.13. Place of loading				I.14. Date and time of departure		
I.15. Means of transport Aeroplane <input type="checkbox"/>		Vessel <input type="checkbox"/> Railway <input type="checkbox"/>	I.16. Entry BCP			
Road vehicle <input type="checkbox"/> Identification:			Other <input type="checkbox"/>	I.17. Accompanying documents Type No		
I.18. Transport conditions Ambient <input type="checkbox"/>		Chilled <input type="checkbox"/>		Frozen <input type="checkbox"/>		
I.19. Container No/Seal No						

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods No Code and CN title				
Species (Scientific name)		Manufacturing plant		Treatment type
Final consumer	Number of packages	Net weight	Batch No	Cold store
<input type="checkbox"/>				Type of packaging

Model SNS

Chilled, frozen, shelled, cooked, prepared or preserved snails intended for human consumption

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.
II.1. Public health attestation		
<p>I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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), and</p>		
I certify that the snails described above were produced in accordance with these requirements, in particular that they:		
<ul style="list-style-type: none"> — come from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004; — have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004; and — have been handled and, where appropriate, shelled, cooked, prepared, preserved, frozen, packaged and stored in a hygienic manner in accordance with the requirements of Section XI of Annex III to Regulation (EC) No 853/2004. 		
Notes		
<p>See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).</p>		
Part I:		
<ul style="list-style-type: none"> — Box reference I.25: Insert the appropriate HS/CN code(s) such as: 0307 60 00 or 1605. — Box reference I.25: <i>Treatment type</i>: fresh, treated. 		
Part II:		
<ul style="list-style-type: none"> — The colour of the stamp and signature must be different from that of the other particulars in the certificate. 		
Official inspector		
Name (in capital letters):	Qualification and title:	
Date:	Signature:	
Stamp:		

Part II: Certification

PART V

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
RENDERED ANIMAL FATS AND GREAVES INTENDED FOR HUMAN CONSUMPTION**

COUNTRY				Official certificate to the EU		
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No			I.2. Certificate reference No	I.2.a IMSOC reference No	
				I.3. Central Competent Authority		
				I.4. Local Competent Authority		
	I.5. Consignee/Importer Name Address Postal code Tel. No			I.6. Operator responsible for the consignment Name Address Postal code		
	I.7. Country of origin	ISO	I.8.	I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No	I.12. Place of destination Name Address		
	I.13. Place of loading			I.14. Date and time of departure		
	I.15. Means of transport Aeroplane <input type="checkbox"/> Vessel <input type="checkbox"/> Other <input type="checkbox"/> Road vehicle <input type="checkbox"/> Railway <input type="checkbox"/> Identification:			I.16. Entry BCP		
	I.18. Transport conditions Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>			I.17. Accompanying documents Type No		
	I.19. Container No/Seal No					

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods No Code and CN title				
Species (Scientific name) Final consumer Number of packages <input type="checkbox"/>		Manufacturing plant Net weight Batch No		Cold store Type of packaging

COUNTRY

Rendered animal fats and greaves intended for human consumption

II. Health information

II.a. Certificate reference No

II.b.

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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), and

I certify that the rendered animal fats and greaves described above were produced in accordance with these requirements, in particular:

- that they come from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;
- that they have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004; and
- that they comply with the requirements of Section XII of Annex III to Regulation (EC) No 853/2004.

II.2. Animal health attestation

I, the undersigned official veterinarian, hereby certify, that the rendered animal fats and greaves described above meet the following requirements and come from

II.2.1. either third countries, territories and parts thereof appearing in the list authorised for export to the Union of fresh meat in accordance with Part I, of Annex II to Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p1);

II.2.1. or third countries, territories and parts thereof authorised for export to the Union of fresh meat of poultry in accordance with Part 1, of Annex I to Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1);

II.2.1. or third countries, territories and parts thereof authorised for export to the Union of meat products of the species of concern subject to the application of the treatment specified for the animal species of origin of the meat product and set out in the list of third countries and territories in Part 1, of Annex II of

Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC (OJ L 312, 30.11.2007, p. 49).

Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

Part I:

- Box reference I.25: Insert the appropriate HS/CN code(s) such as: 1501, 1502, 1503 00, 1504, 1506 00 00, 1516 10, 1517, 1518 00 91, 1518 00 95, 1518 00 99 or 2301.

COUNTRY

Rendered animal fats and greaves intended for human consumption

II. Health information	II.a. Certificate reference No	II.b.						
Part II: — The colour of the stamp and signature must be different from that of the other particulars in the certificate.								
Official veterinarian <table> <tr> <td data-bbox="229 490 480 521">Name (in capital letters):</td> <td data-bbox="1070 490 1305 521">Qualification and title:</td> </tr> <tr> <td data-bbox="229 551 290 582">Date:</td> <td data-bbox="1070 551 1187 582">Signature:</td> </tr> <tr> <td data-bbox="229 611 308 642">Stamp:</td> <td></td> </tr> </table>			Name (in capital letters):	Qualification and title:	Date:	Signature:	Stamp:	
Name (in capital letters):	Qualification and title:							
Date:	Signature:							
Stamp:								

PART VI

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
GELATINE INTENDED FOR HUMAN CONSUMPTION**

COUNTRY				Official certificate to the EU		
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name			I.2. Certificate reference No	I.2.a IMSOC reference No	
	Address			I.3. Central Competent Authority		
	Tel. No			I.4. Local Competent Authority		
	I.5. Consignee/Importer Name			I.6. Operator responsible for the consignment Name		
	Address			Address		
	Postal code			Postal code		
	Tel. No					
	I.7. Country of origin	ISO	I.8.	I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No	I.12. Place of destination Name Address		
	I.13. Place of loading			I.14. Date and time of departure		
I.15. Means of transport			I.16. Entry BCP			
Aeroplane <input type="checkbox"/>	Vessel <input type="checkbox"/>	Other <input type="checkbox"/>	I.17. Accompanying documents Type No			
Road vehicle <input type="checkbox"/>	Railway <input type="checkbox"/>					
Identification:						
I.18. Transport conditions						
Ambient <input type="checkbox"/>	Chilled <input type="checkbox"/>	Frozen <input type="checkbox"/>				
I.19. Container No/Seal No						

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>			
I.21.	I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)
I.25. Description of goods No Code and CN title			
Species (Scientific name) Final consumer Number of packages <input type="checkbox"/>	Manufacturing plant Net weight Batch No		Cold store Type of packaging

COUNTRY		Model GEL Gelatine intended for human consumption	
	II. Health information	II.a. Certificate reference No	II.b.
Part II: Certification	II.1. Public health attestation		
	<p>I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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), and</p> <p>I certify that the gelatine described above was produced in accordance with these requirements, in particular that:</p> <ul style="list-style-type: none"> — it comes from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004; — it has been produced from raw materials that met the requirements of Chapters I and II of Section XIV of Annex III to Regulation (EC) No 853/2004; — it has been manufactured in compliance with the conditions set out in Chapter III of Section XIV of Annex III to Regulation (EC) No 853/2004; — it satisfies the criteria of Chapter IV of Section XIV of Annex III to Regulation (EC) No 853/2004 and of Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1); <p>(¹) and, if of bovine, ovine and caprine animal origin,</p> <p>it has been derived from animals which have passed ante-mortem and post-mortem inspections,</p> <p>(¹) and, except for gelatine derived from hides and skins,</p> <p>(¹) either</p> <ul style="list-style-type: none"> — [it comes from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a negligible BSE risk; — the gelatine does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1) (²); — the gelatine does not contain and is not derived from mechanically separated meat obtained from the bones of bovine, ovine or caprine animals, except for gelatine derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there has been no indigenous BSE cases; — the animals, from which the gelatine is derived were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk; — (¹) [the animals, from which the gelatine is derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the animals were not fed with meat-and-bone meal or greaves, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health]; 		

COUNTRY		Model GEL Gelatine intended for human consumption	
II. Health information	II.a. Certificate reference No	II.b.	
<ul style="list-style-type: none"> — ⁽¹⁾ [the animals, from which the gelatine is derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the gelatine was produced and handled in a manner which ensures that it did not contain and was not contaminated with nervous and lymphatic tissues exposed during the deboning process.]] <p>(¹) Or</p> <ul style="list-style-type: none"> — [it comes from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a controlled BSE risk; — the animals, from which the gelatine is derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity; — the gelatine does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from the bones of bovine, ovine or caprine animals.] <p>(¹) Or</p> <ul style="list-style-type: none"> — [it comes from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region with an undetermined BSE risk; — the animals, from which the gelatine is derived, were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal health Code of the World Organisation for Animal Health; — the animals, from which the gelatine is derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity; — the gelatine is not derived from: <ul style="list-style-type: none"> (i) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001; (ii) nervous and lymphatic tissues exposed during the deboning process; (iii) mechanically separated meat obtained from the bones of bovine, ovine or caprine animals. 			
Notes			
<p>See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).</p>			
Part I:			
<ul style="list-style-type: none"> — Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) using headings such as 3503. 			
Part II:			
<ul style="list-style-type: none"> (¹) Delete as appropriate. (²) The removal of specified risk material is not required if the gelatine is derived from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk. — The colour of the stamp and signature must be different from that of the other particulars in the certificate. 			
Official veterinarian			
Name (in capital letters):		Qualification and title:	
Date:		Signature:	
Stamp:			

PART VII

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
COLLAGEN INTENDED FOR HUMAN CONSUMPTION**

COUNTRY				Official certificate to the EU		
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No			I.2. Certificate reference No	I.2.a IMSOC reference No	
				I.3. Central Competent Authority		
				I.4. Local Competent Authority		
	I.5. Consignee/Importer Name Address Postal code Tel. No			I.6. Operator responsible for the consignment Name Address Postal code		
	I.7. Country of origin	ISO	I.8.	I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No	I.12. Place of destination Name Address		
	I.13. Place of loading			I.14. Date and time of departure		
	I.15. Means of transport Aeroplane <input type="checkbox"/> Vessel <input type="checkbox"/> Other <input type="checkbox"/> Road vehicle <input type="checkbox"/> Railway <input type="checkbox"/> Identification:			I.16. Entry BCP		
	I.18. Transport conditions Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>			I.17. Accompanying documents Type No		
	I.19. Container No/Seal No					

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>			
I.21.	I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)
I.25. Description of goods No Code and CN title			
Species (Scientific name) Final consumer Number of packages <input type="checkbox"/>	Manufacturing plant Net weight Batch No		Cold store Type of packaging

Model COL

COUNTRY

Collagen intended for human consumption

II. Health information

II.a. Certificate reference No

II.b.

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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), and

I certify that the collagen described above was produced in accordance with these requirements, in particular that:

- it comes from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;
- it has been produced from raw materials that met the requirements of Chapters I and II of Section XV of Annex III to Regulation (EC) No 853/2004;
- it has been manufactured in compliance with the conditions set out in Chapter III of Section XV of Annex III to Regulation (EC) No 853/2004;
- it satisfies the criteria of Chapter IV of Section XV of Annex III to Regulation (EC) No 853/2004 and of Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1);

(¹) and, if of bovine, ovine and caprine animal origin,

it has been derived from animals which have passed ante-mortem and post-mortem inspections,

(¹) and, except for collagen derived from hides and skins,

(¹) either

- [it comes from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a negligible BSE risk;
- the collagen does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1) (²);
- the collagen does not contain and is not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except for collagen derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there has been no indigenous BSE cases;
- the animals from which the collagen was derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk;
- (¹) [the animals, from which the collagen is derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the animals were not fed with meat-and-bone meal or greaves, as defined in the OIE Terrestrial Animal Health Code];

COUNTRY		Model COL Collagen intended for human consumption	
II.	Health information	II.a. Certificate reference No	II.b.
	<ul style="list-style-type: none"> — ⁽¹⁾ [the animals, from which the collagen is derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the collagen was produced and handled in a manner which ensures that it did not contain and was not contaminated with nervous and lymphatic tissues exposed during the deboning process.]] (¹) or — [it comes from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a controlled BSE risk; — the animals, from which the collagen is derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity; — the collagen does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from the bones of bovine, ovine or caprine animals.] (¹) or — [it comes from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region with an undetermined BSE risk; — the animals, from which the collagen is derived, were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal health Code of the World Organisation for Animal Health; — the animals, from which the collagen is derived were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity; — the collagen is not derived from: <ul style="list-style-type: none"> (i) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001; (ii) nervous and lymphatic tissues exposed during the deboning process; (iii) mechanically separated meat obtained from the bones of bovine, ovine or caprine animals.] 		
Notes			
See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).			
Part I:			
— Box reference I.25: This certificate may also be used for importing collagen casings.			
— Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) using headings such as 3504 or 3917.			
Part II:			
(1) Delete as appropriate.			
(2) The removal of specified risk material is not required if the collagen is derived from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk.			
— The colour of the stamp and signature must be different from that of the other particulars in the certificate.			
Official veterinarian			
Name (in capital letters):		Qualification and title:	
Date:		Signature:	
Stamp:			

PART VIII

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
RAW MATERIALS FOR THE PRODUCTION OF GELATINE AND COLLAGEN INTENDED FOR HUMAN
CONSUMPTION**

COUNTRY				Official certificate to the EU					
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name			I.2. Certificate reference No		I.2.a IMSOC reference No			
	Address			I.3. Central Competent Authority					
	Tel. No			I.4. Local Competent Authority					
	I.5. Consignee/Importer Name			I.6. Operator responsible for the consignment Name					
	Address			Address					
	Postal code			Postal code					
I.7. Country of origin			ISO	I.8. Region of origin		Code	I.9. Country of destination	ISO	I.10.
I.11 Place of dispatch Name Address			Approval No		I.12. Place of destination Name Address				
I.13. Place of loading				I.14. Date and time of departure					
I.15. Means of transport						I.16. Entry BCP			
Aeroplane <input type="checkbox"/>		Vessel <input type="checkbox"/>		Other <input type="checkbox"/>		I.17. Accompanying documents Type No			
Road vehicle <input type="checkbox"/>		Railway <input type="checkbox"/>							
Identification:									
I.18. Transport conditions									
Ambient <input type="checkbox"/>		Chilled <input type="checkbox"/>		Frozen <input type="checkbox"/>					
I.19. Container No/Seal No									

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>			
I.21.	I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)
I.25. Description of goods No Code and CN title			
Species (Scientific name) Number of packages <input type="checkbox"/>	Nature of commodity Manufacturing plant Net weight Batch No		Cold store Type of packaging

Model RCG

Raw materials for the production of collagen and gelatine intended for human consumption**COUNTRY****II. Health information**

II.a. Certificate reference No

II.b.

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1), Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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), and

I certify that the raw materials described above comply with these requirements, in particular that:

- ⁽¹⁾ [bones, hides and skins of domestic and farmed ruminant animals, pigs and poultry, as well as tendons and sinews described above are derived from animals which were slaughtered in a slaughterhouse and the carcasses of which were found to be fit for human consumption following ante- and post-mortem inspection;]

and/or

- ⁽¹⁾ [wild game hides, skins and bones described above are derived from killed animals whose carcasses have been found to be fit for human consumption following post-mortem inspection;]

and/or

- ⁽¹⁾ [fish skins and bones described above are derived from plants that manufacture fishery products for human consumption which are authorised for export;]

⁽¹⁾ and, if of bovine, ovine and caprine animal origin,

- they have been derived from animals which passed ante-mortem and post-mortem inspections,

⁽¹⁾ and, except for hides and skins of ruminants,

⁽¹⁾ either

- [they come from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a negligible BSE risk;
- they do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1) ⁽⁶⁾;
- they do not contain and are not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except for raw materials derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there has been no indigenous BSE cases;
- the animals, from which the raw materials are derived, were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk;

Model RCG

Raw materials for the production of collagen and gelatine intended for human consumption

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.
<ul style="list-style-type: none"> — (1) [the animals, from which the raw materials are derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the animals were not fed with meat-and-bone meal or greaves, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health]; — (1) [the animals, from which the raw materials are derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the raw materials were produced and handled in a manner which ensures that they did not contain and were not contaminated with nervous and lymphatic tissues exposed during the deboning process.] <p>(1) or</p> <ul style="list-style-type: none"> — [they come from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a controlled BSE risk; — the animals, from which the raw materials of bovine, ovine and caprine animal origin intended for export are derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity; — the raw materials of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from the bones of bovine, ovine or caprine animals;] <p>(1) or</p> <ul style="list-style-type: none"> — [they come from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region with an undetermined BSE risk; — the animals, from which the raw materials are derived, were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health; — the animals from which the raw materials of bovine, ovine and caprine animal origin are derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity; — the raw materials are not derived from: <ul style="list-style-type: none"> (i) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001; (ii) nervous and lymphatic tissues exposed during the deboning process; (iii) mechanically separated meat obtained from the bones of bovine, ovine or caprine animals.] 		
<p>II.2. Animal Health Attestation (1)</p> <p>I, the undersigned official veterinarian, certify that the raw materials described above:</p> <p>II.2.1. consist of animal products that satisfy the animal health requirements below;</p> <p>II.2.2. have been obtained in the country(ies) or region(s) thereof of (1) either [.....] (1) or [.....] (2) (3) (4) from:</p> <p>(1) either</p> <p style="padding-left: 20px;">[II.2.2.1 animals that come from holdings and have remained in that territory since birth or for at least the last three months before slaughter; and</p> <p style="padding-left: 20px;">(1) either [(i) are derived from the species referred to in Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1), satisfying all the relevant animal health import requirements laid down in that Regulation, and that were slaughtered for human consumption on a date for which import into the Union of fresh meat from animals of those species was authorised from the country or territory thereof in accordance with Column 8 of Part 1 of Annex II to that Regulation;]</p>		

Model RCG

Raw materials for the production of collagen and gelatine intended for human consumption

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.
(1) or [(ii) are derived from the species referred to in Commission Regulation (EC) No 119/2009 laying down a list of third countries or parts thereof, for imports into, or transit through, the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements (OJ L 39, 10.2.2009, p. 12), satisfying all the relevant animal health import requirements laid down in that Regulation.]]		
(1) or [II.2.2.1 poultry that have remained in that territory since hatching or have been imported as day-old chicks or slaughter poultry from (a) third country(ies) listed for that commodity in Part 1 of Annex I to Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1), under conditions at least equivalent to those in that Regulation satisfying all the relevant animal health import requirements laid down in that Regulation and were slaughtered for human consumption on a date for which import into the Union of meat from animals of those species was authorised from the country or territory thereof in accordance with Column 6 B of Part 1 to Annex I to that Regulation.		
(1) or [II.2.2.1 animals that have been killed in the wild in that territory (5) and captured and killed in an area: (i) in which within 25 km there has been no case/outbreak of any of the following diseases for which the animals are susceptible: foot and mouth disease, rinderpest, Newcastle disease or highly pathogenic avian influenza during the prior 30 days, nor of classical or African swine fever during the prior 40 days, and (ii) that is situated at a distance that exceeds 20 km from the borders separating another territory of a country or part thereof, which is not authorised on these dates to export these raw materials into the Union, and (iii) in which after killing were transported within 12 hours for chilling either to a collection centre and immediately afterwards to a game-handling establishment, or directly to a game-handling establishment;]		
II.2.3. have been obtained in an establishment around which, within a radius of 10 km, there has been no case/outbreak of the following diseases that the animals are susceptible to: foot and mouth disease, rinderpest, Newcastle disease or highly pathogenic avian influenza, and classical or African swine fever during the prior 30 days or, in the event of a case of one of those diseases, the preparation of raw materials for export to the Union has been authorised only after the removal of all meat and the total cleaning and disinfection of the establishment under the control of an official veterinarian;		
II.2.4. have been obtained and prepared without contact with other materials that do not comply with the conditions required above, and have been handled so as to avoid contamination with pathogenic agents; and		
II.2.5. have been transported in clean and sealed containers or lorries.		
Notes		
See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101)		
Part I:		
— Box reference I.8: provide the code of territory as appearing in Part 1 of Annex I to Regulation (EC) No 798/2008 and/or in Part 1 of Annex I to Regulation (EC) No 119/2009 and/or Part 1 of Annex II to Regulation (EU) No 206/2010.		
— Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) such as 0206, 0207, 0208, 0302, 0303, 0305, 0505, 0506, 0511 91, 0511 99, 4101, 4102 or 4103.		
— Box reference I.25: <i>Nature of commodity:</i> hides, skins, bones, tendons and sinews; <i>Manufacturing plant:</i> includes slaughterhouse, factory vessel, cutting plant, game-handling establishment and processing plant.		

Model RCG

Raw materials for the production of collagen and gelatine intended for human consumption

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.
<p>Part II:</p> <p>(1) Delete as appropriate. In the case of products derived from fishery products, the whole section II.2 should be deleted.</p> <p>(2) The name and ISO code number of the exporting country or territory or zone as laid down in:</p> <ul style="list-style-type: none"> — the Annex II of Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18); — Annex I to Regulation (EC) No 798/2008; — Part 1 of Annex I to Regulation (EC) No 119/2009; — Part 1 of Annex II to Regulation (EC) No 206/2010. <p>(3) If parts of the materials were derived from animals originating from (an)other third country(ies) listed in Annex II to Regulation (EU) No 206/2010 for import of that commodity into the EU, then the code(s) of country(ies) or territory(ies) and of the third country slaughtering the animals shall be stated (the material cannot come from a country or territory that has supplementary guarantees A or F as indicated in column 5 of that Annex).</p> <p>(4) If the meat comes from slaughter poultry originating from an(other) third country(ies) listed in Part 1 of Annex I to Regulation (EC) No 798/2008 for imports of that commodity into the EU, then the code(s) of country(ies) or territory(ies) and of the third country slaughtering the poultry shall be stated.</p> <p>(5) Only for countries from where game meat intended for human consumption of the same animal species is authorised for importation into the Union.</p> <p>(6) The removal of specified risk material is not required if the raw materials derive from animals that are born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk.</p> <p>— The signature and the stamp must be in a different colour to that of the printing.</p> <p>NB Note for the person responsible for the consignment in the EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border control post. The consignment must be transported directly to the manufacturing plant of destination.</p>		
<p>Official veterinarian</p> <p>Name (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Qualification and title:</p> <p>Signature:</p>		

PART IX

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
TREATED RAW MATERIALS FOR THE PRODUCTION OF GELATINE AND COLLAGEN INTENDED FOR
HUMAN CONSUMPTION**

COUNTRY				Official certificate to the EU					
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name			I.2. Certificate reference No		I.2.a IMSOC reference No			
	Address			I.3. Central Competent Authority					
	Tel. No			I.4. Local Competent Authority					
	I.5. Consignee/Importer Name			I.6. Operator responsible for the consignment Name					
	Address			Address					
	Postal code			Postal code					
I.7. Country of origin			ISO	I.8. Region of origin		Code	I.9. Country of destination	ISO	I.10.
I.11 Place of dispatch Name Address			Approval No		I.12. Place of destination Name Address				
I.13. Place of loading				I.14. Date and time of departure					
I.15. Means of transport						I.16. Entry BCP			
Aeroplane <input type="checkbox"/>		Vessel <input type="checkbox"/>		Other <input type="checkbox"/>		I.17. Accompanying documents Type No			
Road vehicle <input type="checkbox"/>		Railway <input type="checkbox"/>							
Identification:									
I.18. Transport conditions									
Ambient <input type="checkbox"/>		Chilled <input type="checkbox"/>		Frozen <input type="checkbox"/>					
I.19. Container No/Seal No									

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods No Code and CN title				
Species (Scientific name) <input type="checkbox"/>	Number of packages	Nature of commodity Manufacturing plant Net weight	Batch No	Cold store Type of packaging

Model TCG

Treated raw materials for the production of gelatine and collagen intended for human consumption

COUNTRY

II. Health information

II.a. Certificate reference No

II.b.

II.1. Public health attestation

I, the undersigned, certify that the treated raw materials described above comply with the following requirements:

— they have been derived from establishments under the control of and listed by the competent authority,
and

— ⁽¹⁾ [bones, hides and skins of domestic and farmed ruminant animals, pigs and poultry described above are derived from animals which were slaughtered in a slaughterhouse and the carcasses of which were found to be fit for human consumption following ante- and post-mortem inspection,]

⁽¹⁾ and/or

— [wild game hides, skins and bones described above are derived from animals whose carcasses were found to be fit for human consumption following post-mortem inspection,]

⁽¹⁾ and/or

— [fish skins and bones described above are derived from plants that manufacture fishery products for human consumption which are authorised for export,]

and

⁽¹⁾ either

— [they are dried bones of species from bovine, ovine, caprine, porcine and equine animals, including farmed and wild animals, poultry including ratites and feathered game for the production of gelatine and collagen, and they are derived from healthy animals slaughtered in a slaughterhouse, and they have been treated as follows:

⁽¹⁾ either

— [crushed to pieces of approximately 15 mm and degreased with hot water at a minimum temperature of 70 °C for at least 30 minutes, a minimum of 80 °C for at least 15 minutes, or a minimum of 90 °C for at least 10 minutes; then separated and subsequently washed and dried for at least 20 minutes in a stream of hot air with an initial minimum temperature of 350 °C, or for 15 minutes in a stream of hot air with an initial temperature of over 700 °C,]

⁽¹⁾ or [sun-dried for a minimum of 42 days at an average temperature of at least 20 °C,]

⁽¹⁾ or [have undergone an acid treatment such that the pH is maintained at less than 6 to the core for at least one hour before drying,]

⁽¹⁾ or [if they are hides and skins of farmed ruminant animals, pig skins, poultry skins or wild game hides and skins, they are derived from healthy animals and they:

⁽¹⁾ either

— [have undergone an alkali treatment which ensures a PH> 12 to the core followed by salting for at least seven days,]

⁽¹⁾ or [were dried for at least 42 days at a temperature of at least 20 °C,]

⁽¹⁾ or [have undergone an acid treatment that provides at least a pH of less than 5 to the core for a minimum of one hour,]

⁽¹⁾ or [have undergone an alkali treatment which ensures a pH > 12 to the core for at least 8 hours,]]

⁽¹⁾ or [if they are bones, hides or skins of farmed ruminant animals, pig skins, poultry skins, fish skins and wild game hides and skins from third countries, parts of third countries or regions thereof referred to in Article 15 to Commission Implementing Regulation (EU) 2019/626 of 5 March 2019 concerning lists of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption, amending Implementing Regulation (EU) 2016/759 as regards these lists (OJ L 131, 17.5.2019, p. 31), that they have undergone any other treatment than those listed above, and that they come from establishments registered or approved in accordance with Regulation (EC) No 852/2004 or in accordance with Regulation (EC) No 853/2004,

Model TCG

Treated raw materials for the production of gelatine and collagen intended for human consumption

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.
<p>(¹) and, if of bovine, ovine and caprine animal origin,</p> <ul style="list-style-type: none"> — they are derived from animals which passed ante-mortem and post-mortem inspections, <p>(¹) and, except for hides and skins of ruminants,</p> <p>(¹) either</p> <ul style="list-style-type: none"> — [they come from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a negligible BSE risk, — they do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1) (⁴), — they do not contain and are not derived from mechanically separated meat obtained from the bones of bovine, ovine or caprine animals, except for treated raw materials derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there has been no BSE indigenous cases, — the animals, from which the treated raw materials are derived, were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk, — (¹) [the animals, from which the treated raw materials are derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and they have not been fed with meat-and-bone meal or greaves, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health]; — (¹) the animals, from which the treated raw materials are derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the products were produced and handled in a manner which ensures that they did not contain and were not contaminated with nervous and lymphatic tissues exposed during the deboning process.]] <p>(¹) or</p> <ul style="list-style-type: none"> — [they come from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a controlled BSE risk, — the animals, from which the treated raw materials of bovine, ovine and caprine animal origin destined for export are derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity, — the treated raw materials of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals,] <p>(¹) or</p> <ul style="list-style-type: none"> — [they come from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region with an undetermined BSE risk, — the animals from which the treated raw materials were derived have not been fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health, 		

Model TCG

Treated raw materials for the production of gelatine and collagen intended for human consumption

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.
<ul style="list-style-type: none"> — the animals, from which the treated raw materials of bovine, ovine and caprine animal origin are derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity, — the treated raw materials are not derived from: <ul style="list-style-type: none"> (i) specified risk material as defined in point 1 of Annex V of Regulation (EC) No 999/2001; (ii) nervous and lymphatic tissues exposed during the deboning process, (iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.]] 		
<p>II.2. Animal Health Attestation ⁽¹⁾</p> <p>I, the undersigned official veterinarian, certify that the treated raw materials described above:</p> <p>II.2.1. consist of animal products that satisfy the animal health requirements below,</p> <p>II.2.2. have been obtained in the country(ies) or region(s) thereof of ⁽¹⁾ [.....] ⁽¹⁾ or [.....] ⁽²⁾ ⁽³⁾,</p> <p>II.2.3. have been obtained and prepared without contact with other materials that do not comply with the conditions required above, and have been handled so as to avoid contamination with pathogenic agents,</p> <p>II.2.4. have been transported in clean and sealed containers or lorries.</p>		
<p>Notes</p>		
<p>See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).</p>		
<p>Part I:</p>		
<ul style="list-style-type: none"> — Box reference I.8: Provide the code of the territory as it appears in: <ul style="list-style-type: none"> — in Part 1 of Annex I to Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1); or — in Part 1 of Annex I to Commission Regulation (EC) No 119/2009 laying down a list of third countries or parts thereof, for imports into, or transit through, the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements (OJ L 39, 10.2.2009, p. 12); or — in Part 1 of Annex II to Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1). — Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) such as: 0210, 0305, 0505, 0506, 0511 91, 0511.99, 1602, 1604, 4101, 4102 or 4103. — Box reference I.25: <ul style="list-style-type: none"> <i>Nature of commodity:</i> hides, skins, bones, tendons and sinews; <i>Manufacturing plant:</i> includes slaughterhouse, factory vessel, cutting plant, game handling establishment and processing plant. <i>Approval number:</i> when applicable. 		

Model TCG

Treated raw materials for the production of gelatine and collagen
intended for human consumption

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.
<p>Part II:</p> <p>(¹) Delete as appropriate. In the case of products derived from fishery products, the whole section II.2 should be deleted.</p> <p>(²) The name and ISO code number of the exporting country or territory or zone as laid down in:</p> <ul style="list-style-type: none"> — Part 1 of Annex II to Regulation (EC) No 206/2010; — Annex I to Regulation (EC) No 798/2008; — Part 1 of Annex I to Regulation (EC) No 119/2009. <p>(³) If parts of the materials were derived from animals originating from an(other) third country(ies) or regions thereof listed Article 15 or 16 (only when treated as laid down in Part II.1) to Implementing Regulation (EU) 2019/626, the code(s) of country(ies) or region(s) shall be stated.</p> <p>(⁴) The removal of specified risk material is not required if the treated raw materials are derived from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk.</p> <ul style="list-style-type: none"> — The signature and the stamp must be in a different colour to that of the printing. <p>NB Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border control post. The consignment must be transported directly to the manufacturing plant of destination.</p> <ul style="list-style-type: none"> — The time of transportation may be included in the duration of treatment. 		
<p>Official veterinarian</p> <p>Name (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Qualification and title:</p> <p>Signature:</p>		

PART X

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
HONEY AND OTHER APICULTURE PRODUCTS INTENDED FOR HUMAN CONSUMPTION**

COUNTRY				Official certificate to the EU		
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No			I.2. Certificate reference No	I.2.a IMSOC reference No	
				I.3. Central Competent Authority		
				I.4. Local Competent Authority		
	I.5. Consignee/Importer Name Address Postal code Tel. No			I.6. Operator responsible for the consignment Name Address Postal code		
	I.7. Country of origin	ISO	I.8.	I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No	I.12. Place of destination Name Address		
	I.13. Place of loading			I.14. Date and time of departure		
	I.15. Means of transport Aeroplane <input type="checkbox"/> Vessel <input type="checkbox"/> Other <input type="checkbox"/> Road vehicle <input type="checkbox"/> Railway <input type="checkbox"/> Identification:			I.16. Entry BCP		
	I.18. Transport conditions Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>			I.17. Accompanying documents Type No		
	I.19. Container No/Seal No					

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods No Code and CN title				
Species (Scientific name)		Manufacturing plant		Treatment type
Final consumer	Number of packages	Net weight	Batch No	Cold store
<input type="checkbox"/>				Type of packaging

Model HON

COUNTRY

Honey and other apiculture products intended for human consumption

II. Health information

II.a. Certificate reference No

II.b.

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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), and

I certify that honey and other apiculture products described above were produced in accordance with these requirements, in particular that they:

- come from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;
- have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004; and
- fulfil the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10), and in particular Article 29 thereof.

Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

Part I:

- Box reference I.11: place of dispatch: Approval number means registration number.
- Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) using headings such as: 0409, 0410, 0510, 1521, 1702 or 2106.
- Box reference I.25: *Treatment type*: state 'ultrasonication', 'homogenisation', 'ultrafiltration', 'pasteurisation', 'no thermal treatment'.

Part II:

- The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official inspector

Name (in capital letters):

Qualification and title:

Date:

Signature:

Stamp:

Part II: Certification

PART XI

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
HIGHLY REFINED CHONDROITIN SULPHATE, HYALURONIC ACID, OTHER HYDOLYSED CARTILAGE
PRODUCTS, CHITOSAN, GLUCOSAMINE, RENNET, ISINGLASS AND AMINO ACIDS INTENDED FOR
HUMAN CONSUMPTION**

COUNTRY				Official certificate to the EU		
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name			I.2. Certificate reference No	I.2.a IMSOC reference No	
	Address			I.3. Central Competent Authority		
	Tel. No			I.4. Local Competent Authority		
	I.5. Consignee/Importer Name			I.6. Operator responsible for the consignment Name		
	Address			Address		
	Postal code			Postal code		
Tel. No						
I.7. Country of origin	ISO	I.8.	I.9. Country of destination	ISO	I.10.	
I.11 Place of dispatch Name Address		Approval No	I.12. Place of destination Name Address			
I.13. Place of loading			I.14. Date and time of departure			
I.15. Means of transport				I.16. Entry BCP		
Aeroplane <input type="checkbox"/>	Vessel <input type="checkbox"/>	Other <input type="checkbox"/>		I.17. Accompanying documents Type No		
Road vehicle <input type="checkbox"/>	Railway <input type="checkbox"/>					
Identification:						
I.18. Transport conditions						
Ambient <input type="checkbox"/>	Chilled <input type="checkbox"/>	Frozen <input type="checkbox"/>				
I.19. Container No/Seal No						

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods No Code and CN title				
Species (Scientific name) Final consumer Number of packages <input type="checkbox"/>		Manufacturing plant Net weight Batch No		Cold store Type of packaging

Model HRP

Highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids intended for human consumption

COUNTRY

II. Health information

II.a. Certificate reference No

II.b.

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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), and

I certify that the highly refined products described above were produced in accordance with these requirements, in particular:

- that they come from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;
- that they have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004;
- that they comply with the requirements of Section XVI of Annex III to Regulation (EC) No 853/2004; and
- ⁽¹⁾ if amino acids, that
 - (i) human hair was not used as a source for their manufacture; and
 - (ii) that they comply with Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ((OJ L 354, 31.12.2008, p. 16).

Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

Part I:

- Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) using headings such as 2833, ex 3913, 2930, ex 2932, 3507 or 3503.

Part II:

⁽¹⁾ Delete as appropriate.

- The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian

Name (in capital letters):

Qualification and title:

Date:

Signature:

Stamp:

PART XII

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
REPTILE MEAT INTENDED FOR HUMAN CONSUMPTION**

COUNTRY				Official certificate to the EU		
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No			I.2. Certificate reference No	I.2.a IMSOC reference No	
				I.3. Central Competent Authority		
				I.4. Local Competent Authority		
	I.5. Consignee/Importer Name Address Postal code Tel. No			I.6. Operator responsible for the consignment Name Address Postal code		
	I.7. Country of origin	ISO	I.8.	I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No	I.12. Place of destination Name Address		
	I.13. Place of loading			I.14. Date and time of departure		
	I.15. Means of transport Aeroplane <input type="checkbox"/> Road vehicle <input type="checkbox"/> Identification:		Vessel <input type="checkbox"/> Railway <input type="checkbox"/>	Other <input type="checkbox"/>	I.16. Entry BCP	
	I.18. Transport conditions Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>		I.17. Accompanying documents Type No			
	I.19. Container No/Seal No					

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods No Code and CN title				
Species (Scientific name) Final consumer Number of packages <input type="checkbox"/>		Manufacturing plant Net weight Batch No		Cold store Type of packaging

COUNTRY

Reptile Meat intended for human consumption

II. Health information

II.a. Certificate reference No

II.b.

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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), and

I certify that the reptile meat described above was produced in accordance with these requirements, in particular:

- that the reptile meat comes from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;
- that the reptile meat has been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004;
- that *Salmonella* has been controlled in the reptile meat using sampling and testing procedures providing at least equivalent guarantees as the requirements once laid down in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1);
- that the reptile meat is obtained from animals that have satisfactorily undergone ante-mortem and post-mortem inspection laid down in Article 73 of Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51);
- ⁽¹⁾ if crocodile or alligator meat, that the carcass has been tested negative during post-mortem inspection for the presence of *Trichinella* spp. in accordance with Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for *Trichinella* in meat (OJ L 212, 11.8.2015, p. 7); and
- that, when applicable, the food has been authorised on the Union market in accordance with Article 6 of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1) and listed in the Union list of novel foods.

Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

Part I:

- Box reference I.25: Insert the appropriate HS/CN code(s) such as 0208 50 00, 0210 93 00, 1506, 1601, 1602 or 1603.

COUNTRY

Reptile Meat intended for human consumption

II. Health information	II.a. Certificate reference No	II.b.						
<p>Part II:</p> <p>(¹) Delete as appropriate.</p> <p>— The colour of the stamp and signature must be different from that of the other particulars in the certificate.</p>								
<p>Official veterinarian</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 60%;">Name (in capital letters):</td> <td style="width: 40%;">Qualification and title:</td> </tr> <tr> <td>Date:</td> <td>Signature:</td> </tr> <tr> <td>Stamp:</td> <td></td> </tr> </table>			Name (in capital letters):	Qualification and title:	Date:	Signature:	Stamp:	
Name (in capital letters):	Qualification and title:							
Date:	Signature:							
Stamp:								

PART XIII

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
INSECTS INTENDED FOR HUMAN CONSUMPTION**

COUNTRY				Official certificate to the EU		
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No			I.2. Certificate reference No	I.2.a IMSOC reference No	
				I.3. Central Competent Authority		
				I.4. Local Competent Authority		
	I.5. Consignee/Importer Name Address Postal code Tel. No			I.6. Operator responsible for the consignment Name Address Postal code		
	I.7. Country of origin	ISO	I.8.	I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No	I.12. Place of destination Name Address		
	I.13. Place of loading			I.14. Date and time of departure		
	I.15. Means of transport Aeroplane <input type="checkbox"/> Road vehicle <input type="checkbox"/> Identification:		Vessel <input type="checkbox"/> Railway <input type="checkbox"/>	Other <input type="checkbox"/>	I.16. Entry BCP	
	I.18. Transport conditions Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.17. Accompanying documents Type No	
	I.19. Container No/Seal No					

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>				
I.21.		I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)	
I.25. Description of goods No Code and CN title				
Species (Scientific name) Final consumer Number of packages <input type="checkbox"/>		Cutting plant/manufacturing plant Net weight Batch No		Cold store Type of packaging

COUNTRY

Model Insects intended for human consumption

II. Health information

II.a. Certificate reference No

II.b.

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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)), and

I certify that the insects described above were produced in accordance with these requirements, in particular:

- that they come from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;
- that they have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex I (primary producing) or Annex II (other stages) to Regulation (EC) No 852/2004;
- that they comply with the requirements once laid down in Section XVII of Annex III to Regulation (EC) No 853/2004, including as regards the use of substrates for feeding;
- when applicable, the food has been authorised on the Union market in accordance with Article 6 of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1) and listed in Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel food (OJ L 351, 30.12.2017, p. 72).

Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

Part I:

- Box reference I.25: Insert the appropriate HS/CN code(s) such as 0106 49 00, 0410 or 2106.

Part II:

(¹) Delete as appropriate

- Box II.1 a programme based on the HACCP principles is not required if the products come directly from a primary producer.
- The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian

Name (in capital letters):

Qualification and title:

Date:

Signature:

Stamp:

PART XIV

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
OTHER PRODUCTS OF ANIMAL ORIGIN INTENDED FOR HUMAN CONSUMPTION NOT COVERED BY
ARTICLES 7 TO 25 OF COMMISSION IMPLEMENTING REGULATION (EU) 2019/628**

COUNTRY				Official certificate to the EU			
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name		I.2. Certificate reference No		I.2.a IMSOC reference No		
	Address		I.3. Central Competent Authority				
	Tel. No		I.4. Local Competent Authority				
	I.5. Consignee/Importer Name		I.6. Operator responsible for the consignment Name				
	Address		Address				
	Postal code		Postal code				
I.7. Country of origin		ISO	I.8.		I.9. Country of destination	ISO	I.10.
I.11 Place of dispatch Name Address		Approval No		I.12. Place of destination Name Address			
I.13. Place of loading				I.14. Date and time of departure			
I.15. Means of transport				I.16. Entry BCP			
Aeroplane <input type="checkbox"/>		Vessel <input type="checkbox"/>		I.17. Accompanying documents			
Road vehicle <input type="checkbox"/>		Railway <input type="checkbox"/>		Type			
Identification:				No			
I.18. Transport conditions							
Ambient <input type="checkbox"/>		Chilled <input type="checkbox"/>		Frozen <input type="checkbox"/>			
I.19. Container No/Seal No							

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>			
I.21.	I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)
I.25. Description of goods No Code and CN title			
Species (Scientific name) Final consumer Number of packages <input type="checkbox"/>	Manufacturing plant Net weight Batch No		Cold store Type of packaging

Model PAO

Other Products of Animal Origin not covered by Articles 7 to 25 of Commission Implementing Regulation (EU) 2019/628 intended for human consumption

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.
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Part II: Certification

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and 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), and

I certify that the products described above were produced in accordance with these requirements, in particular:

- that they come from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;
- that they have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004.

Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

Part I:

- Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) of the World Customs Organisation.

Part II:

- The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian

Name (in capital letters):

Qualification and title:

Date:

Signature:

Stamp:

PART XV

**MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF
SPROUTS AND SEEDS INTENDED FOR THE PRODUCTION OF SPROUTS**

COUNTRY				Official certificate to the EU		
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No			I.2. Certificate reference No	I.2.a IMSOC reference No	
				I.3. Central Competent Authority		
				I.4. Local Competent Authority		
	I.5. Consignee/Importer Name Address Postal code Tel. No			I.6. Operator responsible for the consignment Name Address Postal code		
	I.7. Country of origin	ISO	I.8.	I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No	I.12. Place of destination Name Address		
	I.13. Place of loading			I.14. Date and time of departure		
	I.15. Means of transport Aeroplane <input type="checkbox"/> Vessel <input type="checkbox"/> Other <input type="checkbox"/> Road vehicle <input type="checkbox"/> Railway <input type="checkbox"/> Identification:			I.16. Entry BCP		
	I.18. Transport conditions Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>			I.17. Accompanying documents Type No		
	I.19. Container No/Seal No					

COUNTRY

Official certificate to the EU

I.20. Goods certified as Human consumption <input type="checkbox"/>			
I.21.	I.22.		
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)
I.25. Description of goods No Code and CN title			
Species (Scientific name) Final consumer Number of packages <input type="checkbox"/>	Manufacturing plant Net weight Batch No		Cold store Type of packaging

Certificate for the entry into the Union for placing on the market of sprouts and seeds intended for the production of sprouts

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.
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I, the undersigned official inspector, hereby declare that I am aware of the relevant provisions of Regulation (EC) No 852/2004 and certify that:

- II.1.1. (1) the seeds described above were produced under conditions which comply with Regulation (EC) No 852/2004 and in particular with the general hygiene provisions for primary production and associated operations set out in Part A of Annex I thereto;
- II.1.2. (1) the sprouts were produced in establishments approved in accordance with the requirements laid down in Article 2 of Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council (OJ L 68, 12.3.2013, p. 24);
- II.1.3. (1) the sprouts were produced under conditions which comply with the traceability requirements laid down in Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 16) and respect the microbiological criteria laid down in Annex I to Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

Part I:

- Box reference I.25: Insert the appropriate HS code(s) such as: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90, 0713 10, 0713 33, 0712 34, 0712 35, 0713 39, 0713 40, 0712 50, 0712 60, 0713 90, 0910 99, 1201 10, 1201 90, 1207 50, 1207 99, 1209 10, 1209 21, 1209 91 or 1214 90.
- Box reference I.25: Manufacturing plant: insert the name of the establishments which produced the sprouts or seeds.

Part II:

- (1) Delete as appropriate (e.g. if sprouts or seeds).
- The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those that are embossed or are a watermark.

Official inspector

Name (in capital letters):

Qualification and title:

Date:

Signature:

Stamp:

Part II: Certification

ANNEX IV

**MODEL OFFICIAL CERTIFICATES IN THE CASE OF ANTE-MORTEM INSPECTION AT THE HOLDING OF
PROVENANCE**

Part I: MODEL OFFICIAL CERTIFICATE FOR LIVE ANIMALS

OFFICIAL CERTIFICATE

*for live animals transported to the slaughterhouse in the case of ante-mortem inspection at the
holding of provenance in accordance with Article 5(2)(f) of Commission Delegated
Regulation (EU) 2019/624 ⁽¹⁾.*

Name of the official veterinarian:

No:

1. Identification of the animals

Species:

Number of animals:

Identification marking:

2. Provenance of the animals

Address of holding of provenance:

Identification of house (*):

3. Destination of the animals

The animals will be transported to the following slaughterhouse:

.....

by the following means of transport:

4. Other relevant information

.....

5. Declaration

I, the undersigned, declare that:

— the animals described above were examined before slaughter at the above-mentioned holding
at (time) on (date) and were found to be fit for slaughter,

— the following observations on the health and welfare of animals were made:

— the records and documentation concerning these animals satisfied the legal requirements and do not prohibit the
slaughter of the animals,

— I verified the food chain information

Done at:

(Place)

on:

(Date)

Stamp

.....

(Signature of official veterinarian)

(*) optional

⁽¹⁾ Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

Part II: MODEL OFFICIAL CERTIFICATE FOR POULTRY INTENDED FOR THE PRODUCTION OF FOIE GRAS AND DELAYED EVisCERATED POULTRY

OFFICIAL CERTIFICATE

for poultry intended for the production of foie gras and delayed eviscerated poultry slaughtered at the holding of provenance in accordance with Article 6(2) of Commission Delegated Regulation (EU) 2019/624 (1).

Name of the official veterinarian:

No:

1. Identification of uneviscerated carcasses

Species:

Number:

2. Provenance of uneviscerated carcasses

Address of holding:

3. Destination of uneviscerated carcasses

The uneviscerated carcasses will be transported to the following cutting plant:

4. Declaration

I, the undersigned, declare that:

- the uneviscerated carcasses described above are of birds which were examined before slaughter on the above-mentioned holding at (time) on (date) and found to be fit for slaughter;
- the following observations on the health and welfare of animals were made:
- the records and documentation concerning these animals satisfied the legal requirements and did not prohibit the slaughter of the birds

Done at:

(Place)

on:

(Date)

Stamp

.....

(Signature of official veterinarian)

(1) Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

Part III: MODEL OFFICIAL CERTIFICATE FOR FARMED GAME SLAUGHTERED AT THE HOLDING OF PROVENANCE

OFFICIAL CERTIFICATE

for farmed game slaughtered at the holding in accordance with Article 6(3) of Commission Delegated Regulation(EU) 2019/624 (1).

Name of the official veterinarian:

No:

1. Identification of the animals

Species:

Number of animals:

Identification marking:

2. Provenance of the animals

Address of holding of provenance:

Identification of house (*):

3. Destination of the animals

The animals will be transported to the following slaughterhouse:

.....

by the following means of transport:

4. Other relevant information

.....

5. Declaration

I, the undersigned, declare that:

(1) the animals described above were examined before slaughter at the above-mentioned holding at (time) on (date) and were found to be fit for slaughter,

(2) they were slaughtered at the holding at (time) on (date) and the slaughter and bleeding were carried out correctly,

(3) the following observations on the health and welfare of animals were made:

(4) the records and documentation concerning these animals satisfied the legal requirements and did not prohibit the slaughter of the animals.

Done at:

(Place)

on:

(Date)

Stamp

.....

(Signature of official veterinarian)

(* optional)

(1) Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

Part IV: MODEL OFFICIAL CERTIFICATE FOR FARMED GAME SLAUGHTERED AT THE HOLDING in accordance with point 3a of Section III of Annex III to Regulation (EC) No 853/2004

OFFICIAL CERTIFICATE

For farmed game slaughtered on the holding in accordance with point 3a of Section III of Annex III to Regulation (EC) No 853/2004 and Article 6(4) of Commission Delegated Regulation (EU) 2019/624 (1).

Name of the official veterinarian:

No:

1. Identification of the animals

Species:

Number of animals:

Identification marking:

2. Provenance of the animals

Address of holding of provenance:

Identification of house (*):

3. Destination of the animals

The animals will be transported to the following slaughterhouse:

.....

by the following means of transport:

4. Other relevant information

.....

5. Declaration

I, the undersigned, declare that:

(1) the animals described above were examined before slaughter at the above-mentioned holding at (time) on (date) and were found to be fit for slaughter,

(2) the following observations on the health and welfare of animals were made:

(3) the records and documentation concerning these animals satisfied the legal requirements and did not prohibit the slaughter of the animals.

Done at:

(Place)

on:

(Date)

Stamp

.....

(Signature of official veterinarian)

(* optional

(1) Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

ANNEX V

MODEL OFFICIAL CERTIFICATE IN THE CASE OF EMERGENCY SLAUGHTER OUTSIDE THE SLAUGHTERHOUSE IN ACCORDANCE WITH ARTICLE 4 OF COMMISSION DELEGATED REGULATION (EU) 2019/624 ⁽¹⁾

MODEL OFFICIAL CERTIFICATE IN THE CASE OF EMERGENCY SLAUGHTER OUTSIDE THE SLAUGHTERHOUSE

OFFICIAL CERTIFICATE

In the case of emergency slaughter outside the slaughterhouse

Name of the official veterinarian:

No:

1. Identification of the animals

Species:

Number of animals:

Identification marking:

2. Place of emergency slaughter

Address:

Identification of house (*):

3. Destination of the animals

The animals will be transported to the following slaughterhouse:

.....

by the following means of transport:

4. Other relevant information

.....

5. Declaration

I, the undersigned, declare that:

(1) the animals described above were examined before slaughter at the above-mentioned holding at (time) on (date) and were found to be fit for slaughter,

(2) they were slaughtered at (time) on (date) and the slaughter and bleeding were carried out correctly,

(3) the following was the reason for the emergency slaughter:

(4) the following observations on the health and welfare of animals were made:

(5) The following treatments were administered to the animal(s):

(6) the records and documentation concerning these animals satisfied the legal requirements and did not prohibit the slaughter of the animals.

Done at:

(Place)

on:

(Date)

Stamp

.....

(Signature of official veterinarian)

(*) optional

⁽¹⁾ Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

ANNEX VI

CORRELATION TABLE REFERRED TO IN ARTICLE 32

Regulation (EU) No 211/2013	This Regulation
Article 1	Article 1(2)(b)(ii)
Article 2	Article 2(2)
Article 3	Article 27
Article 4	—
Article 5	—
Annex	Part XV of Annex III

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