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COMMISSION DELEGATED REGULATION (EU) .../...

of XXX

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)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

DRAFT

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EXPLANATORY MEMORANDUM

1. LEGAL CONTEXT OF THIS DELEGATED REGULATION

Regulation (EU) 2017/625 of the European Parliament and of the Council¹ lays down rules for the performance of official controls and other control activities by the competent authorities of the Member States, in particular in relation to the production of products of animal origin intended for human consumption.

This draft Delegated Regulation supplements Regulation (EU) 2017/625 concerning official controls related to the production of meat (meat inspection) and for the production and relaying areas of *Pectinidae*, marine gastropods and *Holothuroidea*.

In principle, meat inspections are carried out by the official veterinarian. This Delegated Regulation provides for a derogation from the basic requirements laid down in Regulation (EU) 2017/625, and is intended to establish the criteria and conditions for certain tasks relating to meat inspections in slaughterhouses and official controls in game-handling establishments and cutting plants, to be carried out by official auxiliaries or other staff designated by the competent authorities under the supervision or under the responsibility of the official veterinarian. It also lays down:

- the criteria and conditions for the performance of ante-mortem inspections outside the slaughterhouse;
- the criteria and conditions for the performance of post-mortem inspections by the official veterinarian in the case of emergency slaughter;
- the specific requirements for official veterinarians, official auxiliaries and other staff designated by the competent authorities;
- the training required of slaughterhouse staff in order to perform certain inspection tasks.

This Delegated Regulation also lays down further derogations concerning official controls for the production of meat from reindeer and grouse in order to continue longstanding local and traditional practices already notified to and favourably assessed by the Commission and the Member States.

In principle, competent authorities must classify production and relaying areas where live bivalve molluscs are harvested. This Delegated Regulation is intended to establish, by way of derogation from the basic requirements laid down in Regulation (EU) 2017/625, the criteria and conditions under which the production and relaying areas of *Pectinidae*, marine gastropods and *Holothuridea* are not to be classified.

¹ 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, 60/425/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).

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THIS DELEGATED REGULATION

The question of who should perform meat inspections was discussed at length during the negotiations with the Council and the European Parliament concerning Regulation (EU) 2017/625 at all stages of the ordinary legislative procedure.

Nevertheless, the Commission invited representatives of the European Parliament and the Member States to participate in expert group meetings during the preparation of this draft Delegated Regulation.

In addition, private stakeholders' organisations were consulted within the framework of the Advisory Group on the Food Chain and Animal and Plant Health.

Finally, before adopting this Delegated Regulation the Commission conducted public consultations in an open and transparent way in accordance with the procedures laid down in the Interinstitutional Agreement on Better Law-Making².

No impact assessment has been carried out, as the Delegated Regulation is not expected to have any significant additional impact compared to the current rules laid down in Regulation (EC) No 854/2004. Although this Delegated Regulation fixes criteria and conditions under which the official veterinarian need not be present and certain official control tasks can be carried out by official auxiliaries or other staff designated by the competent authorities, these mostly reflect current practices and principles and rules already laid down in Regulation (EU) 2017/625. These practices and principles would thus remain unchanged as:

- they are the common, efficient practices that have proven successful for a number of years and guarantee a proper check of health and welfare of animals as well as a sound basis for ensuring the protection of human health;
- they are accepted and used worldwide and any reduction of the control pressure (perceived from our trade partners) would be detrimental to the Union's ability to export products of animal origin for human consumption that have undergone these controls;
- taking into account the aim of equality of treatment applied to imported products of animal origin for human consumption, a change could lead to increased risks for public and animal health in the European Union and would negatively affect the objectives of this initiative.

The outcome of the discussions on Regulation (EU) 2017/625 at the level of Council and of the Parliament clearly indicated the need for such a conservative approach. This was shown, for example, by that Regulation establishing the conditions for the involvement of slaughterhouse staff.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Adopting a Commission Delegated Regulation pursuant to Article 18(7) of Regulation (EU) 2017/625 is also necessary, as Regulation (EU) 2017/625 repeals Regulation (EC) No 854/2004³, which currently lays down specific rules for the organisation of official controls on products of animal origin, with effect from 14 December 2019.

² http://ec.europa.eu/smart-regulation/better_regulation/documents/iaa_blm_final_en.pdf.

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).

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(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, 60/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)⁴, 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 Council⁵, Regulation (EC) No 853/2004 of the European Parliament and of the Council⁶, Regulation (EC) No 1069/2009 of the European Parliament and of the Council⁷ and Council Regulation (EC) No 1099/2009⁸.

⁴ OJ L 95, 7.4.2017, 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).

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

⁸ 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).

- (2) Regulation (EU) 2017/625 repeals Regulation (EC) No 854/2004 of the European Parliament and of the Council⁹ with effect from 14 December 2019. Regulation (EC) No 854/2004 currently lays down specific rules 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 are not affected, 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

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).

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, 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 discontinued slaughter in low-capacity slaughterhouses and game-handling establishments.
- (10) When derogating from the basic requirements on ante-mortem and post-mortem inspection in slaughterhouses and game-handling establishments, criteria and conditions need to be defined. 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 is different in Member States, this 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. 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 harmonize 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 authority 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 *Holothuridea*, when production and relaying areas need not be classified. These criteria and conditions should be established and should include data from official monitoring programmes on fishing grounds.
- (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 for 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) 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 area 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;
- (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) 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 Council¹⁰, 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 relaying area as defined in point 2.6 of Annex I of Regulation (EC) No 853/2004;
- (5) 'staff designated by the competent authority' 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 authority assigns 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 Council¹¹
- (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 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)

¹¹ 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).

- (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' 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.
- (16) 'establishment' means an establishment as defined in Article 2(c) of Regulation (EC) No 852/2004;
- (17) 'Low-capacity slaughterhouse' means a slaughterhouse designated by the competent authority on the basis of a risk analysis, in which the slaughter activities do not take place during the entire working day or on consecutive working days of the week.
- (18) 'Low-capacity game-handling establishment' means a game-handling establishment designated by the competent authority on the basis of a risk analysis, in which the game handling activities do not take place during the entire working day or on consecutive working days 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(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 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/EEC¹² 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 Animal Health Organisation.

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) [SANTE/10281/2018]¹³ 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;

¹² 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).

¹³ Commission Implementing Regulation (EU) .../... of .../... laying down model official certificates for certain animals and goods and amending Implementing Regulation (EU) 2016/759 as regards model certificates (OJ L ..., .../.../..., p.)

- (ii) they show general behavioural disturbance, signs of disease or abnormalities which may make the meat of such animals unfit for human consumption;
 - (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) [SANTE/10281/2018] 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 3 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) [SANTE/10194/2017]¹⁴.

¹⁴ Commission Implementing Regulation (EU) .../... of .../... 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 (OJ L ..., .../..., p. ...)

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 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) [SANTE/10281/2018], accompanying the uneviscerated carcasses to the slaughterhouse or cutting plant or be sent in advance in any format, shall be used 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) [SANTE/10281/2018] 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) [SANTE/10281/2018] 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.
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;
- (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;
 - (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 Council Directive 64/432/EEC;
- (f) when stricter controls are necessary to take account of emerging diseases or particular diseases listed by the World Animal Health Organisation;
- (g) in case of derogation on the timing of post-mortem inspection in accordance with Art 13 of Implementing Regulation (EU) [SANTE/10194/2017].

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 and 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 and colostrum 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 paragraph 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,

*For the Commission
The President
Jean-Claude JUNCKER*

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