

Non-paper in view of a possible delegated act based on Article 18(7) of Regulation (EU) 2017/625 (Official Control Regulation)

Revision dated 20 September 2017

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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 concerns notably official controls related to the production of meat (meat inspection) and for the production and relaying areas of live bivalve molluscs.

In principle, meat inspections are carried out by the official veterinarian. 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 for certain tasks relating to meat inspections in slaughterhouses, and official controls in cutting plants, to be carried out by official auxiliaries or other staff of the competent authorities under the supervision or under the responsibility of the official veterinarian. It will also lay down the criteria and conditions for the performance of ante-mortem inspections outside the slaughterhouse, and post-mortem inspections in the case of emergency slaughter, and the specific requirements for staff of competent authorities, official auxiliaries and slaughterhouse staff to perform certain inspection tasks.

Further derogations are laid down concerning official controls for the production of meat from reindeer and snared grouse.

Finally, for certain molluscs (*Pectinidae*, marine gastropods and *Holothuridea*), it will establish the criteria and conditions for derogations from the classification requirement for production and relaying areas laid down in Regulation (EU) 2017/625 .

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THIS DELEGATED REGULATION

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

Nevertheless, the Commission invited representatives of the European Parliament and the Member States to participate in working 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.

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) 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, 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).

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

No impact assessment has been carried out, as no significant impacts are expected compared to the current rules laid down in existing Union legislation. Though this Delegated Regulation fixes criteria and conditions when the official veterinarian need not be present and when certain official control tasks are being carried out by official auxiliaries or other staff of the competent authorities, most of those reflect current practices today and would thus remain unchanged as:

- they are the common efficient practices that have proven successful during 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 public 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 the public and animal health in the European Union and would negatively affect the objectives of the 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, as shown, for example, by the establishment of the conditions for the involvement of slaughterhouse staff in the rules laid down in that Regulation .

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This initiative for the adoption of 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/iia_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)

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)

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, 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,

(Text with EEA relevance)

[Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other control activities by the competent authorities of the Member States performed in order to verify compliance with Union legislation in the area of, inter alia, food safety at all stages of the production, processing and distribution process. In particular, it provides for official controls to be performed in relation to 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

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).

- (2) In addition 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, (EC) No 853 and (EC) No 1069/2009.. It also provides the possibility to grant certain derogations from those requirements.
- (3) 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 as regards ante-mortem and post-mortem inspections, for the performance of those inspections under the responsibility of the official veterinarian, instead of by the official veterinarian or under his supervision, and for derogations from the classification of areas for the production and relaying of *Pectinidae*, marine gastropods and *echinoderms*, and to allow official controls by staff designated by the competent authorities in cutting plants. Regulation (EU) 2017/625 also provides for rules to be laid down for specific derogations concerning official controls in respect to *Rangifer tarandus tarandus* (reindeer), *Lagopus lagopus* and *Lagopus mutus* (grouse), and for specific minimum requirements for the staff of the competent authorities and for the official veterinarians and for official auxiliaries, and for minimum training requirements for slaughterhouse staff assisting in the performance of tasks related to official controls and certain other control activities.
- (4) The rules laid down in this Regulation should ensure a continuation or smooth transition from 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.
- (5) While ante-mortem inspections are essential for the protection of public health, animal health and animal welfare and therefore should remain the responsibility of the official veterinarian, certain routine tasks may be carried out by the official auxiliary without jeopardising these objectives if certain criteria and conditions are complied with in species other than poultry and lagomorphs. In poultry and lagomorphs, routine tasks may be performed by the official auxiliary under the supervision of the official veterinarian in all cases in accordance with Article 18(2)(b) of Regulation (EU) 2017/625.
- (6) In the event of emergency slaughter, ante-mortem inspections cannot be carried out in the slaughterhouse. However, animals subject to emergency slaughter may still be fit for human consumption subject to a favourable meat inspection. In order to allow the continuation of current practices and limit economic losses for operators, criteria and

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).

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)

conditions should be laid down permitting ante-mortem inspections to be performed outside the slaughterhouse in the event of emergency slaughter.

- (7) In certain species, it is more efficient to evaluate public 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 subject to certain criteria, and in addition criteria should be established for ante-mortem inspections to be performed at the holding of provenance.
- (8) While post-mortem inspections and auditing are essential for the protection of public health, animal health and animal welfare and therefore should remain the responsibility of the official veterinarian, certain routine tasks may be carried out by the official auxiliary without jeopardising 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 small slaughterhouses.
- (9) Ante-mortem inspections might not be performed under optimal conditions in the event of emergency slaughter outside the slaughterhouse. In addition animal subjected to emergency slaughter may represent a higher risk for public health, animal health and animal welfare than animals subjected to routine slaughter. Due to this enhanced risk, post-mortem inspections should therefore always be carried out by the official veterinarian personally in the event of emergency slaughter and it is not appropriate to lay down additional criteria and conditions for such an obligation.
- (10) Official controls on the production of bivalve molluscs are necessary to ensure compliance with the criteria and targets laid down in Union legislation. Official controls on the production of live bivalve molluscs should, in particular, target relaying and production areas for bivalve molluscs and the end product, including criteria and conditions which do not require the classification of production and relaying areas for *Pectinidae*, marine gastropods and *Holothuroidea*.
- (11) Specific derogations from certain requirements for official controls on the meat of *Rangifer tarandus tarandus* (reindeer) by national measures have been notified by Sweden and Finland to the Commission and to the other Member States. In accordance with Regulation (EC) No 854/2004, Member States were allowed to adopt national measures with the aim of enabling the continued use of traditional methods or to accommodate to the needs of food business with a low throughput or that are situated in regions that are subject to special geographic constraints. 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.
- (12) While official controls in cutting plants are essential for the protection of public health and animal health and therefore should remain the responsibility of the official veterinarian, certain routine tasks may be carried out by the official auxiliary without jeopardising these objectives if certain criteria and conditions are complied with.
- (13) In order to maintain high and adequate performance of their tasks and therefore a high level of protection of consumers, of animal health and of animal welfare, specific minimum requirements for staff of the competent authorities and for official

veterinarians and official auxiliaries should be laid down, including specific minimum training requirements.

- (14) In order to maintain high and adequate performance, appropriate minimum training requirements should be laid down for slaughterhouse staff, assisting in the performing of tasks related to official controls and other official control activities laid down in the Regulation.]

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 in order to verify compliance with the requirements of Regulations (EC) No 852/2004, (EC) No 853/2004, (EC) No 1069/2009 and (EC) No 1099/2009. Those specific rules cover:

- a. criteria and conditions for derogations from Article 18(2) of Regulation (EU) 2017/625 on official controls in relation to the production of meat
- b. official controls on wild Pectinidae and marine gastropods and Holothuroidea, which are not filter feeders, harvested outside classified in production areas;
- c. specific derogations for Sweden and Finland in respect of *Rangifer tarandus tarandus*, *Lagopus lagopus* and *Lagopus mutus*;
- d. specific minimum requirements for the official veterinarian, the official auxiliaries and the staff of the competent authorities;
- e. minimum training requirements for slaughterhouse staff.

Article 2

Definitions

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

1. 'Official auxiliary' means a person qualified in accordance with this Regulation, to act in such a capacity, appointed by the competent authority and working under the supervision or responsibility of an official veterinarian in slaughterhouses or game handling establishments related to ante-mortem or post-mortem inspection. *For discussion. For info: Definition OA in R 854/2004: "OA means a person qualified in accordance with this Regulation, to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian."*
2. 'Staff designated by the competent authority' means a person qualified in accordance with this Regulation, to act in such a capacity, appointed by the competent authority

and working under the supervision or responsibility of an official veterinarian when carrying out tasks others than those of the official auxiliary.

3. The definitions laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council¹⁰;
4. The definitions laid down in Regulation (EC) No 852/2004, except for the definition of 'competent authority';
5. The definitions laid down in 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 by way of derogation from the requirements laid down in Article 18(2)(a) of Regulation (EU) 2017/625

- (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 in a slaughterhouse under the supervision of the official veterinarian on species other than poultry and lagomorphs, provided that the tasks within ante-mortem inspections:
 - (a) only concern the verification of the animal's identification and the of food chain information, and no abnormalities have been found during the screening of the animals to ascertain welfare rules;
 - and
 - (b) are purely practical.
- (2) By way of derogation from Article 18(2)(a) of Regulation (EU) 2017/625, ante-mortem inspections may be performed by an official auxiliary in a slaughterhouse under the responsibility of the official veterinarian, provided that:
 - (a) an initial ante-mortem inspection has already been carried out by the official veterinarian at the holding of provenance in accordance with paragraph 4;
 - (b) the tasks only concern the control of animal's identification and the checking of the food chain information and the health certificate accompanying the animals, and no abnormalities have been found during the screening of animals to ascertain welfare rules;
 - (c) the animals are slaughtered on the day of arrival in the slaughterhouse;
 - and
 - (d) the official veterinarian regularly verifies that the official auxiliary is carrying out his/her tasks properly.
- (3) The flexibility provided for in Paragraph (2) does not apply:
 - (a) to animals that have undergone emergency slaughter;
 - (b) to animals suspected of having a disease or condition that may adversely affect human health;

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).

- (c) to bovine animals from herds that have not been declared officially free of tuberculosis;
- (d) to bovine, ovine and caprine animals from herds that have not been declared officially free of brucellosis;
- (e) in the case of an 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 of Council Directive 64/432/EEC (8);
- (f) when stricter controls are necessary to take account of emerging diseases or particular OIE listed diseases.

Article 4

Criteria and conditions establishing when ante-mortem inspections may be performed on domestic ungulates outside the slaughterhouse in the case of emergency slaughter by way of derogation from the requirements laid down in Article 18(2)(a) of Regulation (EU) 2017/625

By way of derogation from Article 18(2)(a) of Regulation (EU) 2017/625, ante-mortem inspections may be performed outside the slaughterhouse on domestic ungulates in the case of emergency slaughter 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.

Article 5

Criteria and conditions laying down when ante-mortem inspections may be performed on certain animals on the holding of provenance by way of derogation from the requirements laid down in Article 18(2)(a) and (b) of Regulation (EU) 2017/625

By way of derogation from Article 18(2)(a) and (b) of Regulation (EU) 2017/625, the competent authority may authorise ante-mortem inspections to be performed on the following species at the holding of provenance in accordance with the following Chapters of Annex I :

- (a) Chapter I for domestic pigs;
- (b) Chapter II for poultry and farmed lagomorphs;
- (c) Chapter III farmed game.

At the expert group meeting of October 6th, participants are requested to express their views on:

- *An extension of species for which AMI at the holding of provenance is allowed*
- *If extended, what should be the conditions (similar to pigs, ...)?*

Article 6

Criteria and conditions for the performance of post-mortem inspections and auditing activities under the responsibility of the official veterinarian, as provided for in Article 18(7)(e), (f) and (i) 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 the official auxiliaries under the responsibility of the official veterinarian in accordance with the criteria and conditions set out in Annex II to this Regulation and subject to compliance with the specific minimum requirements for official auxiliaries set out in Article 9(2) to this Regulation.

However, post-mortem inspections may only be performed by the official veterinarian in the case of emergency slaughter outside the slaughterhouse.
- (2) Auditing activities referred to in Article 18(2)(d) of Regulation (EU) 2017/625 may be performed in slaughterhouses, cutting plants and game-handling establishments by staff designated by the competent authorities under the responsibility of the official veterinarian provided that they are limited to the collection of information regarding good hygiene practices and hazard analysis and critical control point (HACCP)-based procedures and subject to compliance with the specific minimum requirements set out in Article 9(3) to this Regulation.
- (3) Official controls in cutting plants referred to in Article 18(2) (d) may be performed by staff designated by the competent authorities under the responsibility of the official veterinarian provided that the official veterinarian regularly checks the work of such staff and subject to compliance with the specific minimum requirements set out in Article 9(3) to this Regulation

Article 7

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

Official controls on live bivalve molluscs originating from production areas, which are not classified by the competent authority in accordance with Article 18(6) of Regulation (EU) 2017/625, shall be carried out 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 echinoderms, which are not filter feeders, harvested outside classified production areas set out in Chapter IX of that Section.

Article 8

Specific derogations for Sweden and Finland 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 derogation from the official controls requirements laid down in Article 18 of

that Regulation in respect to *Rangifer tarandus tarandus* (reindeer), *Lagopus lagopus* and *Lagopus mutus* (grouse) may be granted by Sweden and Finland in respect of the areas of those Member States listed in Annex III to this Regulation:

- (a) by way of derogation from Article 18(1) of Regulation (EU) 2017/625, official controls shall not be required to be carried out 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 supplying such meat to the final consumer;
 - (b) by way of derogation from Article 18(3) of Regulation 2017/625, slaughterhouse staff may inspect the gastro-intestinal tract after receiving training appropriate to this task in accordance with Article 10.
- (2) By way of derogation from Article 18(1) of Regulation (EU) 2017/625, official controls shall not be required to be carried out on meat derived from *Lagopus lagopus* and *Lagopus mutus*, where they are killed by snaring in the counties of Norrbotten, Västerbotten and Jämtland and the municipality of Älvdalen in Dalarna county during the hunting season in winter.

Article 9

Specific minimum requirements for the official veterinarian, the official auxiliaries and the staff of 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 IV to this Regulation.
Notwithstanding the rules laid down in points 1 to 6 to Chapter I of Annex IV, 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 ante-mortem inspections outside the slaughterhouse and in milk and colostrum production holding, and
 - (b) veterinary students having passed the required studies laid down in point 2 to Chapter I of Annex IV, which are temporarily working at a slaughterhouse in the presence of an (fully qualified) official veterinarian
- (2) Official auxiliaries performing 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 IV to this Regulation.
- (3) Staff designated by the competent authorities performing 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 IV to this Regulation.
- (4) Persons may perform tasks provided for official auxiliaries and staff designated by the competent authorities, if they comply with the minimum specific requirements set out in both Chapters II and III of Annex IV to this Regulation.

Article 10
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, and comply with the minimum training requirements set out in Chapter II of Annex IV to this Regulation to the extent relevant for their assistance tasks.

Article 11
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
[...]