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COMMISSION

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[...] (2021) **XXX** draft

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

of **XXX**

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards specific rules on official controls performed by the competent authorities on animals, products of animal origin and germinal products, follow-up action to be taken by the competent authority in case of non-compliance with identification and registration rules for bovine, ovine and caprine animals or of non-compliance during transit through the Union of certain bovine animals, and repealing Commission Regulation (EC) No 494/98

(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.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2017/625 of the European Parliament and of the Council¹ 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 (Official Controls Regulation) lays down the general rules in that domain.

Regulation (EU) 2017/625 also empowers the Commission to adopt delegated acts supplementing the rules in that Regulation, *inter alia* for specific official controls to verify animal health requirements and actions following established non-compliances. Some of those specific official control rules were laid down in numerous Directives that are now repealed by Regulation (EU) 2016/429 of the European Parliament and of the Council² ('Animal Health Law'). Regulation (EU) 2016/429 however did not replace those specific official control rules, due to the new legal framework for official controls provided for by the Regulation (EU) 2017/625.

The rules laid down in this Delegated Regulation are largely comparable to previous rules, taking into account experience gained in the application of the existing Union rules in the animal health domain. It provides for some specificities on the animal health area defined by Regulation (EU) 2016/429 and its delegated and implementing rules. In particular, it provides for official veterinarians to perform official controls in certain approved establishments keeping animals or producing germinal products of animals, and specific official controls in confined establishments. It also provides supplementary criteria for the risk analysis for the selection of establishments to be inspected during official controls on identification and registration of certain species of animals as well as for measures for handling non-compliant bovine animals transiting the Union in certain situations.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission had written consultations with the Expert Group on animal health (E00930) and on official controls (E00911). The draft Delegated Regulation was also made available to the European Parliament and the Council, with neither institution making any comments. The main elements of the draft act were illustrated to, and discussed with a wide range of stakeholders as part of a meeting of the Animal Health Advisory Committee.

In addition, stakeholders' comments on the draft delegated regulation were collected in the context of the Better Regulation feedback mechanism during the period between ... 2021 and [xx month] 2021 [to be supplemented later on].

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, 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).

² 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).

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted pursuant to Regulation (EU) 2017/625, and in particular Article 20(2), points (a) and (c) thereof.

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

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supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards specific rules on official controls performed by the competent authorities on animals, products of animal origin and germinal products, follow-up action to be taken by the competent authority in case of non-compliance with identification and registration rules for bovine, ovine and caprine animals or of non-compliance during transit through the Union of certain bovine animals, and repealing Commission Regulation (EC) No 494/98

(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)³, and in particular Article 20, paragraph (2), points (a) and (c) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down general rules for official controls performed by the competent authorities for the verification of compliance with rules in a number of areas, including animal health requirements. That Regulation also lays down methods and techniques for official controls, which include inspections of premises, animals and goods under the control of operators. In addition, Regulation (EU) 2017/625 lays down possible actions to be taken by the competent authorities in case of established non-compliance with, among others, animal health requirements referred to in Article 1, paragraph (2), point (d), of that Regulation.
- (2) Regulation (EU) 2016/429 of the European Parliament and of the Council⁴ repealed and replaced 39 acts in the area of animal health as from 21 April 2021. Some of the requirements in the acts repealed by or pursuant to the Regulation (EU) 2016/429 relate, however, to certain animal health-related specificities of official controls and

³ OJ L 95, 7.4.2017, p. 1.

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).

follow-up action to be taken in case of established non-compliances under Regulation (EU) 2017/625 as set out in Article 138 thereof. Such specific rules on official controls and follow-up actions to be taken by the competent authority in case of established non-compliance should therefore be laid down in this Regulation.

- (3) Specificities of official controls and follow-up actions in case of established non-compliances related to animal health are interrelated. They apply to subsequent stages of a given situation and very often, apply to the same types of operators and establishments. Where specific follow-up actions are needed, they should be laid down together with the requirements for specificities of official controls related to animal health. This provides for a comprehensive set of measures enabling an easier implementation and contributing to the overall simplification of the legal framework in this area.
- (4) Performance of official controls and follow-up actions in establishments approved in accordance with Commission Delegated Regulations (EU) 2019/2035⁵, (EU) 2020/686⁶, (EU) 2020/688⁷ or (EU) 2020/990⁸ requires specific qualifications and competencies in the veterinary field. Official controls in those approved establishments involve assessment and verification of a wide variety of specific data and information related to animals kept therein. Some of these data and information are the results of observations made in animals, while others are collected and recorded by operators, animal health professionals, veterinarians, or aquatic animal health professionals. Such data and information can concern among other things the physiological or pathological state of animals, epidemiological factors, the results of physical, clinical or post-mortem examinations and laboratory tests, and data and information collected in relation to biosecurity measures in establishments and the appropriate use and maintenance of equipment and facilities.
- (5) In addition, in germinal product establishments, the complexity and technicality of this particular sector requires specialised knowledge from the competent authority responsible for official controls in order to ensure an efficient and effective execution of its duties.
- (6) It is therefore appropriate that official veterinarians should perform the official controls in approved establishments that keep animals or handle germinal products in accordance with Regulation (EU) 2016/429. Rules on the performance of official controls in those establishments should be set out in this Regulation.
- (7) In addition, in some Member States for historical reasons, or due to the lack of veterinarians dealing with aquatic diseases, there exists a specialised profession called

⁵ Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314 5.12.2019, p. 115).

⁶ Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (OJ L 174, 3.6.2020, p. 1).

⁷ Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140).

⁸ Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals (OJ L 221, 10.7.2020, p. 42).

‘aquatic animal health professionals’. These professionals are traditionally not veterinarians but they practice aquatic animal medicine. This Regulation should therefore respect the decision of those Member States, which recognise that profession. In those cases, official aquatic animal health professionals should be able to undertake activities assigned to official veterinarians when performing official controls in approved aquaculture establishments. In accordance with Article 12(2) of Regulation (EU) 2016/429 these aquatic animal health professionals may undertake activities assigned to veterinarians in animal health area, provided that they are authorised to do so by the Member State concerned under national law. This principle should apply also in this Regulation.

- (8) Among the establishments approved pursuant to Regulation (EU) 2016/429, confined establishments are particular as they often keep a wide variety of animal species permanently and exchange them with other confined establishments. Requirements for approval and the safe operation of confined establishments in relation to quarantine, isolation and other biosecurity measures, disease surveillance and control measures under the responsibility of the establishment’s veterinarians, play an important role to ensure that exchanges of animals do not pose a risk in spreading listed or emerging animal diseases between or within Member States. It is therefore appropriate to specify the official controls that should take place in confined establishments.
- (9) As regards official controls to verify compliance with rules on identification and registration of bovine, ovine and caprine animals, specific criteria should be laid down to assist the competent authorities with the risk analysis for the selection of the animals and establishments to be inspected. When those official controls are performed on a representative sample of animals and those official controls identify non-compliance with identification and registration requirements, the competent authorities should inspect all animals in that establishment as a follow-up action.
- (10) Union rules authorise the transit through the Union of bovine animals for breeding and production which otherwise do not comply with the animal health requirements for entry into the Union, under specific derogations and conditions laid down in Commission Delegated Regulations (EU) 2019/2124⁹ and (EU) 2020/692¹⁰. Such transit should not jeopardise animal and public health in the Union. In case of non-compliance, irregularity or emergency during transit, the competent authority should therefore order the slaughter or killing of those animals, as that is the most appropriate measure to safeguard animal and public health and animal welfare. In those cases, the competent authority should also order the safe disposal of the resulting animal by-

⁹ Commission Delegated Regulation (EU) 2019/2124 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for official controls of consignments of animals and goods in transit, transshipment and onward transportation through the Union, and amending Commission Regulations (EC) No 798/2008, (EC) No 1251/2008, (EC) No 119/2009, (EU) No 206/2010, (EU) No 605/2010, (EU) No 142/2011, (EU) No 28/2012, Commission Implementing Regulation (EU) 2016/759 and Commission Decision 2007/777/EC (OJ L 321, 12.12.2019, p. 73).

¹⁰ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

products in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council¹¹.

- (11) Commission Regulation (EC) No 494/98¹² lays down administrative sanctions to be applied when non-compliances with the conditions or requirements for the identification and registration of bovine animals is established. Delegated Regulation (EU) 2019/2035 did not expressly repeal that Regulation. In addition, the administrative sanctions laid down in Regulation (EC) No 494/98 have become redundant in view of the measures set out in Article 138(2) of Regulation (EU) 2017/625. To ensure legal certainty and consistency, this Regulation should repeal Regulation (EC) No 494/98.
- (12) The rules laid down in this Regulation should apply to the United Kingdom in respect of Northern Ireland, in accordance with Article 5(4) of the Protocol on Ireland/Northern Ireland to the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community in conjunction with Annex 2 to that Protocol,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation supplements Regulation (EU) 2017/625 as regards certain specific rules on official controls by the competent authorities of Member States¹³ in relation to animals, products of animal origin and germinal products to verify compliance with animal health requirements referred to in Article 1, paragraph (2), point (d), of that Regulation and, where necessary, as regards certain actions taken by the competent authorities following official controls:
 - (a) in certain establishments keeping animals;
 - (b) in certain establishments collecting, producing, processing or storing germinal products.
2. This Regulation supplements Regulation (EU) 2017/625 as regards a specific action taken by the competent authorities of Member States following official controls in relation to certain bovine animals in transit.

¹¹ 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 (OJ L 300, 14.11.2009, p. 1).

¹² Commission Regulation (EC) No 494/98 of 27 February 1998 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine animals (OJ L 060, 28.2.1998, p.78).

¹³ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland / Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Regulation references to 'Member States' include the United Kingdom in respect of Northern Ireland.

Article 2

Definitions

For the purposes of this Regulation, the following definitions laid down in Regulation (EU) 2016/429, in Delegated Regulation (EU) 2019/2035, Delegated Regulation (EU) 2020/686, Delegated Regulation (EU) 2020/688, Delegated Regulation (EU) 2020/692 and Delegated Regulation (EU) 2020/990 shall apply:

- (a) ‘establishment’ as defined in Article 4, point (27), of Regulation (EU) 2016/429;
- (b) ‘hatchery’ as defined in Article 4, point (47), of Regulation (EU) 2016/429;
- (c) ‘assembly operation’ as defined in Article 4, point (49), of Regulation (EU) 2016/429;
- (d) ‘assembly centre of dogs, cats and ferrets’ as defined in Article 2, point (7), of Delegated Regulation (EU) 2019/2035;
- (e) ‘animal shelter’ as defined in Article 2, point (8), of Delegated Regulation (EU) 2019/2035;
- (f) ‘control post’ as defined in Article 2, point (9), of Delegated Regulation (EU) 2019/2035;
- (g) ‘environmentally isolated production establishment’ as defined in Article 2, point (10), of Delegated Regulation (EU) 2019/2035;
- (h) ‘approved quarantine establishment’ as defined in Article 3, point (9), of Delegated Regulation (EU) 2020/688;
- (i) ‘confined establishment’ as defined in Article 4, point (48), of Regulation (EU) 2016/429;
- (j) ‘approved germinal product establishment’ as defined in Article 2, point (2), of Regulation (EU) 2020/686;
- (k) ‘approved aquaculture establishment’ as defined in Article 2, point (10), of Delegated Regulation (EU) 2020/990;
- (l) ‘approved group of aquaculture establishments’ as defined in Article 2, point (11), of Delegated Regulation (EU) 2020/990.
- (m) ‘establishment veterinarian’ as defined in Article 2(14) of Delegated Regulation (EU) 2019/2035;
- (n) ‘bovine animal’ as defined in Article 2, point (10), of Delegated Regulation (EU) 2020/692.

Article 3

Official controls in certain approved establishments

1. Official veterinarians or in approved aquaculture establishments and approved groups of aquaculture establishments official veterinarians or official aquatic animal health professionals, shall perform official controls to verify compliance with animal health requirements referred to in Article 1, paragraph (2), point (d), of Regulation (EU) 2017/625 and laid down in and pursuant to Regulation (EU) 2016/429, in the following types of establishments that have obtained approval from the competent authority:
 - (a) hatcheries and establishments keeping poultry;

- (b) assembly operations;
- (c) assembly centres of dogs, cats and ferrets;
- (d) animal shelters for dogs, cats and ferrets;
- (e) control posts;
- (f) environmentally isolated production establishments for bumble bees;
- (g) approved quarantine establishments;
- (h) confined establishments;
- (i) approved germinal product establishments;
- (j) approved aquaculture establishments
- (k) approved groups of aquaculture establishments.

The official controls referred to in the first subparagraph shall also verify that the operators responsible for the approved establishments continue to comply with the approval requirements for those establishments.

2. The official controls referred to in paragraph 1 of this Article shall include inspections referred to in Article 14, point (b), of Regulation (EU) 2017/625 that shall be performed in accordance with at least the minimum frequencies, where such frequencies are set out in Commission Implementing Regulation (EU) [SANTE/7052/2021]¹⁴.
3. The inspections referred to in paragraph 2 may be combined with:
 - (a) official controls referred to in Article 9, paragraph (3) of Regulation (EU) 2017/625;
 - (b) other official controls to verify compliance with requirements referred to in Article 1, paragraph (2), of Regulation (EU) 2017/625; or
 - (c) other official controls, inspections or visits provided for in Union rules.

Article 4

Specific rules on official controls in confined establishments of terrestrial animals

When performing official controls in confined establishments of terrestrial animals, the official veterinarian shall in particular:

- (a) verify through the examination of the movement records that the animals entering the given confined establishment come only from another confined establishment or are quarantined in accordance with Part 9, point 1, of Annex I to Delegated Regulation (EU) 2019/2035;
- (b) verify that the results of the clinical, laboratory and post-mortem examinations carried out by the confined establishment's veterinarian rule out any suspicion of listed or emerging diseases;
- (c) verify that if the presence of listed or emerging diseases is suspected, the operator responsible for the confined establishment notifies that suspicion to the competent

¹⁴ Commission Implementing Regulation (EU) [SANTE/7052/2021] of ... laying down uniform minimum frequencies of certain official controls to verify compliance with Union animal health requirements in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and repealing Regulations (EC) No 1082/2003 and (EC) No 1505/2006 (OJ L NN, DD.MM.YYYY, p. X.)

authority and mitigates the potential risks to spread such diseases within and outside the confined establishment; and

- (d) audit the activity of the confined establishment's veterinarian and the implementation and results of the disease surveillance plan referred to in Part 9, point 2(a), of Annex I to Delegated Regulation (EU) 2019/2035 and in particular verify that the disease surveillance plan has been reviewed and updated at least annually in accordance with those requirements.

Article 5

Specific rules on official controls to verify compliances with requirements on identification and registration of bovine, ovine or caprine animals and on follow-up action in case of non-compliance therewith

1. Official controls to verify compliance with requirements on identification and registration of bovine, ovine or caprine animals shall include inspections referred to in Article 14, point (b), of Regulation (EU) 2017/625 of bovine, ovine or caprine animals in establishments keeping those animals, performed in accordance with at least the minimum frequency set out in Article 6 of Implementing Regulation (EU) [SANTE/7052/2021].
2. The inspections referred to in paragraph 1 may be combined with:
 - (a) official controls referred to in Article 9, paragraph (3), of Regulation (EU) 2017/625;
 - (b) other official controls to verify compliance with requirements referred to in Article 1, paragraph (2), of Regulation (EU) 2017/625; or
 - (c) other official controls, inspections or visits provided for in Union rules.
3. When selecting the establishments to be inspected, the competent authority shall take into account the following criteria in its risk analysis in addition to those set out in Article 9, paragraph (1), of Regulation (EU) 2017/625:
 - (a) the number of animals in an establishment;
 - (b) the species of animals present and identified in an establishment;
 - (c) significant changes in comparison with the number or species of animals in the establishment during the last 5 years; and
 - (d) any other relevant criteria defined by its Member State.
4. Where an inspection referred to in paragraph 1 is performed, the competent authority shall inspect all bovine, ovine and caprine animals in that establishment.
5. By way of derogation from paragraph 4, where the number of animals to be inspected in the establishment exceeds 20, the competent authority may decide to inspect a representative sample of those animals if the number of inspected animals is sufficient to detect 5% of cases of non-compliance at a 95% confidence level.
6. Where an inspection referred to in paragraph 1 is performed on a representative sample of animals in an establishment in accordance with paragraph 5 and that inspection confirms non-compliance with the requirements concerning identification and registration, the competent authority shall inspect all other bovine, ovine and caprine animals in the establishment.

7. By way of derogation from paragraph 6, the competent authority may decide to inspect a representative sample of animals in that establishment ensuring that the number of inspected animals is sufficient for the estimation of non-compliance over 5 % with precision of plus or minus 2 % for a 95 % confidence level.

Article 6

Follow-up action in case of non-compliance during transit through the Union of certain bovine animals

When consignments of bovine animals, which comply with specific animal health conditions for entry into the Union are in transit through the Union pursuant to Article 176, paragraph (1), point (b), of Delegated Regulation (EU) 2020/692 in conjunction with Article 34, paragraph (1), point (a) of Delegated Regulation (EU) 2019/2124, the competent authority shall order the slaughter or killing of the animals and their disposal as a Category 2 material referred to in Article 9, point (f)(i) of Regulation (EC) No 1069/2009, in case of any non-compliance during the movement between the border control post of entry into the Union and the border control post where the consignments leave the Union territory.

Article 7

Repeal

Commission Regulation (EC) No 494/98 is repealed.

Article 7

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*.

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

Done at Brussels,

For the Commission

The President

Ursula VON DER LEYEN