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Brussels, **XXX**  
SANTE/7232/2020  
[...] (2020) **XXX** draft

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

**of **XXX****

**amending Delegated Regulation (EU) 2019/2035 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs**

(Text with EEA relevance)

*This draft has not been adopted or endorsed by the 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. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

## EXPLANATORY MEMORANDUM

### **1. CONTEXT OF THE DELEGATED ACT**

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<sup>1</sup> ('Animal Health Law') lays down rules on transmissible animal diseases and establishments keeping terrestrial animals and hatcheries, and for the traceability of certain kept terrestrial animals and hatching eggs within the Union. It also empowers the Commission to adopt rules to supplement certain non-essential elements of that Regulation by means of delegated acts.

The Commission laid down such rules in 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<sup>2</sup>. Part II of that Regulation includes rules on registration and approval of establishments keeping terrestrial animals including those for assembly operations and those from which hatching eggs or poultry are moved to another Member State. Part III includes rules for the traceability of certain kept terrestrial animals, including rules for the traceability of kept bovine, ovine and caprine animals, as well as marking of hatching eggs.

The rules laid down in this Delegated Regulation amend Regulation (EU) 2019/2035 and further clarify certain provisions in relation to establishments keeping terrestrial animals and hatcheries, and for the traceability of certain kept terrestrial animals and hatching eggs within the Union.

### **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

The Commission had meetings and exchanges with the Expert Group on animal health (E00930). The draft delegated regulation was also made available to the European Parliament and the Council, [neither of which submitted any comments]. There was a meeting with a range of stakeholders as part of the work of the Animal Health Advisory Committee, at which the main elements of the draft act were illustrated and discussed.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

#### **3.1. Summary of the proposed action**

This Delegated Regulation will amend Regulation (EU) 2019/2035 in relation to:

- (a) the rules for registration and approval of establishments from which hatching eggs or poultry are moved to another Member State;
- (b) the traceability provisions of bovine, ovine and caprine animals;
- (c) the rules for the marking of hatching eggs sent to another Member State;
- (d) the requirements for approval of establishments for assembly operations of ungulates.

#### **3.2. Legal basis**

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<sup>1</sup> OJ L 84, 31.3.2016, p. 1

<sup>2</sup> OJ L 314, 5.12.2019, p. 115.

This Delegated Regulation is to be adopted pursuant to Regulation (EU) 2016/429, in particular Article 94(3), Article 97(2), Article 118(1) and Article 122(2) thereof.

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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) 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<sup>3</sup> ('Animal Health Law'), and in particular Article 94(3), Article 97(2), Article 118(1) and Article 122(2) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases that are transmissible to animals or humans. Chapters 1 and 2 of Title I of Part IV, provide for the rules for establishments keeping terrestrial animals and hatcheries, and for the traceability of certain kept terrestrial animals and hatching eggs within the Union. It also empowers the Commission to adopt rules to supplement certain non-essential elements of that Regulation by means of delegated acts.
- (2) Commission Delegated Regulation (EU) 2019/2035 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<sup>4</sup> lays down supplementing rules for registered and approved establishments for kept terrestrial animals and hatching eggs, and for the traceability of certain kept terrestrial animals and hatching eggs. Part II of that Regulation includes rules on registration and approval of establishments keeping terrestrial animals including those for assembly operations and those from which hatching eggs or poultry are moved to another Member State. Part III includes rules for the traceability of kept terrestrial animals, and more specifically Titles I and II of Part III lay down rules for the traceability of kept bovine, ovine and caprine animals, while Title VI provides for marking of hatching eggs.
- (3) Regulation (EU) 2016/429 provides that operators of hatcheries from which hatching eggs or poultry are moved to another Member State and operators of establishments keeping poultry from which poultry intended for purposes other than slaughter or hatching eggs are moved to another Member State shall apply to the competent authority for approval of their establishments. Article 94(3) of that Regulation, however, empowers the Commission to provide for a derogation from the approval obligation in cases of establishments that pose an insignificant risk. Commission Delegated

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<sup>3</sup> OJ L 84, 31.3.2016, p. 1.

<sup>4</sup> OJ L 314, 5.12.2019, p. 115.

Regulation (EU) 2020/688 supplementing Regulation (EU) 2016/429 as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs<sup>5</sup>, however, provides that less than 20 heads of poultry other than ratites and less than 20 hatching eggs other than ratites originate from registered establishments. Article 4 of Regulation (EU) 2019/2035 should, therefore, be amended to provide for a derogation for operators of such establishments from the obligation to apply to the competent authority for approval.

- (4) Paragraph 1 of Article 38 of Regulation (EU) 2019/2035 lays down obligation on operators to identify their kept bovine animals by specific means of identification. Paragraph 2 of that Article provides for a possibility for operators to replace those means of identification, with alternative ones. Similarly, Paragraphs 1 and 2 of Article 45 of that Regulation lays down obligation on operators to identify their kept ovine and caprine animals, while paragraph 4 of that Article provides for a possibility for operators to replace the specified means of identification, with alternative ones.
- (5) Article 269 of Regulation (EU) 2016/429 provides for a possibility for Member States to adopt in certain areas national measures that they can apply within their territories and which are additional to, or more stringent than those laid down in that Regulation. Traceability requirements for kept terrestrial animals and germinal products is one of such areas. Regulation (EU) 2019/2035 does not properly reflect that possibility and in particular the role and responsibility of Member States to ensure a proper implementation of traceability provisions for kept bovine, ovine and caprine animals in the country. This includes the uniform implementation of derogations that may be used by operators. Regulation (EU) 2019/2035 should therefore be amended and clarify the responsibility of Member States which should decide about the application of derogations from traceability requirements of bovine, and ovine and caprine animals, that can be used by operators in the territory of that Member State.
- (6) Article 76 of Regulation (EU) 2019/2035 provides that the means of identification of psittacidae display the identification code of the animal. However, the definition of the identification code of the animal goes beyond the needs for the identification of psittacidae and it presents a significant administrative burden for Member States. Regulation (EU) 2019/2035 should, therefore, be amended to provide that the means of identification of psittacidae display an alphanumeric-code, which enables their identification and provides for a sufficient level of traceability for those animals when they are moved between Member States.
- (7) Article 80 of Regulation (EU) 2019/2035 provides that all hatching eggs are marked with the approval number of the establishment of origin. However, according to Regulation (EU) 2016/429 only establishments that send hatching eggs to another Member State are required to be approved. In addition, Regulation (EU) 2020/688 provides that less than 20 hatching eggs of poultry other than ratites moved to another Member State originate in registered establishments. Regulation (EU) 2019/2035 should, therefore and consistent with the proposed amendment of Article 4, be amended to exclude hatching eggs not moved to another Member State and less than 20 hatching eggs other than ratites moved to another Member State from the requirement to be marked with the approval number of the establishment of origin.
- (8) Article 5 of Regulation (EU) 2019/2035 lays down requirements for granting approval of establishments for assembly operations of ungulates. Detailed requirements are laid down in Part 1 of Annex I to that Regulation. According to Point 1(b) of Part 1 of Annex

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<sup>5</sup> OJ L 174, 3.6.2020, p. 140

I, an establishment should only be granted approval for assembly operations of ungulates if the establishment, at any given time, only accommodates the same category of ungulates of the same species and health status. However, existing assembly centres could have one or more epidemiologically separate animal accommodation areas. The idea of those separate areas is to make sure the animals kept in those areas are not in direct or indirect contact with each other. This makes it possible to keep ungulates from different species, categories or health status in an establishment as long as they are kept in different epidemiologically separate animal accommodation areas. This possibility is not properly reflected in the requirements provided for in point 1(b) of Part 1 of Annex I to Regulation (EU) 2019/2035 and that Annex should be amended to make this possible. Moreover, Delegated Regulation (EU) 2020/688 makes it possible to have ovine and caprine animals in the same consignment because their health requirements are the same. It should therefore be possible to assemble ovine and caprine animals together. A derogation from the main rule that only ungulates from the same species may be assembled together is therefore necessary.

- (9) As Delegated Regulation (EU) 2019/2035 applies from 21 April 2021, this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

*Article 1*

Delegated Regulation (EU) 2019/2035 is amended by the following:

- (1) Article 4 is replaced by the following:

*'Article 4*

*Derogation from the requirement for operators of certain types of establishments to apply to the competent authority for approval*

Operators of the following establishments shall not apply to the competent authority for approval of their establishments in accordance with Article 96(1) of Regulation (EU) 2016/429:

- (a) establishments for assembly operations of equine animals where those animals are gathered for the purposes of competitions, races, shows, training, collective leisure or work activities or in the context of breeding activities;
- (b) hatcheries of captive birds;
- (c) hatcheries from which less than 20 hatching eggs of poultry or less than 20 heads of poultry are moved to another Member State;
- (d) establishments keeping poultry from which less than 20 heads of poultry intended for purposes other than slaughter or less than 20 hatching eggs of poultry are moved to another Member State.'
- (2) In Article 38, point (a) of paragraph 2 should be replaced by the following:
- '(a) one of the conventional ear tags referred to in paragraph 1 by an electronic identifier approved by the competent authority of the Member State where the bovine animals are kept, where such replacement is authorised by that Member State in accordance with Article 41(1);
- (3) In Article 45, point (a) of paragraph 4 should be replaced by the following:

- ‘(a) one of the means of identification referred to in paragraph 2 of this Article, in accordance with the derogations provided for in Article 46, where such derogations are authorised by the Member State where the ovine and caprine animals are kept, in accordance with Article 48(5);’
- (4) In Article 48, point (c) of paragraph 4 is deleted;
- (5) In Article 48, a new paragraph 5 is added:
- ‘5. Member States may authorise to replace one of the means of identification referred to in Article 45(2) in accordance with the derogations provided for in Article 46 for ovine and caprine animals kept in their territory.’
- (6) In Article 76, points (a), (b) and (c) of paragraph 1 are replaced by the following:
- ‘(a) a leg ring as listed in point (h) of Annex III attached at least to one leg of the animal with a visible, legible and indelible display of an alpha-numeric code;
- or
- (b) an injectable transponder as listed in point (e) of Annex III with a legible and indelible display of an alpha-numeric code;
- or
- (c) a tattoo as listed in point (g) of Annex III applied to an animal with a visible and indelible display of an alpha-numeric code.’
- (7) Article 80 is replaced by the following:

*Article 80*

*Obligation of operators as regards the traceability of hatching eggs*

1. Operators of establishments keeping poultry and operators of hatcheries of poultry shall ensure that each hatching egg that is moved to another Member State is marked with the unique approval number of the establishment of origin of the hatching eggs.
  2. The requirement set out in paragraph 1 shall not apply to operators of establishments keeping poultry and operators of hatcheries from which less than 20 hatching eggs of poultry other than ratites are moved to another Member State.’
- (8) In point 1 of Part 1 of Annex I, point (b) is replaced by the following:
- ‘(b) at any given time, the establishment or the epidemiologically separate animal accommodation areas within the establishment must only accommodate the same category of ungulates of the same species and health status;
- By way of derogation from the required separation of species of ungulates in the first subparagraph, animals of the ovine and caprine species may be accommodated at any given time in the establishment or epidemiologically separate animal accommodation areas within the establishment.’

*Article 2*

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

It shall apply from 21 April 2021.

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

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*

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