

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2021/2168

of 21 September 2021

**amending 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**

(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 ('Animal Health Law') <sup>(1)</sup>, and in particular Articles 94(3), 97(2), 118(1) and (2) and 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. In particular, Part IV of that Regulation lays down rules for establishments keeping terrestrial animals and for hatcheries, as well as for the traceability of certain kept terrestrial animals and hatching eggs within the Union. Regulation (EU) 2016/429 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 <sup>(2)</sup> supplements Regulation (EU) 2016/429 as regards rules for establishments keeping terrestrial animals and hatcheries, and for the traceability of certain kept terrestrial animals and hatching eggs. In particular, Part II of that Delegated Regulation lays down rules on the registration and approval of establishments keeping terrestrial animals, including those establishments carrying out assembly operations, and those from which consignments of hatching eggs or poultry are moved to another Member State. In addition, Part III of that Delegated Regulation lays down rules for the traceability of kept terrestrial animals and hatching eggs, and more specifically it lays down rules for the traceability of kept bovine, ovine and caprine animals, and for the marking of hatching eggs.
- (3) The rules laid down in this Regulation are substantively linked and apply to operators transporting or keeping terrestrial animals or hatching eggs. Therefore, in the interest of coherency, simplicity and for their effective application, and to avoid a duplication of rules, they should be laid down in a single act rather than dispersed in a number of separate acts containing many cross-references. This approach is also consistent with the one of principle objectives of Regulation (EU) 2016/429, which was to streamline Union animal health rules and thus make them more transparent and easier to apply.

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

<sup>(2)</sup> 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).

- (4) Regulation (EU) 2016/429 provides that operators of hatcheries from which consignments of hatching eggs or poultry are moved to another Member State, and operators of establishments keeping poultry from which consignments of poultry intended for purposes other than slaughter or hatching eggs are moved to another Member State, are to apply to the competent authority for approval of their establishments. Article 94(3), point (a), of that Regulation empowers the Commission to provide for derogations from the requirement for operators to apply to the competent authority for approval for certain types of establishments that pose an insignificant risk.
- (5) Movement to another Member State of small quantities of poultry other than ratites and hatching eggs from those animals pose a minor risk for the spread of diseases. Furthermore, operators of establishments from which small quantities of such animals and hatching eggs are moved to another Member State cannot for practical reasons comply with all the requirements for approval laid down in Delegated Regulation (EU) 2019/2035. Article 4 of Delegated Regulation (EU) 2019/2035 should, therefore, be amended to provide for a derogation for operators of hatcheries and establishments keeping poultry from which less than 20 heads of poultry other than ratites and less than 20 hatching eggs of poultry other than ratites are moved to another Member State from the obligation to apply to the competent authority for approval.
- (6) Article 38(1) of Delegated Regulation (EU) 2019/2035 provides that operators keeping bovine animals are to ensure that those animals are identified by specified means of identification, while Article 38(2) thereof allows operators to replace those specified means of identification with alternative ones. Similarly, Article 45(1) and (2) of that Delegated Regulation lays down obligations on operators to identify their kept ovine and caprine animals by specified means of identification, while Article 45(4) thereof allows operators to replace those specified means of identification with alternative ones.
- (7) On the other hand, Article 269 of Regulation (EU) 2016/429 provides for the 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 consignments of kept terrestrial animals and germinal products is one of those areas. Delegated Regulation (EU) 2019/2035 does not properly reflect that possibility. Articles 38(2), 45(4) and 48 of Delegated Regulation (EU) 2019/2035 should therefore be amended to clarify that the option provided for operators keeping bovine, ovine or caprine animals to identify those animals by alternative means of identification should be subject to authorisation by the Member State. This clarifies the role and responsibility of Member States that apply national measures in ensuring a proper implementation of additional or more stringent traceability requirements for kept bovine, ovine and caprine animals, as provided for in Article 269 of Regulation (EU) 2016/429.
- (8) Article 76 of Delegated Regulation (EU) 2019/2035 provides that operators keeping psittacidae are to ensure that the means of identification of psittacidae display the identification code of the animal. However, the definition of an identification code laid down in that Delegated Regulation exceeds what is necessary for the identification of psittacidae, and poses a significant administrative burden for Member States. Therefore, Delegated Regulation (EU) 2019/2035 should be amended to provide that the means of identification of psittacidae display instead an alphanumeric code, which enables their identification and provides a sufficient level of traceability for those animals when they are moved between Member States.
- (9) Article 80 of Delegated Regulation (EU) 2019/2035 provides that all hatching eggs are to be marked with the unique approval number of the establishment of origin. However, Regulation (EU) 2016/429 only requires establishments that send hatching eggs to another Member State to be approved. In addition, Commission Delegated Regulation (EU) 2020/688 <sup>(3)</sup> provides that when consignments of less than 20 hatching eggs of poultry other than ratites are moved to another Member State, those eggs are required to originate in registered establishments. Therefore, Delegated Regulation (EU) 2019/2035 should be amended to exclude operators of establishments keeping poultry and operators of hatcheries from which consignments of less than 20 hatching eggs of poultry other than ratites are moved to another Member State from the obligation to ensure that each hatching egg is marked with the unique approval number of the establishment of origin. This amendment is also consistent with the amendments to be made to Article 4 of Delegated Regulation (EU) 2019/2035 by this Regulation.

<sup>(3)</sup> 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).

- (10) Article 5 of Delegated Regulation (EU) 2019/2035 lays down the requirements for the granting of approval of establishments for assembly operations of ungulates, and it provides that the competent authority is to ensure that such establishments comply with certain requirements set out in Part 1 of Annex I to that Regulation. Part 1, point 1(b) of Annex I to Delegated Regulation (EU) 2019/2035 provides that an establishment is only to 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. Those separate areas should be operated in a way which ensures that 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. Part 1 of Annex I to Delegated Regulation (EU) 2019/2035 should therefore be amended to provide for this possibility.
- (11) In addition, Articles 15 to 18 of Delegated Regulation (EU) 2020/688 provide for a possibility to include ovine and caprine animals in the same consignment as both species are subject to the same animal health requirements laid down in that Delegated Regulation. The possibility to assemble a consignment of both ovine and caprine animals together, should also be permitted under Delegated Regulation (EU) 2019/2035. Delegated Regulation (EU) 2019/2035 should therefore be amended to include a derogation from the main rule laid down in Part 1 of Annex I to that Regulation stating that only ungulates of the same species may be assembled together.

HAS ADOPTED THIS REGULATION:

#### *Article 1*

Delegated Regulation (EU) 2019/2035 is amended as follows:

1. Article 4 is replaced by the following:

*'Article 4*

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

By way of derogation from Article 94(1)(a), (c) and (d) of Regulation (EU) 2016/429, operators of the following types of establishments shall not be required to apply to the competent authority for approval of their establishments in accordance with Article 96(1) of that Regulation:

- (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 consignments of 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 consignments of less than 20 heads of poultry intended for purposes other than slaughter or consignments of less than 20 hatching eggs of poultry are moved to another Member State.;
2. in Article 38(2), point (a) is replaced by the following:
    - '(a) one of the conventional ear tags referred to in paragraph 1 of this Article 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(4), point (a) is 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. Article 48 is amended as follows:

- (a) in paragraph 4, point (c) is deleted;
- (b) the following paragraph 5 is added:

'5. Member States may authorise operators to replace one of the means of identification referred to in Article 45(2) in accordance with the derogations provided for in Article 45(4) for ovine and caprine animals kept in their territory.';

5. in Article 76(1), points (a), (b) and (c) are replaced by the following:

'(a) a leg-ring, as listed in Annex III, point (h), attached at least to one leg of the animal with a visible, legible and indelible display of an alphanumeric code;

or

(b) an injectable transponder, as listed in Annex III, point (e), with a legible and indelible display of an alphanumeric code;

or

(c) a tattoo, as listed in Annex III, point (g), applied to the animal with a visible and indelible display of an alphanumeric code.';

6. Article 80 is replaced by the following:

*'Article 80*

#### **Obligations 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. Paragraph 1 shall not apply to:

- (a) operators of establishments keeping poultry from which consignments of less than 20 hatching eggs of poultry other than ratites are moved to another Member State;
- (b) operators of hatcheries from which consignments of less than 20 hatching eggs of poultry other than ratites are moved to another Member State.';

7. in Annex I, in Part 1, point 1 is replaced by the following:

'1. The requirements in relation to isolation and biosecurity measures of establishments for assembly operations of ungulates, as referred to in Article 5, shall be the following:

- (a) appropriate isolation facilities for the ungulates must be available;
- (b) at any given time, the establishment or each of the epidemiologically separate animal accommodation areas within the establishment must only accommodate the same category of ungulates of the same species and health status;
- (c) by way of derogation from the required separation of species of ungulates provided for in point (b), animals of the ovine and caprine species may be accommodated together at any given time in the establishment or in the same epidemiologically separate animal accommodation area within the establishment;
- (d) an appropriate system must be in place to ensure the collection of waste water;
- (e) the areas where the ungulates are kept and any passageways, and material and equipment that comes into contact with them must be cleaned and disinfected after the removal of each batch of ungulates, and where necessary before the introduction of any new batch of ungulates, in accordance with established operational procedures;
- (f) appropriate sanitary breaks must be taken after the cleaning and disinfecting operations and prior to the arrival of any new batch of ungulates in the facilities where ungulates are kept.'.

*Article 2*

This Regulation shall enter into force on the third 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, 21 September 2021.

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

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