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

of XXX

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards animal health certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals

(Text with EEA relevance)

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 ('Animal Health Law')¹ lays down rules on transmissible animal diseases. In particular, Chapter 6 of Title I of Part IV thereof lays down the rules for the production, processing and distribution within the Union of products of animal origin. Chapter 6 also provides for several empowerments for the Commission to adopt delegated acts supplementing the rules already laid down in that Regulation.

Part of the scope of some of those empowerments is already covered by rules laid down in Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for the prevention and control of certain listed diseases². In particular, Delegated Regulation (EU) 2020/687 lays down supplementing rules concerning disease control measures, including risk mitigating measures and restrictions on movements of consignments of products of animal origin produced or processed in restricted zones established in the event of category A, B and C diseases as referred to Article 9(1)(a)(b) and (c) of Regulation (EU) 2016/429, and as defined in Commission Implementing Regulation (EU) 2018/1882 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases³.

This draft Delegated Regulation aims therefore to lay down rules not covered by Commission Delegated Regulation (EU) 2020/687 for the movements of consignments of products of animal origin from terrestrial animals within the Union in the context of the prevention and control of certain listed diseases and emerging diseases. This draft Delegated Regulation follows the same approach as Union acts adopted before Regulation (EU) 2019/429, establishing the conditions for the distribution of products of animal origin, as the rules laid down in those acts have proven to be effective in preventing the spread of those diseases within the Union. Notably, this draft Delegated Regulation follows the same approach as Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption⁴.

This draft Delegated Regulation is adopted within the new animal health legislative framework established by Regulation (EU) 2016/429 which offers more consistency as regards animal health requirements, and more flexibility for the competent authorities of the Member States.

This draft Delegated Regulation lays down principally the following rules supplementing Regulation (EU) 2016/429 as regards animal health, certification and information requirements for movements within the Union of consignments of products of animal origin from terrestrial animals:

- (a) obligations on operators for movements of those consignments;
- (b) the information to be contained in the animal health certificates required to accompany those consignments;

¹ OJ L 84, 31.3.2016, p. 1.

² OJ L [...], [dd/mm/2019], p. [...] [Office of publication: please add references to document C(2019)4057].

³ OJ L 308, 4.12.2018, p. 21

⁴ OJ L 18, 23.1.2003, p. 11.

- (c) the information to be provided by operators to the competent authority for the advance notification of the movements of those consignments;
- (d) the emergency procedures for the notification of movements of those consignments in the event of power cuts and other disturbances of Traces.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission circulated the contents of this draft Delegated Regulation to members of the Expert Group on Animal Health (E00930). The draft Delegated Regulation was also made available to the European Parliament and the Council. There were [...] comments received from them. Elements of the draft act were illustrated to a range of stakeholders within the framework of 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 *[xx month] 2019 and [xx month] 2019 [to be supplemented later on]*. The input received by the various stakeholders in the context of the consultation activities has been taken into account when developing the draft Delegated Regulation.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted within the framework of Regulation (EU) 2016/429, and in particular pursuant to Articles 166(3), 168(3) and 169(5) thereof.

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supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards animal health certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals

(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')⁵, and in particular Articles 166(3), 168(3) and 169(5) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules concerning, inter alia, the production, processing and distribution within the Union of products of animal origin from terrestrial animals. It also provides for the Commission to adopt delegated acts concerning detailed requirements supplementing the rules already laid down in that Regulation and, in particular, on preventive measures, including risk-mitigation measures, and restrictions on movements of consignments of products of animal origin from terrestrial animals, as well as advance notification of such movements, in order to ensure that such products do not cause the spread of listed diseases or emerging diseases within the Union
- (2) In addition, the rules laid down in this act should take account of Union rules on movements of consignments of products of animal origin from terrestrial animals within the Union laid in Union acts adopted before Regulation (EU) 2016/429, and in particular in Council Directive 2002/99/EC, as they have been shown to be effective in combating the spread of animal diseases. The rules laid down in this act should also take account of the experience gained in the application of the rules laid down in those earlier acts, and the rules should be adapted to the new legislative framework for animal health laid down in Regulation (EU) 2016/429.
- (3) Article 166 of Regulation (EU) 2016/429 lays down the general animal health obligations on operators at all stage of the production, processing and distribution of products of animal origin from terrestrial animals, including the movements of consignments of those products within the Union. In particular, it lays down the responsibilities of operators regarding the spread of listed diseases and emerging diseases, and more particularly when emergency measures or movement restrictions have been put in place by the competent authority at the place of production or processing of those products. Controlling the spread of listed diseases and emerging

⁵ OJ L 84, 31.3.2016, p. 1.

diseases is therefore not only the responsibility of the operators, but also the responsibility of the competent authority. This Regulation should therefore lay down a clear obligation on operators to only move consignments of such products produced or processed at places subject to emergency measures or movement restrictions after obtaining the authorisation of the competent authority and subject to any conditions imposed for that authorisation.

- (4) Article 168 of Regulation (EU) 2016/429 lays down certain information requirements as regards the animal health certificate required to accompany movements of consignments of products of animal origin from terrestrial animals, and empowers the Commission to adopt delegated acts supplementing that information. This Regulation should therefore lay down information requirements as regards the animal health certificate required to accompany consignments of such products produced and processed in places subject to emergency measures or movement restrictions as referred to in Article 166(2) of Regulation (EU) 2016/429. This should include information on compliance with any conditions laid down by the competent authority regarding the movements of those consignments. The information requirements to be laid down in this Regulation are to be taken into account in the model animal health certificate for products of animal origin established in a separate implementing act laying down the rules for the uniform application of Regulation (EU) 2017/625 and the AHL Regulation (EU)2016/429 concerning model official certificates, official attestations and model declarations for certain categories of terrestrial animals and germinal products thereof.
- (5) Article 169 of Regulation (EU) 2016/429 establishes the rules for the advance notification of movements of products of animal origin from terrestrial animals to other Member States and empowers the Commission to adopt delegated acts concerning the information requirements for such advanced notification and for emergency procedures for the advance notification in the event of power cuts and other disturbances in ‘Traces’. This Regulation therefore should lay down the information obligations on operators in the advanced notification. In order to harmonise the information provided in the advanced notification to ensure that the competent authority at destination receives all the necessary details on the consignment, this Regulation should also lay down the requirements on the contents of the advance notification based on the situations where this is required in accordance with Regulation (EU) 2016/429 and the conditions that products of animal origin should comply with to be allowed to move to other Member States and details on the emergency procedures for such notifications.
- (6) As the ‘Traces’ system is an integrated component of the Integrated Management System for Official Controls (IMSOC) computerised system as referred to in Articles 131 to 136 of Regulation (EU) 2017/625, the contingency arrangements established for IMSOC pursuant to the rules laid down in Commission Implementing Regulation (EU) 2019/1715⁶ should apply.
- (7) This Regulation establishes a complete set of rules governing the animal health aspects of the movements of consignments of products of animal origin from terrestrial animals within the Union, the contents of the animal health certificate required to accompany such consignments and advance notification obligations. As these rules are to be applied in tandem and are interlinked, they should be laid down in a single act rather than in separate acts with numerous cross-references, in order to facilitate their application, in

⁶ Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation) (OJ L 261, 14.10.2019, p. 37).

the interests of transparency, and to avoid a duplication of rules. This is also in keeping with the approach adopted by Regulation (EU) 2016/429.

- (8) This Regulation should be applicable from 21 April 2021 in accordance with with the date of application of Regulation (EU) 2016/429,

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter and scope

This Regulation supplements the rules laid down in Regulation (EU) 2016/429 regarding movements within the Union of consignments of products of animal origin from terrestrial animals in relation to:

- (a) obligations on operators for movements within the Union of consignments of products of animal origin from terrestrial animals produced or processed in establishments, food businesses or zones subject to emergency measures or movement restrictions as referred to in Article 166(2) of Regulation (EU) 2016/429;
- (b) information requirements for the animal health certificate provided for in Article 167(1) of Regulation (EU) 2016/429 (animal health certification);
- (c) information requirements for the advance notification of movements of those consignments to other Member States, provided for in Article 169(1) of Regulation (EU) 2016/429 (advance notification);
- (d) emergency procedures for the advance notification of movements of those consignments in the event of power cuts and other disturbances of Traces, provided for in Article 169(1) of Regulation (EU) 2016/429.

Article 2

Obligations on operators moving consignments of products of animal origin

Operators shall only move consignments of products of animal origin from terrestrial animals subject to the emergency measures or movement restrictions referred to in Article 166(2) of Regulation (EU) 2016/429 within the Union if:

- (a) such movements are authorised by the competent authority of the place of origin; and
- (b) the consignments comply with the conditions for the authorisation required in accordance with point (a).

Article 3

Animal health certificate for movements of consignments of products of animal origin

In addition to the information required in accordance with Article 168(1) of Regulation (EU) 2016/429, the animal health certificate shall contain the information set out in the Annex to this Regulation.

Article 4
Information obligation on operators for the advance notification of movements of consignments of products of animal origin between Member States

In the advance notification, operators shall provide the competent authority of the Member State of origin with the information set out in the Annex to this Regulation in addition to information required in accordance with Article 168(1) of Regulation (EU) 2016/429, and they shall do so for each consignment of products of animal origin referred to in Article 1 of this Regulation.

Article 5
Emergency procedures

In the event of power cuts or other disturbances of Traces, the competent authority of the place of origin of consignments of products of animal origin referred to in Article 1 of this Regulation to be moved to another Member State shall comply with the contingency arrangements for Traces and Member States' national systems in the event of unplanned or planned unavailability established for the Integrated Management System for Official Controls (IMSOC) in Article 46 of Implementing Regulation (EU) 2019/1715.

Article 6
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 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