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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 23.3.2021 amending Delegated Regulation (EU) 2020/689 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases

Delegations will find attached document C(2021) 1784 final.

Encl.: C(2021) 1784 final



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

of 23.3.2021

**amending Delegated Regulation (EU) 2020/689 supplementing Regulation (EU) 2016/429
of the European Parliament and of the Council as regards rules for surveillance,
eradication programmes, and disease-free status for certain listed and emerging diseases**

(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 for the prevention and control of diseases that are transmissible to animals or humans, including rules for diagnostic methods, for Union surveillance programmes and for the approval by the Commission of eradication programmes. 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) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases².

Article 83 of Delegated Regulation (EU) 2020/689 provides for a derogation from the requirements to obtain approval by the Commission for certain disease-free statuses for aquatic animal diseases. This derogation should be expanded to include the approval of certain eradication programmes for aquatic animal diseases, thereby replacing the requirement for approval by the Commission with a system of Member States' self-declaration. This new derogation will make it easier and potentially quicker for Member States to have the eradication programme approved, thereby decreasing the administrative burden. Article 83 of Delegated Regulation (EU) 2020/689 should therefore be amended.

Article 86 of Delegated Regulation (EU) 2020/689 repeals several acts, with effect from 21 April 2021, that will become obsolete on that date. The rules laid down in Commission Decision 2010/367/EU of 25 June 2010 on the implementation by Member States of surveillance programmes for avian influenza in poultry and wild birds³ have been replaced by Annex II to Delegated Regulation (EU) 2020/689. For the sake of clarity, transparency and legal certainty, Decision 2010/367/EU should be included in the list of acts to be repealed by Article 86 of Delegated Regulation (EU) 2020/689.

After publication of Delegated Regulation (EU) 2020/689, incorrect cross-references and mistakes were noticed in Annex IV thereto and some mistakes also were noticed in Part III of Annex VI thereto. Therefore, some additional minor amendments should also be made to Delegated Regulation (EU) 2020/689 in order to correct it.

Annex VI to Delegated Regulation (EU) 2020/689 lays down the specific requirements as regards certain diseases of aquatic animals. They include the general requirements for health visits and sampling for eradication programmes and the diagnostic and sampling methods for the detection of Category C diseases of aquatic animals:

- As regards the health visits and sampling, the general requirements laid down in that Annex for eradication programmes may also be used for demonstrating and maintaining disease-free status. Therefore, the scope of the general requirements should be expanded to include the demonstration of freedom from disease and its maintenance and Annex VI should be amended accordingly.

¹ OJ L 84, 31.3.2016, p. 1.

² OJ L 174, 3.6.2020, p. 211.

³ OJ L 166, 1.7.2010, p. 22.

- As regards the diagnostic and sampling methods for the detection of infection with HPR-deleted infectious salmon anaemia virus, following latest available information laid down in the Manual of Diagnostic Test for Aquatic Animals of the World Organisation for Animal Health (OIE), they should be updated and Annex VI should be amended accordingly.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The expert group meetings for the purpose of this Delegated Regulation took place on 12 October 2020 and 26 November 2020.

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 the introductory phrase and points (a) and (d) of Article 29, the introductory phrase and points (a) and (b) of Article 31(5), the introductory phrase and point (c) of Article 32 (2), the introductory phrase and points (a) and (b) of Article 41(3), and Article 42(6) thereof,

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

of 23.3.2021

amending Delegated Regulation (EU) 2020/689 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases

(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')⁴, and in particular the introductory phrase and points (a) and (d) of Article 29, the introductory phrase and points (a) and (b) of Article 31(5), the introductory phrase and point (c) of Article 32 (2), the introductory phrase and points (a) and (b) of Article 41(3), and Article 42(6) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or humans, including rules for diagnostic methods, rules for Union surveillance programmes and rules for the approval by the Commission of eradication programmes.
- (2) Commission Delegated Regulation (EU) 2020/689⁵ supplements the rules on surveillance, eradication programmes and disease-free status for certain listed diseases and emerging diseases of terrestrial, aquatic and other animals as provided for in Regulation (EU) 2016/429.
- (3) Article 83 of Delegated Regulation (EU) 2020/689 provides for a derogation from the requirement for the Commission to approve certain disease-free statuses for aquatic animal diseases. In order to reduce the administrative burden this derogation should be expanded to include a similar provision for the approval of certain eradication programmes for aquatic animal diseases.
- (4) When a Member State wishes to obtain the approval of an eradication programme for aquatic animal diseases for its entire territory or for a zone or compartment thereof accounting for more than 75 % of its territory, or which is shared with another Member State or third country, it is required to apply to the Commission for approval. In all other cases, a system of self-declaration by the Member State must be followed.
- (5) The system of self-declaration of an eradication programme for aquatic animal diseases for zones and compartments other than those which are approved by the

⁴ OJ L 84, 31.3.2016, p.1.

⁵ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211).

Commission is designed to give transparency to the process and to make it easier and potentially quicker for Member States to have the eradication programme approved. The entire process should be completed electronically unless the Commission or another Member State raises concerns which cannot be resolved satisfactorily. If there are concerns that cannot be resolved satisfactorily, the declaration must be submitted to the Standing Committee on Plants, Animals, Food and Feed.

- (6) Commission Decision 2010/367/EU⁶ lays down minimal requirements for surveillance programmes for avian influenza in poultry and in wild birds and sets out technical guidelines in its annexes. Those requirements are now laid down in Annex II to Delegated Regulation (EU) 2020/689. For the sake of clarity and transparency Decision 2010/367/EU should be included in the list of acts to be repealed by Article 86 of Delegated Regulation (EU) 2020/689.
- (7) After publication of Delegated Regulation (EU) 2020/689, incorrect cross-references were noticed in Annex IV to that Regulation. Those cross-references should be corrected.
- (8) Annex VI to Delegated Regulation (EU) 2020/689 lays down the specific requirements as regards diseases of aquatic animals. They include the general requirements for health visits and sampling for eradication programmes. The general requirements may also be used for demonstrating and maintaining disease-free status.
- (9) Section 5 of Chapter 2 of Part II of Annex VI to Delegated Regulation (EU) 2020/689 lays down the diagnostic and sampling methods for the detection of infection with HPR-deleted infectious salmon anaemia virus. Following the latest available information laid down in the Manual of Diagnostic Test for Aquatic Animals of the World Organisation for Animal Health (OIE)⁷, the diagnostic and sampling methods should be updated.
- (10) After publication of Delegated Regulation (EU) 2020/689 in the *Official Journal of the European Union*, some mistakes were noticed in Part II of Annex IV and in Part III of Annex VI to that Regulation. Those mistakes should be corrected.
- (11) Delegated Regulation (EU) 2020/689 should therefore be amended accordingly.
- (12) As Delegated Regulation (EU) 2020/689 applies from 21 April 2021, this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2020/689 is amended as follows:

1. Article 83 is replaced by the following:

‘Article 83

Derogations from approval by the Commission for certain disease-free statuses and certain eradication programmes for aquatic animal diseases

1. By way of derogation from the requirement to submit eradication programmes to the Commission for approval as provided for in Article 31(1)(b) and Article 31(2) of Regulation (EU) 2016/429 or from the requirements to obtain

⁶ Commission Decision 2010/367/EU of 25 June 2010 on the implementation by Member States of surveillance programmes for avian influenza in poultry and wild birds (OJ L 166, 1.7.2010, p. 22).

⁷ <https://www.oie.int/standard-setting/aquatic-manual/access-online/>

approval by the Commission for disease-free status laid down in Article 36(4) and 37(4) of that Regulation, for aquatic animal diseases, such approval for zones or compartments which cover less than 75 % of the territory of a Member State, and where the water catchment supplying the zone or compartment is not shared with another Member State or third country, shall be gained in accordance with the following procedure:

- (a) a Member State makes a provisional declaration of freedom or of the establishment of an eradication programme for the zone or compartment, which fulfils the requirements as set out in this Regulation;
 - (b) this provisional declaration is published electronically by the Member State, and the Commission and Member States are alerted to the publication;
 - (c) 60 days after publication, the provisional declaration shall take effect and the zone or compartment referred to in this paragraph shall achieve disease-free status or have the eradication programme approved.
2. Within the 60-day period referred to in point (c) of paragraph 1, the Commission or Member States may seek clarification or additional information in relation to the supporting evidence provided by the Member State making the provisional declaration.
 3. Where written comments are made by at least one Member State, or the Commission, within the period referred to in point (c) of paragraph 1 indicating concerns relating to the evidence which supports the declaration, the Commission, the Member State which made the declaration and where relevant, the Member State which has sought clarification or additional information, shall together examine the submitted evidence in order to resolve the concerns.

In such cases, the period referred to in point (c) of paragraph 1 shall be prolonged automatically for 60 days from the date on which the first concerns were raised. There shall be no further prolongation of this period.

4. Where the process referred to in paragraph 3 fails, the provisions laid down in Articles 31(3), 36(4) and 37(4) of Regulation (EU) 2016/429 shall apply.
2. In Article 86, the following indent is inserted after the sixth indent:

‘– Decision 2010/367/EU;’;
 3. Annexes IV and VI to Delegated Regulation (EU) 2020/689 are amended in accordance with the Annex to this Regulation.

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*.

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, 23.3.2021

For the Commission
The President
Ursula VON DER LEYEN