COMMISSION DELEGATED REGULATION (EU) 2021/881

of 23 March 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') ([1]), 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) 2020/689 ([2]) 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 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/EU ([3]) 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.

([1]) OJ L 84, 31.3.2016, p. 1.

([2]) 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).

([3]) 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).

(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) ([4]), 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 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]) https://www.oie.int/standard-setting/aquatic-manual/access-online/

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 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes IV and VI to Delegated Regulation (EU) 2020/689 are amended as follows:

(1) Annex IV is amended as follows:

(a) in Part II, in Chapter 1, Section 1 is amended as follows:

(i) point 1(c) is replaced by the following

'(c) since the beginning of the testing or sampling referred to in point (b)(i), all bovine animals introduced into the establishment originate from establishments free from infection with MTBC and:

(i) originate from a Member State or a zone free from infection with MTBC; or

(ii) are bovine animals over 6 weeks of age and have tested negative in an immunological test:

during the 30 days prior to their introduction into the establishment; or

during the 30 days after their introduction provided they have been kept isolated during this period; and';

(ii) point 2 is replaced by the following:

'2. By way of derogation from point 1, the status free from infection with MTBC may be granted to an establishment if all bovine animals originate from establishments free from infection with MTBC and:

(a) originate from a Member State or a zone free from infection with MTBC; or

(b) if they are bovine animals over 6 weeks of age, they have tested negative to an immunological test:

(i) during the 30 days prior to their introduction into the establishment; or

(ii) during the 30 days after their introduction provided they have been kept in isolation during this period.';

(b) in Part VI, Chapter 1 is amended as follows:

(i) in Section 3, point 2(a) is replaced by the following:

'(a) the requirements laid down in point 1(c) and (d) of Section 1 and point 1(b)(c) and (d) and, if relevant, point 2 of Section 2 are fulfilled.';

(ii) in Section 4, point 2 is replaced by the following:

'2. If the status free from BVD has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in point 1(c) and (d) of Section 1 and point 1(b), (c) and (d) and, if relevant, point 2 of Section 2 are fulfilled.';

(2) Annex VI is amended as follows:

(a) Part II is amended as follows:

(i) in Chapter 1, in Section 1, the introductory phrase is replaced by the following:

'Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:';

(ii) Chapter 2 is amended as follows:

— in Section 1, the introductory phrase is replaced by the following:

'Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:';

— Section 5 is replaced by the following:

Section 5

Diagnostic and sampling methods

1. The organs or tissue material to be sampled and examined must be:

(a) Histology: anterior-kidney, liver, heart, pancreas, intestine, spleen and gill;

(b) Immunohistochemistry: mid-kidney and heart including valves and *bulbus arteriosus*;

(c) Conventional RT-PCR and RT-qPCR analysis: mid-kidney and heart;

(d) Virus culture: mid-kidney, heart and spleen;

Organ pieces from a maximum of five fish may be pooled.

2. The diagnostic method to be used to grant or to maintain the status free from infection with HPR-deleted ISAV in accordance with Sections 2, 3 and 4 must be RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene of positive samples in accordance with the detailed methods and procedures which must be those approved by the EURL for fish diseases.

In the case of a positive sequencing result for HPR-deleted ISAV, further samples must be tested before the implementation of the initial control measures provided for in Articles 55 to 65.

Those samples must be tested as follows in accordance with the detailed methods and procedures approved by the EURL for fish diseases:

(a) Screening of the samples by RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene of positive samples to verify HPR-deletion; or

(b) Detection of ISAV antigen in tissue preparations by means of specific antibodies against ISAV; or

(c) Isolation in cell culture and subsequent identification of HPR-deleted ISAV.

3. When a suspicion of infection with HPR-deleted ISAV must be confirmed or ruled out in accordance with Article 55, the following visit, sampling and testing procedure must comply with the following requirements:

(a) The suspected establishment must be subject to at least one health visit and one sampling of 10 moribund fish, when clinical signs or post-mortem lesions consistent with infection with HPR-deleted ISAV are observed, or a minimum of 30 fish when clinical signs or *post-mortem* lesions are not observed. Samples shall be tested using one or more of the diagnostic methods set out in point 2 in accordance with the detailed diagnostic methods and procedures approved by the EURL for fish diseases;

(b) In the case of a positive result for infection with HPR-deleted ISAV, further samples shall be tested before the implementation of the initial control measures provided in Article 58. A suspected case of infection with HPR-deleted ISAV shall be confirmed in accordance with the following criteria using one or more of the detailed diagnostic methods and procedures approved by the EURL for fish diseases:

(i) Detection of ISAV by RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene to verify HPR-deletion; or

(ii) Detection of ISAV in tissue preparations by means of specific antibodies against ISAV; or

(iii) Isolation and identification of ISAV in cell culture from at least one sample from any fish from the establishment;

(c) Where the presence of clinical, gross pathological or histopathological findings consistent with infection are observed, the findings must be corroborated using one or more of the diagnostic methods set out in point 3(b), in accordance with the detailed methods and procedures approved by the EURL for fish diseases.

The suspicion of HPR-deleted ISAV may be ruled out, if tests and health visits over a period of 12 months from the date of the suspicion are found to reveal no further evidence of the presence of the virus.';

(iii) in Chapter 3, in Section 1, the introductory phrase is replaced by the following:

'Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:';

(iv) in Chapter 4, in Section 1, the introductory phrase is replaced by the following:

'Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:';

(v) in Chapter 5, in Section 1, the introductory phrase is replaced by the following:

'Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:';

(vi) in Chapter 6, in Section 1, the introductory phrase is replaced by the following:

'Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:';

(b) Part III is amended as follows:

(i) in Chapter 3, in Section 3, in point (b), the introductory phrase is replaced by the following:

'(b) repopulation occurs using molluscs that originate from establishments which are:';

(ii) in Chapter 4, in Section 3, in point (b), the introductory phrase is replaced by the following:

'(b) repopulation occurs using molluscs that originate from establishments which are:';

(iii) in Chapter 5, in Section 3, in point (b), the introductory phrase is replaced by the following:

'(b) repopulation occurs using molluscs that originate from establishments which are:';

(iv) in Chapter 6, in Section 3, in point (b), the introductory phrase is replaced by the following:

'(b) repopulation occurs using crustaceans that originate from establishments which are:'.