COMMISSION IMPLEMENTING REGULATION (EU) 2023/1451

of 13 July 2023

amending Implementing Regulation (EU) 2020/2002 as regards disease notification and the information to be submitted by the Member States for the approval and reporting of compulsory and optional eradication programmes and in applications for disease-free status

(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 Articles 23, 35 and 40 thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for animal diseases that are transmissible to animals or humans, including provisions for disease notification and reporting, Union surveillance programmes, eradication programmes and disease-free status.
- (2) Commission Delegated Regulation (EU) 2020/689 (²) supplements Regulation (EU) 2016/429 and lays down rules on surveillance, eradication programmes and disease-free status for certain listed and emerging animal diseases.
- (3) To ensure the uniform application in the Union of the provisions for disease notification and reporting, Union surveillance programmes, eradication programmes and disease-free status laid down in Regulation (EU) 2016/429 and in Delegated Regulation (EU) 2020/689, implementing rules on the information, formats and procedural requirements for the surveillance programmes, eradication programmes and for disease-free status are laid down in Commission Implementing Regulation (EU) 2020/2002 (3).
- (4) Experience gained with the submission of information concerning the outcome of the approved eradication programmes, and applications for disease-free status in the period since the date of application of Implementing Regulation (EU) 2020/2002, and especially in light of data already available in the computerised Animal Disease Information System (ADIS) provided for in Article 22 of Regulation (EU) 2016/429, shows that certain elements of the information currently required by that Implementing Regulation are not essential for the Commission to assess the applications for disease-free status. Those elements should not be required, in order to reduce the administrative burden on Member States. Therefore, Implementing Regulation (EU) 2020/2002 should be amended accordingly.

⁽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 Implementing Regulation (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system (OJ L 412, 8.12.2020, p. 1).

- (5) The information to be provided on the results of the implementation of eradication programmes is available in the ADIS. The draft eradication programmes submitted to the Commission for approval should also be submitted electronically via the ADIS, in order to ensure coherence.
- (6) Furthermore, experience gained in the application of Implementing Regulation (EU) 2020/2002, has indicated that it is necessary to clarify certain provisions of Annexes V, VI and VII thereto, to ensure that it is clear that the territorial scope of an approved eradication programme concerning aquatic animals, and the approval of disease-free status for those animals, may apply at the level of Member State, zone or compartment. Annexes V, VI and VII to Implementing Regulation (EU) 2020/2002 should therefore be amended accordingly.
- (7) Delegated Regulation (EU) 2020/689 provides for several derogations which are relevant for the submission of an eradication programme for a category B or category C disease of aquatic animals in accordance with Section 4 of Annex VII to Implementing Regulation (EU) 2020/2002. Currently, only one such derogation is referred to in that Annex. Implementing Regulation (EU) 2020/2002 should, therefore, be amended to ensure that all the relevant derogations are referred to in Section 4 of Annex VII thereto.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2020/2002 is amended as follows:

(1) Article 7 is replaced by the following:

'Article 7

Union reporting on the annual results of the implementation of approved eradication programmes

- 1. Member States shall submit to the Commission by 30 April of every year reports on the results of the implementation of their ongoing approved eradication programmes.
- 2. The reports referred to in paragraph 1 shall contain for every year, covering the previous calendar year, the information specified in:
- (a) Section 1 of Annex V for eradication programmes for category B and C diseases of terrestrial animals based on granting disease-free status at the level of establishments;
- (b) Section 2 of Annex V for eradication programmes for infection with rabies virus (RABV);
- (c) Section 3 of Annex V for eradication programmes for infection with bluetongue virus (serotypes 1-24) (infection with BTV);
- (d) Section 4 of Annex V for eradication programmes for category B and C diseases of aquatic animals.
- 3. The reports referred to in paragraph 1 shall be submitted electronically via the ADIS.';
- (2) in Article 8, paragraph (2) is deleted;
- (3) Article 10 is amended as follows:
 - (a) the introductory phrase in paragraph 1 is replaced by the following:

'Member States shall submit to the Commission for approval:';

- (b) the following paragraph 3 is added:
 - 3. The eradication programmes referred to in paragraph 1 shall be submitted electronically via the ADIS';
- (4) in Article 11, the introductory phrase in paragraph 1 is replaced by the following:

'Member States shall, when applying to the Commission for recognition of disease-free status in accordance with Sections 1 and 2 of Chapter 4 of Part II of Delegated Regulation (EU) 2020/689, with the exception of the information previously provided in reports referred to in Article 7 of this Regulation, include in their applications the relevant information specified in:';

(5) Annexes V, VI and VII to Implementing Regulation (EU) 2020/2002 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.

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

Done at Brussels, 13 July 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes V, VI and VII to Implementing Regulation (EU) 2020/2002 are amended as follows:

- (1) in Annex V:
 - (a) Section 1, point 6 is replaced by the following:
 - '6. Information on the establishments and animals concerned located in the territory in accordance with point 5, by zone, if more than one zone is included in the territorial scope of the programme:
 - (a) number of establishments keeping animals of the targeted animal population excluding establishments falling under the derogation in accordance with Article 19 of Commission Delegated Regulation (EU) 2020/689 (*) at 31 December;
 - (b) number of animals of the targeted animal population kept in the establishments referred to in point (a) at 31 December;
 - (c) number of establishments with disease-free status including establishments with suspended disease-free status, with vaccination or without vaccination, where relevant, out of the number of establishments referred to in point (a) at 31 December;
 - (d) number of animals kept in the establishments referred to in point (c);
 - (e) number of establishments confirmed infected during the reporting period.
 - (*) 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).';
 - (b) Section 4, point 6 is replaced by the following:
 - '6. Information on the aquaculture establishments and animals concerned located in the territory referred to in point 5 by Member State, zone or compartment:
 - (a) number of approved aquaculture establishments and number of registered aquaculture establishments keeping animals of the targeted animal population and, where relevant, sampling points in wild populations, which are included in the eradication programme at 31 December;
 - (b) number of aquaculture establishments and, where relevant, sampling points in wild populations, out of the number of establishments or sampling points referred to in point (a), which are not infected at 31 December;
 - (c) number of infected aquaculture establishments and, where relevant, sampling points in wild populations with confirmed case(s) out of the number of establishments and sampling points referred to in point (a) at 31 December;
 - (d) number of new infected aquaculture establishments and, where relevant, sampling points in wild populations, with confirmed case(s) out of the number of establishments and sampling points referred to in point (a) at 31 December.';
- (2) Annex VI is amended as follows:
 - (a) the title is replaced by the following:

'Information to be included in applications for the recognition of disease-free status of Member States or zones as regards diseases of terrestrial and aquatic animals and in applications for the recognition of disease-free status of compartments as regards diseases of aquatic animals in accordance with Article 11';

- (b) Section 6 is amended as follows:
 - (i) points 1 to 7 are replaced by the following:
 - '1. in the case of eradication programmes for infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept bovine animals by zone, if more than one zone is included in the territorial scope of the programme:

- (a) number of establishments keeping bovine animals, excluding establishments falling under the derogation in accordance with Article 19 of Delegated Regulation (EU) 2020/689 at 31 December of each year for the last three years;
- (b) number of bovine animals kept in the establishments referred to in point (a) at 31 December of each year for the last three years;
- (c) number of establishments keeping bovine animals with the status free from infection with *Brucella* abortus, B. melitensis and B. suis without vaccination including establishments with suspended disease-free status at 31 December of each year for the last three years;
- (d) number of bovine animals kept in the establishments referred to in point (c) at 31 December of each year for the last three years;
- (e) number of establishments keeping bovine animals tested with a serological test for infection with Brucella abortus, B. melitensis and B. suis each year for the last three years;
- (f) number of establishments with suspicion following the testing referred to in point (e) each year for the last three years;
- (g) number of abortion cases from kept bovine animals that may have been caused by infection with Brucella abortus, B. melitensis and B. suis investigated each year for the last three years;
- (h) date of last confirmed case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in kept bovine animals;
- date of last vaccination against infection with Brucella abortus, B. melitensis and B. suis of kept bovine animals;
- 2. in the case of eradication programmes for infection with *Brucella abortus*, *B. melitensis* and *B. suis* as regards kept ovine and caprine animals, by zone, if more than one zone is included in the territorial scope of the programme:
 - (a) number of establishments keeping ovine or caprine animals, excluding establishments falling under the derogation in accordance with Article 19 of Delegated Regulation (EU) 2020/689 at 31 December of each year for the last three years;
 - (b) number of ovine and caprine animals kept in the establishments referred to in point (a) at 31 December of each year for the last three years;
 - (c) number of establishments keeping ovine or caprine animals with the status free from infection with Brucella abortus, B. melitensis and B. suis without vaccination including establishments with suspended disease-free status at 31 December of each year for the last three years;
 - (d) number of ovine and caprine animals kept in the establishments referred to in point (c) at 31 December of each year for the last three years;
 - (e) number of establishments keeping ovine or caprine animals tested for infection with *Brucella abortus*, B. *melitensis* and B. *suis* each year for the last three years;
 - (f) number of establishments with suspicion following the testing referred to in point (e) each year for the last three years;
 - (g) number of abortion cases from ovine or caprine animals that may have been caused by infection with *Brucella abortus*, *B. melitensis* and *B. suis* investigated each year for the last three years;
 - (h) date of last confirmed case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in kept ovine or caprine animals;
 - (i) date of last vaccination against infection with Brucella abortus, B. melitensis and B. suis of kept ovine or caprine animals;

- 3. in the case of eradication programmes for infection with MTBC, by zone, if more than one zone is included in the territorial scope of the programme:
 - (a) number of establishments keeping bovine animals, excluding establishments falling under the derogation in accordance with Article 19 of Delegated Regulation (EU) 2020/689 at 31 December of each year for the last three years;
 - (b) number of bovine animals kept in the establishments referred to in point (a) at 31 December of each year for the last three years;
 - (c) number of establishments keeping bovine animals with the status free from infection with MTBC including establishments with suspended disease-free status at 31 December of each year for the last three years;
 - (d) number of bovine animals kept in the establishments referred to in point (c) at 31 December of each year for the last three years;
 - (e) number of establishments keeping bovine animals tested for MTBC each year for the last three years;
 - (f) number of establishments with suspicion following the testing referred to in point (e) each year for the last three years;
 - (g) number of bovine animals slaughtered, presenting suspected lesions of infection with MTBC that have been investigated each year the last three years;
 - (h) number of establishments confirmed infected with MTBC each year the last three years;
- 4. in the case of eradication programmes for EBL, by zone, if more than one zone is included in the territorial scope of the programme:
 - (a) number of establishments keeping bovine animals, excluding establishments falling under the derogation in accordance with Article 19 of Delegated Regulation (EU) 2020/689 at 31 December of each year for the last three years;
 - (b) number of bovine animals kept in the establishments referred to in point (a) at 31 December of each year for the last three years;
 - (c) number of establishments keeping bovine animals with the status free from EBL including establishments with suspended disease-free status at 31 December of each year for the last three years;
 - (d) number of bovine animals kept in the establishments referred to in point (c) at 31 December of each year for the last three years;
 - (e) number of establishments keeping bovine animals tested for EBL each year for the last three years;
 - (f) number of establishments with suspicion following the testing referred to in point (e) each year for the last three years;
 - (g) number of samples from slaughtered bovine animals over 24 months of age with tumors that could be caused by EBL being subjected to laboratory examination to confirm or rule out the presence of EBL each year for the last three years;
 - (h) number of establishments confirmed infected with EBL each year for the last three years;
- 5. in the case of eradication programmes for IBR/IPV, by zone, if more than one zone is included in the territorial scope of the programme:
 - (a) number of establishments keeping bovine animals, excluding establishments falling under the derogation in accordance with Article 19 of Delegated Regulation (EU) 2020/689 at 31 December of each year for the last three years;
 - (b) number of bovine animals kept in the establishments referred to in point (a) at 31 December of each year for the last three years;

- (c) number of establishments with the status free from IBR/IPV including establishments with suspended disease-free status at 31 December of each year for the last three years;
- (d) number of bovine animals kept in the establishments referred to in point (c) at 31 December of each year for the last three years;
- (e) number of establishments tested for IBR/IPV each year for the last three years;
- (f) number of establishments with suspicion following the testing referred to in point (e) each year for the last three years;
- (g) number of establishments confirmed infected with IBR/IPV each year for the last three years;
- (h) date of prohibition of vaccination against IBR/IPV of kept bovine animals;
- 6. in the case of eradication programmes for infection with ADV, by zone, if more than one zone is included in the territorial scope of the programme:
 - (a) number of establishments keeping porcine animals, excluding establishments falling under the derogation in accordance with Article 19 of Delegated Regulation (EU) 2020/689 at 31 December of each year for the last three years;
 - (b) number of porcine animals kept in the establishments referred to in point (a) at 31 December of each year for the last three years;
 - (c) number of establishments with the status free from infection with ADV including establishments with suspended disease-free status at 31 December of each year for the last three years;
 - (d) number of porcine animals kept in the establishments referred to in point (c) at 31 December of each year for the last three years;
 - (e) number of establishments where surveillance has been carried out to discover any clinical, virological or serological evidence of infection with ADV each year for the last three years;
 - (f) number of porcine animals tested in the establishments referred to in point (e) each year for the last three years;
 - (g) number of establishments confirmed infected with ADV each year for the last three years;
 - (h) date of prohibition of vaccination against ADV of kept porcine animals;
- 7. in the case of eradication programmes for BVD, by zone, if more than one zone is included in the territorial scope of the programme:
 - (a) number of establishments keeping bovine animals, excluding establishments falling under the derogation in accordance with Article 19 of Delegated Regulation (EU) 2020/689 at 31 December of each year for the last three years;
 - (b) number of bovine animals kept in the establishments referred to in point (a) at 31 December of each year for the last three years;
 - (c) number of establishments with the status free from BVD including establishments with suspended disease-free status at 31 December of each year for the last three years;
 - (d) number of bovine animals kept in the establishments referred to in point (c) at 31 December of each year for the last three years;
 - (e) number of establishments tested for BVD each year for the last three years;
 - (f) number of establishments with suspicion following the testing referred to in point (e) each year for the last three years;

- (g) number of establishments confirmed infected with BVD each year for the last three years;
- (h) date of prohibition of vaccination against BVD of kept bovine animals;';
- (ii) point 10 is replaced by the following:
 - '10. in the case of eradication programmes for category B and C diseases of aquatic animals, supply the following information for each year of the programme, by Member State, zone or compartment, as relevant to the territorial scope:
 - (a) number of approved aquaculture establishments, and where relevant, the number of registered aquaculture establishments keeping animals of the targeted animal population and sampling points in wild populations, which are included in the eradication programme, as well as maps showing the location of establishments and sampling points in wild populations;
 - (b) number of aquaculture establishments and, where relevant, sampling points in wild populations, out of the number of establishments and sampling points referred to in point (a), which are not infected;
 - (c) number of animal health visits per approved and where relevant, registered aquaculture establishments;
 - (d) number of samplings per approved and where relevant, registered aquaculture establishments and sampling points in wild populations, as well as details of species, results of sampling (positive or negative) and water temperatures at the time of sampling;
 - (e) number of infected aquaculture establishments and, where relevant, sampling points in wild populations with confirmed cases(s) out of the number of establishments referred to in point (a);
 - (f) number of new infected aquaculture establishments and, where relevant, sampling points in wild populations with confirmed case(s) out of the number of establishments referred to in point (a).';
- (3) Annex VII is amended as follows:
 - (a) in Section 1, point 9 is replaced by the following:
 - '9. The intermediate targets of the eradication programme related to the disease-specific criteria for obtaining disease-free status, including at least:
 - (a) the expected annual decrease of the number of infected establishments;
 - (b) the expected annual increase of the number of disease-free establishments.';
 - (b) in Section 4, points 5 and 6 are replaced by the following:
 - '5. A description of the epidemiological situation in the Member State, zone or compartment, as relevant to the territorial scope of the programme, including:
 - (a) the number of approved aquaculture establishments and the number of registered aquaculture establishments keeping animals of the targeted animal population, by type of production and by health status;
 - (b) listed species kept in the aquaculture establishments referred to in point (a) by health status;
 - (c) maps indicating:
 - (i) the geographical location of the aquaculture establishments referred to in point (a) and the relevant water catchment areas; and
 - (ii) the geographical distribution of cases of infection with the relevant category B or C disease for a period covering at least the past 5 years;
 - (d) information as regards the epidemiological situation in wild aquatic animals, where relevant.

- 6. A description of the disease control strategy of the eradication programme in accordance with Article 46 of Delegated Regulation (EU) 2020/689 including at least:
 - (a) the sampling schemes and diagnostic methods to be used in accordance with Annex VI to Delegated Regulation (EU) 2020/689 for:
 - (i) health visits and sampling in aquaculture establishments;
 - (ii) targeted surveillance in wild populations, where relevant;
 - (b) the disease control measures to be applied in the event of a confirmed case;
 - (c) the biosecurity and risk mitigating measures to be implemented;
 - (d) vaccination schemes, where relevant;
 - (e) the measures to be implemented as regards wild aquatic animals and the number and geographical location of sampling points where relevant;
 - (f) the derogations to be applied in accordance with Article 47(4), Article 51(2) or Article 53 of Delegated Regulation (EU) 2020/689, where relevant;
 - (g) coordinated measures with other Member States or third countries, where relevant.'.