Council of the
European Union

Brussels, 26 March 2021
(OR. en)

7350/21
ADD 1

AGRILEG 57
VETER 20
DELACT 57

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	23 March 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2021) 1784 final ANNEX
Subject:	ANNEX to the COMMISSION DELEGATED REGULATION 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 ANNEX.

Encl.: C(2021) 1784 final ANNEX

EUROPEAN
COMMISSION

Brussels, 23.3.2021
C(2021) 1784 final

ANNEX

ANNEX

to the

COMMISSION DELEGATED REGULATION

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

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:'.