

II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/260

of 11 February 2021

approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU

(notified under document C(2021) 773)

(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 Article 226(3) thereof,

Whereas:

- (1) Council Directive 2006/88/EC ⁽²⁾ lays down, inter alia, the animal health requirements to be applied for the placing on the market, the importation and the transit of aquaculture animals and products thereof, minimum preventive measures aimed at increasing the awareness of diseases in aquaculture animals, and minimum control measures to be applied in the event of suspicion of, or an outbreak of certain diseases in aquatic animals. That Directive is repealed by Regulation (EU) 2016/429 with effect from 21 April 2021.
- (2) Article 9(1)(d) of Regulation (EU) 2016/429 concerns the control rules which apply in relation to listed diseases for which measures are needed to prevent their spread, whether on entry into the Union or as a result of movements between Member States.
- (3) Union aquaculture is extremely diverse as regards the species grown and the production systems used across Member States, and it is likely that this diversity will increase over time. Consequently certain diseases which are not listed under Article 9(1)(d) of Regulation (EU) 2016/429, may nonetheless be relevant to certain Member States either because the species is present in those Member States, or because of the type of aquaculture production methods employed in those Member States. Where a disease other than a listed disease, as referred to in Article 9(1)(d) of Regulation (EU) 2016/429, constitutes a significant risk to the health of aquatic animals in those Member States, Member States may, in order to control the spread of the disease, adopt national measures pursuant to Article 226(1) of that Regulation, provided these measures are appropriate and necessary to the goals to be achieved.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

- (4) In order to ensure that the national measures proposed by a Member State are appropriate and necessary, the Commission is to be notified in advance of any measures that may affect the movements of aquatic animals between Member States, so that the measures can be approved, or if necessary, amended.
- (5) Certain Member States have received approval to adopt national measures for the purposes of limiting the impact of certain diseases on aquaculture animals pursuant to Article 43 of Directive 2006/88/EC. Commission Decision 2010/221/EU ⁽³⁾ sets out the details of those Member States and the diseases for which they have national measures in place.
- (6) Certain Member States have obtained disease-free status for Koi herpes virus disease, or are implementing an approved eradication or surveillance programme for that disease under Directive 2006/88/EC. However, Koi herpes virus disease is now listed as a category E disease pursuant to Commission Implementing Regulation (EU) 2018/1882 ⁽⁴⁾, meaning it is a listed disease for which there is a need for surveillance within the Union. It may therefore, be considered for national measures pursuant to Article 226 of Regulation (EU) 2016/429.
- (7) To ensure a smooth transition to the new regime under Regulation (EU) 2016/429, Member States concerned are to seek approval for national measures under Article 226(2) of Regulation (EU) 2016/429 from 21 April 2021.
- (8) The Commission has assessed the measures proposed by the Member States concerned, taking into account the standards of the World Organisation for Animal Health (OIE) ⁽⁵⁾, and the overall impact on the Union of the diseases in question and of the measures proposed. The Commission considers that the Member States concerned have demonstrated the appropriateness and necessity of those measures to warrant their approval in order to prevent the introduction of the diseases in question in their territories, or to control their spread between Member States. The Member States concerned should be listed in the Annexes to this Decision, as appropriate.
- (9) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (Withdrawal Agreement), and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, Regulation (EU) 2016/429, as well as the Commission acts based on it, applies to and in the United Kingdom in respect of Northern Ireland after the end of the transition period provided for in the Withdrawal Agreement. For that reason, the United Kingdom (Northern Ireland) should be listed in the Annexes to this Decision, as appropriate.
- (10) In order to protect the health status of Member States with national measures approved for a particular disease pursuant to Article 226(3) of Regulation (EU) 2016/429, consignments of species of aquatic animals which are susceptible to the diseases in question are required to originate from a Member State, or part thereof, which is free from the same disease. Such consignments are to be accompanied by an official certificate attesting to this disease-free status.
- (11) Animal health certificates attesting as to the place of origin of a consignment destined for a Member State, or part thereof, which has national measures approved pursuant to Article 226(3) of Regulation (EU) 2016/429, are included in the relevant model official certificates for the movement of aquatic animals between Member States set

⁽³⁾ Commission Decision 2010/221/EU of 15 April 2010 approving national measures for limiting the impact of certain diseases in aquaculture animals and wild aquatic animals in accordance with Article 43 of Council Directive 2006/88/EC (OJ L 98, 20.4.2010, p. 7).

⁽⁴⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 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 diseases (OJ L 308, 4.12.2018, p. 21).

⁽⁵⁾ The OIE Aquatic Animal Health Code and the OIE Manual of Diagnostic Tests for Aquatic Animals.

out in Commission Implementing Regulation (EU) 2020/2236 ⁽⁶⁾. These animal health certificates are to be used when aquatic animals of listed species are destined for a Member State or part thereof for which the Commission has approved national measures in accordance with Article 226(3) of Regulation (EU) 2016/429.

- (12) The national measures approved by this Decision should only apply for as long as they continue to be appropriate and necessary in order to prevent the introduction of the diseases to the Member States concerned, or to control their spread between Member States. To allow the Commission to make a regular assessment of the appropriateness and necessity of such measures, and to provide an opportunity to amend the measures if necessary, the Member States should send an annual report to the Commission detailing the functioning of the measures in the previous year. Such annual reports and other relevant reporting should include certain information set out in Commission Implementing Regulation (EU) 2020/2002 ⁽⁷⁾.
- (13) Eradication programmes approved in accordance with Article 226(3) of Regulation (EU) 2016/429 should lead to an improvement in the disease situation within a reasonable period of time. In the interest of coherence, this period of time should not be longer than the period within which an eradication programme for a category C disease is to be completed. The period of application of an eradication programme approved in accordance with Article 226(3) of Regulation (EU) 2016/429 should, therefore, not exceed 6 years from the date of its initial approval by the Commission. In duly justified cases, and at the request of the Member State concerned, the Commission should have the possibility of extending the period of application of the eradication programme for an additional 6-year period. This maximum period of application is laid down in order to give an adequate period of time within which an eradication programme may be completed, whilst at the same time, preventing the disproportionate and long-lasting disruption of movements of aquatic animals within the Union.
- (14) In the interest of clarity of Union legislation, Decision 2010/221/EU should be repealed.
- (15) As Regulation (EU) 2016/429 has a date of application of 21 April 2021, this Decision should also apply from that date.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

This Decision approves the national measures which have been adopted by those Member States or parts of those Member States which are listed in Annexes I and II in order to limit the impact of certain diseases affecting aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429, and lays down:

- (a) conditions for the initial and continued approval of those measures;
- (b) restrictions on the movement of aquatic animals between Member States;
- (c) reporting obligations of Member States.

⁽⁶⁾ Commission Implementing Regulation (EU) 2020/2236 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals, official certification regarding such certificates and repealing Regulation (EC) No 1251/2008 (OJ L 442, 30.12.2020, p. 410).

⁽⁷⁾ 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 computerized information system (OJ L 412, 8.12.2020, p. 1).

*Article 2***Approval of national measures in disease-free areas**

The Member States or parts thereof, which are listed in the second and fourth column of the table in Annex I, are considered free from the diseases listed in the first column of that table and are granted approval to adopt national measures in accordance with Article 226(3) of Regulation (EU) 2016/429.

*Article 3***Approval of eradication programmes for diseases which are subject to national measures**

1. The eradication programmes adopted by the Member States listed in the second column of the table in Annex II for the diseases which are subject to national measures and which are listed in the first column of that table, in respect of the areas listed in the fourth column thereof, are approved.
2. The period of application of an eradication programme shall not exceed 6 years from the date of its initial approval by the Commission. In duly justified cases, the Commission may, at the request of the Member State concerned, extend the period of application of the eradication programme for an additional 6-year period.

*Article 4***Movements between Member States or parts thereof, of aquatic animals of susceptible species which are subject to national measures including eradication programmes**

Aquatic animals of species susceptible to the diseases set out in the second column of Annex III shall only be moved to Member States or parts thereof which are listed in the second and fourth column of the tables in Annexes I or II if they:

- (a) originate from a Member State or part thereof, which is listed in the second and fourth column of the table in Annex I as being free from the disease in question; and
- (b) are accompanied by an official certificate issued by the competent authority of the Member State of origin, drawn up in accordance with an appropriate model animal health certificate set out in Chapters 1, 2, 3 or 5 of Annex I to Implementing Regulation (EU) 2020/2236, specifying the guarantees relevant for the specific national measures in question.

*Article 5***Annual reporting by Member States**

1. By 30 April each year at the latest, the Member States listed in the second column of the tables in Annexes I and II shall submit a report to the Commission on the approved national measures for the disease-free status of those Member States and parts thereof referred to in Article 2, or for the eradication programmes referred to in Article 3, as appropriate.
2. The report referred to in paragraph 1 shall include:
 - (a) information on the measures which have been taken in the previous calendar year to maintain the disease-free status, including at least the information set out in Annex III to Implementing Regulation (EU) 2020/2002; or
 - (b) information on the evolution of the eradication programme, including details of the testing which has been carried out in the previous calendar year and at least the information set out in Section 4 of Annex V to Implementing Regulation (EU) 2020/2002.

3. The report referred to in paragraph 1 shall outline the reasons why the disease-free status or the eradication programme as appropriate, should continue to apply for a further calendar year. Particular reference shall be made to the availability of treatments, vaccines, disease resistant stocks, or other relevant developments should one or more of these have become a viable option for the prevention and control of the disease in question since the submission of the previous report.

Article 6

Amendment of approved national measures

The national measures set out in Annexes I and II may be amended by the Commission should the information referred to in Article 5(3), or other such information relating to developments in animal health, indicate that the establishment of movement restrictions between Member States is no longer necessary or justified in order to prevent the introduction, or to control the spread, of a particular disease.

Article 7

Repeal

Commission Decision 2010/221/EU is repealed with effect from 21 April 2021.

Article 8

Application

This Decision shall apply from 21 April 2021.

Article 9

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 11 February 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX I

Member States ⁽¹⁾ or parts thereof regarded as being free from certain diseases affecting aquatic animals and for which the national measures are approved in accordance with Article 226(3) of Regulation (EU) 2016/429

Disease	Member State	Code	Geographical demarcation of the area for which the national measures are approved
Koi herpes virus disease (KHV)	Ireland	IE	Whole territory
	United Kingdom (Northern Ireland)	UK(NI)	Northern Ireland
Spring viraemia of carp (SVC)	Denmark	DK	Whole territory
	Finland	FI	Whole territory
	Hungary	HU	Whole territory
	Ireland	IE	Whole territory
	Sweden	SE	Whole territory
	United Kingdom (Northern Ireland)	UK(NI)	Northern Ireland
Bacterial kidney disease (BKD)	Ireland	IE	Whole territory
	United Kingdom (Northern Ireland)	UK(NI)	Northern Ireland
Infectious pancreatic necrosis (IPN)	Finland	FI	Continental parts of the territory
	Sweden	SE	Continental parts of the territory
Infection with <i>Gyrodactylus salaris</i> (GS)	Finland	FI	Water catchment areas of the Tenojoki and Näätämöjoki; the water catchment areas of the Paatsjoki, Tuulomajoki, and Utuanjoki are considered as buffer zones
	Ireland	IE	Whole territory
	United Kingdom (Northern Ireland)	UK(NI)	Northern Ireland

⁽¹⁾ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex, references to Member States include the United Kingdom in respect of Northern Ireland.

Ostreid herpesvirus – 1 μ var (OsHV-1 μ var)	Ireland	IE	Compartment 1: Sheephaven Bay Compartment 3: Killala, Broadhaven and Blacksod Bays Compartment 4: Streamstown Bay Compartment 5: Bertraghboy and Galway Bays Compartment A: Tralee Bay Hatchery
	United Kingdom (Northern Ireland)	UK(NI)	Territory of Northern Ireland except Dundrum Bay, Killough Bay, Lough Foyle, Carlingford Lough, Larne Lough and Strangford Lough
Infection with salmonid alphavirus (SAV)	Finland	FI	Continental parts of the territory

ANNEX II

Member States ⁽¹⁾ or parts thereof with eradication programmes for certain diseases affecting aquatic animals and for which the national measures are approved in accordance with Article 226(3) of Regulation (EU) 2016/429

Disease	Member State	Code	Geographical demarcation of the area for which the national measures are approved
Bacterial kidney disease (BKD)	Sweden	SE	Continental parts of the territory
Infectious pancreatic necrosis (IPN)	Sweden	SE	Coastal parts of the territory

⁽¹⁾ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex, references to Member States include the United Kingdom in respect of Northern Ireland.

ANNEX III

Species of aquatic animals which are susceptible to diseases for which certain Member States ⁽¹⁾ have adopted national measures in accordance with Article 226(3) of Regulation (EU) 2016/429

Disease	Susceptible species
Koi herpes virus disease (KHV)	As set out in column 3 of the table in the Annex to Implementing Regulation (EU) 2018/1882
Spring viraemia of carp (SVC)	Bighead carp (<i>Aristichthys nobilis</i>), goldfish (<i>Carassius auratus</i>), crucian carp (<i>Carassius carassius</i>), grass carp (<i>Ctenopharyngodon idellus</i>), common carp and koi carp (<i>Cyprinus carpio</i>), silver carp (<i>Hypophthalmichthys molitrix</i>), sheatfish (<i>Silurus glanis</i>), tench (<i>Tinca tinca</i>), orfe (<i>Leuciscus idus</i>)
Bacterial kidney disease (BKD)	All species of <i>Salmonidae</i>
Infectious pancreatic necrosis (IPN)	Brook trout (<i>Salvelinus fontinalis</i>), brown trout (<i>Salmo trutta</i>), Atlantic salmon (<i>Salmo salar</i>), (<i>Oncorhynchus</i> spp.) whitefish (<i>Coregonus lavaretus</i>)
Infection with <i>Gyrodactylus salaris</i> (GS)	Atlantic salmon (<i>Salmo salar</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), Arctic char (<i>Salvelinus alpinus</i>), North American brook trout (<i>Salvelinus fontinalis</i>), grayling (<i>Thymallus thymallus</i>), North American lake trout (<i>Salvelinus namaycush</i>), brown trout (<i>Salmo trutta</i>) and any species which has been in contact with these species
Ostreid herpes virus 1 μ var (OsHV-1 μ var)	Pacific oyster (<i>Crassostrea gigas</i>)
Infection with salmonid alphavirus (SAV)	Atlantic salmon (<i>Salmo salar</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), brown trout (<i>Salmo trutta</i>)

⁽¹⁾ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex, references to Member States include the United Kingdom in respect of Northern Ireland.