Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU)

## **COMMISSION DECISION**

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

(notified under document C(2010) 1850)

(Text with EEA relevance)

(2010/221/EU)

### THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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<sup>(1)</sup>, and in particular Article 43(2) thereof,

#### Whereas:

- (1) Commission Decision 2004/453/EC of 29 April 2004 implementing Council Directive 91/67/EEC as regards measures against certain diseases in aquaculture animals<sup>(2)</sup> approves the disease-free status of certain Member States or parts thereof as regards spring viraemia of carp (SVC), bacterial kidney disease (BKD), infectious pancreatic necrosis virus (IPN) and infection with *Gyrodactylus salaris* (GS) (approved disease-free areas), and control or eradication programmes of certain Member States (approved control or eradication programmes) as regards SVC, BKD and IPN.
- (2) Member States with approved disease-free areas or with approved control or eradication programmes pursuant to Decision 2004/453/EC may require additional guarantees for consignments of live aquaculture fish of susceptible species to the relevant diseases intended for farming, which are to be introduced into those areas. Those additional guarantees consist of the requirement that those consignments must originate from an area with an equivalent health status as the place of destination.
- (3) Directive 2006/88/EC repealed and replaced Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products<sup>(3)</sup>. However, Directive 2006/88/EC provides that Decision 2004/453/EC is to continue to apply for the purpose of Directive

Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- 2006/88/EC pending the adoption of the necessary provisions in accordance with that Directive, which are to be adopted not later than three years after its entry into force.
- (4) Article 43 of Directive 2006/88/EC provides that a Member State may take measures to prevent the introduction of, or to control diseases not listed in Part II of Annex IV thereto which constitute a significant risk for the animal health situation of aquaculture animals or wild aquatic animals in that Member State. Those measures are not to exceed the limits of what is appropriate and necessary to prevent the introduction of or control of, such diseases.
- (5) The Member States which have been granted the right to require additional guarantees pursuant to Decision 2004/453/EC have provided the Commission with information on the disease situation as regards the diseases for which they have approved disease-free areas or approved control or eradication programmes. They have demonstrated the appropriateness and necessity of continuing requiring national measures in the form of placing on the market, import and transit requirements, in accordance with Article 43 of Directive 2006/88/EC.
- (6) Consequently, Member States which were granted the right to require additional guarantees in accordance with Decision 2004/453/EC for the introduction of aquaculture animals of susceptible species into approved disease-free areas or areas with approved control or eradication programmes should be allowed to continue to apply these measures as national measures approved in accordance with Article 43 of Directive 2006/88/EC.
- (7) In addition, Finland has provided information to support the finding that it is no longer necessary to regard certain water catchment areas as buffer zones in order to protect the disease-free status regarding SVC and IPN.
- (8) In the interests of simplification of Union legislation, the specific placing on the market, import and transit requirements for consignments of aquaculture animals and wild aquatic animals intended for areas with approved national measures, should be included in the provisions and model animal health certificates laid down in Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species<sup>(4)</sup>.
- (9) The national measures approved by this Decision should only be applied as long as they are appropriate and necessary. Therefore, the Member States should send a yearly report to the Commission on the functioning of the national measures.
- (10) Any suspicion of the presence of a relevant disease in areas listed as disease-free in Annex I to this Decision should be investigated and during the investigation movement restrictions should be applied to protect other Member States with approved national measures as regards the same disease. In addition, to facilitate the necessary reassessment of the approved national measures, any subsequent disease confirmation should be notified to the Commission and to the other Member States.

Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- (11) The eradication programmes should lead to an improvement in the disease situation within a reasonable period of time. In the second half of 2011, the disease situation in the areas covered by such programmes should be reassessed and the appropriateness of the national measures re-evaluated. Therefore, this Decision should provide for those measures to apply only until 31 December 2011.
- (12) In the interest of clarity of Union legislation, Decision 2004/453/EC should be expressly repealed.
- In order to prevent any disruption of trade, consignments of aquaculture animals which are accompanied by an animal health certificate issued in accordance with Annex III to Decision 2004/453/EC should be permitted to be placed on the market until 30 June 2010, subject to certain conditions.
- (14) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

# I<sup>F1</sup>Article 1

# Subject matter and scope

This Decision approves the national measures of Member States listed in Annexes I, II and III hereto for limiting the impact and spread of certain diseases in aquaculture animals and wild aquatic animals in accordance with Article 43(2) of Directive 2006/88/ EC.]

#### **Textual Amendments**

**F1** Substituted by Commission Decision of 24 March 2011 amending Decision 2010/221/EU as regards the approval of national measures for preventing the introduction of ostreid herpesvirus 1 μvar (OsHV-1 μvar) into certain areas of Ireland and the United Kingdom (notified under document C(2011) 1825) (Text with EEA relevance) (2011/187/EU).

### Article 2

# Approval of certain national measures for limiting the impact of certain diseases not listed in Part II of Annex IV to Directive 2006/88/EC

- 1 The Member States and parts thereof listed in the second and fourth column of the table in Annex I shall be regarded as free of the diseases listed in the first column of that table (disease-free areas).
- The Member States referred to in paragraph 1 may require that the following consignments introduced into a disease-free area comply with the requirements set out in points (a) and (b) with respect to those diseases for which it is regarded as disease-free:
  - a aquaculture animals intended for farming, relaying areas, put and take fisheries, open ornamental facilities and restocking must comply with:

Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- (i) the placing on the market requirements laid down in Article 8a of Regulation (EC) No 1251/2008;
- (ii) the import requirements laid down in Article 10 of Regulation (EC) No 1251/2008;
- (iii) the transit and storage requirements laid down in Article 16 of Regulation (EC) No 1251/2008;
- b ornamental aquatic animals intended for closed ornamental facilities must comply with:
  - (i) the import requirements laid down in Article 11 of Regulation (EC) No 1251/2008;
  - (ii) the transit and storage requirements laid down in Article 16 of Regulation (EC) No 1251/2008.

#### Article 3

# Approval of national eradication programmes regarding certain diseases not listed in Part II of Annex IV to Directive 2006/88/EC

- The eradication programmes adopted by the Member States listed in the second column of the table in Annex II for the diseases listed in the first column of that table, in respect of the areas listed in the fourth column thereof (eradication programmes), are approved.
- For a period until [F231 December 2013], the Member States listed in the table in Annex II may require that consignments of the aquaculture animals referred to in Article 2(2) (a) and (b), introduced into an area subject to an eradication programme comply with the requirements set out in those points with respect to the diseases covered by that eradication programme.

#### **Textual Amendments**

**F2** Substituted by Commission Implementing Decision of 8 December 2011 amending Decision 2010/221/EU as regards national measures for preventing the introduction of certain aquatic animal diseases into parts of Ireland, Finland and Sweden (notified under document C(2011) 9002) (Text with EEA relevance) (2011/825/EU).

# **I**<sup>F3</sup>Article 3a

# Approval of national surveillance programmes regarding ostreid herpesvirus 1 µvar (OsHV-1 µvar)

- 1 The surveillance programmes regarding ostreid herpes virus 1  $\mu$ var (OsHV-1  $\mu$ var) adopted by the Member States listed in the second column of the table in Annex III in respect of the areas listed in the fourth column thereof (surveillance programmes), are approved.
- 2 For a period until 30 April 2013, the Member States listed in the table in Annex III may require that the following consignments introduced into an area listed in the fourth column of that Annex comply with the following requirements:

Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- a consignments of Pacific oysters intended for farming and relaying areas must comply with the placing on the market requirements laid down in Article 8a of Regulation (EC) No 1251/2008;
- b consignments of Pacific oysters must comply with the placing on the market requirements laid down in Article 8b of Regulation (EC) No 1251/2008 where such consignments are intended for dispatch centres, purification centres or similar businesses before human consumption which are not equipped with an effluent treatment system validated by the competent authority that:
  - (i) inactivates enveloped viruses; or
  - (ii) reduces the risk of transmitting diseases to the natural waters to an acceptable level.]

#### **Textual Amendments**

**F3** Inserted by Commission Decision of 24 March 2011 amending Decision 2010/221/EU as regards the approval of national measures for preventing the introduction of ostreid herpesvirus 1 μvar (OsHV-1 μvar) into certain areas of Ireland and the United Kingdom (notified under document C(2011) 1825) (Text with EEA relevance) (2011/187/EU).

# **I**<sup>F1</sup>Article 4

# Reporting

- By 30 April each year at the latest, the Member States listed in Annexes I and II shall submit a report to the Commission on the approved national measures referred to in Articles 2 and 3.
- 2 By 31 December each year at the latest, the Member States listed in Annex III shall submit a report to the Commission on the approved national measures referred to in Article 3a.
- 3 The reports provided for in paragraphs 1 and 2 shall include at least up-to-date information on:
  - a significant risks for the animal health situation of aquaculture animals or wild aquatic animals posed by the diseases, for which the national measures apply, and the necessity and appropriateness of those measures;
  - b national measures taken to maintain the disease-free status, including any testing that has been carried out; information concerning such testing must be provided using the model form set out in Annex VI to Commission Decision 2009/177/EC<sup>(5)</sup>;
  - c the evolution of the eradication or surveillance programme, including any testing that has been carried out; information concerning such testing must be provided using the model form set out in Annex VI to Decision 2009/177/EC.]

### **Textual Amendments**

**F1** Substituted by Commission Decision of 24 March 2011 amending Decision 2010/221/EU as regards the approval of national measures for preventing the introduction of ostreid herpesvirus 1 μvar (OsHV-1 μvar) into certain areas of Ireland and the United Kingdom (notified under document C(2011) 1825) (Text with EEA relevance) (2011/187/EU).

Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

#### Article 5

## Suspicion and detection of diseases in disease-free areas

- Where a Member State listed in Annex I hereto suspects the presence of a disease in an area which is listed as a disease-free area for that disease in that Annex, that Member State shall take measures at least equivalent to those laid down in Article 28, Article 29(2), (3) and (4) and Article 30 of Directive 2006/88/EC.
- Where the epizootic investigation confirms the detection of the disease referred to in paragraph 1, the Member State concerned shall inform the Commission and the other Member States thereof, and of any measures taken to contain and control that disease.

# **I**<sup>F3</sup>Article 5a

# Suspicion and detection of ostreid herpesvirus 1 µvar (OsHV-1 µvar) in areas with surveillance programmes

- Where a Member State listed in Annex III suspects the presence of OsHV-1  $\mu$ var, in an area listed in the fourth column of that Annex, that Member State shall take measures at least equivalent to those laid down in Article 28, Article 29(2), (3) and (4) and Article 30 of Directive 2006/88/EC.
- Where the epizootic investigation confirms the detection of OsHV-1  $\mu$ var in areas referred to in paragraph 1, the Member State concerned shall inform the Commission and the other Member States thereof, and of any measures taken to contain that disease.]

#### **Textual Amendments**

**F3** Inserted by Commission Decision of 24 March 2011 amending Decision 2010/221/EU as regards the approval of national measures for preventing the introduction of ostreid herpesvirus 1 μvar (OsHV-1 μvar) into certain areas of Ireland and the United Kingdom (notified under document C(2011) 1825) (Text with EEA relevance) (2011/187/EU).

# Article 6

## Repeal

Decision 2004/453/EC is repealed.

References to the repealed Decision shall be construed as references to this Decision.

# Article 7

# **Transitional provisions**

For a transitional period until 31 July 2010, consignments of aquaculture animals accompanied by an animal health certificate in accordance with Annex III to Decision 2004/453/EC may be placed on the market provided that they reach their place of final destination before that date.

Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Article 8

# **Applicability**

This Decision shall apply from 15 May 2010.

Article 9

Addressees

This Decision is addressed to the Member States.

Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

# IF4ANNEX I

### **Textual Amendments**

**F4** Substituted by Commission Decision of 7 December 2010 amending Annexes I and II to Decision 2010/221/EU as regards approved national measures by Hungary and the United Kingdom for spring viraemia of carp (notified under document C(2010) 8617) (Text with EEA relevance) (2010/761/EU).

MEMBER STATES AND AREAS REGARDED AS BEING FREE OF THE DISEASES LISTED IN THE TABLE AND APPROVED TO TAKE NATIONAL MEASURES TO PREVENT THE INTRODUCTION OF THOSE DISEASES IN ACCORDANCE WITH ARTICLE 43(2) OF DIRECTIVE 2006/88/EC

Disease	Member State	Code	Geographical demarcation of the area with approved national measures
Spring viraemia of carp (SVC)	Denmark	DK	Whole territory
	Ireland	IE	Whole territory
	Hungary	HU	Whole territory
	Finland	FI	Whole territory
	Sweden	SE	Whole territory
	United Kingdom	UK	The whole territory of the United Kingdom; the territories of Guernsey, Jersey and the Isle of Man
Bacterial kidney	Ireland	IE	Whole territory
disease (BKD)	United Kingdom	UK	The territory of Northern Ireland; the territories of Jersey and the Isle of Man.
Infectious pancreatic necrosis virus (IPN)	Finland	FI	The continental parts of the territory
	Sweden	SE	The continental parts of the territory
	United Kingdom	UK	The territory of the Isle of Man
Infection with Gyrodactylus salaris (GS)	Ireland	IE	The whole territory
	Finland	FI	The water catchment areas of the Tenojoki and Näätämönjoki; the water catchment areas of the Paatsjoki,

Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

		Luttojoki, and Uutuanjoki are considered as buffer zones.
United Kingdom	UK	The whole territory of the United Kingdom; the territories of Guernsey, Jersey and the Isle of Man]

# [F2ANNEX II

MEMBER STATES AND PARTS THEREOF WITH ERADICATION PROGRAMMES AS REGARDS CERTAIN DISEASES IN AQUACULTURE ANIMALS, AND APPROVED TO TAKE NATIONAL MEASURES TO CONTROL THOSE DISEASES IN ACCORDANCE WITH ARTICLE 43(2) OF DIRECTIVE 2006/88/EC

Disease	Member State	Code	Geographical demarcation of the area with approved national measures
Bacterial kidney disease (BKD)	Finland	FI	The following water catchment areas: Kymijoki, Juustilanjoki, Hounijoki, Tervajoki, Vilajoki, Urpalanjoki, Vaalimaanjoki, Virojoki, Vehkajoki, Summajoki, Vuoksi, Jänisjoki, Kiteenjoki- Tohmajoki, Hiitolanjoki, Tenojoki, Näätämöjoki, Uutuanjoki, Paatsjoki, Tuulomajoki
	Sweden	SE	The continental parts of the territory
Infectious pancreatic necrosis virus (IPN)	Sweden	SE	The coastal parts of the territory

Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

### **ANNEX III**

MEMBER STATES AND AREAS WITH SURVEILLANCE PROGRAMMES REGARDING OSTREID HERPESVIRUS 1 MNAR (OSHV-1 MNAR), AND APPROVED TO TAKE NATIONAL MEASURES TO CONTROL THAT DISEASE IN ACCORDANCE WITH ARTICLE 43(2) OF DIRECTIVE 2006/88/EC

Disease	Member State	Code	Geographical demarcation of the areas with approved national measures (Member States, zones and compartments)
Ostreid herpesvirus 1 μνατ (OsHV-1 μνατ)	Ireland	IE	Compartment 1: Sheephaven Bay Compartment 2: Gweebara Bay Compartment 3: Drumcliff, Killala, Broadhaven and Blacksod Bays Compartment 4: Streamstown Bay Compartment 5: Bertraghboy and Galway Bays Compartment 6: Shannon Estuary and Poulnasharry, Askeaton and Ballylongford Bays Compartment 7: Kenmare Bay Compartment 8: Dunmanus Bay Compartment 9: Kinsale and Oysterhaven Bays
	United Kingdom	UK	The territory of Great Britain except Whitstable Bay, Kent The territory of Northern Ireland, except Killough Bay, Lough Foyle and Carlingford Lough The territory of Guernsey]

Changes to legislation: There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- **(1)** OJ L 328, 24.11.2006, p. 14.
- (2) OJ L 156, 30.4.2004, p. 5.
- (**3**) OJ L 46, 19.2.1991, p. 1.
- (4) OJ L 337, 16.12.2008, p. 41.
- (5) [F1OJ L 63, 7.3.2009, p. 15.]

#### **Textual Amendments**

**F1** Substituted by Commission Decision of 24 March 2011 amending Decision 2010/221/EU as regards the approval of national measures for preventing the introduction of ostreid herpesvirus 1 μvar (OsHV-1 μvar) into certain areas of Ireland and the United Kingdom (notified under document C(2011) 1825) (Text with EEA relevance) (2011/187/EU).

### **Status:**

Point in time view as at 10/12/2011.

# **Changes to legislation:**

There are outstanding changes not yet made to Commission Decision 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 (notified under document C(2010) 1850) (Text with EEA relevance) (2010/221/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.