Commission Regulation (EU) No 175/2010 of 2 March 2010 implementing Council Directive 2006/88/EC as regards measures to control increased mortality in oysters of the species Crassostrea gigas in connection with the detection of Ostreid herpesvirus 1 μvar (OsHV-1 μvar) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 175/2010

of 2 March 2010

implementing Council Directive 2006/88/EC as regards measures to control increased mortality in oysters of the species *Crassostrea gigas* in connection with the detection of Ostreid herpesvirus 1 μvar (OsHV-1 μvar)

(Text with EEA relevance)

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[(1)], and in particular Articles 41(3) and 61(3) thereof,

Whereas:

(1) Directive 2006/88/EC lays down the animal health requirements to be applied for the placing on the market of aquaculture animals and products thereof. In addition, it lays down minimum preventive measures to be applied in the event of a suspicion of, or an outbreak of certain diseases in aquatic animals.

(2) Article 41 of that Directive provides that Member States are to take appropriate measures to control an emerging disease situation and prevent that disease from spreading. In the case of an emerging disease situation, the Member State concerned is to inform the Commission, the Member States and EFTA Member States without delay, where the findings are of epidemiological significance to another Member State.

(3) Increased mortality in oysters of the species *Crassostrea gigas* (*Crassostrea gigas* oysters) were detected in several areas in France and in Ireland during the late spring and summer of 2008. It was attributed to a combination of adverse environmental factors together with the presence of bacteria of the genus Vibrio and the presence of the Ostreid herpesvirus-1 (OsHV-1) including a newly described genotype of that virus named OsHV-1 μvar.

(4) The French authorities informed the Commission, the Member States and EFTA Member States on the situation and on the measures taken in August 2008, and the matter was brought to the attention of the Standing Committee on the Food Chain and Animal Health in September 2008.

(5) In spring 2009 increased mortality attributed to the same combination of factors was again detected in France, Ireland and the Channel Islands. While the causes of the

mortalities still remain uncertain, the epidemiological investigations undertaken in Ireland and the United Kingdom in 2009 suggest that OsHV-1 µvar play a major role in the mortalities.

(6) The competent authority of those Member States and of the Channel Islands informed the Commission of the situation and the measures taken and the matter was brought to the attention of the Standing Committee on the Food Chain and Animal Health several times.

(7) The containment measures taken by the competent authority in those Member States and of the Channel Islands to control the emerging disease situation were mainly based on the restriction of movements of *Crassostrea gigas* oysters out of the areas affected by increased mortalities.

(8) In view of the reoccurrence of the emerging disease situation in 2009 and its possible repetition and risk for further spread in spring and summer 2010, and on the basis of the experience gained, it is appropriate and necessary to extend the measures already taken by the affected Member States.

(9) To ensure uniform conditions for the implementation of the requirements of Directive 2006/88/EC regarding emerging diseases, and to ensure that the measures taken provide sufficient protection against further spread whilst not imposing unnecessary restrictions on movements of *Crassostrea gigas* oysters, it is needed to coordinate the measures as regards this emerging disease situation at a European Union level.

(10) When the competent authorities are informed that increased mortality in the *Crassostrea gigas* oysters has been detected, sampling and testing should be carried out to detect or rule out the presence of OsHV-1 µvar.

(11) When the presence of virus genotype OsHV-1 µvar has been confirmed, disease control measures should be implemented by the Member States including the establishment of a containment area. When defining the containment area certain factors set out in this Regulation should be taken into account. Those disease control measures should last until inspections have shown that the increased mortalities have ceased.

(12) Restriction to the movements out of the containment areas of *Crassostrea gigas* oysters should be laid down to limit the risk of spread of the disease. However, certain derogations should be provided for where the risk of spreading the disease is reduced. These derogations affects movements of certain *Crassostrea gigas* oysters intended for farming or relaying areas in another containment area or intended for human consumption. To ensure traceability of consignments of *Crassostrea gigas* oysters intended for farming or relaying areas, they should be accompanied by an animal health certificate. When completing the certificate the explanatory notes set out in Annex V to 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[(2)] should be taken into account.

(13) With the aim to gain further knowledge on the status of this emerging disease situation in the Union and in particular in Member States and compartments not yet affected, and to ensure an early detection of any occurrence of OsHV-1 µvar, Member States may wish to establish programmes with targeted sampling and testing for the early detection of OsHV-1 µvar. *Crassostrea gigas* oysters originating from areas which have been subject to containment measures in 2009 in accordance with national measures or in 2010 in accordance with this Regulation should be subject to additional animal health requirements if introduced for farming or relaying purposes into Member States or compartments covered by such a programme, as long as OsHV-1 µvar is not detected in that Member State or compartment.

(14) To ensure that data collected in different Member States in the context of programmes with targeted sampling and testing for the early detection of OsHV-1 µvar are comparable, certain requirements on the content of such programmes should be laid down.

(15) The availability of accurate and timely information on the situation as regards the detection of OsHV-1 µvar in the Member States is a key element to ensure a proper control of the emerging disease situation. For that purpose, Member States should inform the Commission and the other Member States of the first confirmed presence of the OsHV-1 µvar virus on their territories in 2010 without undue delay.

(16) In addition, advantage should be taken of the internet-based information pages drawn up in accordance with Article 10 of Commission Decision 2009/177/EC of 31 October 2008 implementing Council Directive 2006/88/EC as regards surveillance and eradication programmes and disease-free status of Member States, zones and compartments[(3)].

(17) To ensure transparency and timely access to the relevant information on the emerging disease situation, Member States should make available to the European Commission and to other Member States information concerning the containment areas, areas previously subjected to containment measures, but where the absence of OsHV-1 µvar has been demonstrated and programmes established for the early detection of the OsHV-1 µvar.

(18) As there are still great uncertainties as regards the emerging disease situation, the measures provided for in this Regulation should apply until the end of December 2010.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Definition

For the purposes of this Regulation, OsHV-1 µvar means a genotype of the virus Ostreid herpesvirus-1 (OsHV-1) which is defined on the basis of partial sequence data exhibiting

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 175/2010. (See end of Document for details)*

a systematic deletion of 12 base pairs in ORF 4 of the genome in comparison with OsHV-1 (GenBank # AY509253).

Article 2

Sampling, testing and establishment of containment areas

1 When increased mortality in oysters of the species *Crassostrea gigas* (*Crassostrea gigas* oysters) is detected, the competent authority shall:

a take samples in accordance with Part A of Annex I;

b test for the presence of OsHV-1 µvar in accordance with the diagnostic methods set out in Part B of Annex I.

2 When the results of the tests referred to in paragraph 1(b) reveal the presence of OsHV-1 µvar, the competent authority shall establish a containment area. That area shall be defined on the basis of a case-by-case analysis taking into account the factors influencing the risk for the spread of the disease set out in Part C of Annex I.

3 Member States shall inform the Commission and other Member States without undue delay of the first containment area established on their territory in 2010.

Article 3

Placing on the market requirements for *Crassostrea gigas* oysters originating from a containment area referred to in Article 2

1 *Crassostrea gigas* oysters originating from containment areas established in accordance with Article 2(2), shall not be moved out of that area.

2 By way of derogation from paragraph 1, consignments of *Crassostrea gigas* oysters may be moved out of the containment area where:

a they are intended for another containment area established in accordance with Article 2(2);

b they are originating from a part of the containment area, including hatcheries, not affected by the increased mortalities and the consignment has been subject to:

(i) sampling in accordance with Part A of Annex I; and

(ii) testing for the presence of OsHV-1 µvar in accordance with the diagnostic methods set out in Part B of Annex I, with all results being negative;

c they are intended for further processing, purification centres, dispatch centres or processing establishments before human consumption which are 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;

d they are intended for human consumption and packed and labelled for that purpose in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council[4], and are:

(i) no longer able to survive as living animals if returned to the environment from which they originate; or

(ii) intended for further processing without temporary storage at the place of processing;

e the consignments or products thereof are intended for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004.

3 The consignments referred to in paragraph 2(a) and (b) and intended for farming or relaying areas shall be accompanied by an animal health certificate completed in accordance with the model set out in Annex II to this Regulation and the explanatory notes set out in Annex V to Regulation (EC) No 1251/2008.

Article 4

Lifting of measures provided for in Articles 2 and 3

The competent authority may lift the control measures as regards the containment areas established in accordance with Article 2(2) and the placing on the market restrictions provided for in Article 3 after it has carried out two consecutive inspections 15 days apart that show that the increased mortality has ceased.

Article 5

Placing on the market requirements for *Crassostrea gigas* oysters originating from a compartment previously subjected to control measures due to increased mortalities in *Crassostrea gigas* oysters in connection with OsHV-1 µvar

1 *Crassostrea gigas* oysters that are placed on the market and originating from a compartment which has been subject to containment measures either in 2009 or 2010 due to increased mortalities in *Crassostrea gigas* oysters in connection with OsHV-1 µvar shall:

a be accompanied by an animal health certificate completed in accordance with the model set out in Annex II to this Regulation and the explanatory notes set out in Annex V to Regulation (EC) No 1251/2008, if the animals:

(i) are intended for Member States or compartments which have established a programme for the early detection of OsHV-1 µvar, and in which OsHV-1 µvar is not detected; and

(ii) are intended for farming or relaying areas;

b originate from a compartment where the absence of OsHV-1 µVar is demonstrated by sampling and testing carried out in accordance with Part A of Annex I; and

c comply with the animal health requirements set out in the model certificate, referred to in point (a).

2 A programme for the early detection of OsHV-1 µvar referred to in paragraph 1(a)(i) shall comply with the following requirements:

a the programme must be declared to the Standing Committee on the Food Chain and Animal Health;

b such declaration must be in conformity with point 1, points 5.1, 5.2, 5.3, 5.5, and 5.9, and points 6 and 7 of the model form set out in Annex II to Decision 2009/177/EC;