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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)

(OJ L 52, 3.3.2010, p. 1)

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		No	page	date
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(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.

([1]) OJ L 328, 24.11.2006, p. 14.

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(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 ([1]) should be taken into account.

([1]) OJ L 337, 16.12.2008, p. 41.

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(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 [1].

(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,

[1] OJ L 63, 7.3.2009, p. 15.

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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 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;

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(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 ([1]), 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

([1]) OJ L 139, 30.4.2004, p. 55.

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(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;

(c) the programme must include:

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

(ii) testing for the presence of OsHV-1 µvar in accordance with the diagnostic methods set out in Part B of Annex I.

3. Paragraph 1 shall apply one week from the date of the meeting of the Standing Committee on the Food Chain and Animal Health at which the programme referred to in paragraph 1(a)(i) was declared.

Article 6

Internet-based information page

1. Member States shall make available to the Commission and the other Member States:

(a) a list of containment areas and the factors that have been taken into account to define such areas, including a description of the geographical boundaries of the relevant area, established in accordance with Article 2(2);

(b) a list of compartments including a description of the geographical boundaries of the relevant area:

(i) which have been subject to containment measures in 2009 due to increased mortalities in *Crassostrea gigas* oysters in connection with OsHV-1 µvar;

(ii) where the absence of OsHV-1 µvar has been demonstrated by a testing carried out in accordance with Parts A and B of Annex I in samples taken in the containment area;

(c) declarations of programmes referred to in Article 5(2), including a description of the geographical boundaries of the relevant area.

2. The information provided for in paragraph 1 shall be kept up-to-date and made available through the internet-based information pages established in accordance with Article 10 of Decision 2009/177/EC.

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Article 7

Reporting

By 1 October 2010 at the latest, Member States shall submit a report to the Commission on programmes declared in accordance with Article 5(2).

The report shall be in conformity with the model form set out in Annex VI to Decision 2009/177/EC.

Article 8

Entry into force and application

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

It shall apply from 15 March 2010 to ►M1 30 April 2011 ◄.

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

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ANNEX I

PART A

Sampling

1. *Sampling for the purposes of Article 2*

Samples as provided for in Article 2 shall consist of at least 12 individuals of *Crassostrea gigas* oysters. When selecting those animals weak, gaping or freshly dead (not decomposed) individuals shall be sampled and they shall be collected from the compartment where the mortality is observed.

2. *Sampling for the purposes of Article 3(2)(b), 5(1)(b) and 5(2)*

(a) Sampling for the purposes of Article 3(2)(b) shall consist of:

(i) in the case of larvae, five pools of at least 50 mg of whole animals collected between 4 and 8 days after fecundation including shell per consignment;

(ii) in the case of spat smaller than 6 mm, 30 pools of 300 mg of whole animals including shell per consignment;

(iii) in the case of oysters bigger than 6 mm, 150 individuals per consignment.

When selecting those animals, all parts of the consignment must be proportionally represented in the sample. If weak, gaping or freshly dead (not decomposed) animals are present, primarily such animals shall be selected.

(b) Sampling for the purposes of Article 5(2) shall consist of at least 150 individuals of *Crassostrea gigas* per sampling points. All farms or mollusc farming areas in the Member State or compartment covered by the programme shall be sampled.

Sampling for the purposes of Article 5(1)(b) shall consist of at least 150 individuals of *Crassostrea gigas* oysters per compartment.

When selecting those animals, the following criteria shall be taken into account:

— If weak, gaping or freshly dead (not decomposed) animals are present, primarily such animals shall be selected. If such animals are not present, the animals selected shall include healthy molluscs less than 12 months old.

— When sampling in farms in which more than one water source is utilised for production, animals representing all water sources must be included for sampling in such a way that all parts of the farm are proportionally represented in the sample.

— When sampling in mollusc farming areas, animals from a sufficient number of sampling points, at least three sampling points, shall be included in the sample in such a way that all parts of the mollusc farming area are proportionally represented in the sample, including natural beds present in the mollusc farming area. The main factors to be considered for the selection of these sampling points are: previous detection of OsHV-1 µvar in the area, stocking density, water flows, bathymetry and management practices.

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(c) The sampling provided for in Article 5(2) shall be carried out in the period of the year when prevalence of OsHV-1 µvar in the Member State or compartment is known to be maximal. When such data is not available, sampling shall be carried out just after the period when the water temperature exceeds 16 °C or at the time of the year when the temperature normally reaches its yearly maximum.

(d) The sampling provided for in Article 5(1)(b) shall preferably be carried out in the period of the year described in point c. If samples are collected outside that period of the year, the sampled oysters must be maintained under conditions equivalent to those described in point c for a period suitable for the detection of OsHV-1 µvar, before being tested.

PART B

Diagnostic methods of detecting OsHV-1 µvar

1. *Scope*

This procedure explains a standard diagnostic method to be used for OsHV-1 µvar detection and identification by Polymerase Chain Reaction (hereinafter PCR). It allows distinguishing between OsHV-1 and OsHV-1 µvar.

When appropriate, in order to optimise the reaction conditions and to suit the equipment and conditions in their own laboratory, the laboratories may apply modifications to the methods described in this Annex, provided that an equal sensitivity and specificity can be demonstrated.

2. *Definition*

OsHV-1 µvar is defined in Article 1 of this Regulation.

3. *Equipment and environmental conditions*

The diagnostic test used for OsHV-1 µvar detection and identification by PCR requires the equipment and environmental conditions classically used for PCR assays as follows:

— A closed hood equipped with an UV producing system to eliminate potential contaminations when preparing PCR mix.

— Two complete sets of pipettes (2 µl; 20 µl; 200 µl and 1 000 µl), the first one for DNA extraction, and the second one for PCR mix preparation.

— Three different pipettes: one pipette (2 µl) to dispense samples in PCR mix, one pipette (20 µl) for EB sampling and another pipette (20 µl) to load PCR products in agarose gels.

— Filter pipette tips (2 µl; 20 µl; 200 µl and 1 000 µl) for DNA extraction, PCR mix preparation and sample dispensing.

— Pipette tips (20 µl) to collect EB and to load amplification products in agarose gel.

— A thermal cycler to perform amplifications.

— A horizontal electrophoresis system for PCR products electrophoresis.

— An UV table to observe PCR products after agarose gel electrophoresis.

— A system to acquire pictures of the gels.

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The manipulator must wear a lab coat and some gloves during all the different steps described bellow. Lab coat and gloves must be changed preferably after each main step: DNA extraction, preparation of PCR mix, sample dispensing, amplification and gel loading.

It is recommended to perform these different steps in different rooms. More particularly, amplification and gel loading/electrophoresis should take place in a room separate from DNA extraction, PCR mix preparation and DNA dispensing.

4. *Procedure*

4.1. Sample preparation

Live or freshly dead (not decomposed) oysters, which can be previously frozen, are processed for DNA extraction.

Samples are processed differently according to their size:

(a) For larvae, pools of 50 mg of the whole animals (including the shell) completed with 200 µl of distilled water are crushed and centrifuged at 1 000 g for 1 minute.

(b) For spat smaller than or of 6 mm, pools of 300 mg of the whole animals (including the shell) completed with 1 200 µl of distilled water are crushed and centrifuged at 1 000 g for 1 minute.

(c) For spat between 6 and 15 mm in size, all the soft tissues of each animal are crushed individually.

(d) For animals bigger than 15 mm, pieces of gills and mantle are isolated.

DNA extraction is performed using the QIAamp® DNA Mini Kit (QIAGEN) and following the instructions for Tissue Test Protocol.

The further sample preparation is performed in the following order:

1. Place 100 µl of supernatant for samples referred to in (a) and (b) or 10 to 50 mg of tissues for samples referred to point (c) and (d) in a 1,5 ml microcentrifuge tube and add 180 µl of Buffer ATL.

2. Add 20 µl Proteinase K, mix by vortexing and incubate at 56 °C until the tissue is completely lysed (overnight). Vortex occasionally during incubation to disperse sample. Briefly centrifuge the 1,5 ml microcentrifuge tube to remove drops from the lid.

3. Add 200 µl Buffer AL to the sample, mix by pulse-vortexing for 15 s and incubate at 70 °C for 10 minutes. Briefly centrifuge the 1,5 ml microcentrifuge tube to remove drops from the lid.

4. Add 200 µl ethanol (96-100 %) to the sample, and mix by pulse-vortexing for 15 s. Briefly centrifuge the 1,5 ml microcentrifuge tube to remove drops from the lid.

5. Carefully apply the mixture from step 4 to the QIAamp Spin Column (in a 2 ml collection tube) without wetting the rim. Close the cap and centrifuge at 10 000 rpm for 1 min. Place the QIAamp Spin Column in a clean 2 ml collection tube (provided in the kit) and discard the tube containing the filtrate.

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6. Carefully open the QIAamp Spin Column and add 500 µl Buffer AW1 without wetting the rim. Close the cap and centrifuge at 10 000 rpm for 1 min. Place the QIAamp Spin Column in a clean 2 ml collection tube (provided in the kit) and discard the collection tube containing the filtrate.

7. Carefully open the QIAamp Spin Column and add 500 µl Buffer AW2 without wetting the rim. Close the cap and centrifuge at full speed (14 000 rpm) for 3 min.

8. (Optional) Place the QIAamp Spin Column in a new 2ml collection tube (not provided in the kit) and discard the collection tube containing the filtrate. Centrifuge at full speed (14 000 rpm) for 1 min.

9. Place the QIAamp Spin Column in a clean 1,5 ml microcentrifuge tube (not provided in the kit) and discard the collection tube containing the filtrate. Carefully open the QIAamp Spin Column and add 100 µl of distilled water. Incubate 5 minutes at room temperature and centrifuge at 10 000 rpm for 1 min.

10. Control the quality and efficacy of the extraction (for example by measuring OD (260 nm) under spectrophotometer or after electrophoresis in agarose gel).

11. Prepare dilution of your samples in order to have a final DNA concentration of 50-100 ng/µl.

12. DNA solutions are kept at 4 °C until PCR analyses are performed.

Other commercial kits may be used for the DNA extractions provided they have been demonstrated to give similar results.

4.2. *Polymerase Chain Reaction (PCR)*

4.2.1. Reactives

— 10 X Buffer (furnished with the Taq DNA polymerase)

— $MgCl_2$ (furnished with the DNA polymerase) (25 mM)

— Taq DNA Polymerase (Goldstar, Eurogentec) 5 U/µl

— dNTP (dATP, dCTP, dGTP, dTTT) Master Mix (20mM) must be diluted 10 fold (at 2 mM) before use

— d H_2O (distilled H_2O free of DNA and RNA)

4.2.2. Primers

The following primers [1] must be used:

CF (10 µM)

CR (10 µM)

[1] These primers or descriptions thereof may be obtained from the Community Reference Laboratory for Mollusc Diseases (LGP-Ifremer, av de Mus de Loup, 17390 La Tremblade, France).

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4.2.3. PCR mix

PCR mix for each tube is:

	Volume per tube	Final concentration
Buffer (10 X)	5 µl	1 X
$MgCl_2$ (25 mM)	5 µl	2,5 mM
dNTP (2 mM)	5 µl	0,2 mM
CF (10 µM)	1 µl	0,2 µM
CR (10 µM)	1 µl	0,2 µM
Taq polymérase (5U/µl)	0,5 µl	2,5 U
dH_2O	31,5 µl	

— 49 µl of this PCR mix is dispensed in each PCR tube

— 1 µl of extracted DNA (50-100 ng/µl) is added to each tube

4.2.4. Controls

Two types of control are used:

— Negative controls consist of dH_2O (1 µl for 49 µl of PCR mix). They aim at detecting potential reactive contamination or working environment. One negative control should be included every 10 samples or after each batch of samples.

— Positive controls consist of plasmidic DNA containing the OsHV-1 target genome region CF-CR. They aim at checking the efficacy of the PCR reaction. One positive control should be included for each PCR analysis. Positive controls are available from the Community Reference Laboratory.

4.2.5. Amplification

Amplification cycles are performed in a thermal cycle apparatus.

— Initial denaturation: 2 min at 94 °C

— Amplification: 35 cycles (1 min at 94 °C, 1 min at 50 °C and 1 min at 72 °C)

— Final elongation: 5 min at 72 °C

4.3. *Electrophoresis*

4.3.1. Reactives

— 50 X TAE (can be bought directly ready for use):

Tris base (40 mM) 242 g

Acetic glacial acid (40 mM) 57,1 ml

$Na_2EDTA.2H_2O$ (1 mM) 18,61 g

dH_2O for 1 liter

Ajust at pH 8

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— Agarose gel 2,5 % in 1 X TAE

Ethidium bromide (0,5 μg/ml) added after cooling the gel.

— Loading blue dye:

Bromophenol blue 0,25 %

Cyanol xylene FF 0,25 %

Sucrose 40 %

Keep at 4 °C.

Use diluted 6 times (2 μl of loading blue buffer for 10μl of PCR products).

— Molecular weight marker:

SmartLadder SF (Eurogentec): a ready-to-use molecular weight marker including 9 regularly spaced bands from 100 to 1 000 bp.

4.3.2. Agarose gel preparation

1. Weight 2,5 g of agarose, add 100 ml of 1 X TAE and heat until the mix is melted.

2. After cooling the solution, ethidium bromide is added (5 μl for 100 ml of agarose gel) and the solution is disposed in a specific mould equipped with combs (to form slots).

3. When gel is polymerised, combs are removed and gel is placed in a horizontal electrophoresis system containing enough 1 X TAE to the cover agarose gel.

4. 10 μl of PCR products are mixed with 2 μl of blue dye (6 X) and disposed in the slots.

5. One whole is dedicated to the molecular weight marker (5 μl).

6. A voltage of 50 to 150 volts is applied during 30 min to 1 hour depending on the gel size and thickness.

7. Gel is observed under UV.

4.4. *Interpretation*

The presence of OsHV-1 μvar in a sample is indicated by the presence of a band of the appropriate size (157 bp instead of 173 bp for OsHV-1) on a 2,5 % agarose gel with all negative controls negative and all positive controls positive.

PART C

Definition of the containment area

The following factors influencing the risks for the spread of the disease shall be taken into account when defining the containment area in accordance with Article 2(2):

(a) the number, rate and distribution of molluscs on the farm or mollusc farming area infected;

(b) distance and density of neighbouring farms or mollusc farming areas;

(c) proximity to processing establishments, contact farms or contact mollusc farming areas;

(d) species present at the farms or mollusc farming areas;

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(e) farming practices applied in the affected and the neighbouring farms or mollusc farming areas; and

(f) hydrodynamic conditions and other factors of epizootiological significance identified.

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ANNEX II

Model animal health certificate for the placing on the market of *Crassostrea gigas* oysters intended for farming and relaying areas

EUROPEAN UNION **Intra trade certificate**

Part I: Details of consignment presented

I.1. Consignor Name Address Postal code	I.2. Certificate reference number	I.2.a. Local reference number:
	I.3. Central Competent Authority	
	I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code	I.6.	
	I.7.	
I.8. Country of origin ISO code	I.9.	I.10. Country of destination ISO code / I.11.
I.12. Place of origin/Place of harvest Approved aquaculture holding ☐ Other ☐ Name Approval number Address Postal code	I.13. Place of destination Approved aquaculture holding ☐ Other ☐ Name Approval number Address Postal code	
I.14. Place of loading Postal code	I.15. Date and time of departure	
I.16. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification:	I.17. Transporter Name Approval number Address Postal code Member State	
I.18. Animal species/product	I.19. Commodity code (CN code) **03.07**	
	I.20. Number/quantity	
I.21.	I.22. Number of packages	
I.23. Identification of container/seal number	I.24. Type of packaging	
I.25. Animals certified as/products certified for Breeding ☐ Relaying ☐		
I.26. Transit through third country ☐ Third country ISO code Exit point Code Entry point BIP unit no.:	I.27. Transit through Member States ☐ Member State ISO code Member State ISO code Member State ISO code	
I.28. Export ☐ Third country ISO code Exit point Code	I.29.	
I.30.		
I.31. Identification of the animals Species (Scientific name) Quantity		

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EUROPEAN UNION

For the placing on the market of *Crassostrea gigas* oysters intended for farming and relaying areas

Part II: Certification

II. **Health information**	II.a. Certificate reference number	II.b.

([1])([2])[II.1 **Requirements for Crassostrea gigas oysters originating from a containment area established in accordance with Article 2 of Regulation (EU) No 175/2010**

I, the undersigned official inspector, hereby certify that the *Crassostrea gigas* oysters referred to in Part I of this certificate:

II.1.1 originate from an area subject to disease control measures regarding increased mortalities in *Crassostrea gigas* oysters in connection with OsHV-1 µvar;.

([1])[II.1.2 are allowed to be placed on the market according to Article 3(2)(a) of Regulation (EU) No 175/2010;]

([1])[II.1.2 are originating from a part of the containment area not affected by the increased mortalities and the consignment has been subject to sampling and testing in accordance with Annex I to Regulation (EU) No 175/2010 in *Crassostrea gigas* oysters with negative result;]]

([1])([3])[II.2 **Requirements for *Crassostrea gigas* oysters originating from a Member State or compartment previously subjected to containment measures as regards increased mortalities in *Crassostrea gigas* oysters in connection with OsHV-1 µvar and intended for Member States or compartments subject to a programme for the early detection of OsHV-1 µvar**

I, the undersigned official inspector, hereby certify that the *Crassostrea gigas* oysters referred to in Part I of this certificate:

II.2.1 come from a farm or mollusc farming area where, according to the records of the farm or mollusc farming area, there is no indication of increased mortalities;

II.2.2 originate from a compartment, where the absence of OsHV-1 µvar is demonstrated by a sampling and testing carried out in accordance with Annex I to Regulation (EU) No 175/2010 in *Crassostrea gigas* oysters.]

II.3 **Transport and labelling requirements**

I, the undersigned official inspector, hereby certify that:

II.3.1 the *Crassostrea gigas* oysters referred to in Part I of this certificate are placed under conditions, including with a water quality, that do not alter their health status;

II.3.2 the transport container prior to loading is clean and disinfected or previously unused;

II.3.3 the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.8 to I.13 of Part I of this certificate, and the following statement:

either ([1])['*Crassostrea gigas* oysters intended for farming/relaying in an area subject to a programme for the early detection of OsHV-1 µvar']

or (1)['*Crassostrea gigas* oysters intended for farming/relaying in an area subject to disease control measures and originating from an area subject to disease control measures'].

Notes

Part I:

— Box I.12: If appropriate, use the authorisation number for the farm or mollusc farming area in question.

— Box I.13: If appropriate, use the authorisation number for the farm or mollusc farming area in question.

— Box I.20 and I.31: As regards quantity, give the total number.

— Box I.25: Use the option 'Breeding' if intended for farming, 'Relaying' if intended for relaying.

▼B

EUROPEAN UNION

For the placing on the market of *Crassostrea gigas* oysters intended for farming and relaying areas

II. **Health information**	II.a. Certificate reference number	II.b.

Part II:

([1]) Keep as appropriate.

([2]) Part II.1 of this certificate applies to consignments of *Crassostrea gigas* oysters originating from a containment area established in accordance with Article 2(2) of Regulation (EU) No 175/2010 and which according to Article 3(2)(a) or (b) of that Regulation is allowed to leave that area.

([3]) Part II.2 of this certificate applies to consignments of *Crassostrea gigas* oysters referred to in Article 5(1) of Regulation (EU) No 175/2010, intended for Member States or compartments subject to a programme for the early detection of OsHV-1 µvar and which originate from an area which previously were subject to containment measures regarding increased mortalities in *Crassostrea gigas* oysters.

Official inspector

Name (in capital letters): Qualification and title:

Local Veterinary Unit: No of the related LVU:

Date: Signature:

Stamp