

COUNCIL DIRECTIVE 95/70/EC

of 22 December 1995

introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Whereas molluscs are listed in Annex II to the Treaty; whereas the marketing of molluscs constitutes an important source of revenue for the aquaculture sector;

Whereas the mollusc diseases referred to in Annex A, list II, to 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 ⁽³⁾, have a very serious effect on the shellfish industry; whereas other diseases having a similar effect occur in third countries, whereas a list of such diseases should be drawn up and the Commission should be given the ability to adjust that list in the light of developments in the animal-health field;

Whereas an outbreak of such diseases can quickly take on epizootic proportions, causing mortality and disturbances on a scale liable considerably to reduce the profitability of shellfish-farming;

Whereas it is therefore necessary to establish at Community level the measures to be taken in the event of outbreaks of disease, in order to ensure rational development of shellfish-farming and to contribute to the protection of animal health in the Community;

Whereas Member States should report to the Commission and the other Member States all cases of abnormal mortality observed in bivalve molluscs;

Whereas, in such an event, measures must be taken aimed at preventing the spread of the disease, in particular with regard to the removal of live bivalve molluscs from the farms or zones concerned;

Whereas a thorough epidemiological investigation is essential to determine the origin of the disease and to prevent further spread;

Whereas, in order to ensure an effective system of control, diagnosis of the diseases must be harmonized and carried out under the auspices of responsible laboratories, the coordination of which may be ensured by a reference laboratory designated by the Community;

Whereas, in order to ensure uniform implementation of this Directive, a Community inspection procedure should be established;

Whereas common measures for the control of diseases form a minimum basis for maintaining a uniform standard of animal health;

Whereas the Commission should be entrusted with the task of adopting the necessary implementing measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive establishes minimum Community measures for the control of the diseases affecting bivalve molluscs referred to in this Directive.

Article 2

1. For the purposes of this Directive, the definitions laid down in Article 2 of Directive 91/67/EEC and Article 2 of Directive 91/492/EEC ⁽⁴⁾ shall apply as necessary.

2. In addition, 'observed abnormal mortality' shall mean sudden mortality affecting approximately 15 % of stocks and occurring over a short period between two inspections (confirmed within 15 days). In hatchery a mortality shall be considered abnormal when the farmer cannot obtain larvae during a period which included successive spawns from different broodstocks. In nursery

⁽¹⁾ OJ No C 285, 13. 10. 1994, p. 9.

⁽²⁾ OJ No C 109, 1. 5. 1995, p. 2.

⁽³⁾ OJ No L 46, 19. 2. 1991, p. 1. Directive as last amended by Directive 95/22/EC (OJ No L 243, 11. 10. 1995, p. 1).

⁽⁴⁾ Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs (OJ No L 268, 24. 9. 1991, p. 1). Directive as amended by the 1994 Act of Accession.

a mortality shall be considered abnormal when a sudden sizeable mortality occurs in a short time on a number of tubes.

Article 3

Member States shall ensure that all farms rearing bivalve molluscs:

1. are registered by the official service; this registration must be kept constantly up to date;
2. keep a record of:
 - (a) live bivalve molluscs entering the farm, containing all information relating to their delivery, their number or weight, their size and their origin;
 - (b) bivalve molluscs leaving the farm for reimmersion, containing all information relating to their dispatch, their number or weight, their size and destination;
 - (c) observed abnormal mortality.

This record, which shall be open to scrutiny by the official service at all times, on demand, shall be updated regularly and kept for four years.

Article 4

1. Member States shall ensure that a monitoring and sampling programme is applied in bivalve mollusc farms, farming areas and harvested natural beds in order to observe whether there is an abnormal mortality and keep track of the health situation of stocks.

In addition, the official service may apply the above programme to purification centres and storage tanks which discharge water into the sea.

If, during application of this programme, any abnormal mortality is observed, or if the official service has information giving it reason to suspect the presence of diseases, the following measures shall be taken:

- a list shall be drawn up of the sites where the diseases referred to in Annex A, list II to Directive 91/67/EEC are present, provided that such diseases are not the subject of a programme approved pursuant to the aforementioned Directive,
- a list shall be drawn up of the sites at which abnormal mortality has been observed as a result of the presence of the diseases referred to in Annex D, or on which the official service has information giving it reason to suspect the presence of diseases,
- monitoring of the evolution and geographical spread of the diseases referred to in the first and second indents.

2. The detailed rules for implementing this Article, and *inter alia* the rules to be applied for establishing the programme referred to in paragraph 1, particularly as regards the frequency and timetable of monitoring, procedures for taking samples (statistically representative volume) and methods of diagnosis, shall be adopted in accordance with the procedure provided for in Article 10.

Article 5

1. Member States shall ensure that the suspected presence of any diseases referred to in Article 4 and any abnormal mortality rate observed in bivalve molluscs in farms, in farming areas or in harvested natural beds or in purification centres or storage tanks which discharge water into the sea is notified as soon as possible to the official service by the shellfish-farmers or any other person who has made such observations.

2. In the case referred to in paragraph 1, the official service in the Member States shall ensure that:

- (a) samples are taken for examination in an approved laboratory;
- (b) pending the result of the examination referred to in (a), no molluscs leave the affected farm, farming area or harvested natural beds or purification centres or storage tanks which discharge water into the sea for relaying or reimmersion in another farm or in the aquatic environment, unless authorized by the official service.

3. If the examination referred to in paragraph 2 (a) fails to demonstrate the presence of a pathogen, the restrictions referred to in paragraph 2 (b) shall be lifted.

4. If the examination referred to in paragraph 2 shows the presence of a pathogen causing the observed abnormal mortality capable of being the cause of that mortality, or of a pathogen of one of the diseases referred to in Article 4, an epizootic investigation must be carried out by the official service in order to determine the possible means of contamination and to investigate whether molluscs have left the farm, the farming area or the harvested natural beds for relaying or reimmersion elsewhere during the period preceding observation of the abnormal mortality.

If the epizootic investigation shows that the disease has been introduced into one or more farms, farming areas or harvested natural beds as a result *inter alia* of molluscs being moved, the provisions of paragraph 2 shall apply.

However, by way of derogation from Article 3 (1) (c) of Directive 91/67/EEC, the official service may, within its

territory, authorize the movement of live bivalve molluscs to other farms, farming areas or harvested natural beds which are infected with the same disease.

If necessary, further appropriate measures may be decided on in accordance with the procedure in Article 10.

5. The official service shall ensure that the Commission and the other Member States are immediately informed, in accordance with the current Community procedures, of any cases of abnormal mortality rates observed involving a pathogen, of any measures taken to analyse and control the situation and of the cause of the mortality.

Article 6

1. Sampling and laboratory testing for the determination of the cause of abnormal mortality of bivalve molluscs shall be carried out using the methods established in accordance with the procedure laid down in Article 10.

2. Member States shall ensure that in each Member State a national reference laboratory is designated, with facilities and expert personnel enabling it to carry out the testing referred to in paragraph 1.

3. By way of derogation from paragraph 2, Member States which do not have a national laboratory competent in the matter may use the services of a national laboratory with competence in the matter in another Member State.

4. The list of national reference laboratories for diseases of bivalve molluscs is set out in Annex C.

5. National reference laboratories shall cooperate with the Community reference laboratory referred to in Article 7.

Article 7

1. The Community reference laboratory for diseases of bivalve molluscs is indicated in Annex A.

2. Without prejudice to Decision 90/424/EEC of 26 June 1990⁽¹⁾ on expenditure in the veterinary field and in particular Article 28 thereof, the functions and duties of the laboratory referred to in paragraph 1 shall be those laid down in Annex B.

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 19. Decision last amended by Decision 94/370/EC (OJ No L 168, 2. 7. 1994, p. 31).

Article 8

1. Commission experts may, to the extent necessary to ensure uniform application of this Directive, carry out on-the-spot checks. In so doing, they may carry out random, non-discriminatory checks to ensure that the competent authority is monitoring compliance with the requirements of this Directive.

The Commission shall inform the Member States of the results of these checks.

2. The checks referred to in paragraph 1 shall be carried out in collaboration with the competent authority.

3. The Member State in whose territory the inspections are carried out shall provide the experts with any assistance they require to accomplish their task.

4. Detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 10.

Article 9

Annex A shall be amended as necessary by the Council, acting by a qualified majority on a proposal from the Commission.

Annexes B, C and D may be amended as necessary in accordance with the procedure laid down in Article 10.

Article 10

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Standing Veterinary Committee, (hereinafter referred to as 'the Committee'), set up by decision 68/361/EEC⁽²⁾, by its Chairman, either on his own initiative or at the request of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within the time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

⁽²⁾ OJ No L 255, 18. 10. 1968, p. 23.

- (b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months, from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 11

By 31 December 1999 at the latest, the Commission shall submit a report to the Council which has been drawn up, if necessary after consulting the Scientific and veterinary Committee, taking account of experience acquired in applying this Directive and of technical and scientific developments, accompanied where appropriate by any proposals for amendments.

The Council shall act by a qualified majority on any such proposals.

Article 12

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 June 1997. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. However, from the date laid down in paragraph 1, Member States may, subject to the general rules of the Treaty, maintain or apply for their production stricter provisions than those laid down by this Directive. They shall notify the Commission of any such measure.

3. Member States shall communicate to the Commission the main provisions of national law which they adopt in the field governed by this Directive.

Article 13

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Article 14

This Directive is addressed to the Member States.

Done at Brussels, 22 December 1995.

For the Council

The President

L. ATIENZA SERNA

ANNEX A

COMMUNITY REFERENCE LABORATORY FOR DISEASES OF BIVALVE MOLLUSCS

IFREMER
Boîte Postale 133
17390 La Tremblade
France

ANNEX B

FUNCTIONS AND DUTIES OF THE COMMUNITY REFERENCE LABORATORY FOR DISEASES OF BIVALVE MOLLUSCS

The function and duties of the Community reference laboratory shall be:

1. to coordinate, in consultation with the Commission, the methods employed in Member States for diagnosing diseases of bivalve molluscs, specifically by:
 - (a) building up and retaining a collection of histological slides, strains or isolates of the relevant pathogens and making these available to approved laboratories in the Member States;
 - (b) organizing periodic comparative tests of diagnostic procedures at Community level;
 - (c) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Community;
 - (d) characterizing isolates of pathogens by the most up-to-date and appropriate methods to allow greater understanding of the epizootiology of the disease;
 - (e) keeping abreast of developments in the surveillance, epizootiology and prevention of the relevant diseases throughout the world;
 - (f) retaining expertise on relevant disease pathogens to enable rapid differential diagnosis;
2. to assist actively in the diagnosis of disease outbreaks in Member States by receiving pathogen isolates for confirmatory diagnosis, characterization and epizootic studies;
3. to facilitate the training or retraining of experts in laboratory diagnosis with a view to the harmonization of diagnostic techniques throughout the Community;
4. to collaborate as regards methods of diagnosing exotic diseases, with the competent laboratories in third countries where those diseases are prevalent.

ANNEX C

NATIONAL REFERENCE LABORATORIES FOR DISEASES OF BIVALVE MOLLUSCS

Germany: Bundesforschungsanstalt für Viruskrankheiten der Tiere
Anstaltsteil Insel Riems
D-0-2201 Insel Riems
Germany

Spain: Instituto de investigaciones marinas del C.S.I.C.
C/Eduardo Cabello, No 6
36208 Vigo (Pontevedra)
Spain

France: IFREMER
Boîte postale 133
17390 La Tremblade
France

Greece: Κέντρο Κτηνιατρικών Ιδρυμάτων Θεσσαλονίκης
Ινστιτούτο Λοιμωδών και Παρασιτικών Νοσημάτων
Τμήμα Παθολογίας Υδροβίων Οργανισμών
26^{ης} Οκτωβρίου 80
54627 Θεσσαλονίκη
Greece

Ireland: Fisheries Research Centre
Abbotstown
Castleknock
Dublin 15
Ireland

Italy: Istituto zooprofilattico sperimentale delle Venezie
Sezione diagnostica di Basaldella di Campoformido
Laboratorio di Ittiopatologia
Via della Roggia, 92
33030 Basaldella di Campoformido (UD)
Italy

Netherlands: Rijksinstituut voor visserijonderzoek (RIVO-DLO)
Haringkade 1
Postbus 68
1970 AB IJmuiden
Netherlands

United Kingdom: Fish Diseases Laboratory
The Nothe
Weymouth
Dorset DT4 8UB
United Kingdom

The Marine Laboratory
PO box 101
Victoria Road
Aberdeen AB9 8DB
United Kingdom

ANNEX D

Diseases	Pathogens	Sensitive species
Haplosporidiosis	<i>Haplosporidium nelsoni</i> <i>Haplosporidium costale</i>	<i>Crassostrea virginica</i> <i>Crassostrea virginica</i>
Perkinosis	<i>Perkinsus marinus</i> <i>Perkinsus olseni</i>	<i>Crassostrea virginica</i> <i>Haliotis rubra</i> <i>H. Laevigata</i>
Mikrokytosis	<i>Mikrokytos mackini</i> <i>Mikrokytos roughleyi</i>	<i>Crassostrea gigas</i> <i>O. edulis</i> <i>O. puelchana</i> <i>O. denselomellosa</i> <i>Tiostrea chilensis</i> <i>Saccostrea commercialis</i>
Iridovirosis	Oyster velar virus	<i>Crassostrea gigas</i>
Marteiliosis	<i>Marteilia sidneyi</i>	<i>Saccostrea commercialis</i>
