

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(94) 401 final
Brussels, 23.09.1994

94/0213 (CNS)

Proposal for a

COUNCIL DIRECTIVE

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

Outbreaks of certain diseases affecting bivalve molluscs (e.g. oysters, mussels) can quickly take epizootic proportions causing mortality and disturbances on a scale liable to severely reduce the profitability of mollusc farming, and consequently have an influence on the internal market in bivalve molluscs. It is therefore necessary to establish at Community level control measures for the event of an outbreak of such disease.

The proposed measures aim at preventing the spread of diseases likely to cause important losses. For that purpose it is intended to establish a surveillance system for mollusc diseases occurring in farms or natural growing beds. Such system must allow to identify the sites where problems occur. In such event, samples will have to be taken for examination in an approved laboratory. If the presence of a disease is confirmed, the official service shall take the necessary actions to control the situation.

It is further proposed that in order to ensure an efficient application of the control system, the diagnosis of the diseases must be harmonised and must be carried out under the auspices of approved laboratories, the coordination of which may be carried out by a reference laboratory designated and financed by the Community. This laboratory can obtain such financial contribution under Council Decision 90/424/EEC on expenditure in the veterinary field⁽¹⁾.

The proposed measure comes under the Common Agricultural Policy. In order to obtain the measures objectives, it is necessary to adopt a Directive.

The measures take the form of a Directive, its implementation will be the responsibility of the Member States.

Proposal for a
COUNCIL DIRECTIVE
of
Introducing minimum Community measures
for the control of 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⁾,

Having regard to the opinion of the Economic and Social Committee⁽³⁾,

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 molluscs diseases referred to in Annex A, list II to Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products⁽⁴⁾, amended by Directive 93/54/EEC⁽⁵⁾ have a devastating effect on the shellfish industry; whereas other diseases having a similar effect occur in third countries;

Whereas an outbreak of such diseases can quickly take on epizootic proportions causing mortality and disturbances on a scale liable to reduce severely the profitability of the shellfish growing sector;

(1) OJ NO L

(2) OJ NO L

(3) OJ NO L

(4) OJ No L 46 of 19. 2.1991, p. 1

(5) OJ No L 175 of 19.07.1993, p. 34

Whereas it is therefore necessary to establish at Community level the control measures to be taken in the event of outbreaks of disease, in order to ensure a rational development of the shellfish growing sector 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 important mortalities in bivalve molluscs;

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

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

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 carried out 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 DECISION:

Article 1

This Directive defines the minimum Community measures for the control of diseases affecting bivalve molluscs.

Article 2

For the purpose of this Directive, the definitions laid down in Article 2 of Directive 91/67/EEC shall apply.

Article 3

Member States shall ensure that all farms rearing or growing bivalve molluscs:

1. are registered by the official service; this registration must be kept constantly up to date;
2. keep a record of:
 - (a) bivalve molluscs entering the farm, containing all information relating to their delivery, their number or weight, their size, 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 shall be open to scrutiny by the official service.

Article 4

1. Member States shall ensure that a permanent monitoring and sampling programme is applied in bivalve mollusc farms and natural beds.

This programme aims at:

- establishing a list of sites where the diseases referred to in Annex A, list II of Directive 91/67/EEC are present;
 - monitoring the evolution and the geographical spread of the diseases referred to in the first indent.
2. The detailed rules for the application of this Article, and in particular the rules to be applied for establishing the programme referred to in paragraph 1, are laid down in accordance with the procedure provided for in Article 10.

Article 5

1. Member States shall ensure that any abnormally high mortality of bivalve molluscs in farms or in natural beds is notified as soon as possible to the official service.
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 farm, the affected area or the natural beds for reimmersion in another farm or in the aquatic environment, unless authorized by the official service;
3. If the examination referred to in paragraph 2 shows the presence of a disease, an epizootic investigation must be carried out in order to determine the possible ways of introduction of a disease and to investigate whether molluscs have left the farm or the natural beds for reimmersion elsewhere during the period proceeding the mortalities.
4. If the examination referred to in paragraph 2a) fails to demonstrate the presence of a disease, the restrictions referred to in paragraph 2b) are lifted.
5. The official service shall ensure that the Commission and the other Member States are informed without delay of abnormally high mortalities related to a disease, the actions taken to investigate the matter and to control the situation, and the cause of the mortalities.

Article 6

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

2. The testing referred to in point 1 shall be carried out by a laboratory approved by the official service. The official service of a Member State may designate a laboratory approved in another Member State for carrying out these tests. Where necessary, and in any case where the cause of the mortalities remains unresolved, the approved laboratory shall cooperate with the Community reference laboratory referred to in Article 7.
3. The Member States shall communicate the list of approved laboratories to the Commission and to the other Member States.

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, 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.

Article 8

Commission experts may, in collaboration with the competent authorities, and in so far as is necessary to ensure uniform application of this Directive, make on-the-spot checks. The Commission shall inform the Member States of the result of the checks carried out.

A Member State in whose territory a check is being carried out shall give all the necessary assistance to the experts in carrying out their duties.

The detailed rules for implementing this Article shall be determined in accordance with the procedure laid down in Article 10.

Article 9

The Annexes to this Directive may be amended in accordance with the procedure laid down in Article 10.

Article 10

1. The Commission shall be assisted by the Standing Veterinary Committee set up by Council Decision 68/361/EEC⁽¹⁾, hereinafter referred to as "the Committee".
2. Where the procedure laid down in this Article is to be used, the following rules shall apply:

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 a time limit which the Chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

Article 11

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the provisions of this Directive not later than 1 July 1996; they shall notify the Commission thereof.

When Member States adopt these measures, 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 the Member States.

(1) OJ N° L 255, 18.10.1968, p. 23

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

Article 12

This directive shall enter into force 20 days after its publication in the Official Journal of the European Communities.

Article 13

This Directive is addressed to the Member States.

Done at Brussels,

For the Council,

Annex A

Community reference laboratory
for diseases of bivalve molluscs

IFREMER
Boite Postale 133
17390 LA TREMBLADE
FRANCE

Annex B

Functions and duties of the
Community reference laboratory for diseases of molluscan shellfish

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

1. To coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing diseases of molluscan shellfish, 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.

ISSN 0254-1475

COM(94) 401 final

DOCUMENTS

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Catalogue number : CB-CO-94-424-EN-C

ISBN 92-77-80720-2

Office for Official Publications of the European Communities
L-2985 Luxembourg

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