



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.06.1997

COM(97) 310 final

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Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DECISION
on reference laboratories for monitoring bacteriological and viral contamination
of bivalve molluscs

(presented by the Commission)

EXPLANATORY MEMORANDUM

Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and placing on the market of live bivalve molluscs¹ stipulates that, in the absence of routine virus testing procedures and the establishment of virological standards, health checks of bivalve molluscs must be based on faecal bacteria counts. However, scientific studies since the adoption of the Directive have shown the unreliability of faecal bacteria as indicators of pathogenic viruses in bivalve molluscs.

Several hundred consumers of oysters in the Community were affected by an outbreak of gastro-enteritis in January 1997. Investigations showed that the oysters complied with the standards on faecal bacteria laid down in Directive 91/492/EEC. New analytical techniques revealed the presence of a pathogenic virus in the oysters and helped to evaluate a better virus indicator for routine use. This epidemic has demonstrated the urgent need for a new type of check for viral and microbial contaminations of bivalve molluscs.

The development and application of these new techniques will require the network of national laboratories responsible for checking viral and microbial contaminations of bivalve molluscs to coordinate their efforts. With this in mind, a Community reference laboratory should be designated to coordinate the activities of the national reference laboratories so as to ensure a standard inspection system and an equivalent level of consumer health protection throughout the Community. Among laboratories specializing in bacteriological and viral techniques, the laboratory of the Centre for Environment, Fisheries and Aquaculture Science, Weymouth, has volunteered to assume the task of coordinating the national laboratories.

The laboratory of the Centre for Environment, Fisheries and Aquaculture Science, Weymouth, fulfils the conditions laid down for taking on the responsibilities and functions of the Community reference laboratory and is also entitled to receive Community funding under the terms laid down in Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field².

¹ OJ No L 268, 24.9.1991, p. 1, as last amended by the Treaty of Accession for Austria, Finland and Sweden.

² OJ No L 224, 18.8.1990, p. 19, as last amended by Council Decision 94/370/EC of 21 June 1994 (OJ No L 168, 2.7.1994, p. 94).

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission³,

Having regard to the opinion of the Economic and Social Committee⁴,

Acting in accordance with the procedure laid down in Article 189b of the Treaty⁵,

Whereas implementation of the single market requires, for health protection in the veterinary and plant health sectors, standardized checks on product cleanliness; whereas this requirement applies especially to the viral and bacteriological contamination of bivalve molluscs;

Whereas the Annex to 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 molluscs⁶, as amended by the Act of Accession of Austria, Finland and Sweden, lays down in particular requirements on bacteriological and viral contamination of live bivalve molluscs;

Whereas Chapter V(8) of the Annex to that Directive states that, in the absence of routine virus testing procedures and the establishment of virological standards, health checks must be based on faecal bacteria counts;

Whereas scientific progress has shown faecal bacteria to be an unreliable indicator of the presence of viruses in live bivalve molluscs; whereas to protect public health it is therefore necessary to base the health check on some other indicator;

Whereas the development of new analytical techniques for viruses and reliable indicators of bivalve mollusc contamination requires coordination of the activities of the network of national laboratories;

Whereas to ensure an effective system of monitoring checks for viruses, each Member State should designate a national reference laboratory responsible for coordinating the requisite tests in that State;

³ OJ No C

⁴ OJ No C

⁵ OJ No C

⁶ OJ No L 268, 24.9.1991, p. 1.

Whereas to ensure a standardized system throughout the Community, the Community reference laboratory responsible for coordinating the checks on viral and bacteriological contamination carried out by each national laboratory should be designated; whereas the operating terms and functions of the Community reference laboratory should be laid down; whereas those responsible for the laboratory must undertake to carry out the tasks laid down in this Decision under the terms provided for herein;

Whereas the reference laboratory can be granted Community financial assistance under the terms of Article 28 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field⁷, as last amended by Decision 94/370/EC⁸,

HAVE ADOPTED THIS DECISION:

Article 1

Each Member State shall designate one or more national reference laboratories for monitoring viral and bacteriological contaminations of bivalve molluscs. It shall inform the Commission, which shall publish the list of the national reference laboratories and any updates to it in the *Official Journal of the European Communities*.

Article 2

1. Each national reference laboratory shall be responsible for:
 - (a) coordinating the activities of the national laboratories responsible for viral and bacteriological analyses of bivalve molluscs in the relevant Member State;
 - (b) assisting the competent authority in the Member State to organize a system for monitoring viral and bacteriological contamination of bivalve molluscs;
 - (c) organizing on a regular basis comparative tests between the various national laboratories responsible for the viral and bacteriological testing of bivalve molluscs;
 - (d) disseminating the information provided by the Community reference laboratory referred to in Article 3 to the competent authorities and national laboratories responsible for the viral and bacteriological testing of bivalve molluscs.
2. The national laboratories shall collaborate with the Community reference laboratory referred to in Article 3.

Article 3

The laboratory of the Centre for Environment, Fisheries and Aquaculture Science at Weymouth in the United Kingdom is hereby designated as the Community reference laboratory for monitoring the viral and bacteriological contamination of bivalve molluscs.

⁷ OJ No L 224, 18.8.1990, p. 19.

⁸ OJ No L 168, 2.7.1994, p. 31.

Article 4

The Community reference laboratory shall be responsible for:

- (a) supplying information on analytical methods and comparative testing to the national reference laboratories;
- (b) coordinating the application by the national reference laboratories of the methods referred to in point (a), by organizing comparative testing in particular;
- (c) coordinating research into new analytical methods and informing the national reference laboratories of progress made in this area;
- (d) organizing training and advanced courses for the staff of the national reference laboratories;
- (e) collaborating with the laboratories responsible for the bacteriological and viral analysis of bivalve molluscs in third countries;
- (f) providing scientific and technical assistance to the Commission, especially in cases where test results are contested between Member States.

Article 5

The Community reference laboratory shall satisfy the following operating conditions:

- (a) staff must be qualified and have sufficient knowledge of the techniques applied in the bacteriological and viral analysis of bivalve molluscs;
- (b) the equipment and substances necessary for carrying out the tasks laid down in Article 4 must be available;
- (c) an appropriate administrative structure must be in place;
- (d) the confidential nature of certain subjects, results and reports must be observed by the staff;
- (e) the principles of good laboratory practice accepted internationally must be followed;
- (f) an up-to-date list of the reference substances held by the Community Bureau of References must be available, along with an up-to-date list of the manufacturers and suppliers of these substances.

Article 6

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

Article 7

This Decision is addressed to the Member States.

Done at Brussels,

**For the European Parliament
The President**

**For the Council
The President**

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