

COUNCIL DECISION

of 29 April 1999

on reference laboratories for monitoring bacteriological and viral contamination of bivalve molluscs

(1999/313/EC)

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 opinions of the European Parliament ⁽²⁾,

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

(1) 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 molluscs ⁽⁴⁾ lays down in particular requirements on bacteriological and viral contamination of live bivalve molluscs;

(2) 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;

(3) 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 other indicators;

(4) 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;

(5) Whereas, to ensure an effective monitoring system with regard to virus testing and the establishment of standards for virological and bacteriological contamination, and to introduce routine procedures and reliable methods for detecting viruses and bacteria, each Member State should designate a

national reference laboratory responsible for coordinating the requisite tests in that State;

(6) Whereas, to ensure a standardised system throughout the Community, the Community reference laboratory responsible for coordinating the checks on viral and bacteriological contamination of bivalve molluscs 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;

(7) Whereas this Community 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 field ⁽⁵⁾,

HAS ADOPTED THIS DECISION:

Article 1

Each Member State shall designate a national reference laboratory 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;

⁽¹⁾ OJ C 267, 3.9.1997, p. 15.

⁽²⁾ OJ C 304, 6.10.1997, p. 79 and opinion of 13 April 1999 (not yet published in the Official Journal).

⁽³⁾ OJ C 355, 21.11.1997, p. 63.

⁽⁴⁾ OJ L 268, 24.9.1991, p. 1. Directive as last amended by Directive 97/79/EC (OJ L 24, 30.1.1998, p. 31).

⁽⁵⁾ OJ L 224, 18.8.1990, p. 19. Decision as last amended by Decision 94/370/EC (OJ L 168, 2.7.1994, p. 31).

- (b) assisting the competent authority in the Member State to organise a system for monitoring viral and bacteriological contamination of bivalve molluscs;
 - (c) organising on a regular basis comparative tests between the various national laboratories responsible for the said analyses;
 - (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 said analyses.
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.

Article 4

The Community reference laboratory shall be responsible for the following tasks:

- (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 organising comparative testing in particular;
- (c) coordinating research into new analytical methods and informing the national reference laboratories of progress made in this area;
- (d) organising 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;

- (g) helping the reference laboratories to implement an appropriate system of quality assurance based on the principles of good laboratory practice (GLP) and the EN 45 000 criteria.

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 day of its publication in the *Official Journal of the European Communities*.

Article 7

This Decision is addressed to the Member States.

Done at Luxembourg, 29 April 1999.

For the Council

The President

W. MÜLLER