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COUNCIL DIRECTIVE

of 15 July 1991

laying down the health conditions for the production and the placing on the market of live bivalve molluscs

(91/492/EEC)

(OJ L 268, 24.9.1991, p. 1)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Council Directive 97/61/EC of 20 October 1997	L 295	35	29.10.1997
►**M2**	Council Directive 97/79/EC of 18 December 1997	L 24	31	30.1.1998
►**M3**	Council Regulation (EC) No 806/2003 of 14 April 2003	L 122	1	16.5.2003

Amended by:

►**A1**	Act of Accession of Austria, Sweden and Finland	C 241	21	29.8.1994
	(adapted by Council Decision 95/1/EC, Euratom, ECSC)	L 1	1	1.1.1995

▼B

COUNCIL DIRECTIVE

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laying down the health conditions for the production and the placing on the market of live bivalve molluscs

(91/492/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic 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, with a view to achieving the internal market and more especially to ensure the smooth operation of the common organization of the market in fishery products established by Regulation (EEC) No 3796/81 ([4]) as last amended by Regulation (EEC) No 2886/89 ([5]), it is essential that the placing on the market of live bivalve molluscs should no longer be hindered by disparities existing in the Member States in respect of health requirements; whereas this will enable production and placing on the market to be better harmonized and bring about competition on equal terms while ensuring quality products for the consumer.

Whereas Council Directive 79/923/EEC of 30 October 1979 on the quality required of shellfish waters ([6]) lays down that it is necessary to establish the health requirements to be observed for shellfish products;

Whereas these requirements should be laid down for all stages during harvesting, handling, storage, transport and distribution of live bivalve molluscs in order to safeguard the public health of consumers; whereas these requirements shall apply equally to echinoderms, tunicates and marine gastropods;

Whereas it is important, should a health problem occur after the placing on the market of live bivalve molluscs to be able to trace back the establishment of dispatch and the harvesting area of origin; whereas it is therefore necessary to introduce a registration and labelling system which will enable the route of a batch after harvesting to be followed;

Whereas it is important that the public health standards for the final product must be specified; whereas, however, scientific and technological knowledge is not always advanced enough to lay down definitive solutions for certain health problems and whereas it is therefore necessary, in order to guarantee optimal protection of public health, to set up a Community system to ensure rapid adoption and where necessary reinforcement of the health standards to safeguard human health from virus contamination or other hazards;

Whereas live bivalve molluscs obtained from harvesting areas which do not permit direct, safe consumption may be rendered safe by submitting them to a purification process or by relaying in clean water over a relatively long period; whereas it is therefore necessary to define production areas from which molluscs can bet gathered for direct human consumption, or from which they have to be purified or relayed;

([1]) OJ No C 84, 2. 4. 1990, p. 29.
([2]) OJ No C 183, 15. 7. 1991.
([3]) OJ No C 332, 31. 12. 1990, p. 1.
([4]) OJ No L 379, 31. 12. 1981, p. 1.
([5]) OJ No L 282, 2. 10. 1989, p. 1.
([6]) OJ No L 281, 10. 11. 1979, p. 47.

▼B

Whereas it is primarily the responsibility of the producers to ensure that the bivalve molluscs are produced and placed on the market in compliance with the health requirements prescribed; whereas the competent authorities must, by carrying out checks and inspections, ensure that producers comply with those requirements; whereas the competent authorities must in particular submit harvesting areas to a regular control to ensure that molluscs from these harvesting areas do not contain microorganisms and toxic substances in quantities which are considered to be dangerous to human health;

Whereas control measures organized on a Community level must be introduced to guarantee the uniform application in all Member States of the standards laid down in this Directive;

Whereas the rules, principles and safeguard measures established by Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries ([1]), should apply to the case in question;

Whereas in the context of trade between the Member States, the rules laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade, with a view to the completion of the internal market ([2]) as amended by Directive 90/675/EEC should also be applied;

Whereas live bivalve molluscs produced in a third country and intended to be placed on the market in the Community must not qualify for more favourable conditions than those applied in the Community; whereas provision must be made for a Community procedure for checking the conditions in third countries of production and of the placing on the market, in order to allow the Community to apply a common import system based on conditions of equivalence;

Whereas, so that account may be taken of particular circumstances, derogations should be granted to certain establishments already operating before 1 January 1993 so as to allow them to adapt to all the requirements laid down in this Directive;

Whereas, in the case of living animals that are edible whilst they are alive, a derogation should be made, with regard to the durability date, to the rules of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale ([3]) as last amended by Directive 91/72/EEC ([4]);

Whereas provision should be made for the possibility of adopting transitional measures in order to cover the absence of certain implementing rules;

Whereas the Commission should be entrusted with the task of adopting certain measures for implementing this Directive; whereas to that end, procedures should be laid down introducing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive lays down health conditions for the production and placing on the market of live bivalve molluscs which are intended for

([1]) OJ No L 373, 31. 12. 1990, p. 1.
([2]) OJ No L 395, 30. 12. 1989, p. 13.
([3]) OJ No L 33, 8. 2. 1979, p. 1.
([4]) OJ No L 42, 16. 1. 1991, p. 27.

▼B

immediate human consumption or for further processing before consumption.

With the exception of the provisions on purification, this Directive applies to echinoderms, tunicates and marine gastropods.

Article 2

For the purposes of this Directive, the following definitions shall apply:

1. *'bivalve molluscs'* means filter-feeding lamellibranch molluscs;
2. *'marine biotoxins'* means poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxin;
3. *'clean sea water'* means sea water or brackish water which is to be used under the conditions laid down in this Directive and which is free from microbiological contamination and toxic and objectionable substances occurring naturally or after discharge in the environment such as those listed in the Annex to Directive 79/923/EEC, in such quantities as may adversely affect the health quality of bivalve molluscs or to impair their taste;
4. *'competent authority'* means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence;
5. *'conditioning'* means the storage of live bivalve molluscs, whose quality does not indicate the need for relaying or treatment in a purification plant, in tanks or any other installation containing clean sea water or in natural sites to remove sand, mud or slime;
6. *'gatherer'* means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market;
7. *'production area'* means any sea, estuarine or lagoon area containing natural deposits of bivalve molluscs or sites used for cultivation of bivalve molluscs from which live bivalve molluscs are taken;
8. *'relaying area'* means any sea, estuarine or lagoon area approved by the competent authority, with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs;
9. *'dispatch centre'* means any approved on-shore or off-shore installation for the reception, conditioning, washing, cleaning, grading and wrapping of live bivalve molluscs fit for human consumption;
10. *'purification centre'* means an approved establishment with tanks fed by naturally clean sea water or sea water that has been cleaned by appropriate treatment, in which live bivalve molluscs are placed for the time necessary to remove microbiological contamination, so making them fit for human consumption;
11. *'relaying'* means an operation whereby live bivalve molluscs are transferred to approved sea or lagoon areas or approved estuarine areas under the supervision of the competent authority for the time necessary to remove contamination. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening;
12. *'means of transport'* means those parts set aside for goods in automobile vehicles, rail vehicles and aircraft, the holds of vessels and containers for transport by land, sea or air;
13. *'wrapping'* means an operation whereby live bivalve molluscs are placed in packaging material adequate for the purpose;
14. *'consignment'* means a quantity of live bivalve molluscs handled in a dispatch centre or treated in a purification centre and subsequently intended for one or more customers;
15. *'batch'* means a quantity of live bivalve molluscs collected from a production area and subsequently intended for delivery to an approved dispatch centre, purification centre, relaying area or processing plant as appropriate;

▼B

16. *'placing on the market'* means the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market of live bivalve molluscs for human consumption either raw or for the purpose of processing in the Community, excluding the direct transfer on the local market in small quantities by the coastal fisherman to the retailer or the consumer which must be subject to the health checks laid down by national rules for checking on retail business;

17. *'importation'* means the introduction of live bivalve molluscs into the territory of the Community from third countries;

18. *'faecal coliform'* means facultative, aerobic, gram-negative, non-sporeforming, cytochrome oxidase negative, rod-shaped bacteria that are able to ferment lactose with gas production in the presence of bile salts, or other surface active agents with similar growth-inhibiting properties, at 44 ºC ± 0,2 ºC within 24 hours at least;

19. *'E. coli'* means faecal coliforms which also form indole from tryptophan at 44 ºC ± 0,2 ºC within 24 hours.

CHAPTER II

Provisions for Community production

Article 3

1. The placing on the market of live bivalve molluscs for immediate human consumption shall be subject to the following conditions:

(a) they must originate from production areas which comply with the requirements laid down in Chapter I of the Annex; however, in the case of pectinidae, this provision shall apply only to aquaculture products as defined in Article 2 (2) of Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and placing on the market of fishery products [1];

(b) they must have been harvested and transported from the production area to a dispatch centre, purification centre, relaying area or processing plant under the conditions laid down in Chapter II of the Annex;

(c) where provided for in this Directive, they must have been relaid in suitable areas approved for that purpose and complying with the conditions laid down in Chapter III of the Annex;

(d) they must have been handled hygienically, and where appropriate, they must have been purified in establishments approved for that purpose and complying with the requirements of Chapter IV of the Annex;

(e) they must comply with the criteria set out in Chapter V of the Annex;

(f) health controls must have been carried out in accordance with Chapter VI of the Annex;

(g) they must have been appropriately wrapped in accordance with Chapter VII of the Annex;

(h) they must have been stored and transported under satisfactory conditions of hygiene in accordance with Chapters VIII and IX of the Annex;

(i) they must bear a health mark as provided for in Chapter X of the Annex.

2. Live bivalve molluscs intended for further processing must comply with the relevant requirements of paragraph 1 and be processed in accordance with the requirements of Council Directive 91/493/EEC.

[1] See page 15 of this Official Journal.