

**EUROPEAN COMMUNITIES (LIVE BIVALVE MOLLUSCS) (HEALTH CONDITIONS
FOR
PRODUCTION AND PLACING ON THE MARKET) REGULATIONS 1996**

I, Sean Barrett, Minister for the Marine, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving effect to Council Directive 91/492/EEC of 15 July, 1991, hereby make the following regulations:

REG 1

Citation

1. These Regulations may be cited as the European Communities (Live Bivalve Molluscs) (Health Conditions for Production and Placing on the Market) Regulations, 1996.

1 O.J. L268/1, 1991, pp 1-14

REG 2

Commencement

2. These Regulations shall come into operation on the 27th day of May, 1996.

REG 3

Interpretation

3. (1) In these Regulations —

"the Annex" means the Annex to the Council Directive;

"authorised officer" means —

(a) an officer of the Minister or of the Minister for Agriculture, Food and Forestry authorised in writing to be an authorised officer for the purposes of these Regulations, or

(b) an officer of a health board (established under the Health Act, 1960) authorised in writing by the chief executive officer of the health board to be an authorised officer for the purposes of these Regulations;

"Council Directive" means Council Directive 91/492/EEC, as amended or replaced by any regulation, directive or decision of the European Community;

"the Minister" means the Minister for the Marine.

(2) A word or expression that is used in these Regulations and is also used in the Council Directive has, unless the contrary intention appears, the same meaning in these Regulations as it has in the Council Directive.

(3) In these Regulations —

(i) a reference to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other provision is intended;

(ii) a reference to a paragraph or subparagraph is to the paragraph

or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

REG 4

Application

4. These Regulations apply to live bivalve molluscs which are intended for immediate human consumption or for further processing before consumption and, with the exception of the provisions on purification, to echinoderms, tunicates and marine gastropods, but shall not apply to the transport of any such products in small quantities by coastal fishermen to a retailer or to any retail transfer.

REG 5

5 Restriction on placing on the market

5. (1) A person shall not place on the market live bivalve molluscs for immediate human consumption unless they comply with the conditions specified in paragraph 1 of Article 3 of the Council Directive

(2) A person shall not place on the market live bivalve molluscs intended for further processing unless they comply with the relevant requirements of paragraph (1) and have been processed in accordance with the requirements of Council Directive 91/493/EEC.

2 OJ No. L268, 1991, pp 15—33

(3) Notwithstanding the provisions of paragraph (1), the provisions of Chapter I of the Annex, in so far as they relate to pectinidae, apply only to aquaculture products as defined in Article 2(2) of Council Directive 91/493/EEC.

REG 6

6. In relation to the organisation of, and the action to be taken following, checks of destination and the implementation of safeguard measures, the rules laid down in Council Directive 89/662/EEC³ (as amended or replaced by an amending Regulation, Directive or Decision of the European Community) as regards live bivalve molluscs, echinoderms, tunicates and marine gastropods shall apply.

2OJ No. L-, 1989,pp-.

REG 7

Dispatch and Purification Centres

7. (1) A person shall not operate a dispatch centre or a purification centre unless the centre has been approved by the Minister under this Regulation.
- (2) A person who intends to operate a dispatch centre or a purification centre shall apply in writing for approval to the Minister in such form as the Minister may from time to time decide.
- (3) The Minister may approve or refuse to approve a dispatch centre or a purification centre, or approve such a centre subject to such conditions as he or she may from time to time specify.
- (4) When deciding on an application the Minister shall apply the relevant criteria contained in Chapter IV of the Annex.
- (5) Where the Minister approves a dispatch centre or a purification centre under this Regulation, he or she shall assign an approval number to the centre.
- (6) In the event of—
- (i) a change in the ownership of a dispatch centre or purification centre, or
 - (ii) a significant change in—
 - (a) the premises or the equipment therein (otherwise than by way of repairs or maintenance), or
 - (b) the method of operation in the premises,
- the approval shall lapse and it shall be necessary for the person operating the centre to re-apply for approval under this Regulation.
- (7) Where following inspection and monitoring of a dispatch centre or a purification centre by an authorised officer the Minister is satisfied that a requirement of these Regulations is not being complied with the Minister may suspend or revoke the approval granted in respect of that dispatch centre or purification centre.
- (8) A person shall not operate a dispatch centre or a purification centre in respect of which an approval under this Regulation has been suspended or revoked.
- (9) The Minister shall not refuse to approve a dispatch centre or purification centre or suspend or revoke an approval under this Regulation without—
- (a) notifying in writing the applicant for or holder of an approval of his or her intention to refuse, suspend or revoke the approval, as the case may be;
 - (b) specifying the reason for the intended refusal, suspension or revocation, as the case may be; and
 - (c) affording the applicant for, or holder of an approval an opportunity of making representations or having representations made on his or her behalf to the Minister in relation to the proposed refusal, suspension or revocation within 21 days of the issue of notification under this paragraph by the Minister.
- (10) A person operating a dispatch centre or a purification centre

shall ensure that representative numbers of samples of species to which these Regulations apply are regularly taken and analysed for the purpose of Article 4 of the Council Directive and that a register is kept for that purpose.

(11) Notwithstanding any provision of this Regulation, the Minister may, where he or she is satisfied that there is a serious and immediate risk to human health, suspend without notice an approval under this Regulation.

REG 8

Production and relaying areas

8. (1) The Minister shall designate those production areas from which live bivalve molluscs may be taken and in designating a production area under this Regulation shall comply with the conditions specified in Chapter I of the Annex.

(2) The Minister may approve relaying areas and in the event of his approving a relaying area shall comply with the conditions specified in paragraphs 6 and 7 of Chapter III of the Annex.

(3) Where a production area or relaying area ceases to comply with the relevant requirements of these Regulations the Minister shall revoke a designation or approval under this Regulation.

(4) The Minister shall compile and maintain a list of designated production areas and designated relaying areas and make such list publicly available.

REG 9

Laboratories

9. (1) A person shall not operate a laboratory for use by a person operating a dispatch centre or a purification centre unless the laboratory has been recognised by the Minister.

(2) Any person who intends to operate a laboratory for such use shall apply for recognition in writing to the Minister in such form as the Minister may from time to time decide.

(3) The Minister shall grant recognition under this Regulation to a laboratory which—

(i) participates in a performance assessment scheme approved by the Minister, and

(ii) uses methods for bacteriological examination approved by the Minister.

(4) In approving an appropriate assessment scheme or methods of bacteriological examination for the purposes of this Regulation, the Minister shall have regard to the requirements of the Council Directive.

(5) The Minister shall notify an applicant in writing of the result of an application under this Regulation and, in the case of a refusal, shall state in writing the reasons for the refusal.

(6) Where the Minister is satisfied that a laboratory fails to meet

the requirements specified in paragraph (3), the Minister may refuse or revoke a recognition under this Regulation.

(7) The Minister shall not refuse a recognition under this Regulation without

- (a) notifying in writing the applicant of his or her intention to refuse the recognition;
- (b) specifying the reason for the intended refusal; and
- (c) affording the applicant an opportunity of making representations or having representations made on his or her behalf to the Minister in relation to the intended refusal.

REG 10

Imports from Third Countries

10. (1) Subject to paragraph (2), a person shall not import into the State from a country which is not a Member State of the European Community live bivalve molluscs which do not satisfy the import conditions required by Chapter III of the Council Directive.

(2) Until such time as the European Commission, acting pursuant to Chapter III of the Council Directive, produces a list or lists of third countries and establishments within such countries where conditions of production and placing on the market are equivalent to those applied in the European Community, a person shall not import into the State live bivalve molluscs from those third countries and establishments unless the Minister is satisfied that such countries and establishments apply provisions at least equivalent to those governing the production and placing on the market of live bivalve molluscs in the European Community.

(3) For the purposes of paragraph (2), in deciding whether the conditions of production and placing on the market in third countries and establishments are at least equivalent to those in the Union, the Minister shall have regard to relevant factors specified in Chapter III of the Council Directive.

(4) A person importing into the State consignments of live bivalve molluscs from a third country or establishment shall produce at the place of importation a duly completed certificate (which shall be known as a "health certificate") in the English language in such form as the Minister may from time to time specify.

REG 11

Powers of Authorised Officers

11. (1) An authorised officer may, for the purposes of these Regulations, at all times—

- (i) enter any dispatch centre, purification centre, or any laboratory or means of transport used in relation to live bivalve molluscs,
- (ii) carry out or cause to be carried out such inspections, tests, and checks of the distribution or production centre, laboratory or means of transport and of any equipment, machinery or plant therein,

and inspect and examine any species to which these Regulations apply found therein and, where appropriate, require it to be kept for such period, and at such place, as the authorised officer may direct;

(iii) require the owner of or any person connected with the centre, laboratory or means of transport, to furnish such information and produce such records (including computerised documents) and other documents to the authorised officer which are within the power of procurement of the owner or person as may reasonably be required for the purposes of the authorised officer's functions under these Regulations,

(iv) examine and take copies of any such records or documents or extracts from such records or documents,

(v) take and remove (without payment) such samples of any such species or any other matter found in the centre, laboratory or means of transport and carry out or have carried out on the samples or matter such examinations, tests and checks and analyses, in accordance with any relevant provision of the Council Directive as the authorised officer considers necessary,

(vi) confiscate any such species which are unfit for human consumption and which would constitute an immediate threat to public health.

(vii) do anything consequential, ancillary, incidental or supplementary to any of the foregoing matters.

(2) The owner of or any person connected with any such centre, laboratory or means of transport shall afford to an authorised officer such facilities as are reasonably necessary to enable the authorised officer to perform his or her functions under these Regulations.

(3) An authorised officer shall be furnished by the Minister or by the chief executive officer of the relevant health board with a certificate of appointment as an authorised officer and when exercising any power conferred on an authorised officer by these Regulations shall, if so requested by a person, produce the certificate for the inspection of the person.

REG 12

Prosecution of offences.

12. An offence under these Regulations may be prosecuted by the Minister after consultation with the chief executive officer of the relevant health board or by the chief executive officer of the relevant health board after consultation with the Minister.

REG 13

Fees

13. (1) In respect of the granting of any approval or recognition under these Regulations and of the performance of functions under these Regulations, the Minister may charge such fees, as the Minister, with the consent of the Minister for Finance may, from time to time, determine.

(2) A fee payable under this Regulation shall be payable by the owner or person in charge of the dispatch centre, purification centre or laboratory of which the approval or recognition concerned relates.

(3) The Minister may refuse to grant such approval or recognition until payment of fees payable under this Regulation has been made in full.

(4) Fees under this Regulation shall be collected and taken in such manner as the Minister directs and shall be paid or disposed of for the benefit of the Exchequer in accordance with the directions of the Minister for Finance.

(5) A fee payable under this Regulation may be recovered by the Minister from the person by whom it is payable as a simple contract debt in any court of competent jurisdiction.

(6) A fee payable under this Regulation shall not exceed an amount equal to the costs, estimated by the Minister, incurred in relation to the approval or recognition concerned and the performance of functions under these Regulations to the dispatch performance of functions under these Regulations to the dispatch centre, purification centre or laboratory concerned by authorised officers for the purpose of the approval or recognition.

REG 14

Offences

14. (1) A person who fails to comply with any requirement of these Regulations shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,000, or to imprisonment for a term not exceeding six months, or to both.

(2) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of a person, being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person as well as the body corporate shall be guilty of an offence and be liable to be proceeded against as if he was guilty of the first-mentioned offence.

REG 15

Revocation

15. The Shellfish (Handling, Storage and Transport) Regulations, 1979 (S.I. No. 157 of 1979), are hereby revoked.

GIVEN under my Official Seal,

This 27th day of May , 1996

EXPLANATORY MEMORANDUM

This order implements Council Directive No. 91/492/EEC laying down the health conditions for the production and placing on the market of live bivalve molluscs.