## EUROPEAN COMMUNITIES (FISHERY PRODUCTS) (HEALTH CONDITIONS AND HYGIENE RULES FOR PRODUCTION AND PLACING ON THE MARKET) REGULATIONS, 1996.

I, SEÁN 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 9½93/EEC¹ of 22 July, 1991, and Council Directive 92/48/EEC² of 16 June, 1992, hereby make the following Regulations:
<sup>1</sup> O.J. No, L268, 24.9.91, p. 15.
<sup>2</sup> O.J. No. L187, 7.7.92, p. 41.
Citation.
1. These Regulations may be cited as the European Communities (Fishery Products) (Health Conditions and Hygiene Rules for Production and Placing on the Market) Regulations, 1996.
Commencement.
2. These Regulations shall come into operation on the 10th day of June, 1996.

Interpretation.
3. (1) In these Regulations—
"authorised officer" means—
(i) an officer of the Minister, or
(ii) an officer of the Minister for Agriculture, Food and Forestry who is authorised in writing by the Minister for the purposes of these Regulations, or
(iii) an officer of a health board who is authorised in writing by the chief executive officer of the health board to be an authorised officer for the purposes of these Regulations;
"the Council Directive of 1991" means Council Directive 9½93/EEC, as amended or replaced by any regulation, directive or decision of the European Communities;
"the Council Directive of 1992" means Council Directive 92/48/EEC, as amended or replaced by any regulation, directive or decision of the European Communities;
"the Minister" means the Minister for the Marine;
"third country" means a country other than a Member State of the European Communities.
(2) A word or expression that is used in these Regulations and is also used in the Council Directive of 1991 has, unless the contrary intention appears, the same meaning in these Regulations as it has in that Directive.
(3) A word or expression that is used in these Regulations and is also used in the Council Directive of 1992 has, unless the contrary intention appears, the same meaning in these Regulations as it has in that Directive.

(4) In these Pagulations
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(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.
Application.
<b>4.</b> These Regulations apply to the production and placing on the market of fishery products and to the minimum hygiene rules applicable, in accordance with Article 3.1 (a) (i) of the Council Directive of 1991, to fishery products intended for human consumption, but excluding retail sales of such products.
Placing on market generally.
5. A person shall not place on the market—
(a) fishery products caught in their natural environment unless they have complied with the conditions specified in Article 3.1 of the Council Directive of 1991,
(b) aquaculture products unless they have complied with the conditions specified in Article 3.3 of the Council Directive of 1991.
(c) bivalve molluscs when processed unless they satisfy the requirements of Articles 3.1 (c) to 3.1 (g) of the Council Directive of 1991, in addition to complying with the relevant provisions of Council Directive 9½92/EEC³ of 15 July, 1991,

<sup>3</sup>O.J. No. L268, 24.9.91, p. 1.

(d) poisonous fish of the following families, namely, Tetraodontidae, Molidae, Diodontidae, Canthigasteridae, or fishery products containing biotoxins such as ciguatera toxins or muscle paralysing toxins,
(e) fishery products handled on board fishing vessels unless they comply with the general hygiene conditions laid down in Annex I of the Council Directive of 1992,
(f) fishery products from fishing vessels designed and equipped to preserve such products on board under satisfactory conditions for more than 24 hours unless they comply with the hygiene conditions laid down in Annex I and Annex II of the Council Directive of 1992, but not including fishery products from vessels equipped for keeping fish, shellfish and molluscs alive without other means of conservation aboard.
Gutting of fishery products.
<b>6.</b> A person who is in charge of the gutting of fishery products caught in their natural environment shall ensure that, where gutting is possible from a technical and commercial viewpoint, it is carried out as quickly as possible after the products have been caught or landed.
Care of live fishery products.
7. A person who is in charge of the survival conditions of fishery products caught in their natural environment which are intended to be placed on the market alive shall ensure that the products are at all times kept under the most suitable survival conditions.
Cooking of shrimps and molluses on board.
<b>8.</b> The master or skipper of a fishing vessel having shrimps or molluscs on board intended for cooking shall ensure that the cooking of such products on board shall comply with Chapter III, section 1 (5) and Chapter IV, section IV (7) of the Annex to the Council Directive of 1991.

Responsibility for own checks.
<b>9.</b> A person responsible for an establishment shall carry out own checks in accordance with Article 6.1 of the Council Directive of 1991.
Establishments, factory vessels, auction markets and wholesale markets.
10. A person shall not engage in activities associated with the placing on the market of fishery products for human consumption unless the premises from which the activities are undertaken consist of an establishment or factory vessel approved or an auction market or wholesale market registered pursuant to these Regulations.
11. In relation to the organisation of, and the action to be taken following the inspection to be carried out by the Member States of Destination, and the protective measures to be implemented, the rules laid down in Council Directive 89/662/EEC <sup>4</sup> of 11 December, 1989 (as amended or replaced by an amending regulation, directive or decision of the European Community) as regards fishery products intended for human consumption, shall apply.
<sup>4</sup> O.J No. L395, 30.12.89, p. 13.
Approval of establishments and factory vessels.
<b>12.</b> (1) A person shall not operate an establishment or a factory vessel unless it has been approved by the Minister under this Regulation.
(2) A person who intends to operate an establishment or a factory vessel 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 an establishment or a factory vessel, or may approve such an establishment or factory vessel 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 Chapters III, IV, VI, VII and VIII of the Annex to the Council Directive of 1991 in relation to establishments and the relevant criteria contained in Chapter I of the Annex to the Council Directive of 1991 in relation to factory vessels.
(5) Where the Minister approves an establishment or a factory vessel under this Regulation, he or she shall assign an approval number to the establishment or factory vessel.
(6) In the event of—
(i) a change in the ownership of an establishment or a factory vessel or
(ii) a significant change in—
(a) the establishment or factory vessel or the equipment therein (otherwise than by way of repairs or maintenance), or
(b) the method of operation of the establishment or factory vessel,
the approval shall lapse and it shall be necessary for the person operating the establishment or factory vessel to reapply for the approval under this Regulation.
(7) Where, following inspection and monitoring of an establishment or a factory vessel 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 establishment or factory vessel.

- (8) A person shall not operate an establishment or a factory vessel in respect of which an approval under this Regulation has been suspended or revoked.
- (9) The Minister shall not refuse to approve an establishment or a factory vessel 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 date of issue of notification under this paragraph by the Minister.
- (10) A person operating an establishment or a factory vessel shall ensure that representative numbers of samples of products to the production of which these Regulations apply are regularly taken and analysed for the purpose of Article 6.1, third indent, of the Council Directive of 1991 and that a record is kept for that purpose, in accordance with Article 6.1, fourth indent, of the Council Directive of 1991.
- (11) Notwithstanding any other provision of this Regulation, the Minister may, where satisfied that there is a serious and immediate risk to human health, suspend or revoke without notice an approval under this Regulation.

Approval of laboratories.

- **13.** (1) A person shall not operate a laboratory for use by a person operating an establishment, factory vessel, wholesale market, auction market or vessel engaged in the cooking of shrimps and molluscs on board or a fishing vessel to which the Council Directive of 1992 applies (which six types of operation are referred to hereafter in these Regulations as "Regulation 13 operation") unless the laboratory has been approved by the Minister.
- (2) Any person who intends to operate a laboratory for such use shall apply for approval in writing to the Minister in such form as the Minister may from time to time decide.

(3) The Minister shall grant approval under this Regulation to a laboratory which—
(i) participates in a performance assessment scheme approved by the Minister, and
(ii) uses methods of analysis approved by the Minister.
(4) In approving an assessment scheme or methods of analysis for the purposes of this Regulation, the Minister shall have regard to the requirements of the Council Directive of 1991.
(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 an approval under this Regulation.
(7) The Minister shall not refuse 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 or revoke the approval, as the case may be,
(b) specifying the reason for the intended refusal or revocation, as the case may be; and
(c) affording the applicant for, or the 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 intended refusal or revocation, as the case may be.
Approval of detergents, disinfectants and similar substances.
14. (1) A person operating a Regulation 13 operation shall not use detergents, disinfectants and similar substances (which three types of substances are referred to hereafter in this Regulation as "a Regulation 14 product") in the course of operating a Regulation 13 operation unless they have been approved by the Minister and are used in such a way that they do not have adverse effect on machinery, equipment and products.

(2) The Minister shall maintain a list of Regulation 14 products.
(3) A person seeking or wishing to supply or use a Regulation 14 product shall apply for an approval under paragraph (1) in writing to the Minister in such form as the Minister may from time to time decide.
(4) An application under paragraph (3) shall be accompanied by such technical specifications and samples as the Minister may require.
(5) When deciding on an application under paragraph (3) the Minister shall have regard to the criteria referred to in paragraph (1).
(6) The Minister may approve or may refuse an application under paragraph (1) or may grant such an approval subject to specified conditions.
(7) Notwithstanding any other provision of this Regulation, the Minister may, where satisfied that there is a serious and immediate risk to human health, suspend or revoke without notice an approval under paragraph (1).
(8) A person shall not supply or use a Regulation 14 product in respect of which an approval under paragraph (1) has been suspended or revoked.
(9) The Minister may from time to time require the supplier or user of an approved product to submit to the Minister samples for the purpose of enabling the Minister to be satisfied that the Regulation 14 product continues to be suitable for the purposes of the approval under paragraph (1).
(10) The Minister shall notify the holder of an approval under this Regulation in writing of the reasons for the suspension and the circumstances in which the suspension may be lifted, and such holder may appeal the suspension to the Minister.

(11) An appeal shall be in writing, and accompanied by such supplementary information, documents and validated technical data as the Minister considers necessary to satisfy the Minister concerning the requirements of these Regulations.
Registration of wholesale and auction markets.
<b>15.</b> (1) A person shall not operate a wholesale market or an auction market unless the market has been registered by the Minister under these Regulations.
(2) A person who intends to operate a wholesale market or an auction market shall apply in writing for registration to the Minister in such form as the Minister may from time to time decide.
(3) The Minister may register or refuse to register a wholesale market or an auction market, or may register such a market subject to such conditions as he or she may from time to time specify.
(4) When deciding on an application under this Regulation the Minister shall apply the relevant criteria contained in Chapter II of the Annex to the Council Directive of 1991.
(5) Where the Minister registers a wholesale market or an auction market under this Regulation he or she shall assign a registration number to the market.
(6) In the event of—
(i) a change in the ownership of a wholesale or auction market, 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 registration shall lapse and it shall be necessary for the person operating the market to reapply for registration under this Regulation.
(7) Where, following inspection and monitoring of a wholesale or auction market 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 registration granted in respect of that market.
(8) A person shall not operate a wholesale market or an auction market in respect of which a registration under this Regulation has been suspended or revoked.
(9) The Minister shall not refuse to register a wholesale market or an auction market, suspend or revoke a registration under this Regulation without—
(a) notifying in writing the applicant for or holder of a registration of his or her intention to refuse, suspend or revoke the registration 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, a registration 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 date of issue of notification under this paragraph by the Minister.
(10) Notwithstanding any other provision of this Regulation, the Minister may, where satisfied that there is a serious and immediate risk to human health, suspend or revoke without notice a registration under this Regulation.
(11) (a) The provisions of paragraphs (1) to (10), other than paragraphs (4) and (6), shall apply, with any necessary modifications, to the registration of vessels engaged in the cooking of shrimps and molluscs on board.

- (b) When deciding on an application for such registration the Minister shall apply the criteria contained in Chapter III, section 1 (5) and Chapter IV, section IV (7) of the Annex to the Council Directive of 1991.
- (c) The master or skipper of a vessel engaged in the cooking on board of shrimps and molluscs shall ensure that representative samples of such products are regularly taken and analysed for the purpose of Chapter IV, section IV (7) of the Annex to the Council Directive of 1991, and that a record is kept for that purpose in accordance with Article 6.1, fourth indent, of the Council Directive of 1991.

Imports from Third Countries.

- **16.** (1) Subject to paragraph (2), only fishery products which satisfy the specific import conditions required by Article II of the Council Directive of 1991 may be imported into the State from third countries.
- (2) Until such time as a list of third countries and establishments within such countries where conditions of production, storage, dispatch and placing on the market are equivalent to those applied in the Member States has been produced under the Council Directive of 1991, imports shall be permitted only from those third countries and establishments which satisfy the Minister that they apply provisions at least equivalent to those governing the production and placing on the market in the Member States.
- (3) For the purposes of paragraph (2), in deciding whether the conditions of production, storage, dispatch and placing on the market in third countries and establishments are equivalent to those in the Member States the Minister shall have regard to the factors listed in Article 11 of the Council Directive of 1991.
- (4) Until a list referred to in paragraph (2) has been produced, the Minister shall require consignments of fishery products imported into the State from a third country or establishments within such countries to be accompanied by a health certificate in the English language comprising such information and in such form as the Minister may from time to time decide.
- (5) Fishery products caught in their natural environment by a fishing vessel flying the flag of a third country shall undergo the checks laid down in Article 18 (3) of Council Directive 90/675/EEC<sup>5</sup> of 10 December, 1990 laying down the principles governing the organisation of veterinary checks on products entering a Member State from a third country.

- (6) Fishery products may be imported directly from an establishment or factory vessel in a third country where the latter is unable to provide the guarantees laid down in Article 11, paragraph 3 of the Council Directive of 1991 provided that the establishment or factory vessel in question has received special approval following an inspection carried out in accordance with Article 11, paragraph 2 of the Council Directive of 1991.
- (7) Notwithstanding any other provision of this Regulation, the Minister may, where satisfied that there is a serious and immediate risk to human health, refuse to permit the importation of fishery products into the State.
- (8) The organisation of and the follow up to the inspections to be carried out on imported fishery products shall be done in accordance with Article 12 of the Directive of 1991.

Powers of Authorised Officers.

- 17. (1) An authorised officer may, for the purposes of these Regulations, at all times—
  - (i) enter any Regulation 13 operation or any laboratory or means of transport used in relation to fishery products;
  - (ii) carry out or cause to be carried out such inspections, tests, and checks of the Regulation 13 operation, laboratory or means of transport and of any equipment, machinery or plant therein, and inspect and examine any products to which these Regulations apply or other matter found therein and, where appropriate, require such products or matter 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 Regulation 13 operation, laboratory or means of transport to furnish such information and produce such records and other documents (including computerised records and documents) to the authorised officer which are within the power of procurement of such 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 fishery products or any other matter found in the Regulation 13 operation, 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 of 1991 and the Council Directive of 1992 as the authorised officer considers necessary,
- (vi) confiscate any such fishery products which are unfit for human consumption and which would constitute an immediate threat to public health,
- (vii) do anything consequential, ancillary, incidential or supplementary to any of the foregoing matters.
- (2) The owner of or any person connected with a Regulation 13 operation, 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 any person, produce the certificate for the inspection of the person.

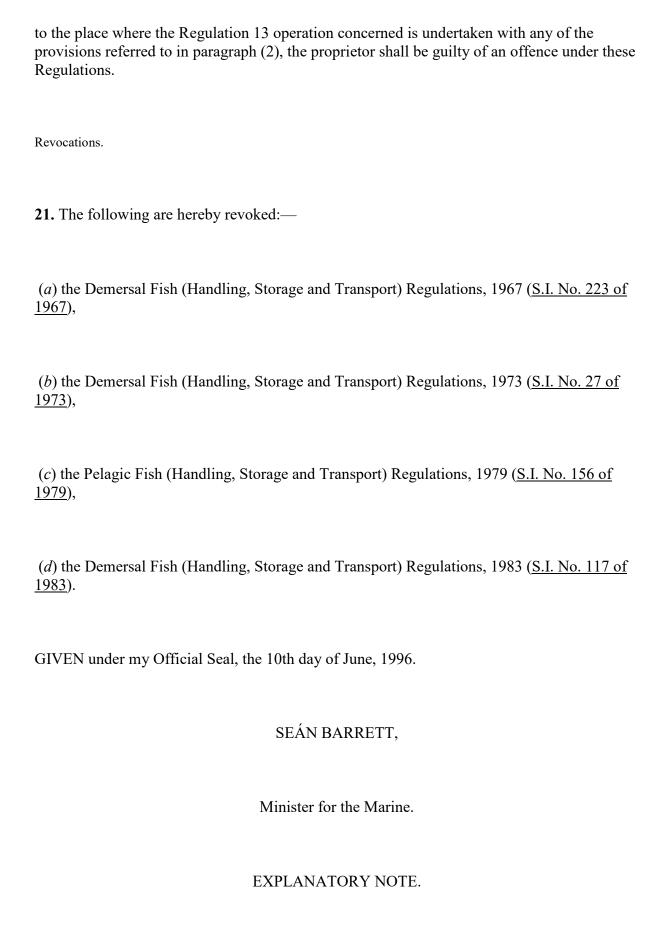
Prosecution of offences.

**18.** 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.

Fees.

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

(2) A fee payable under this Regulation shall be payable by the applicant for such approval or registration.
(3) The Minister may refuse to grant such approval or registration 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 cost, estimated by the Minister, incurred in relation to the approval or registration concerned and the performance of functions under these Regulations in relation to the Regulation 13 operation (other than a fishing vessel), laboratory or means of transport concerned by authorised officers for the purposes of the approval or registration.
Offences.
<b>20.</b> (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.
(3) If the owner or person connected with a Regulation 13 operation fails to take all reasonable steps to secure the compliance of any person employed in, or any person admitted



This order implements Council Directive 9½93/EEC laying down the health conditions for the production and the placing on the market of fishery products.