
STATUTORY INSTRUMENTS

1998 No. 994

FOOD

**The Food Safety (Fishery Products and
Live Shellfish) (Hygiene) Regulations 1998**

<i>Made</i>	- - - -	<i>6th April 1998</i>
<i>Laid before Parliament</i>		<i>8th April 1998</i>
<i>Coming into force</i>	- -	<i>29th April 1998</i>

The Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales acting jointly in relation to England and Wales, and the Secretary of State for Scotland in relation to Scotland, in exercise of the powers conferred on them by sections 6(4), 16(1), 17(1), 18(1)(c), 26(1)(b) and (3), 48(1) and 49(2) of, and paragraphs 2(2), 5(1) and (2), 6(1) and 7(1) of Schedule 1 to, the Food Safety Act 1990⁽¹⁾, and the Minister of Agriculture, Fisheries and Food and the Secretary of State acting jointly, being Ministers designated⁽²⁾ for the purposes of section 2(2) of the European Communities Act 1972⁽³⁾ in relation to the common agricultural policy of the European Community, in exercise of the powers conferred on them by the said section 2(2), and in each case in exercise of all other powers respectively enabling them in that behalf, after consultation (so far as is required by section 48(4) of the Food Safety Act 1990) with such organisations as appear to them to be representative of interests likely to be substantially affected, hereby make the following Regulations—

PART I

GENERAL

Citation and commencement

1. These Regulations may be cited as the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998 and shall come into force on 29th April 1998.

(1) 1990 c. 16; section 6(4) of the 1990 Act was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c. 40). See section 4(1) of the 1990 Act, which contains a definition of “the Ministers” which is relevant to the powers being exercised in the making of these Regulations.

(2) S.I. 1972/1811.

(3) 1972 c. 68.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“the Act” means the Food Safety Act 1990;

“approved import conditions for fishery products” means the conditions for the importation of fishery products which are laid down in any Commission Decision listed in Part I of Schedule 1;

“approved import conditions for live shellfish” means the conditions for the importation of live shellfish which are laid down in any Commission Decision listed in Part II of Schedule 1;

“approved relaying area” means a relaying area which, if situated (or treated as situated⁽⁴⁾) in part of Great Britain, is designated as a relaying area in accordance with regulation 3(2) by the food authority for that part of Great Britain;

“aquaculture products” means—

- (a) all fishery products born and raised in controlled conditions until placed on the market as a foodstuff; and
- (b) all seawater fish, freshwater fish or crustaceans caught in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption, other than fish or crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date, if they are merely kept alive without any attempt being made to increase their size or weight;

“auction or wholesale market” means any premises where the display and sale by wholesale of fishery products, but no other activities associated with the production and placing on the market of fishery products, takes place;

“batch” means, with regard to—

- (a) fishery products, a quantity of fishery products obtained under practically identical circumstances;
- (b) live shellfish, a quantity of live shellfish collected from a production area and subsequently intended for delivery to an approved dispatch centre, purification centre, relaying area or processing plant;

“bivalve molluscs” means filter-feeding lamellibranch molluscs;

“chilling” means the process of cooling fishery products to a temperature approaching that of melting ice;

“clean seawater” means, with regard to the production of—

- (a) fishery products for human consumption, seawater or briny water which is free from any microbiological contamination, harmful substances or toxic marine plankton in such quantities as may affect the health quality of fishery products, and which is used under the conditions laid down in these Regulations;
- (b) live shellfish for human consumption, seawater or brackish water which is to be used under the conditions laid down in these Regulations 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 Council Directive [79/923/EEC](#)⁽⁵⁾, in such quantities as may adversely affect the health quality of shellfish or impair their taste;

“conditioning” means the storage of live shellfish in tanks or any other installation containing clean seawater or in natural sites to remove sand, mud or slime;

“consignment”, except in the expression “private consignment”, means, with regard to—

(4) See regulation 55(4).

(5) OJ No. L281, 10.11.79, p.47; this Directive was last amended by Council Directive [91/692/EEC](#) (OJ No. L377, 31.12.91, p.48).

- (a) fishery products, a quantity of such products bound for one or more customers in the country of destination and conveyed at any one time by one means of transport only;
- (b) live shellfish, a quantity of such shellfish handled in a dispatch centre or treated in a purification centre and subsequently intended for one or more customers;

“designated bivalve production area” means an area of seawaters or brackish waters designated by the Ministers in accordance with regulation 3(1) as an area from which live bivalve molluscs may be taken;

“dispatch centre” means any on-shore or off-shore installation for the reception, conditioning, washing, cleaning, grading and wrapping of live shellfish fit for human consumption;

“*E. coli*” means faecal coliforms which also form indole from tryptophan at 44°C plus or minus 0.2°C within 24 hours;

“establishment” means, with regard to the production of fishery products for human consumption, any premises where fishery products are prepared, processed, chilled, frozen, packaged or stored, other than—

- (a) cold stores where only the handling of wrapped products takes place; or
- (b) auction or wholesale markets where only display and sale by wholesale takes place;

“EEA Agreement” means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992(6) as adjusted by the Protocol signed at Brussels on 17th March 1993(7);

“EEA State” means a State which is a Contracting Party to the EEA Agreement;

“factory vessel” means any vessel on which fishery products undergo one or more of the following operations—filleting, slicing, skinning, mincing, freezing or processing—followed by packaging, but the following are not deemed to be factory vessels—

- (a) fishing vessels in which only shrimps and molluscs are cooked on board; and
- (b) fishing vessels on board which only freezing is carried out;

“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°C plus or minus 0.2°C within 24 hours;

“fishery products” means—

- (a) all seawater or freshwater animals, including their roes; and
- (b) parts of such animals, except in circumstances where they—
 - (i) are combined (in whatever way) with other foodstuffs, and
 - (ii) comprise less than 10% of the total weight of the combined foodstuffs,

but excluding aquatic mammals, frogs and aquatic animals covered by Community acts other than the Fishery Products Directive, and parts of such mammals, frogs and aquatic animals;

“the Fishery Products Decisions” means the Commission Decisions listed in Part III of Schedule 1;

“the Fishery Products Directive” means Council Directive 91/493/EEC(8) of 22nd July 1991 laying down the health conditions for the production and placing on the market of fishery products, as adapted for the purposes of the EEA Agreement(9) and as amended(10);

(6) OJ No. L1, 3.1.94, p.3.

(7) OJ No. L1, 3.1.94, p.572.

(8) OJ No. L268, 24.9.91, p.15.

(9) See paragraph 24 of the basic texts in Annex I to the EEA Agreement.

“the Fishing Vessels Directive” means Council Directive [92/48/EEC](#)(**11**) of 16th June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with article 3(1)(a)(i) of the Fishery Products Directive;

“food authority” means—

- (a) with regard to England—
 - (i) as respects the Isles of Scilly, the Council of the Isles of Scilly,
 - (ii) as respects the City of London (including the Temples), the Common Council,
 - (iii) as respects any other part of England—
 - (a) if it is situated in a port health district, the port health authority for that district, or
 - (b) if it is not situated in a port health district, the London borough, district council or unitary authority in whose area that part is situated;
- (b) as respects any part of Wales—
 - (i) if it is situated in a port health district, the port health authority for that district, or
 - (ii) if it is not situated in a port health district, the county or county borough council in whose area that part is situated;
- (c) as respects any part of Scotland—
 - (i) if it is situated in the district of a port local authority or joint port local authority, the port local authority or joint port local authority for that district, or
 - (ii) if it is not situated in the district of a port local authority or joint port local authority, the council constituted under section 2 of the Local Government etc. (Scotland) Act 1994(**12**) in whose area that part is situated;

“fresh products” means any fishery products whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, which have not undergone any treatment to ensure preservation other than chilling;

“frozen products” means fishery products which have undergone a freezing process;

“gatherer” means any natural or legal person who collects live shellfish by any means from a production area for the purposes of handling and placing on the market;

“the Health Checks Decision” means Commission Decision [94/356/EC](#)(**13**) of 20th May 1994 laying down detailed rules for the application of the Fishery Products Directive as regards own health checks on fishery products;

“healthmark” means a healthmark which (as the context requires) is in accordance with—

- (a) Chapter X of Schedule 2;
- (b) any law in force in another EEA State, Northern Ireland, the Isle of Man or the Channel Islands which is intended to give effect to the results to be achieved by Chapter X of the Annex to the Live Bivalve Molluscs Directive; or
- (c) any approved imported conditions for live shellfish;

“imported” means imported into Great Britain, but only if the product in question was not imported from another part of the British Islands(**14**);

(10) Council Directive [91/493/EEC](#) was last amended by Council Directive [95/71/EC](#) (OJ No. L332, 30.12.95, p.40).

(11) OJ No. L187, 7.7.92, p.41.

(12) [1994 c. 39](#).

(13) OJ No. L156, 23.6.94, p.50.

(14) “British Islands” means the United Kingdom, the Channel Islands and the Isle of Man; *See* section 5 of and Schedule 1 to the Interpretation Act [1978 \(c. 30\)](#).

“laying” means a foreshore, bed, pond, pit, ledge, float or similar place, including a relaying area, where live shellfish are liable to be gathered, harvested or deposited;

“the Live Bivalve Molluscs Directive” means Council Directive 91/492/EEC(15) of 15th July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs, as adapted for the purposes of the EEA Agreement(16) and as amended(17);

“marine biotoxins” means poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxins;

“means of transport” means those parts set aside for goods in automobile vehicles (which includes trailers), rail vehicles, aircraft or vessels, and containers for transport by land, sea or air;

“movement document” means—

- (a) in relation to any batch of live shellfish transported from a production area to—
 - (i) an approved relaying area in Great Britain,
 - (ii) a dispatch or purification centre approved in accordance with Part II of these Regulations, or
 - (iii) a processing plant in Great Britain,a movement document which meets the requirements of paragraph 6(4) and (5) of Chapter II of Schedule 2;
- (b) in relation to any batch of live shellfish transported from a production area to—
 - (i) an approved relaying area in Northern Ireland, the Channel Islands or the Isle of Man,
 - (ii) a dispatch or purification centre approved in accordance with any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved in relation to the approval of dispatch and purification centres by the Live Bivalve Molluscs Directive, or
 - (iii) a processing plant in Northern Ireland, the Channel Islands or the Isle of Man,a movement document which meets the requirements of any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by paragraph 6 of Chapter II of the Annex to the Live Bivalve Molluscs Directive;
- (c) in relation to any batch of live shellfish in transit from a production area to—
 - (i) a relaying area,
 - (ii) a dispatch or purification centre, or
 - (iii) a processing plant;which is situated elsewhere, a movement document which meets the requirements of paragraph 6(4) and (5) of Chapter II of Schedule 2;

“packaging” means, in relation to fishery products, the procedure for protecting fishery products by a wrapper, a container or any other suitable device;

“permanent transport authorization” means a written authorization which has been—

- (a) issued by a food authority and which meets the requirements of paragraph 6(8) of Chapter II of Schedule 2;

(15) OJ No. L268, 24.9.91, p.1.

(16) See paragraph 25 of the basic texts in Annex I to the EEA Agreement.

(17) Council Directive 91/492/EEC was last amended by the last sub-paragraph of point 8 of Chapter V of the Annex to the Act of Accession of Austria, Finland and Sweden.

- (b) granted by a competent authority in Northern Ireland, the Channel Islands or the Isle of Man and which meets the requirements of any law in force in those territories which is intended to give effect to the results to be achieved by the final unnumbered paragraph of paragraph 6 of Chapter II of the Annex to the Live Bivalve Molluscs Directive;

“placing on the market” means, with regard to—

- (a) fishery products, the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market in the European Community, except for—
- (i) retail sales (which includes retail sales to catering businesses and sales by catering businesses), and
 - (ii) direct transfers on local markets of small quantities by fishermen to retailers or consumers in the circumstances specified in regulation 41; and
- (b) live shellfish, the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market of live shellfish for human consumption either raw or for the purposes of processing in the European Community, except for direct transfers on local markets of small quantities by coastal fishermen to retailers or consumers in the circumstances specified in regulation 20;

“potable water” has the same meaning as in the Food Safety (General Food Hygiene) Regulations 1995⁽¹⁸⁾;

“preserve” means the process whereby products are packaged in hermetically sealed containers and subjected to heat treatment to the extent that any micro-organisms that might proliferate are destroyed or inactivated, irrespective of the temperature at which the product is to be stored;

“private consignment” means a quantity of fishery products or live shellfish is—

- (a) imported solely as trade samples; or
- (b) not being imported by way of trade, and which—
 - (i) forms part of a traveller’s personal luggage, or
 - (ii) has been sent to a person, other than a body of persons corporate or unincorporate, in Great Britain;

“private laying” means a laying where live shellfish are usually harvested or deposited by the owner or by a tenant of the laying;

“processed” means—

- (a) except in relation to shellfish, having undergone a chemical or physical process such as the heating, smoking, salting, dehydration or marinating of chilled or frozen products, or a combination of these various processes;
- (b) in relation to shellfish, any process or any combination of processes such as those referred to in sub-paragraph (a) above, unless as a result of that process or combination of processes the shellfish remain alive;

“production area” means any sea, estuarine or lagoon area containing natural deposits of shellfish or sites used for the cultivation of shellfish (including relaying areas) from which live shellfish are taken;

“purification centre” means an establishment with tanks fed by naturally clean seawater or seawater which 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;

⁽¹⁸⁾ S.I. 1995/1763; there are no relevant amending instruments.

“relaying” means an operation whereby live bivalve molluscs are transferred to a sea, lagoon or estuarine area in order to remove contamination, but does not include a transfer to an area more suitable for further growth or fattening;

“relaying area” means any sea, lagoon or estuarine area with boundaries clearly marked and indicated by buoys, posts or any other fixed means which is used exclusively for the natural purification of live bivalve molluscs;

“Sea Fisheries Committee” means a local fisheries committee for a sea fisheries district constituted under the Sea Fisheries Regulation Act 1966⁽¹⁹⁾;

“shellfish” means only bivalve molluscs, echinoderms, tunicates and marine gastropods;

“tenant”, in relation to a private laying, includes any person authorised by the owner or by any other holder of an interest in the laying to harvest from or deposit at that laying;

“third country” means any country or territory which is not part of the European Economic Area;

“unitary authority” means an authority in England which is the sole principal council for its local government area;

“wrapping” means, in relation to live shellfish, any operation whereby live shellfish are placed in packaging material adequate for the purpose.

(2) As respects any Commission Decision listed in Part I or II of Schedule 1 (“a listed Decision”), where the European Commission publishes in an amending Decision—

- (a) a revised list of approved establishments, dispatch centres, purification centres, factory vessels, freezer vessels or production areas which is to replace a list annexed to or contained in an Annex to a listed Decision; or
- (b) any revision of an existing list of approved establishments, dispatch centres, purification centres, factory vessels, freezer vessels or production areas which is for incorporation into a list contained in an Annex to a listed Decision,

the listed Decision shall be read subject to the changes contained in the amending Decision.

(3) In these Regulations, unless the context otherwise requires, a reference—

- (a) to a numbered Part is to the Part of these Regulations bearing that number;
- (b) to a numbered regulation or Schedule is to the regulation in or Schedule to these Regulations bearing that number;
- (c) in a Schedule to a numbered Chapter is to the Chapter of that Schedule bearing that number;
- (d) in a regulation or Chapter of a Schedule to a numbered or lettered paragraph is to the paragraph in that regulation or Chapter bearing that number or letter;
- (e) in a paragraph to a lettered or numbered sub-paragraph is to the sub-paragraph in that paragraph bearing that letter or number.

PART II

PRODUCTION AND PLACING ON THE MARKET OF LIVE SHELLFISH

Designation of areas as designated bivalve production areas

3.—(1) The Ministers shall designate sea waters and brackish waters from which live bivalve molluscs may be taken in accordance with the requirements of this Part and shall specify as respects each area of water designated by them whether it is—

- (a) a class A area from which live bivalve molluscs can be gathered as specified in Part 1 of Chapter I of Schedule 2;
- (b) a class B area from which live bivalve molluscs can be gathered as specified in Part 2 of Chapter I of Schedule 2;
- (c) a class C area from which live bivalve molluscs can be gathered as specified in Part 3 of Chapter I of Schedule 2,

and any such designation may be subject to such limitation, condition or restriction as appears to the Ministers to be called for by article 5(2) of the Live Bivalve Molluscs Directive.

(2) Each food authority shall, wherever possible, designate as a relaying area any area within their district which—

- (a) fulfils the conditions required for designation as a class A or B area specified in paragraph (1)(a) and (b); and
- (b) in their opinion is suitable for the relaying of live bivalve molluscs if the conditions specified in Parts 2 and 3 of Chapter I of Schedule 2 and in Chapter III of Schedule 2 are satisfied,

and, where the Ministers have notified the food authority that specified conditions relating to the matters mentioned in Chapter III of Schedule 2 should be complied with as respects the operation of the relaying area, the food authority shall make that designation subject to those conditions.

(3) The food authority shall notify the Ministers of any designation made under paragraph (2) and of its terms.

Designation of areas as prohibited areas for live shellfish production

4. The Ministers may at any time designate any area as an area unsuitable, for health reasons, for the production or collection of—

- (a) live bivalve molluscs;
- (b) live echinoderms, tunicates and marine gastropods;
- (c) live shellfish,

and any such area shall be designated, as appropriate, as a “designated prohibited area for live bivalve mollusc production”, a “designated prohibited area for live echinoderm, tunicate and marine gastropod production” or a “designated prohibited area for live shellfish production”.

Alterations to designated areas

5.—(1) The Ministers may in appropriate circumstances and at any time—

- (a) vary the boundary of any area designated under regulation 3(1) or 4;
- (b) impose any limitation, restriction or condition on the use of any area designated under regulation 3(1) or 4;

- (c) alter the class of any designated bivalve production area or any area within a designated bivalve production area;
 - (d) revoke the designation of a designated bivalve production area, if the area is no longer suitable for the gathering of live bivalve molluscs;
 - (e) vary or revoke the designation of any area designated under regulation 4.
- (2) A food authority may at any time—
- (a) in appropriate circumstances, vary the designation of a relaying area made under regulation 3(2);
 - (b) if a relaying area designated in accordance with regulation 3(2) is no longer suitable for the relaying of live bivalve molluscs, revoke the designation of that relaying area,
- and shall communicate any such variation or revocation to the Ministers.

Lists of designated production and relaying areas

- 6.—(1) The Ministers shall maintain and publish—
- (a) a list of designated bivalve production areas; and
 - (b) a list of any areas which food authorities have designated as suitable for the relaying of live bivalve molluscs,
- and amendments to these lists shall be published from time to time.
- (2) The Ministers shall send a copy of the lists mentioned in paragraph (1), and any amendments to them to—
- (a) each food authority;
 - (b) trade associations which appear to them to represent the interests of food businesses which are likely to be directly affected by this Part of these Regulations.
- (3) Each food authority shall take such action as they consider sufficient to bring any part of the lists mentioned in paragraph (1) which relates to their area to the attention of any harvester, handler or operator of a dispatch or purification centre who is carrying out commercial operations with respect to live bivalve molluscs in their area.

Temporary prohibition orders concerning production areas

- 7.—(1) Subject to paragraph (4), a food authority may, if it is satisfied that the consumption of live shellfish taken from a production area is likely to cause a risk to public health, make a temporary prohibition order prohibiting the collecting of any live shellfish from that area.
- (2) A temporary prohibition order shall cease to have effect at the expiration of a period of 28 days after it was made, unless earlier revoked by the food authority making the order.
- (3) Forthwith after making such an order, a food authority shall—
- (a) in the case of a private laying, refer the matter to the Ministers and serve a notice on every owner and tenant of the laying whose name and address can with reasonable diligence be ascertained containing the following information—
 - (i) the reasons for the food authority making the order, and
 - (ii) any action which the food authority is requesting the Ministers to take pursuant to regulation 4 or 5(1), and in particular the detail of any proposed conditions or restrictions;
 - (b) in the case of any other production area, affix notices in the vicinity of the area and take any other steps it considers appropriate to bring the order to the attention of those affected,

and in either case send a copy of the order and notice to the Ministers and to any Sea Fisheries Committee in whose district the production area is situated.

(4) A food authority shall not make a temporary prohibition order in respect of any production area if they have made such an order in respect of that area within the preceding 28 days, unless the Ministers give consent to such action.

Collecting live shellfish from prohibited areas

8. No person shall collect—

- (a) live bivalve molluscs from a designated prohibited area for live bivalve mollusc production;
- (b) live echinoderms, tunicates or marine gastropods from a designated prohibited area for live echinoderm, tunicate and marine gastropod production;
- (c) live shellfish from—
 - (i) a designated prohibited area for live shellfish production, or
 - (ii) a laying which is the subject of a temporary prohibition order.

Requirements relating to the harvesting, transporting and relaying of live shellfish

9. No person shall—

- (a) harvest or transport from a production area to a dispatch centre or processing plant any live echinoderms, tunicates or marine gastropods otherwise than in accordance with Chapter II of Schedule 2;
- (b) harvest or transport from a production area to a relaying area, dispatch centre, purification centre or processing plant any live bivalve molluscs otherwise than in accordance with Chapter II of Schedule 2; or
- (c) relay any live bivalve molluscs otherwise than at a designated relaying area and in accordance with the applicable conditions for relaying in Chapter III of Schedule 2,

if they are intended for placing on the market for human consumption.

Requirement for the approval of dispatch or purification centres

10. No person shall operate a dispatch or purification centre unless it has been approved by the food authority for the area in which the centre is situated.

Approval of dispatch or purification centres

11.—(1) An application for an approval for a dispatch or purification centre shall be made to the food authority for the area in which the centre is situated.

(2) An application pursuant to paragraph (1) shall be—

- (a) made in writing; and
- (b) accompanied by such supplementary information, documents, plans, and diagrams as are necessary to enable the food authority to determine the application.

(3) An approval in respect of a dispatch centre may only be granted if the food authority is satisfied that it meets such of the conditions set out in Sections I, II and IV of Chapter IV of Schedule 2 as apply to it.

(4) An approval in respect of a purification centre may only be granted if the food authority is satisfied that it meets—

- (a) such of the conditions set out in Sections I, II and III of Chapter IV of Schedule 2 as apply to it; and
- (b) any additional conditions of which the food authority has been notified by the Ministers pursuant to paragraph (5).

(5) An approval for a dispatch or purification centre under this regulation may be granted subject to limitations as to the particular activities approved, the method of operation approved and intensity of use approved, and where the Ministers notify the food authority that specified conditions for the operation of a purification centre relating to matters mentioned in Chapter IV of Schedule 2 should be complied with, the food authority shall give their approval subject to those conditions.

(6) The food authority shall give written notification to each person who makes an application pursuant to paragraph (1) of the result of their application and, in the case of refusal, of the reasons for that refusal.

- (7) If an application pursuant to paragraph (1) is approved, the food authority shall—
- (a) designate the dispatch or purification centre with a unique approval number; and
 - (b) notify the Secretary of State of the approval and the approval number allocated.

Appeals against a refusal to grant an approval or against any conditions or limitation in approvals

- 12.—(1) A person who is aggrieved by a decision taken by a food authority—
- (a) to refuse to grant an approval for a dispatch or purification centre; or
 - (b) to impose any limitation or condition in an approval granted for a dispatch or purification centre,

may appeal to a magistrates' court or, in Scotland, to the sheriff, and section 37(3) to (6) of the Act shall apply in relation to such an appeal as it applies in relation to an appeal under section 37(1)(c).

- (2) Where an appeal against—
- (a) a limitation as to the particular activities approved, the method of operation approved or the intensity of use approved; or
 - (b) a condition notified to the food authority by the Ministers in accordance with regulation 11(5),

is brought in accordance with paragraph (1)(b), the appellant may continue to operate the centre free of the limitation or condition which is being appealed against while the appeal is pending, and an appeal shall be regarded as pending for these purposes until it is finally disposed of, is struck out for want of prosecution or is withdrawn.

(3) Where an appeal is brought in accordance with paragraph (1)(b) against a condition notified to the food authority by the Ministers in accordance with regulation 11(5), the food authority shall inform the Ministers that such an appeal has been brought.

- (4) Where an appeal is brought in accordance with paragraph (1), the court may—
- (a) affirm any decision to refuse an approval;
 - (b) grant the approval either in its original form or with such modifications as the court may in the circumstances think fit;
 - (c) remit the matter to the food authority with the court's opinion on it; or
 - (d) make such other order in relation to the matter as the court thinks fit.

Obligations on food business proprietors operating dispatch or purification centres

13. A food business proprietor who is operating a dispatch or purification centre at which live shellfish which are intended for placing on the market are handled shall ensure that—

- (a) the requirements of the approval for his centre and of the applicable provisions of Chapter IV of Schedule 2 are complied with as respects his centre;
- (b) regular microbiological checks are carried out on—
 - (i) those of his shellfish which he is required to check for microbiological contamination in order to comply with the requirements set out in Chapter IV of Schedule 2, and
 - (ii) if he is a purification centre proprietor, the water for use in the purification system at this centre, by or in laboratories which meet the applicable requirements of Chapter IV of Schedule 2; and
- (c) the results of the checks mentioned in sub-paragraph (b)(i) are recorded in a historical record which, in relation to each area from which the shellfish come, gives details of the health quality of the shellfish from that area both before and after handling at the centre.

Variation of approvals for dispatch or purification centres

14.—(1) A person may at any time apply to a food authority for the authority to vary or revoke any term or limitation in any approval for a dispatch or purification centre granted to him, and subject to paragraph (2), the food authority may, in appropriate circumstances, vary any such term or limitation.

(2) A food authority may only vary or revoke any additional condition of which the food authority has been notified by the Ministers pursuant to regulation 11(5) with the consent of the Ministers.

(3) Any person who is aggrieved by a decision of a food authority to refuse to vary any term or limitation of any approval for a dispatch or purification centre may appeal to a magistrates' court or, in Scotland, to the sheriff, and section 37(3) to (6) of the Act shall apply in relation to such an appeal as it applies in relation to an appeal under section 37(1)(c) of the Act.

(4) Where an appeal is brought in accordance with paragraph (3) against a refusal to vary a condition notified to the food authority by the Ministers in accordance with regulation 11(5), the food authority shall inform the Ministers that such an appeal has been brought.

- (5) Where an appeal is brought in accordance with paragraph (3), the court may—
 - (a) affirm any decision to refuse to vary the term or limitation in the approval;
 - (b) vary the term or limitation in the approval;
 - (c) remit the matter to the food authority with the court's opinion on it; or
 - (d) make such other order in relation to the matter as the court thinks fit.

Revocation of approvals for dispatch or purification centres

15.—(1) A food authority may revoke an approval of a dispatch or purification centre situated in its area if, after inspection of or any inquiry into the method of operation of the centre, they are satisfied that—

- (a) there has been a serious (on animal or public health grounds) and manifest breach of the conditions or limitations subject to which the approval was granted or of the applicable provisions of Chapter IV of Schedule 2;
- (b) the food business proprietor who is operating the centre is either unable or not prepared to ensure that the breach is remedied; and
- (c) there is in force in relation to that dispatch or purification centre—
 - (i) a prohibition order under section 11 of the Act, or

(ii) an emergency prohibition order under section 12 of that Act,
and as a consequence of the order, commercial operations with regard to live shellfish which are for placing on the market for human consumption may not be carried out at that dispatch or purification centre.

(2) A proprietor who is aggrieved by a decision to revoke an approval for a dispatch or purification centre may appeal to a magistrates' court or, in Scotland, to the sheriff, and section 37(3) to (6) of the Act shall apply in relation to such an appeal as it applies in relation to an appeal under section 37(1) (c) of the Act.

- (3) A revocation under this regulation shall take effect—
- (a) immediately after the time for appealing against it has elapsed; or
 - (b) if an appeal is brought, immediately after the appeal is finally disposed of, struck out for want of prosecution or withdrawn,

and when a food authority informs the food business proprietor who is operating a dispatch or purification centre of a decision to revoke the approval for the centre, they shall explain to the proprietor in writing when the revocation will take effect (including when it will take effect if an appeal is brought).

Wrapping of live shellfish

16. A proprietor of a food business in the course of which live shellfish which are intended for placing on the market for human consumption are wrapped or repackaged shall ensure that the wrapping or repackaging of such shellfish is in accordance with the applicable requirements of those set out in Chapter VII of Schedule 2.

Storage and transportation of live shellfish after dispatch

17. A proprietor of a food business in the course of which live shellfish which are intended for placing on the market for human consumption are stored or transported after they have left a dispatch or purification centre, shall ensure that such shellfish are stored and transported in accordance with the applicable requirements of those set out in Chapters VIII and IX of Schedule 2.

Splitting consignments of live shellfish

18.—(1) A person other than the final consumer who splits the contents of a consignment of live shellfish which are not wrapped in individual consumer-sized parcels shall keep—

- (a) any healthmark which is attached to the consignment; or
- (b) a copy of any certificate required in accordance with regulation 45(2) which accompanied that consignment,

for a period of not less than 60 days from the date of the splitting of the contents of that consignment.

(2) A person who repackages a consignment of live shellfish in accordance with paragraph 3 of Chapter VII of Schedule 2 shall keep the original healthmark (if one was required) which was attached to the consignment for a period of not less than 60 days from the date of the splitting of the contents of that consignment.

Placing live shellfish on the market

19.—(1) Subject to paragraphs (2) to (4), no person shall place on the market for immediate human consumption any live shellfish, unless—

- (a) they originate, if they are live bivalve molluscs, from a bivalve production area which—

- (i) has been designated a class A area, a class B area or a class C area in accordance with regulation 3(1), and any condition or limitation specified in Chapter I of Schedule 2 in relation to that class of area has been complied with,
 - (ii) has been identified, pursuant to any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter I of the Annex to the Live Bivalve Molluscs Directive, as an area from which bivalve molluscs may be collected, and any condition or limitation derived from that Chapter which relates to that production area has been complied with, or
 - (iii) if they are imported for relaying, was of the same standard as an area designated as a class B area or a class C area in accordance with regulation 3(1)(b) or (c), and any condition or limitation specified in Chapter I of Schedule 2 for that production area has been complied with;
- (b) they have been harvested, kept and transported to any approved dispatch centre, approved purification centre or approved relaying area to which they are thereafter transferred in accordance with the applicable requirements of—
- (i) Chapter II of Schedule 2, or
 - (ii) any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter II of the Annex to the Live Bivalve Molluscs Directive,
- accompanied by a valid movement document or a valid permanent transport authorisation;
- (c) if they are live bivalve molluscs, they have, where necessary, been relaid in accordance with—
- (i) Chapter III of Schedule 2, or
 - (ii) any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter III of the Live Bivalve Molluscs Directive;
- (d) they have been handled hygienically and, if they are live bivalve molluscs, they have, where appropriate, been purified at a purification centre which has been approved in accordance with—
- (i) regulation 11, or
 - (ii) any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved in relation to the approval of purification centres by the Live Bivalve Molluscs Directive;
- (e) they are as specified in Chapter V of Schedule 2;
- (f) they have been wrapped in accordance with the applicable requirements of Chapter VII of Schedule 2;
- (g) they have been stored and transported in accordance with the applicable requirements of Chapter VIII of Schedule 2;
- (h) they comprise or form part of a consignment which bears a healthmark—
- (i) unless head (ii) or (iii) applies, which is in accordance with Chapter X of Schedule 2,
 - (ii) which, if they comprise or form part of a consignment which has been given a healthmark in accordance with any law in force in another EEA State, Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter X of the Annex to the Live Bivalve Molluscs Directive, is in accordance with that law,

(iii) which, if they comprise or form part of a consignment from a third country in respect of which the European Commission has adopted approved import conditions, is in accordance with those approved import conditions,

but a healthmark is not required in relation to live shellfish which originate from a third country in respect of which the European Commission has not adopted approved import conditions, unless those live shellfish have been repackaged in accordance with paragraph 3 of Chapter VII of Schedule 2;

(i) if they are imported live shellfish, prior to importation such of the requirements specified in regulations 44 and 45 as are applicable to his case are satisfied in relation to those live shellfish which he places on the market.

(2) Paragraph (1)(a) shall not apply to—

(a) pectinidae, unless they are aquaculture products; or

(b) any imported live bivalve molluscs, unless they were harvested from seawaters or brackish waters within British fishery limits⁽²⁰⁾.

(3) Paragraph (1)(b) and (c) shall not apply to imported live shellfish, unless their country of dispatch is part of the British Islands.

(4) Paragraph (1)(h)(ii) to (iii) shall not apply in circumstances where, in Great Britain, a person repackages live shellfish from a country or territory other than Great Britain in accordance with paragraph 3 of Chapter VII of Schedule 2.

Direct transfers of live shellfish on local markets

20.—(1) Regulations 9, 16, 17 and 19 shall not apply to a direct transfer to a retailer or final consumer in the United Kingdom of a small quantity of—

(a) live bivalve molluscs gathered from a class A designated bivalve production area; or

(b) live echinoderms, tunicates or marine gastropods,

which are as specified in Chapter V of Schedule 2 by a coastal fisherman who is part of the direct transfers scheme.

(2) A coastal fisherman is part of the direct transfers scheme for the purposes of paragraph (1) if, prior to gathering live shellfish for the first time in any calendar year in the district of a food authority, he notifies the food authority of his intention to do so and supplies them with the following information—

(a) his name, address and telephone number;

(b) the address where he keeps the equipment he uses for gathering;

(c) the intended place of landing of gathered live shellfish;

(d) the address where he intends to put the gathered live shellfish when landed;

(e) if applicable, the name, address and approval number of any dispatch or purification centre to which he intends to send live shellfish after gathering,

and if he notifies the food authority of any changes to the information originally supplied.

(3) For the purposes of paragraph (1) a “small quantity” means an amount which comprises part of the coastal fisherman’s annual allowance.

(4) For the purposes of paragraph (3), a coastal fisherman’s annual allowance is a total amount of not more than 25 tonnes of live shellfish in a calendar year, and although that total amount may comprise of amounts of one or more species, in that total amount the amount of any species listed

⁽²⁰⁾ See sections 1(5) and 10(2)(b) of the Fishery Limits Act 1976 (c. 86).

in column (a) of the table below shall not exceed the maximum amount for that species mentioned in column (b) of that table—

Table

<i>(a)</i> <i>Species</i>	<i>(b)</i> <i>Maximum amount</i>
Cockles	25.0 tonnes
Oysters	5.0 tonnes
King Scallops	5.0 tonnes
Queen Scallops	10.0 tonnes
Mussels	20.0 tonnes
Other Live Bivalve Molluscs	10.0 tonnes
Marine Gastropods	20.0 tonnes

PART III

PRODUCTION AND PLACING ON THE MARKET OF FISHERY PRODUCTS

Registration of fishing vessels on board which shrimps or molluscs are cooked

21.—(1) A person operating a fishing vessel on board which shrimps or molluscs are, for the purposes of a food business, processed by cooking shall, unless such processing is to be supplemented subsequently by cooking, comply with paragraphs (2) and (4).

(2) The person operating the fishing vessel shall, prior to engaging for the first time in such cooking, notify the food authority for the area in which the vessel is based in writing of his intention to do so, and shall at the same time supply the authority with the following information—

- (a) the name of the vessel,
- (b) the usual place of landing of the processed products,
- (c) the name and address of the owner of the vessel,

and he shall notify the food authority in writing of any changes to the information originally supplied.

(3) Each food authority shall maintain a register of all the information supplied pursuant to paragraph (2).

(4) Any cooking on board a fishing vessel of shrimps or molluscs shall be in accordance with the requirements of—

- (a) paragraph 5 of Section I of Chapter III of Schedule 3; and
- (b) paragraph 7 of Section IV of Chapter IV of Schedule 3.

Hygiene conditions for fishing vessels

22.—(1) A food business proprietor who is operating a fishing vessel on board which fishery products which are intended for placing on the market for human consumption are handled shall ensure that the applicable provisions of Part I of Schedule 4 are complied with as respects his vessel.

(2) A food business proprietor who is operating a fishing vessel—

- (a) which is designed and equipped to preserve fishery products on board under satisfactory conditions for more than 24 hours, other than those equipped for keeping fish and shellfish alive without other means of conservation on board; and
- (b) on board which fishery products which are intended for placing on the market for human consumption are handled,

shall also ensure that the applicable provisions of Part II of Schedule 4 are complied with as respects his vessel.

- (3) Ship owners, or their representatives, who are operating a fishing vessel—
 - (a) which is designed and equipped to preserve fishery products on board under satisfactory conditions for more than 24 hours, other than those equipped for keeping fish and shellfish alive without other means of conservation on board; and
 - (b) on board which fishery products which are intended for placing on the market for human consumption are handled,

shall take all the measures necessary to prevent persons liable to contaminate fishery products from working on and handling them, until there is evidence that such persons can do so without risk.

(4) The Ministers shall keep up-to-date for control purposes a list of the vessels equipped in accordance with paragraphs 7 and 8 of Part II of Schedule 4, with the exception however of vessels equipped with removable containers which, without prejudice to paragraph 5 of Part II of Schedule 4, are not engaged regularly in preserving fish in chilled seawater.

Operation of a factory vessel or fishery products establishment without an approval

23.—(1) No person shall operate a fishery products establishment unless it has been approved by the food authority for the area in which it is situated.

- (2) No person shall operate a British Islands factory vessel unless it has been approved—
 - (a) by the food authority for the area which includes the place at which the vessel usually lands fishery products in Great Britain; or
 - (b) in accordance with any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved in relation to the approval of factory vessels by the Fishery Products Directive.

Approval of factory vessels and fishery products establishments

24.—(1) An application for an approval for a factory vessel or fishery products establishment shall be made to—

- (a) in the case of an establishment, the food authority in whose area the establishment is situated; and
 - (b) in the case of a factory vessel, the food authority for the area which includes the place at which the vessel usually lands fishery products in Great Britain.
- (2) An application pursuant to paragraph (1) shall be—
- (a) made in writing; and
 - (b) accompanied by such supplementary information, documents, plans and diagrams as are necessary to enable the food authority to determine the application.

(3) An approval in respect of a factory vessel may only be granted if the food authority is satisfied that it meets such of the conditions set out in Chapters I and II of Schedule 3 as apply to it.

(4) An approval in respect of a fishery products establishment may only be granted if the food authority is satisfied that it meets such of the conditions set out in Chapters III and IV of Schedule 3 as apply to it.

(5) An approval for a factory vessel or establishment under this regulation may be granted subject to limitations as to the particular activities approved, the method of operation approved and the intensity of use approved.

(6) The food authority shall give written notification to each person who makes an application pursuant to paragraph (1) of the result of the application and, in the case of refusal, of the reasons for that refusal.

(7) If an application pursuant to paragraph (1) is approved, the food authority shall—

- (a) designate the establishment or vessel with a unique approval number; and
- (b) notify the Secretary of State of the approval and the approval number allocated.

Requirement for the registration of auction or wholesale markets

25. No person shall operate an auction or wholesale market unless that market has been registered with the food authority in whose area it is situated.

Registration of auction and wholesale markets

26.—(1) An application for registration for an auction or wholesale market shall be made to the food authority in whose area it is situated.

(2) An application pursuant to paragraph (1) shall be—

- (a) made in writing; and
- (b) accompanied by such supplementary information, documents, plans and diagrams as are necessary to enable the food authority to determine the application.

(3) An auction or wholesale market may only be registered if the food authority is satisfied that it meets such of the conditions set out in Chapters II and III of Schedule 3 as apply to it.

(4) The food authority shall give written notification to each person who makes an application pursuant to paragraph (1) of the result of the application and, in the case of refusal, of the reasons for that refusal.

(5) If an application pursuant to paragraph (1) is accepted, the food authority shall—

- (a) designate the market with a unique registration number; and
- (b) notify the Secretary of State of the registration and the registration number allocated.

Appeals against decisions under this Part to refuse to register or to grant an approval or against any conditions or limitations in such approvals

27.—(1) A person who is aggrieved by a decision taken by a food authority—

- (a) to refuse to grant an approval for a factory vessel or fishery products establishment;
- (b) to impose any limitation or condition in an approval granted for a factory vessel or fishery products establishment; or
- (c) to refuse to register an auction or wholesale market,

may appeal to a magistrates' court or, in Scotland, to the sheriff, and section 37(3) to (6) of the Act shall apply in relation to such an appeal as it applies in relation to an appeal under section 37(1) (c) of the Act.

(2) Where an appeal against a limitation as to the particular activities approved, the method of operation approved or the intensity of use approved is brought in accordance with paragraph (1) (b), the appellant may continue to operate the establishment or vessel free of the limitation which is being appealed against while the appeal is pending, and an appeal shall be regarded as pending for these purposes until it is finally disposed of, is struck out for want of prosecution or is withdrawn.

- (3) Where an appeal is brought in accordance with paragraph (1), the court may—
- (a) affirm any decision to refuse an approval or to register;
 - (b) accept an application to register;
 - (c) grant an approval either in its original form or with such modifications as the court may in the circumstances think fit;
 - (d) remit the matter to the food authority with the court's opinion on it; or
 - (e) make such other order in relation to the matter as the court thinks fit.

Obligations upon food business proprietors operating establishments and factory vessels

28.—(1) A food business proprietor who is operating an approved fishery products establishment or an approved British Islands factory vessel shall ensure that, as respects his establishment or vessel, the requirements of the approval for his establishment or vessel are complied with.

(2) A food business proprietor who is operating a factory vessel on board which fishery products which are intended for placing on the market for human consumption are handled shall ensure that the applicable provisions of Chapters I and II of Schedule 3 are complied with as respects his vessel.

(3) A food business proprietor who is operating an establishment at which fishery products which are intended for placing on the market for human consumption are handled shall ensure that the applicable provisions of Chapters III and IV of Schedule 3 are complied with as respects his establishment.

(4) A food business proprietor who is operating a factory vessel or fishery products establishment shall carry out checks at his vessel or establishment based on the following principles—

- (a) identification of points critical to ensuring safe and hygienic production in his vessel or establishment on the basis of the manufacturing processes used, and for these purposes a critical point is any point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels;
- (b) establishment and implementation of methods for monitoring and checking such critical points;
- (c) taking samples for analysis in a laboratory recognised by the food authority for the purpose of checking—
 - (i) cleaning and disinfection methods, and
 - (ii) compliance with the standards established by this Part of these Regulations,and in deciding whether or not to recognise a laboratory, food authorities shall have regard to any relevant guidance issued by the Ministers;
- (d) keeping a written record or a record registered in an indelible fashion of the preceding points which shall be made available to the food authority on request, and that record shall —
 - (i) satisfy any applicable requirements of article 6.2 of the Health Checks Decision, and
 - (ii) include results of the different checks for a period going back at least 2 years,and in the course of so doing, he shall have regard to any relevant recommendations in the Annex to the Health Checks Decision.

(5) The proprietor shall ensure that all staff involved in checks under paragraph (4) receive adequate training in order to participate effectively in their implementation.

(6) If the results of the proprietor's checks under paragraph (4) reveal a serious health risk or suggest one might exist, the proprietor shall immediately notify the food authority of that risk or possible risk and such notification shall be confirmed in writing by the proprietor within 48 hours.

Notice of arrival obligation for masters of third country factory vessels

29. The master of a factory vessel of a third country shall, before landing any fishery products in Great Britain which are for placing on the market, give the food authority for the port at which he intends to land those fishery products notice of arrival of at least 24 hours.

Obligations upon food business proprietors operating auction or wholesale markets

30. A food business proprietor who is operating an auction or wholesale market at which fishery products which are intended for placing on the market for human consumption are handled shall ensure that the applicable provisions of Chapters II and III of Schedule 3 are complied with as respects his market.

Variation of approvals for factory vessels or establishments

31.—(1) A person may at any time apply to a food authority for it to vary any term or limitation in any approval for a factory vessel or fishery products establishment granted to him, and the food authority may vary any such term or limitation.

(2) Any person who is aggrieved by a decision of a food authority to refuse to vary a term or limitation in any approval for a factory vessel or fishery products establishment may appeal to a magistrates' court or, in Scotland, to the sheriff, and section 37(3) to (6) of the Act shall apply in relation to such an appeal as it applies in relation to any appeal under section 37(1)(c) of the Act.

(3) Where an appeal is brought in accordance with paragraph (2), the court may—

- (a) affirm any decision to refuse to vary the term or limitation in the approval;
- (b) vary the term or limitation in the approval;
- (c) remit the matter to the food authority with the court's opinion on it; or
- (d) make such other order in relation to the matter as the court thinks fit.

Revocation of approvals for factory vessels or establishments and cancellation of market registrations

32.—(1) A food authority may revoke an approval of an establishment situated in its area or a factory vessel which they approved if, after inspection of or any inquiry into the method of operation of the establishment or vessel, they are satisfied that—

- (a) there has been a serious (on animal or public health grounds) and manifest breach of the conditions or limitations subject to which the approval was granted or of the applicable provisions of Chapters I to IV of Schedule 3;
- (b) the food business proprietor who is operating the establishment or vessel is either unable or not prepared to ensure that the breach is remedied; and
- (c) there is in force in relation to that establishment or vessel—
 - (i) a prohibition order under section 11 of the Act, or
 - (ii) an emergency prohibition order under section 12 of the Act,

and as a consequence of the order, commercial operations with regard to fishery products which are for placing on the market for human consumption may not be carried out at that establishment or on board that vessel.

(2) A food authority may cancel the registration of an auction or wholesale market situated in their area if, after inspection of or any inquiry into the method of operation of the market, they are satisfied that—

- (a) there has been a serious (on animal or public health grounds) and manifest breach of the applicable provisions of Chapter II or III of Schedule 3;
- (b) the food business proprietor who is operating the market is either unable or not prepared to ensure that the breach is remedied; and
- (c) there is in force in relation to that market—
 - (i) a prohibition order under section 11 of the Act, or
 - (ii) an emergency prohibition order under section 12 of the Act,

and as a consequence of the order, commercial operations with regard to fishery products which are for placing on the market for human consumption may not be carried out at that market.

(3) A proprietor who is aggrieved by a decision to revoke an approval for a factory vessel or a fishery products establishment or cancel the registration of an auction or wholesale market may appeal to a magistrates' court or, in Scotland, to the sheriff, and section 37(3) to (6) of the Act shall apply in relation to such an appeal as it applies in relation to an appeal under section 37(1)(c) of the Act.

(4) A revocation or cancellation under this regulation shall take effect—

- (a) after the time for appealing against it has elapsed; or
- (b) if an appeal is brought, after the appeal is finally disposed of, struck out for want of prosecution or withdrawn,

and when a food authority informs a food business proprietor operating a factory vessel or fishery products establishment of a decision to revoke the approval for the vessel or establishment or a food business proprietor operating an auction or wholesale market of a decision to cancel the registration of that market, they shall explain to the proprietor in writing when the revocation or cancellation will take effect (including when it will take effect if an appeal is brought).

Gutting of fishery products

33. Where gutting of a fishery product which is intended for placing on the market for human consumption is possible from a technical and commercial standpoint, a food business proprietor who has control over the timing of the gutting of the product shall ensure that it is carried out as soon as possible after the product has been caught or landed.

Packaging of fishery products

34. A proprietor of a food business in the course of which fishery products which are intended for placing on the market for human consumption are packaged shall ensure that the packaging of such products is in accordance with the applicable requirements of those set out in Chapter VI of Schedule 3.

Storage and transportation of fishery products

35. A proprietor of a food business in the course of which fishery products which are intended for placing on the market for human consumption are stored or transported shall ensure that such

products are stored, except at cold stores where only the handling of wrapped products takes place, and transported in accordance with any applicable requirements of those set out in Chapter VIII of Schedule 3.

Placing fishery products on the market

36.—(1) Subject to paragraph (2), no person shall place on the market for human consumption any fishery products, unless—

- (a) if they have been handled on board a British Islands fishing vessel, the applicable requirements of—
 - (i) Schedule 4, or
 - (ii) any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by the Fishing Vessels Directive, have been satisfied in relation to those fishery products;
- (b) if they have been handled on board a British Islands factory vessel, the applicable requirements of—
 - (i) Chapter I of Schedule 3, or
 - (ii) any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter I of the Annex to the Fishery Products Directive, have been satisfied in relation to those fishery products;
- (c) if they were landed in the British Islands, during and after landing the applicable requirements of—
 - (i) Chapter II of Schedule 3, or
 - (ii) any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter II of the Annex to the Fishery Products Directive, have been satisfied in relation to those fishery products;
- (d) where gutting of those fishery products is or was possible from a technical and commercial viewpoint, gutting was carried out as quickly as possible after the products were caught or landed;
- (e) at an establishment on land in the British Islands, they have been handled and, where appropriate, packaged, prepared, processed, frozen, defrosted, stored hygienically and inspected in accordance with the applicable requirements of—
 - (i) Chapters III and IV of Schedule 3, or
 - (ii) any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapters III and IV of the Annex to the Fishery Products Directive;
- (f) they—
 - (i) in Great Britain, have been subject to such of the health control and monitoring of production conditions described in Chapter V of Schedule 3 as is appropriate in the particular circumstances of the case, or
 - (ii) in Northern Ireland, the Channel Islands or the Isle of Man, have been subject to such of the health control and monitoring of production conditions described in Chapter V of the Annex to the Fishery Products Directive, as provided for in any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give

effect to the results to be achieved by that Chapter, as is appropriate in the particular circumstances of the case,

unless the competent authority authorised the transfer of those fishery products *ex quay* to an approved establishment or registered auction or wholesale market to be checked there, in which case a check on the conditions of landing is not required;

- (g) they have been appropriately packaged in accordance with Chapter VI of Schedule 3;
- (h) they comprise or form part of a consignment which bears an identification mark—
 - (i) unless head (ii) or (iii) applies, which is in accordance with Chapter VII of Schedule 3,
 - (ii) which, if they comprise or form part of a consignment which has been given an identification mark in accordance with any law in force in another EEA State, Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter VII of the Annex to the Fishery Products Directive, is in accordance with that law,
 - (iii) which, if those fishery products originate in a country in respect of which the European Commission has adopted approved import conditions for fishery products, is in accordance with those approved import conditions,

but an identification mark is not required in relation to any fishery products which have been landed in a third country in respect of which the European Commission has not adopted any approved import conditions;

- (i) except at cold stores where only the handling of packaged products takes place, they have been stored and transported in accordance with Chapter VIII of Schedule 3;
 - (j) if they are imported products, prior to importation the requirements specified in regulations 42 and 43 which are applicable to his case are satisfied in relation to those fishery products;
 - (k) any additional requirements in regulations 37 and 38 which are applicable to his case are satisfied in relation to those fishery products.
- (2) Paragraph (1)(a) to (c) shall not apply to aquaculture products.

Placing aquaculture products on the market

37. No person shall place fishery products which are aquaculture products on the market for human consumption, unless—

- (a) they have been slaughtered under appropriate conditions of hygiene;
- (b) they have not been soiled with earth, slime or faeces;
- (c) if they were not processed immediately after being slaughtered, they have been kept chilled.

Placing processed shellfish on the market

38.—(1) Subject to paragraphs (2) and (3), no person shall place fishery products which are processed shellfish on the market for human consumption unless, prior to processing, there were satisfied in relation to those processed shellfish those of the requirements of regulation 19 to which those products would have been subject if, when they were processed, they had instead been kept for placing on the market as live shellfish.

(2) For the purposes of paragraph (1), regulation 19 shall apply as if, where reference is made in regulation 19(1)(b) to transportation to an approved dispatch centre, reference had also been made

to transportation to a processing plant, and the requirements in relation to movement documents and permanent transport authorizations set out in regulation 19(1)(b).

(3) Paragraph (1) shall not apply to imported fishery products which were processed before they were imported.

Fishery products to be placed on the market alive

39. A person with control over the survival conditions of a fishery product for human consumption which is to be placed on the market alive shall ensure that it is at all times kept under the most suitable survival conditions.

Prohibition on placing certain fishery products on the market

40. No person shall sell, supply in the course of a food business or place on the market for human consumption—

- (a) poisonous fish of any of the following families: Tetraodontidae, Molidae, Diodontidae, and Canthigasteridae; or
- (b) fishery products containing biotoxins such as ciguatera toxins or muscle-paralysing toxins.

Direct transfers of fishery products on local markets

41.—(1) Regulations 33 to 39 shall not apply to a direct transfer to a retailer or final consumer in the United Kingdom of a small quantity of fishery products by a fisherman.

(2) For the purposes of paragraph (1), a “small quantity” means an amount which comprises part of the fisherman’s annual allowance.

(3) For the purposes of paragraph (2), a fisherman’s annual allowance is a total amount of not more than 25 tonnes of fishery products in a calendar year, and although the total amount may comprise of amounts of one or more species, in that total amount the amount of processed shellfish of any species listed in column (a) of the table below shall not exceed the maximum amount for that species mentioned in column (b) of that table—

Table

<i>(a)</i> <i>Species</i>	<i>(b)</i> <i>Maximum amount</i>
Cockles	25.0 tonnes
Oysters	5.0 tonnes
King Scallops	5.0 tonnes
Queen Scallops	10.0 tonnes
Mussels	20.0 tonnes
Other Bivalve Molluscs	10.0 tonnes
Marine Gastropods	20.0 tonnes.

PART IV

IMPORT CONDITIONS FOR FISHERY PRODUCTS AND LIVE SHELLFISH

General restriction on importing fishery products

42. Subject to regulation 46, no person shall import any fishery products which are for human consumption unless they are products in respect of which—

- (a) the applicable requirements of the Fishery Products Directive, the Fishing Vessels Directive, the Live Bivalve Molluscs Directive and the Fishery Products Decisions are satisfied (the requirements of these Directives and Decisions which are capable of being applicable in these circumstances are those mentioned in Part IV of Schedule 1); and
- (b) any additional conditions imposed under regulation 43 are satisfied.

Additional conditions relating to certain third country imports of fishery products

43.—(1) Subject to paragraph (4) and regulation 46, no person shall import any fishery products which are for human consumption—

- (a) from a third country;
- (b) from another country or territory within the European Community if those fishery products do not originate from within the European Economic Area⁽²¹⁾, except where those products were in free circulation in that country or territory within the European Community;
- (c) from an EEA State which is not also a member State of the European Community, except where those fishery products originate from within the European Economic Area,

unless the conditions specified in paragraph (2) or alternatively, if those fishery products originate in a country in respect of which the European Commission has adopted approved import conditions for fishery products and those fishery products fall within the scope of those approved import conditions, paragraph (3) are satisfied in relation to those fishery products which he imports.

(2) The conditions in paragraph (2) referred to in paragraph (1) are that the fishery products—

- (a) if dispatched to Great Britain from their country of origin—
 - (i) before 22nd April 1998—
 - (aa) have their country of origin shown clearly on their labelling, and
 - (bb) are only to be marketed in the British Islands or in an EEA State other than the United Kingdom according to the derogation mentioned in article 3.2 of Commission Decision [97/296/EC](#)⁽²²⁾ drawing up the list of third countries from which the import of fishery products is authorised for human consumption,
 - (ii) on or after 22nd April 1998, originate in one of the third countries listed in Part II of the Annex to Commission Decision [97/296/EC](#);
- (b) come from an approved establishment or vessel inspected by a competent authority of the State of origin of those products;
- (c) comprise or are part of a consignment which is accompanied by a numbered, original, duly completed health certificate which—
 - (i) comprises a single sheet of paper,

⁽²¹⁾ See protocol 4 (on rules of origin) annexed to the EEA Agreement, as amended by the Decision of the EEA Joint Committee No. 6/94 amending protocol 4 to the EEA Agreement (OJ No. L95, 14.4.94, p.22).

⁽²²⁾ OJ No. L122, 14.5.97, p.21.

- (ii) is drawn up in English and, if necessary, in an official language of the country or territory for which those fishery products are destined,
 - (iii) contains the information mentioned in the specimen health certificate set out in the Annex to Commission Decision 95/328 EC(23) of 25th July 1995 establishing health certification for fishery products from third countries which are not yet covered by a specific decision, and
 - (iv) contains the health attestation mentioned in that specimen health certificate, duly signed and dated by an official inspector duly appointed by the competent authority of the State of origin of those products; and
- (d) if they are or include processed shellfish, the processed shellfish (or parts thereof) originate in one of the third countries listed in the Annex to Commission Decision 97/20/EC establishing the list of third countries fulfilling the equivalence conditions for the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods(24), but this paragraph shall not apply to adductor muscles, completely separated from viscera and gonads, of wild pectinidae.
- (3) The conditions in paragraph (3) referred to in paragraph (1) are that a person importing fishery products in circumstances where those products—
- (a) originate in a third country in respect of which the European Commission has adopted approved import conditions for fishery products; and
 - (b) fall within the scope of those approved import conditions,
- shall import those products in accordance with those approved import conditions.
- (4) Fishery products which—
- (a) originate in a third country;
 - (b) were caught in their natural environment; and
 - (c) have not or had not been on land prior to their importation into the European Community,
- need not be accompanied by any health certificate which would otherwise be required under paragraph (2) or (3).
- (5) In paragraph (1) 22nd April 1998 means the date on which the derogation mentioned in article 3.2 of Commission Decision 97/296/EC comes to an end or, if that date is deferred, the deferred date.

General restriction on importing live shellfish

44.—(1) Subject to paragraph (2) and regulation 46, no person shall import any live shellfish which are for human consumption, unless (without prejudice to any restrictions imposed under the Fish Health Regulations 1992(25) or the Shellfish and Specified Fish (Third Country Imports) Order 1992(26))—

- (a) they are products in respect of which the applicable requirements of the Live Bivalve Molluscs Directive are satisfied (the requirements of this Directive which are capable of being applicable in these circumstances are those mentioned in Part V of Schedule 1); and
- (b) any additional conditions imposed under regulation 45 are satisfied,

in relation to those live shellfish which he imports.

(2) Live bivalve molluscs belonging to the species *Acanthocardia tuberculatum* may be imported from Spain which were harvested from production areas where the paralytic shellfish poison level

(23) OJ No. L191, 12.8.95, p.32.

(24) OJ No. L6, 10.1.97, p.46.

(25) S.I. 1992/3300; amended by S.I. 1993/2255, 1994/1448 and 1995/886.

(26) S.I. 1992/3301.

in the edible parts of these molluscs is higher than 80 micrograms per 100 grams but lower than 300 micrograms per 100 grams, but only if the conditions set out in articles 2 and 3 of Commission Decision [96/77/EC\(27\)](#) of 18th January 1996 establishing the conditions for the harvesting and processing of certain bivalve molluscs coming from areas where the paralytic shellfish poison level exceeds the limit laid down by the Live Bivalve Molluscs Directive are satisfied in relation to those molluscs which are imported from such production areas.

Additional conditions relating to certain third country imports of live shellfish

45.—(1) Subject to regulation 46, no person shall import any live shellfish which are for human consumption—

- (a) from a third country;
- (b) from another country or territory within the European Community if those live shellfish do not originate from within the European Economic Area(**28**), except where those live shellfish were in free circulation in that country or territory within the European Community;
- (c) from an EEA State which is not also a member State of the European Community, except where those live shellfish originate from within the European Economic Area,

unless the conditions specified in paragraph (2) or alternatively, if those live shellfish originate in a country in respect of which the European Commission has adopted approved import conditions for live shellfish and those live shellfish fall within the scope of those approved import conditions, paragraph (3) are satisfied in relation to those live shellfish which he imports.

(2) The conditions in paragraph (2) referred to in paragraph (1) are that—

- (a) the live shellfish originate in one of the third countries listed in the Annex to Commission Decision [97/20/EC](#) establishing the list of third countries fulfilling the equivalence conditions for the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods;
- (b) the live shellfish shall have been harvested from a production area checked and approved by the competent authority of the State of origin of those shellfish;
- (c) if the live shellfish are for direct human consumption, those live shellfish comprise or are part of a consignment which is accompanied by a numbered, original, duly completed health certificate which—
 - (i) comprises a single sheet of paper,
 - (ii) is drawn up in English and, if necessary, in an official language of the country or territory for which those live shellfish are destined,
 - (iii) contains the information mentioned in the specimen health certificate set out in Annex I to Commission Decision [96/333/EC\(29\)](#) establishing health certification of live bivalve molluscs, echinoderms, tunicates and marine gastropods from third countries which are not covered by a specific decision, and
 - (iv) contains the health attestation mentioned in that specimen health certificate, duly signed, stamped and dated (all of which shall be in a colour different from that of the other printing on the certificate) by an official inspector duly appointed by the competent authority of the State of origin of those shellfish;

(27) OJ No. L15, 20.1.96, p.46.

(28) See protocol 4 (on rules of origin) annexed to the EEA Agreement, as amended by the Decision of the EEA Joint Committee No. 6/94 amending protocol 4 to the EEA Agreement (OJ No. L95, 14.4.94, p.22).

(29) OJ No. L127, 25.5.96, p.33.

- (d) if the live shellfish are for purification in an approved purification centre, for relaying at a designated relaying area or for processing at an approved establishment, those live shellfish comprise or are part of a consignment which is accompanied by a numbered, original, duly completed health certificate which—
- (i) comprises a single sheet of paper,
 - (ii) is drawn up in English and, if necessary, in an official language of the country or territory for which those live shellfish are destined,
 - (iii) contains the information mentioned in the specimen health certificate set out in Annex II to Commission Decision 96/333/EC, and
 - (iv) contains the health attestation mentioned in that specimen health certificate, duly signed, stamped and dated (all of which shall be in a colour different from that of the other printing on the certificate) by an official inspector duly appointed by the competent authority of the State of origin of those live shellfish.
- (3) The conditions in paragraph (3) referred to in paragraph (1) are that a person importing live shellfish in circumstances where those live shellfish—
- (a) originate in a third country in respect of which the European Commission has adopted approved import conditions for live shellfish; and
 - (b) fall within the scope of those approved import conditions,
- shall import those live shellfish in accordance with those approved import conditions.

Exemption for private consignments

- 46.** This Part shall not apply to a person importing a private consignment—
- (a) from a country or territory within the European Community, unless that consignment is a consignment of trade samples which weighs more than 10 kilograms; or
 - (b) from any other country or territory, if that consignment weighs 1 kilogram or less.

PART V

INSPECTION CHARGES FOR DIRECT LANDINGS FROM THIRD COUNTRY VESSELS

Interpretation of Part V

- 47.—**(1) In this Part, unless the context otherwise requires—
- “chargeable transaction” shall be construed in accordance with regulation 48(1);
- “ECU” means European Currency Unit, and any reference in this Part to a specified number of ECU shall be taken to be a reference to the sterling equivalent of that number of ECU;
- “reducible element” shall be construed in accordance with regulation 50(1);
- “relevant fishery products” means imported fishery products which—
- (a) originate in a country or territory which is not part of the customs territory of the European Community other than Greenland;
 - (b) were caught in their natural environment;
 - (c) have not or had not been on land prior to their importation or proposed importation into the European Community;
 - (d) are or will be landed in Great Britain; and

- (e) are intended for placing on the market for human consumption;
- “third country direct landings charge” shall be construed in accordance with regulation 48(1);
- “vendor” includes an agent selling fishery products on behalf of the owner or master of a fishing vessel.

(2) The sterling equivalent of any amount expressed in this Part as a number of ECU shall be converted to sterling at the official rate, which is published annually in the C Series of the Official Journal of the European Communities normally on the first working day of the month of September.

Charge in respect of official checks on third country direct landings

48.—(1) When any relevant fishery products are sold for the first time in Great Britain (referred to in this Part as a “chargeable transaction”), the vendor of those products shall include in the price which the first purchaser is required to pay for them an amount referred to in this Part as the “third country direct landings charge”.

- (2) Subject to regulation 50, the amount of the third country direct landings charge shall be—
 - (a) in respect of allaying the expenditure incurred in carrying out the checks mentioned in Section II of Chapter V of Schedule 3 (special checks), ECU 1 per tonne of relevant fishery products for the first 50 tonnes and ECU 0.5 per tonne thereafter, except that any charge in respect of—
 - (i) herring of the species *Clupea harengus*,
 - (ii) sardines of the species *Sardina pilchardus*,
 - (iii) mackerel of the species *Scomber scombrus* or *Scomber japonicus*,
 - (iv) horse mackerel,
 - (v) anchovies,
 - (vi) picarels of the species *Maena smaris*,shall not exceed ECU 50 per consignment unloaded, if the actual costs do not exceed that amount; and
 - (b) in respect of allaying the expenditure incurred in carrying out checks on vessels and on conditions of landing, ECU 1 per tonne,

and the vendor of the products to which the amount relates shall be entitled to recover the amount from the first purchaser as a civil debt.

Sum payable by vendors to food authorities

49.—(1) Subject to paragraph (2), a sum equal to the amount of any third country direct landings charge which a vendor is required to include in the purchase price of any relevant fishery products shall be payable by him to the food authority in whose area the chargeable transaction takes place.

(2) If the chargeable transaction takes place before the fishery products are landed in Great Britain, a sum equal to the amount of any third country direct landings charge which a vendor is required to include in the purchase price shall be payable by him to the food authority responsible for the checks provided for in Section II of Chapter V of Schedule 3 in respect of those products.

(3) Any sum payable to a food authority under this regulation shall be recoverable as a civil debt.

The reducible element of the charge

50.—(1) A vendor who enters into a chargeable transaction may, with the consent of the food authority for the area where the chargeable transaction takes place, reduce by such amount as the food authority considers reasonable the part of the third country direct landings charge which is calculated

in accordance with regulation 48(2)(a) (referred to in this Part hereafter as “the reducible element”) in circumstances where any of the checks mentioned in Section II of Chapter V of Schedule 3 are or were facilitated by one or more of the following factors—

- (a) the fish are or were graded for freshness and/or size in accordance with relevant national or Community rules;
- (b) the first sale transactions are or were grouped together, in particular at an auction or wholesale market,

except that the reducible element shall not be reduced by more than 55% of the total amount that the reducible element would be, if it were not reduced.

(2) A vendor who considers that in respect of a chargeable transaction a food authority has unreasonably refused to consent—

- (a) to a reduction in the reducible element of the charge; or
- (b) to a reduction in the reducible element of the charge by a larger amount than the amount by which the food authority has agreed that the reducible element of the charge may be reduced,

may appeal against the food authority’s decision to a magistrates' court or, in Scotland, to the sheriff, and section 37(3) to (6) of the Act shall apply in relation to such an appeal as it applies in relation to an appeal under section 37(1)(c) of the Act.

(3) On an appeal, the court may—

- (a) confirm the decision of the food authority;
- (b) reduce the amount of the reducible element of the charge to the level it thinks fit, except that the court shall not reduce the reducible element by an amount which results in a total reduction of more than 55% of the total amount that the reducible element would be, if it were not reduced.

(4) Pending the outcome of the appeal—

- (a) the original amount of the charge shall remain payable by the first purchaser to the vendor; and
- (b) a sum equal to the original amount of the charge shall remain payable by the vendor to the food authority,

but if after the court’s decision the amount of the charge needs to be recalculated, the new amount of the charge, and the sum equal to that new amount which is payable to the food authority, shall have effect from the date on which the original charge was made.

(5) If, as a result of the recalculation of the amount of a third country direct landings charge by a court, a vendor of relevant fishery products has made an overpayment to a food authority in respect of a sum payable under this Part, the food authority shall reimburse the vendor as appropriate.

Collection and remittance arrangements

51.—(1) A vendor who has entered into a chargeable transaction shall within seven days after the end of the week during which the chargeable transaction took place make a return to the food authority in respect of the chargeable transaction, and he shall include in that return the following information—

- (a) the date of the chargeable transaction;
- (b) a description of the fishery products sold (sufficient for the purposes of identifying whether any of the products fall into one of the categories listed in regulation 48(1)(a));
- (c) the net weight of each description of fishery products sold;
- (d) the purchaser;

- (e) the amount of the third country direct landings charge;
 - (f) the amount of any reduction in the reducible element of the charge; and
 - (g) the place of landing of the fishery products sold and the country or territory in which the products originate⁽³⁰⁾.
- (2) In any case where, in respect of any relevant fishery products—
- (a) the food authority responsible for checks on vessels and on conditions of landing (“the general monitoring authority”); or
 - (b) the food authority responsible for the checks provided for in Section II of Chapter V of Schedule 3 (“the special checks authority”),

is different from the food authority to which the first vendor of the products is required to pay a sum equal to the amount of the third country direct landings charge (“the recipient authority”), the recipient authority shall remit to the general monitoring authority or, as the case may be, the special checks authority a sum equal to any amount received from the vendor which is referable to checks for which the general monitoring authority or, as the case may be, the special checks authority is responsible.

PART VI

ENFORCEMENT, PENALTIES AND REVOCATIONS

Functions of the Ministers and food authorities

52.—(1) Subject to paragraph (2)(b), the Ministers shall perform the functions assigned to them by Chapters III and VI of Schedule 2.

- (2) Each food authority shall perform—
- (a) the functions assigned to them by Chapters III and VI of Schedule 2; and
 - (b) any function of the Ministers specified in paragraph 1 of Chapter VI of Schedule 2 which the Ministers require the food authority to undertake on their behalf.

(3) The Ministers and food authorities shall perform the functions assigned to them by Chapter V of Schedule 3.

Offences and penalties

53.—(1) If a person contravenes any provision of regulations 8 to 10, 13, 16 to 19(1), 21(1), (2) and (4), 22(1) to (3), 23, 25, 28 to 30, or 33 to 40, he shall be guilty of an offence against these Regulations.

(2) Subject to paragraph (3), a person guilty of an offence against these Regulations shall be liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum;
- (b) on conviction on indictment, to a fine or imprisonment for a term not exceeding 2 years or both.

(3) Any person who—

⁽³⁰⁾ See Council Regulation (EEC) No. 2193/92 establishing the Community Customs Code (OJ No. L302, 19.10.92, p.1), Title II, Chapter 2 (Origin of Goods).

- (a) without reasonable cause, fails to give any person acting on behalf of a food authority in matters arising under Part V any assistance or information which that person may reasonably require of him in connection with such matters; or
- (b) in purported compliance with any such requirement as is mentioned in sub-paragraph (a) intentionally or recklessly furnishes information which is false or misleading in a material particular,

shall be guilty of an offence, and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

- (4) A food authority in England or Wales may institute proceedings under paragraph (3).

Enforcement of Parts II and III

54. Except where otherwise specified, each food authority shall enforce and execute Parts II and III within their area.

Application of provisions of the Act for the purposes of Parts II and III

55.—(1) The following provisions of the Act shall apply for the purposes of Parts II and III as they apply for the purposes of sections 8, 14 and 15 of the Act, and unless the context otherwise requires, a reference in them to the Act shall for the purposes of Parts II and III be construed as a reference to these Regulations—

- (a) section 3 (presumptions that food intended for human consumption);
- (b) section 20 (offences due to fault of another person);
- (c) section 21 (defence of due diligence);
- (d) section 30(8) (which relates to documentary evidence);
- (e) section 33 (obstruction etc. of officers);
- (f) section 34 (time limit for prosecutions);
- (g) section 36 (offences by body corporate), subject to the following modifications—
 - (i) after the words “body corporate”, at the three places where they occur in section 36(1) of the Act, there shall be inserted the words “or Scottish partnership”, and
 - (ii) for the word “secretary” there shall be substituted the words “secretary, partner”;
- (h) section 44 (protection of officers acting in good faith).

(2) Section 6(3) of the Act (discharge of duties of food authorities by Ministers) shall apply as respects functions imposed on food authorities under Parts II and III as it does as respects a duty imposed on a food authority by section 6(2) of the Act.

(3) Section 32 of the Act (powers of entry) shall apply for the purposes of Parts II and III as though—

- (a) any reference to premises included a reference to a fishing vessel, a factory vessel or any vessel used for the transporting of live shellfish to a relaying area or dispatch or purification centre (in so far as it does not already do so);
- (b) and any reference to an occupier included a reference to the master or other person in charge of a vessel mentioned in sub-paragraph (a) (in so far as it does not already do so).

(4) Section 58(1) of the Act (territorial waters and continental shelf) shall apply for the purposes of Parts II and III as it applies for the purposes of the Act.

Enforcement of Part IV

56. For the purposes of the Products of Animal Origin (Import and Export) Regulations 1996⁽³¹⁾ (in this paragraph referred to as “the Import and Export Regulations”)—

- (a) the conditions set out in Part IV shall be treated as health conditions (whether or not they are health conditions as defined in the Import and Export Regulations); and
- (b) those conditions shall be enforced as health conditions—
 - (i) by a local authority or the Minister (or by an authorised officer of the local authority or the Minister), which ever has the responsibility under the Import and Export Regulations for enforcing health conditions in the particular circumstances of the case,
 - (ii) in accordance with the procedures set out in the Import and Export Regulations, and
 - (iii) subject to the penalties and other sanctions set out in the Import and Export Regulations.

Food treated as failing to comply with food safety requirements

57.—(1) A food authority may certify any fishery products or live shellfish in respect of which any applicable requirements of Part II or III are not met as being a food or food source which fails to comply with these Regulations.

(2) Any fishery products or live shellfish which in accordance with paragraph (1) are certified as being a food or food source which fails to comply with these Regulations may be treated for the purpose of section 9 of the Act as failing to comply with food safety requirements.

Amendment of other Regulations

58.—(1) After sub-paragraph (h) of paragraph (2) of regulation 3 of the Food Premises (Registration) Regulations 1991⁽³²⁾ there shall be inserted—

- “(i) as a dispatch centre, purification centre, factory vessel or fishery products establishment which is approved under, or an auction or wholesale market which is registered under, the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998. unless”.

(2) Regulation 3(2) of the Food Safety (General Food Hygiene) Regulations 1995⁽³³⁾ shall be amended as follows—

- (a) sub-paragraphs (a) to (e) shall be omitted; and
- (b) after sub-paragraph (m) there shall be inserted the following paragraph—
 - “(n) the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998.”.

(3) Regulation 3 of the Food Safety (Temperature Control) Regulations 1995⁽³⁴⁾ shall be amended as follows—

- (a) paragraph (2)(a) to (e) shall be omitted;
- (b) in paragraph (2), after sub-paragraph (l) there shall be inserted the following sub-paragraph—
 - “(m) the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998.”;

⁽³¹⁾ S.I. 1996/3124; there are no relevant amending instruments.

⁽³²⁾ S.I. 1991/2825; amended by S.I. 1992/2037, 1993/2022, 1994/1029 and 3082, and 1995/539, 540, 1763, 2148 and 3205.

⁽³³⁾ S.I. 1995/1763; as amended by S.I. 1995/3205.

⁽³⁴⁾ S.I. 1995/2200; as amended by S.I. 1995/3205.

- (c) in paragraph (3), for the words from “regulated by” to “unless,” there shall be substituted the words “regulated by Part III of the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998, unless,”.
- (4) The Products of Animal Origin (Import and Export) Regulations 1996 shall be amended as follows—
- (a) in regulation 1(2)—
- (i) the definitions of “bivalve molluscs” and “other shellfish” shall be omitted,
 - (ii) in the definition of “fishery products”, for the words “Food Safety (Fishery Products) Regulations 1992” there shall be inserted the words “Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998”, and
 - (iii) after the definition of “import” there shall be inserted the following definition—
““live shellfish” has the same meaning as in the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998;”;
- (b) in each of the following provisions—
- (i) regulation 21(1),
 - (ii) regulation 22(1),
 - (iii) regulation 23(b) and (c),
 - (iv) regulation 24(3), and
 - (v) regulation 25(3),
- the words “bivalve molluscs or other” shall be omitted and
- (c) in Schedule 2 for paragraphs 1 to 4 there shall be substituted the following paragraph
“The Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998”.

Revocations and transitional provision

59.—(1) The Regulations specified in column (1) of Schedule 5 are hereby revoked to the extent specified in column (3) of Schedule 5.

(2) Any premises (which includes vessels) recognised immediately before these Regulations come into force as registered or approved by a food authority in accordance with any of the Regulations revoked by paragraph (1) shall be treated as registered or (as the case may be) approved in accordance with and for the purposes of these Regulations.

6th April 1998

Jeff Rooker
Minister of State Ministry of Agriculture,
Fisheries and Food

Signed by authority of the Secretary of State for Health

6th April 1998

Tessa Jowell
Minister for Public Health
Department of Health

6th April 1998

Win Griffiths
Parliamentary Under Secretary of State Welsh
Office

6th April 1998

Sam Galbraith
Parliamentary Under Secretary of State Scottish
Office

SCHEDULE 1

Regulations 2(1) and (2), 42(a) and 44(1)

(a)

IMPORTS

PART I

APPROVED IMPORT CONDITIONS FOR FISHERY PRODUCTS

1. Commission Decision [93/436/EEC](#) laying down special import conditions governing imports of fishery products originating in Chile(**35**).
2. Commission Decision [93/437/EEC](#) laying down special import conditions governing imports of fishery products originating in Argentina(**36**).
3. Commission Decision [93/494/EEC](#) laying down special conditions governing imports of fishery products originating in the Faroe Islands(**37**).
4. Commission Decision [93/495/EEC](#) laying down special conditions governing imports of fishery products originating in Canada(**38**).
5. Commission Decision [94/198/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in Brazil(**39**).
6. Commission Decision [94/200/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in Ecuador(**40**).
7. Commission Decision [94/269/EC](#) laying down special conditions governing imports of fishery and aquaculture products originating in Colombia(**41**).
8. Commission Decision [94/323/EC](#) laying down special conditions governing imports of fishery products originating in Singapore(**42**).
9. Commission Decision [94/324/EC](#) laying down special conditions governing imports of fishery and aquaculture products originating in Indonesia(**43**).

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- (35) OJ No. L202, 12.8.93, p.31; amended by Commission Decision [93/620/EC](#) (OJ No. L297, 2.12.93, p.31), Commission Decision [94/188/EC](#) (OJ No. L89, 6.4.94, p.21), Commission Decision [94/675/EC](#) (L268, 19.10.94, p.22, and a corrigendum in OJ No. L298, 19.11.94, p.49), Commission Decision [95/164/EC](#) (OJ No. L108, 13.5.95, p.174), Commission Decision [96/31/EC](#) (OJ No. L9, 12.1.96, p.6), Commission Decision [96/220/EC](#) (OJ No. L74, 22.3.96, p.75) and Commission Decision [96/674/EC](#) (OJ No. L313, 3.12.96, p.29).
- (36) OJ No. L202, 12.8.93, p.42; amended by Commission Decision [93/525/EEC](#) (OJ No. L252, 9.10.93, p.30), Commission Decision [94/341/EC](#) (OJ No. L151, 17.6.94, p.41), Commission Decision [95/299/EC](#) (OJ No. L184, 3.8.95, p.49), Commission Decision [96/31/EC](#), Commission Decision [96/262/EC](#) (OJ No. L89, 10.4.96, p.36) and Commission Decision [97/276/EC](#) (OJ No. L108, 25.4.97, p.53).
- (37) OJ No. L232, 15.9.93, p.37; amended by Commission Decision [95/151/EC](#) (OJ No. L100, 3.5.95, p.22) and Commission Decision [96/31/EC](#).
- (38) OJ No. L232, 15.9.93, p.43; amended by Commission Decision [93/606/EEC](#) (OJ No. L289, 24.11.93, p.26), Commission Decision [94/287/EC](#) (OJ No. L122, 17.5.94, p.38), Commission Decision [94/674/EC](#) (OJ No. L267, 18.10.94, p.15), Commission Decision [94/989/EC](#) (OJ No. L378, 31.12.94, p.64), Commission Decision [95/351/EC](#) (OJ No. L203, 29.8.95, p.13), Commission Decision [95/549/EC](#) (OJ No. L310, 22.12.95, p.74) and Commission Decision [96/31/EC](#).
- (39) OJ No. L93, 12.4.94, p.26; amended by Commission Decision [96/31/EC](#) and Commission Decision [96/193/EC](#) (OJ No. L61, 12.3.96, p.43).
- (40) OJ No. L93, 12.4.94, p.34; amended by Commission Decision [94/840/EC](#) (OJ No. L352, 31.12.94, p.21), Commission Decision [95/177/EC](#) (OJ No. L117, 24.5.95, p.42) and Commission Decision [96/31/EC](#).
- (41) OJ No. L115, 6.5.94, p.38; amended by Commission Decision [94/469/EC](#) (OJ No. L194, 29.7.94, p.85), Commission Decision [95/332/EC](#) (OJ No. L192, 15.8.95, p.30) and Commission Decision [96/31/EC](#).
- (42) OJ No. L145, 10.6.94, p.19; amended by Commission Decision [96/31/EC](#).
- (43) OJ No. L145, 10.6.94, p.23; amended by Commission Decision [95/34/EC](#) (OJ No. L44, 26.2.95, p.67) and Commission Decision [96/31/EC](#).

10. Commission Decision [94/325/EC](#) laying down special conditions governing imports of fishery and aquaculture products originating in Thailand(44).

11. Commission Decision [94/448/EC](#) laying down special conditions governing imports of fishery and aquaculture products originating in New Zealand(45).

12. Commission Decision [94/766/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in Taiwan(46).

13. Commission Decision [94/778/EC](#) laying down special conditions for the import of frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Turkey(47).

14. Commission Decision [95/30/EC](#) laying down special conditions governing imports of fishery and aquaculture products originating in Morocco(48).

15. Commission Decision [95/90/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in Albania(49).

16. Commission Decision [95/173/EC](#) laying down special conditions governing imports of fishery and aquaculture products originating in Peru(50).

17. Commission Decision [95/190/EC](#) laying down special conditions governing imports of fishery and aquaculture products originating in the Philippines(51).

18. Commission Decision [95/454/EC](#) laying down special conditions governing imports of fishery and aquaculture products originating in the Republic of Korea(52).

19. Commission Decision [95/538/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in Japan(53).

20. Commission Decision [96/355/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in Senegal(54).

21. Commission Decision [96/356/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in Gambia(55).

22. Commission Decision [96/425/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in Mauritania(56).

23. Commission Decision [96/606/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in Uruguay(57).

(44) OJ No. L145, 10.6.94, p.30; amended by Commission Decision [94/704/EC](#) (OJ No. L285, 4.11.94, p.28), Commission Decision [95/178/EC](#) (OJ No. L117, 24.5.95, p.35) and Commission Decision [96/31/EC](#).

(45) OJ No. L184, 20.7.94, p.16; amended by Commission Decision [94/705/EC](#) (OJ No. L285, 4.11.94, p.33), Commission Decision [95/179/EC](#) (OJ No. L117, 24.5.95, p.40), Commission Decision [95/310/EC](#) (OJ No. L186, 5.8.95, p.70), Commission Decision [96/31/EC](#) and Commission Decision [96/254/EC](#) (OJ No. L86, 4.4.96, p.75).

(46) OJ No. L305, 30.11.94, p.31; amended by Commission Decision [96/31/EC](#) and Commission Decision [96/255/EC](#) (OJ No. L86, 4.4.96, p.81).

(47) OJ No. L312, 6.12.94, p.40; amended by Commission Decision [96/31/EC](#).

(48) OJ No. L42, 24.2.95, p.32; amended by Commission Decision [95/298/EC](#) (OJ No. L184, 3.8.95, p.48) and Commission Decision [96/459/EC](#) (OJ No. L191, 1.8.96, p.48).

(49) OJ No. L70, 30.3.95, p.27; amended by Commission Decision [95/235/EC](#) (OJ No. L156, 7.7.95, p.82).

(50) OJ No. L116, 23.5.95, p.41; amended by Commission Decision [95/311/EC](#) (OJ No. L186, 5.8.95, p.78).

(51) OJ No. L123, 3.6.95, p.20; amended by Commission Decision [96/256/EC](#) (OJ No. L86, 4.4.96, p.83).

(52) OJ No. L264, 7.11.95, p.37.

(53) OJ No. L304, 16.12.95, p.52.

(54) OJ No. L137, 8.6.96, p.24.

(55) OJ No. L137, 8.6.96, p.31.

(56) OJ No. L175, 13.7.96, p.27.

(57) OJ No. L269, 22.10.96, p.18.

24. Commission Decision [96/607/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in South Africa**(58)**.

25. Commission Decision [96/608/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in Malaysia**(59)**.

26. Commission Decision [96/609/EC](#) laying down special conditions governing the import of fishery and aquaculture products originating in the Ivory Coast**(60)**.

PART II

APPROVED IMPORT CONDITIONS FOR LIVE SHELLFISH

1. Commission Decision [93/387/EEC](#) laying down special conditions for the import of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Morocco**(61)**.

2. Commission Decision [94/777/EC](#) laying down special conditions for the import of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Turkey**(62)**.

3. Commission Decision [95/174/EC](#) laying down special conditions for the import of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Peru**(63)**.

4. Commission Decision [95/453/EC](#) laying down special conditions for the import of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in the Republic of Korea**(64)**.

5. Commission Decision [96/675/EC](#) laying down special conditions for the import of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Chile**(65)**.

PART III

THE FISHERY PRODUCTS DECISIONS

1. Commission Decision [93/25/EEC](#) approving certain treatments to inhibit the development of pathogenic micro-organisms in bivalve molluscs and marine gastropods**(66)**.

2. Commission Decision [93/51/EEC](#) on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish**(67)**.

3. Commission Decision [93/140/EEC](#) laying down the detailed rules relating to the visual inspection for the purpose of detecting parasites in fishery products**(68)**.

4. Commission Decision [93/351/EEC](#) determining analysis methods, sampling plans and maximum limits for mercury in fishery products**(69)**.

5. The Health Checks Decision.

(58) OJ No. L269, 22.10.96, p.23.

(59) OJ No. L269, 22.10.96, p.32.

(60) OJ No. L269, 22.10.96, p.37.

(61) OJ No. L166, 8.7.93, p.40; amended by Commission Decision [93/530/EEC](#) (OJ No. L258, 16.10.93, p.32); Commission Decision [94/767/EC](#) (OJ No. L305, 30.11.94, p.36) and Commission Decision [96/31/EC](#).

(62) OJ No. L312, 6.12.94, p.35; amended by Commission Decision [95/275/EC](#) (OJ No. L167, 18.7.95, p.26) and Commission Decision [96/31/EC](#).

(63) OJ No. L116, 23.5.95, p.47.

(64) OJ No. L264, 7.11.95, p.35.

(65) OJ No. L313, 3.12.96, p.38.

(66) OJ No. L16, 25.1.93, p.22; amended by Commission Decision [97/275/EC](#) (OJ No. L108, 25.4.97, p.52).

(67) OJ No. L13, 21.1.93, p.11.

(68) OJ No. L56, 9.3.93, p.42.

(69) OJ No. L144, 16.6.93, p.23.

6. Commission Decision [95/149/EC](#) fixing the total volatile basic nitrogen (TVB-N) limit values for certain categories of fishery products and specifying the analysis methods to be used(70).

PART IV

APPLICABLE REQUIREMENTS RELATING TO IMPORTED FISHERY PRODUCTS

As respects imported fishery products, the requirements of the Fishery Products Directive, the Fishing Vessels Directive, the Live Bivalve Molluscs Directive and the Fishery Products Decisions which are capable of being applicable are—

- (a) in relation to fishery products other than aquaculture products or processed bivalve molluscs, echinoderms, tunicates or marine gastropods, those set out in—
 - (i) articles 3.1(a) to (g), 3.2, 4, 5 and 6.1 of the Fishery Products Directive,
 - (ii) article 1 of the Fishing Vessels Directive,
 - (iii) articles 1 to 4 of Commission Decision [93/51/EEC](#),
 - (iv) articles 2 to 4 of Commission Decision [93/140/EEC](#),
 - (v) articles 1 to 3 of Commission Decision [93/351/EEC](#),
 - (vi) articles 1.3 and 6.2 of the Health Checks Decision, and
 - (vii) articles 1 and 2 of Commission Decision [95/149/EC](#);
- (b) in relation to fishery products which are aquaculture products, those set out in—
 - (i) articles 3.1(c) to (g), 3.3, 4, 5 and 6.1 of the Fishery Products Directive,
 - (ii) articles 1 to 4 of Commission Decision [93/51/EEC](#),
 - (iii) articles 2 to 4 of Commission Decision [93/140/EEC](#),
 - (iv) articles 1 to 3 of Commission Decision [93/351/EEC](#),
 - (v) articles 1.3 and 6.2 of the Health Checks Decision, and
 - (vi) articles 1 and 2 of Commission Decision [95/149/EC](#);
- (c) in relation to fishery products which are processed bivalve molluscs, echinoderms, tunicates or marine gastropods, those set out in—
 - (i) articles 3.1(a) and (c) to (g), 3.4, 5 and 6.1 of the Fishery Products Directive,
 - (ii) article 3.1(a) to (i) and 3.2 (as read with article 1) and article 4 of the Live Bivalve Molluscs Directive,
 - (iii) article 1 of Commission Decision [93/25/EEC](#),
 - (iv) articles 1 to 4 of Commission Decision [93/51/EEC](#),
 - (v) article 2 of Commission Decision [93/140/EEC](#),
 - (vi) articles 1 to 3 of Commission Decision [93/351/EEC](#), and
 - (vii) articles 1.3 and 6.2 of the Health Checks Decision.

PART V

APPLICABLE REQUIREMENTS RELATING TO IMPORTED LIVE SHELLFISH

As respects imported live shellfish, the requirements of the Live Bivalve Molluscs Directive which are capable of being applicable are those set out in article 3.1(a) to (i) and 3.2 (read with article 1) and article 4.

SCHEDULE 2

Regulations 2(1), 3(1) and (2), 9, 11(3) to
(5), 13, 15 to 20 and 52

PRODUCTION AND PLACING ON THE MARKET CONDITIONS FOR LIVE SHELLFISH
(BASED ON THE CORRESPONDING PROVISIONS OF THE ANNEX TO THE LIVE BIVALVE
MOLLUSCS DIRECTIVE)

CHAPTER I

CONDITIONS FOR PRODUCTION AREAS

PART 1

CLASS A AREAS

Areas to be designated class A areas

1. An area from which live bivalve molluscs can be gathered for direct human consumption provided such molluscs satisfy the requirements specified in Chapter V.

PART 2

CLASS B AREAS

Areas to be designated class B areas

2. An area from which live bivalve molluscs may be gathered but only placed on the market for human consumption—

- (a) after treatment in a purification centre or after relaying (followed, where necessary, by treatment in a purification centre); or
- (b) after heat treatment by an approved process in an approved establishment.

Conditions in relation to a class B area

3. Prior to relaying, treatment in a purification centre or heat treatment, the live bivalve molluscs from these areas must not exceed in 90% of samples the limits of—

- (a) a five-tube, three-dilution MPN-test of 6,000 faecal coliforms per 100 grams of flesh; or
- (b) 4,600 *E. coli* per 100 grams of flesh.

4. After any necessary relaying, purification and treatment, the live bivalve molluscs must satisfy the requirements of Chapter V.

PART 3

CLASS C AREAS

Areas to be designated class C areas

5. An area from which live bivalve molluscs can be gathered but placed on the market for human consumption only after—

- (a) a relaying period of at least 2 months, followed, where necessary, by treatment in a purification centre; or
- (b) heat treatment by an approved process in an approved establishment.

Conditions in relation to a class C area

6. The live bivalve molluscs from these areas must not, prior to relaying and any periods of purification or heat treatment, exceed the limits of—

- (a) a five-tube, three-dilution MPN-test of 60,000 faecal coliforms per 100 grams of flesh; or
- (b) 46,000 *E. coli* per 100 grams of flesh.

7. After any necessary relaying, purification and treatment, the live bivalve molluscs must satisfy the requirements of Chapter V.

CHAPTER II

REQUIREMENTS FOR HARVESTING AND TRANSPORTATION OF BATCHES TO A DISPATCH OR PURIFICATION CENTRE, RELAYING AREA OR PROCESSING PLANT

1. Harvesting techniques must not cause excessive damage to the shells or tissue of live shellfish.
2. Live shellfish must be adequately protected from crushing, abrasion or vibration after harvesting and must not be exposed to extremes of hot or cold temperature.
3. Techniques for harvesting, transporting, landing and handling live shellfish must not result in additional contamination of the product, nor in a significant reduction in the quality of the product, nor in any changes significantly affecting their ability to be treated by purification, processing or relaying.
4. Live shellfish must not be re-immersed in water which could cause additional contamination between harvesting and landing.

5.—(1) The means of transport used for transporting live shellfish must be used under conditions which protect the latter from additional contamination and crushing of shells, and must permit adequate drainage and cleaning.

(2) In the event of bulk transport over long distances of live shellfish to a dispatch centre, purification centre, relaying area or processing plant, the means of transport must be equipped in such a way as to ensure the best survival conditions possible, and in particular must comply with the requirements laid down in paragraph 2 of Chapter IX.

6.—(1) A movement document, as prescribed in this paragraph, for the identification of each batch of live shellfish during transport from the production area to a dispatch centre, purification centre, relaying area or processing plant shall be issued by the food authority, on request, to the

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gatherer for completion by the gatherer in respect of each batch in a way which is both legible and indelible.

(2) The gatherer shall ensure the completed movement document accompanies each batch at all times.

(3) If a batch in respect of which a movement document has been issued is split for any reason, the person having control of the original batch at the time of the splitting shall ensure that the information accompanying the original batch accompanies each sub-batch in the same form as the movement document together with the full name and address of the person splitting the batch.

(4) A movement document shall be in the following form—

LIVE SHELLFISH MOVEMENT DOCUMENT	
.....	
Movement Document No.	
Issued by:	
Date of Issue:	
.....	
Name of gatherer	Signature of gatherer
.....	
Food Authority where shellfish landed	Address of gatherer
.....	
Date of gathering	Location of production area and, if live bivalve molluscs, class of production area (A, B or C)
.....	
Name of shellfish species being moved (common and scientific) and quantity of shellfish being moved	Place of destination, including (if applicable) approval number
.....	
Date of receipt	
Place of receipt	
.....	
REMINDER—This document is to be kept by the person receiving the shellfish for a period of not less than 60 days.	

(5) Each movement document must be numbered permanently in sequence by the food authority.

(6) Each food authority shall keep a register indicating the number of each movement document together with the name of the person collecting the live shellfish and of the person to whom the document was issued.

(7) The person receiving a movement document for each batch of live shellfish shall put on it the date the batch was received by either a dispatch centre, purification centre, relaying area or processing plant and shall keep it available for inspection for a period of at least 60 days.

(8) If gathering is or is to be carried out by a person employed by the person who operates the dispatch centre, purification centre, relaying area or processing plant of destination, the food authority may, if satisfied that the gatherer will comply with the requirements of Part II concerning gathering and handling, issue to the gatherer a permanent transport authorization (which may be withdrawn at any time) absolving the gatherer from the requirement to use movement documents for transfers from a production area specified in that authorization to a dispatch centre, purification centre, relaying area, or processing plant specified in that authorization.

7. If a production or relaying area is closed temporarily, pursuant to regulation 7, the food authority shall refrain from issuing further movement documents and permanent transport authorizations for that area and the food authority may suspend the validity of any such documentations or authorizations already issued for the area.

CHAPTER III

CONDITIONS FOR RELAYING LIVE BIVALVE MOLLUSCS

The following conditions must be met—

1. live bivalve molluscs must be gathered and transported, under the supervision of the food authority, in accordance with the requirements of Chapter II;
2. techniques for handling live bivalve molluscs intended for relaying must permit the resumption of filter-feeding activity after immersion in natural waters;
3. live bivalve molluscs must not be relaid at a density which does not permit purification;
4. live bivalve molluscs must be immersed in seawater at the relaying area for an appropriate period which must exceed the time taken for levels of faecal bacteria to become reduced to the levels permitted by these Regulations and in particular either the standards specified in Chapter V or the standards in Part 2 of Chapter I where relaying is to be followed by purification;
5. the minimum water temperature for effective relaying must, where necessary, be determined for each species of live bivalve mollusc and each approved relaying area, by the Minister and the food authority for the area where the laying is situated, acting jointly, and be announced by the food authority;
6. the boundaries of the sites must be physically delineated by buoys, poles or any other fixed means; there must be a minimum distance of 300 metres between relaying areas, and also between relaying areas and production areas;
7. sites within a relaying area must be well separated to prevent mixing of batches; the 'all in, all out' system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed;
8. permanent records of the source of live bivalve molluscs, relaying periods, relaying areas and subsequent destination of the batch after relaying must be kept by the operators of relaying areas for inspection by the food authority;
9. after harvesting from the relaying area, batches must, during transport from the relaying area to the approved dispatch centre, purification centre or processing plant, be accompanied by the movement document referred to in paragraph 6 of Chapter II, unless a permanent transport authorization has been issued by a food authority.

CHAPTER IV

CONDITIONS FOR THE APPROVAL OF DISPATCH OR PURIFICATION CENTRES

Section I

General conditions relating to premises and equipment

Centres must not be located in areas which are close to objectionable odours, smoke, dust and other contaminants. The location must not be subject to flooding by ordinary high tides or run-off from surrounding areas.

Centres must have at least—

1. on premises where live shellfish are handled or stored—
 - (a) buildings or facilities of sound construction, designed and maintained adequately for the purpose of preventing contamination of live bivalve molluscs by any type of waste, dirty water, fumes, dirt or by the presence of rodents or other animals;
 - (b) flooring which is easy to keep clean and is laid in such a way as to facilitate drainage;
 - (c) adequate working space to allow for satisfactory performance of all operations;
 - (d) durable walls which are easy to clean;
 - (e) adequate natural or artificial lighting;
2. access to an appropriate number of changing rooms, wash basins and lavatories; there must be a sufficient number of wash basins close to the lavatories;
3. adequate equipment for washing tools, containers and equipment;
4. facilities for the supply and, where appropriate, storage of exclusively potable water or facilities for the supply of clean seawater. Facilities supplying non-potable water may be authorised. The water concerned may not come into direct contact with live shellfish or be used for cleaning or disinfecting containers, plant or equipment which come into contact with live shellfish. Pipes and outlets carrying non-potable water must be clearly distinguished from those carrying potable water;
5. equipment and instruments or their surfaces which are intended to come into contact with live shellfish must be made of corrosion-resistant material which is easy to wash and clean repeatedly.

Section II

General hygiene requirements

A high degree of cleanliness and hygiene must be required of staff, premises, equipment and working conditions—

1. staff who treat or handle live shellfish must in particular wear clean working clothes and, where appropriate, gloves which are suitable for the work in which the person is engaged;
2. staff are obliged to refrain from personal behaviour, such as spitting, which could result in contamination of live shellfish; any person suffering from an illness which can be transmitted by live shellfish must be temporarily prohibited, until recovery, from working with or handling these products;
3. any rodents, insects or other vermin found must be destroyed and further infestation prevented. Domestic animals must not enter the facilities;
4. premises, equipment and instruments used for handling live shellfish must be kept clean and in a good state of repair; equipment and instruments must be thoroughly cleaned at the end of the day's work and at such other times as may be appropriate;
5. premises, instruments and equipment must not be used for purposes other than the handling of live shellfish without authorization by the food authority;
6. waste products must be stored hygienically in a separate area and, where appropriate, in covered containers suitable for the purpose intended. Waste material must be removed from the vicinity of the establishment at appropriate intervals;

7. the finished products must be stored under cover and must be kept away from the areas where animals other than live bivalve molluscs, echinoderms, tunicates or marine gastropods— such as crustaceans—are handled.

Section III

Requirements for purification centres

In addition to the requirements under Sections I and II, the following conditions must be met—

1. the floors and walls of the purification tanks and any water storage containers must have a smooth, hard and impermeable surface and be easy to clean by scrubbing or use of pressurised water. The base of the purification tanks must be sufficiently sloped and be equipped with drainage sufficient for the volume of work;

2. live bivalve molluscs must be washed free of mud with pressurised clean seawater or potable water before purification. The initial washing may also be carried out in the purification tanks before purification commences, the drainage pipes being kept open during the entire initial washing and sufficient time being allowed thereafter for the system to be flushed clean before the purification process begins;

3. the purification tanks must be supplied with a sufficient flow of seawater per hour and per tonne of live bivalve molluscs treated;

4. clean seawater or seawater cleaned by treatment must be used for purifying live bivalve molluscs; the distance between the seawater intake point and the waste water outlets must be sufficient to avoid contamination; if treatment of the seawater is necessary, the process shall be authorised once its effectiveness has been verified by the Ministers; water used to prepare seawater from its major constituent chemicals must be potable water;

5. operation of the purification system must allow live bivalve molluscs to rapidly resume filter feeding activity, remove sewage contamination, not to become recontaminated and be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market;

6. the quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre; the live bivalve molluscs must be continuously purified for a period sufficient to allow the microbiological standards laid down in Chapter V to be met. This period starts from the moment at which the live bivalve molluscs in the purification tanks are adequately covered by the water until the moment when they are removed. The purification centre must take account of the data relating to the raw materials (the type of bivalve mollusc, its area or origin, microbe content, etc.) in case it is necessary to extend the purification period so as to ensure that the live bivalve molluscs meet the bacteriological requirements of Chapter V;

7. should a purification tank contain several batches of molluscs, they must be of the same species and come from the same production area or different areas conforming to the same health conditions. The length of the treatment must be based on the time required by the batch needing the longest period of purification;

8. containers used to hold live bivalve molluscs in purification systems must have a construction which allows seawater to flow through; the depth of layers of live bivalve molluscs should not impede the opening of shells during purification;

9. no crustaceans, fish or other marine species must be kept in a purification tank in which live bivalve molluscs are undergoing purification;

10. after completion of purification, the shells of live bivalve molluscs must be washed thoroughly by hosing with potable water or clean seawater; this may take place in the purification tank if necessary; the washing water must not be recirculated;

11. purification centres must have their own laboratories or secure the services of a laboratory equipped with the necessary facilities for checking the efficiency of purification by use of microbiological specifications. Laboratory facilities outside the centres must be acceptable to the food authority;

12. purification centres must regularly keep a record of the following data—

- results of microbiological tests on purification system water entering the purification tanks;
- results of microbiological tests on unpurified live bivalve molluscs;
- results of microbiological tests on purified live bivalve molluscs;
- dates and quantities of live bivalve molluscs delivered to the purification centre and corresponding movement document numbers;
- the times of filling and emptying of purification systems (purification times);
- dispatch details of consignments after purification;

these records must be completed and accurate, legible and recorded in a permanent ledger book which must be available for inspection by the food authority or a person authorized by the Ministers;

13. purification centres must accept only those batches of live bivalve molluscs which are accompanied by a movement document or permanent transport authorization. Purification centres dispatching batches of live bivalve molluscs to dispatch centres must provide a movement document or permanent transport authorization;

14. every package containing purified live bivalve molluscs must be provided with a label certifying that all molluscs have been purified.

Section IV

Requirements for dispatch centres

1. In addition to the requirements under Sections I and II, the following conditions must be met—

- (a) conditioning must not cause any contamination of the product, conditioning facilities must be used in accordance with procedures recognised by the Ministers, with special regard to the bacteriological and chemical quality of the seawater used in those facilities;
- (b) equipment and containers in the conditioning facilities must not constitute a source of contamination;
- (c) procedures for calibration of live shellfish must not result in additional contamination of the product or in any changes affecting the ability of the product to be transported and stored after wrapping;
- (d) any washing or cleaning of live shellfish must be carried out using pressurised clean seawater or potable water; cleaning water may not be recycled.

2. Dispatch centres must accept only those batches of live shellfish which are accompanied by the movement document referred to in paragraph 6 of Chapter II, and coming from an approved production area, relaying area or purification centre.

3. Dispatch centres must have their own laboratories or secure the services of a laboratory equipped with the necessary facilities for checking *inter alia*, whether the shellfish comply with the microbiological standards of Chapter V. Laboratory facilities outside the centre must be acceptable to the food authority. However, these requirements do not apply to dispatch centres obtaining molluscs exclusively and directly from a purification centre where they have been examined after purification.

4. Dispatch centres must keep the following data at the disposal of the food authority—

- results of microbiological tests on live bivalve molluscs from an approved production area or relaying area;

- dates and quantities of live shellfish delivered to the dispatch centre and corresponding movement document numbers;
- dispatch details.

These data must be classified chronologically and preserved for a period to be laid down by the food authority, but not less than three months.

5. Dispatch centres situated aboard vessels shall be subject to the conditions laid down in paragraphs 1(b), (c) and (d) and in paragraphs 3 and 4. The conditions laid down in Section I and II shall apply *mutatis mutandis* to such dispatch centres although special conditions may be laid down in accordance with the procedure laid down in article 12 of the Live Bivalve Molluscs Directive.

CHAPTER V

REQUIREMENTS CONCERNING LIVE SHELLFISH

Live shellfish intended for immediate human consumption must comply with the following requirements—

1. the possession of visual characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion, and normal amounts of intravalvular liquid;
2. they must contain less than 300 faecal coliforms or less than 230 *E. coli* per 100 grams of mollusc flesh and intravalvular liquid based on a five-tube, three-dilution MPN-test or any other bacteriological procedure shown to be of equivalent accuracy;
3. they must not contain salmonella in 25 grams of mollusc flesh;
4. they must not contain toxic or objectionable compounds occurring naturally or added to the environment such as those listed in the Annex to Directive 79/923/EEC in such quantities that the calculated dietary intake exceeds the permissible daily intake (PDI) or that the taste of the molluscs may be impaired;
5. the upper limits as regards the radionuclide contents must not be excessive;
6. the total Paralytic Shellfish Poison (PSP) content in the edible parts of molluscs that is the whole body or any part edible separately must not exceed 80 micrograms per 100 grams of mollusc flesh in accordance with the biological testing method—in association if necessary with a chemical method for detection of Saxitoxin. If the results of such tests are challenged, the reference method shall be the biological method;
7. the customary biological testing methods must not give a positive result to the presence of Diarrhetic Shellfish Poison (DSP) in the edible parts of molluscs that is the whole body or any part edible separately;
8. in the absence of routine virus testing procedures and the establishment of virological standards, health checks must be based on faecal bacteria counts.

Any examination for checking compliance with the requirements of this Chapter must be carried out in accordance with methods which may from time to time be approved for the purpose of these Regulations by the Ministers.

CHAPTER VI

PUBLIC HEALTH CONTROL AND MONITORING OF PRODUCTION

1. The Ministers shall undertake, or may require food authorities to undertake on their behalf, the periodic monitoring of bivalve mollusc relaying and production areas to determine—

- (a) whether toxin producing plankton are present in production and relaying waters or biotoxins are present in live bivalve molluscs; and
- (b) whether chemical or microbiological contaminants are present.

2. A food authority shall undertake periodic monitoring of live bivalve mollusc relaying and production areas in order to—

- (a) preclude any malpractice with regard to the origin and destination of the live bivalve molluscs;
- (b) determine the microbiological quality of the live bivalve molluscs in relation to the production and relaying areas.

3.—(1) Sampling plans for the purposes of paragraphs 1 and 2 of this Chapter shall in particular take account of—

- (a) likely variations in faecal contamination at each production and relaying area;
- (b) possible variations in production and relaying areas in the presence of plankton containing marine biotoxins;
- (c) possible contamination of the molluscs in the production and relaying area.

(2) Sampling plans referred to in sub-paragraph (1)(b) above shall be carried out as follows—

- (a) in relation to monitoring, periodic sampling shall be organised to detect changes in the composition of the plankton containing toxins and the geographical distribution of the plankton;
- (b) where periodic sampling leads to a suspicion of accumulation of toxins in mollusc flesh, intensive sampling shall be carried out and molluscs from the relevant area shall not be placed on the market until new sampling has provided satisfactory toxicity test results;
- (c) where intensive sampling is to be carried out, it shall consist of—
 - (i) monitoring plankton in the growing and fishing waters by increasing the number of sampling points and the number of samples, and
 - (ii) the carrying out of toxicity tests using the molluscs from the affected area which are most susceptible to contamination.

4.—(1) Laboratory tests shall be carried out by the food authority to check compliance with the requirements for the end product as laid down in Chapter V.

(2) A control system shall be established by the food authority to verify that the level of marine biotoxins does not exceed safety limits.

5.—(1) A food authority shall inspect establishments at regular intervals and those inspections shall include, in particular, checks—

- (a) to determine whether the approval conditions are still being complied with;
- (b) on the cleanliness of the premises, facilities, equipment and on staff hygiene;
- (c) to determine whether the live shellfish are handled and treated correctly;
- (d) on the correct application and functioning of purification or conditioning systems;

- (e) on the ledger books referred to in paragraph 12 of Section III of Chapter IV;
 - (f) on the correct use of healthmarks.
- (2) The checks referred to in paragraph (1) above may include the taking of samples for laboratory tests.
- (3) The results of such tests must be notified to the persons responsible for the establishments.
6. A food authority shall check on the storage and transport conditions for consignments of live shellfish.

CHAPTER VII

WRAPPING

- 1.—(1) Live shellfish must be wrapped under satisfactory conditions of hygiene.
- (2) The wrapping material or container of such molluscs or shellfish shall—
- (a) not impair the organoleptic characteristics of the live shellfish;
 - (b) not be capable of transmitting substances harmful to human health to the live shellfish;
 - (c) be strong enough to give adequate protection to the live shellfish.
2. Oysters must be wrapped with the concave shell downwards.
3. All wrappings of live shellfish must be sealed and remain sealed from the dispatch centre until delivery to the consumer or retailer, but wrappings may be unwrapped and repackaged provided that—
- (a) the person who unwraps the product keeps records of the origin of all live shellfish received and of the place of dispatch;
 - (b) live shellfish from different dispatch centres are not mixed when repackaged; and
 - (c) a healthmark is provided on the new packaging which is in accordance with Chapter X.

CHAPTER VIII

PRESERVATION AND STORAGE

1. In any storing rooms, live shellfish must be kept at a temperature which does not adversely affect their quality and viability; the wrapping must not come into contact with the floor of the store room, but must be placed on a clean, raised surface.
2. Re-immersion in or spraying with water of live shellfish must not take place after they have been wrapped and have left the dispatch centre except in the case of a retail sale at the dispatch centre.

CHAPTER IX

TRANSPORT FROM THE DISPATCH CENTRE

1. Except where paragraph 3 of Chapter VII applies, consignments of live shellfish intended for human consumption must be transported wrapped in sealed parcels from the dispatch centre until offered for sale to the consumer or retailer.
2. The means of transport used for consignments of live shellfish must have the following characteristics—

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- (a) their interior walls and any other parts which might come into contact with the live shellfish must be made of corrosion-resistant materials, and the walls must be smooth and easy to clean;
 - (b) they must be suitably equipped to provide efficient protection of the live shellfish against extremes of heat and cold, contamination with dirt or dust, and damage to the shells from vibration and abrasion;
 - (c) the live shellfish must not be transported with other products which might contaminate them.
3. Live shellfish must be transported and distributed using closed vehicles or containers which maintain the product at a temperature which does not adversely affect quality and viability.
4. The parcels containing live shellfish must not be transported in direct contact with the floor of the vehicle or container but must be supported on raised surfaces or by some other means which prevents such contact.
5. Where ice is used in transporting consignments of live shellfish, it must have been made from potable water or clean seawater.

CHAPTER X

MARKING OF CONSIGNMENTS

1. Without prejudice to the requirements of the Food Labelling Regulations 1996(71) and subject to paragraph 4, all parcels in a consignment of live shellfish shall be provided with a healthmark so that the original dispatch centre may be identified at all times during transport and distribution until retail sale, and the healthmark shall be in the following form—

HEALTHMARK LIVE SHELLFISH	
Country of dispatch	Approval number of dispatch centre
Species consigned (scientific name)	Species consigned (common name)
Day and month of wrapping	
[EITHER 'WARNING: THESE ANIMALS MUST BE ALIVE WHEN SOLD' OR DATE OF DURABILITY]	

- 2.—(1) The healthmark may be—
- (a) printed on the wrapping material;
 - (b) affixed as a separate label to the wrapping material;
 - (c) put inside the wrapping; or
 - (d) of a twist-tie or staple design.
- (2) A self-adhesive healthmark must not be used, unless it is not detachable.

(71) S.I. 1996/1499.

- (3) All types of healthmark must be for single use only and are not transferable.
3. The healthmark must be durable and waterproof, and the information presented must be legible, indelible and in easily decipherable characters.
4. Where a person repackages any live shellfish in accordance with paragraph 3 of Chapter VII, the healthmark provided on the new wrapping shall be in the form set out in paragraph 1, except that it shall also contain—
- (a) if the live shellfish originate—
 - (i) in the European Economic Area or in a third country in respect of which the European Commission has adopted import conditions for live shellfish, the approval number of the original dispatch centre, or
 - (ii) in a third country in respect of which the European Commission has not adopted approved import conditions for live shellfish, the original dispatch details; and
 - (b) if the consignment was unwrapped—
 - (i) at a registered market, the registration number of the market where the consignment was unwrapped, or
 - (ii) elsewhere than at a registered market, the full name and address of the person repackaging the consignment.

SCHEDULE 3

Regulations 21(4), 24(3) and (4), 26(3),
28(2) and (3), 30, 32(1)(a) and (2)(a), 34 to
36, 48(2), 49(2), 50(1), 51(2)(b) and 52(3)

PRODUCTION AND PLACING ON THE MARKET CONDITIONS FOR FISHERY PRODUCTS

(BASED ON THE CORRESPONDING PROVISIONS OF THE ANNEX TO THE FISHERY
PRODUCTS DIRECTIVE)

CHAPTER I

CONDITIONS APPLICABLE TO FACTORY VESSELS

Section I

Conditions concerning design and equipment

1. The minimum requirements for factory vessels are as follows—
 - (a) a reception area set aside for taking fishery products on board, designed and arranged into pounds or pens that are large enough to allow each successive catch to be separated. The reception area and its movable parts must be easy to clean. It must be designed in such a way as to protect the products from the sun or the elements and from any source of dirt or contamination;
 - (b) a system for conveying fishery products from the reception area to the work area that conforms with rules of hygiene;
 - (c) work areas that are large enough for the preparation and processing of fishery products in proper conditions of hygiene. They must be designed and arranged in such a way as to prevent any contamination of the products;

- (d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste processing unit operates on board, a separate hold must be designated for the storage of these by-products;
 - (e) a place for storing packaging materials that is separate from the product preparation and processing areas;
 - (f) special equipment for pumping waste or fishery products that are unfit for human consumption either directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to cleaning, separate areas must be allocated for that purpose;
 - (g) equipment providing a supply of potable water or pressurised clean seawater. The seawater intake must be situated in a position where it is not possible for the water being taken in to be affected by discharges into the sea of waste water, waste and engine coolant outlets;
 - (h) a suitable number of changing rooms, wash basins and toilets, the latter not opening directly onto areas where fishery products are prepared, processed or stored. The wash basins must be equipped with appliances for washing and drying the hands that comply with hygiene requirements; the wash-basin taps must not be hand-operable.
2. Areas used for the preparation and processing or freezing/quick-freezing of fishery products must have—
- (a) a non-slip floor that is also easy to clean and disinfect and equipped for easy drainage of water. Structures and fixtures must have limber holes that are large enough not to be obstructed by fish waste and to allow water to drain freely;
 - (b) walls and ceilings that are easy to clean, particularly where there are pipes, chains or electricity conduits;
 - (c) the hydraulic circuits must be arranged or protected in such a way as to ensure that it is not possible for any leakage of oil to contaminate fishery products;
 - (d) adequate ventilation and, where necessary, proper vapour extraction;
 - (e) adequate lighting;
 - (f) appliances for cleaning and disinfecting tools, equipment and fittings;
 - (g) appliances for cleaning and disinfecting the hands with taps that are not hand-operable and with single use towels.
3. Equipment and tools such as cutting benches, containers, conveyors, gutting or filleting machines etc. must be resistant to seawater corrosion, easy to clean and disinfect and well-maintained.
4. Factory vessels which freeze fishery products must have—
- (a) a refrigeration plant sufficiently powerful to lower the temperature rapidly so as to achieve a core temperature that complies with the specifications of these Regulations;
 - (b) refrigeration plants sufficiently powerful to keep fishery products in the storage holds at a temperature that complies with the specifications of these Regulations. The storage holds must be equipped with a temperature recording system placed so that it can easily be consulted.

Section II

Conditions of hygiene relating to on-board handling and storage of fishery products

1. A qualified person on board the factory vessel must be responsible for applying good fishery products manufacturing practices. That person shall have the authority to ensure that the provisions of these Regulations are applied and shall make available to inspectors the programme for inspecting

and checking critical points as applied on board, a register containing that person's comments and the temperature recordings that may be required.

2. The general conditions of hygiene applicable to areas and equipment shall be those laid down in Section IIA of Chapter III.

3. The general conditions of hygiene applicable to staff shall be those laid down in Section IIB of Chapter III.

4. Heading, gutting and filleting must be carried out under the conditions of hygiene laid down in paragraphs 2 to 4 of Section I of Chapter IV.

5. On-board processing of fishery products must be carried out under the conditions of hygiene laid down in paragraphs 2 and 3 of Section II, Section IV and Section V of Chapter IV.

6. Fishery products must be wrapped and packaged under the conditions of hygiene laid down in Chapter VI.

7. On-board storage of fishery products must be carried out under the conditions of hygiene laid down in paragraphs 1 and 2 of Chapter VIII.

8.—(1) Subject to sub-paragraph (2), any on-board processing (in particular any cooking) of shrimps or molluscs must be undertaken in accordance with such of—

- (a) the approved treatments set out in Commission Decision [93/25/EEC](#) approving certain treatments to inhibit the development of pathogenic micro-organisms in bivalve molluscs and marine gastropods; and
- (b) the standards and other obligations set out in Commission Decision [93/51/EEC](#) on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish,

as are appropriate in the particular circumstances of the case.

(2) For the purposes of Commission Decision [93/51/EEC](#)—

- (a) the reference in article 2 to a processing plant shall be treated as if it were a reference to a factory vessel;
- (b) the reference in article 3(1) to the requirements of article 6 of the Council Directive shall be treated as if it were a reference to regulation 28; and
- (c) the reference to competent authorities in the first indented paragraph of article 3(2) shall be treated as a reference to the food authority which approved the factory vessel in question.

CHAPTER II

REQUIREMENTS DURING AND AFTER LANDING

1. Unloading and landing equipment must be constructed of material which is easy to clean and disinfect and must be kept in a good state of repair and cleanliness.

2. During unloading and landing, contamination of fishery products must be avoided. It must in particular be ensured that—

- unloading and landing operations proceed rapidly;
- fishery products are placed without unnecessary delay in a protected environment at the temperature required on the basis of the nature of the product and, where necessary, in ice in transport, storage or market facilities, or in an establishment;

- equipment and handling practices that cause unnecessary damage to the edible parts of the fishery products are not authorised.
- 3.** Parts of auction or wholesale markets where fishery products are displayed for sale must—
- (a) be covered and have walls which are easy to clean;
 - (b) have waterproof flooring which is easy to wash and disinfect and laid in such a way as to facilitate the drainage of water and have a hygienic waste water disposal system;
 - (c) be equipped with sanitary facilities with an appropriate number of wash basins and flush lavatories. Wash basins shall be supplied with materials for cleaning the hands and single use hand towels;
 - (d) be well lit to facilitate the inspection of fishery products provided for in Chapter V;
 - (e) when they are used for display or storage of fishery products, not be used for other purposes; vehicles emitting exhaust fumes which may impair the quality of the fishery products must not be admitted to markets; undesirable animals must not be admitted;
 - (f) be cleaned regularly and at least after each sale, crates must, after each sale, be cleaned and rinsed inside and outside with potable water or clean seawater, where required, they must be disinfected;
 - (g) have displayed in a prominent position signs prohibiting smoking, spitting, eating and drinking;
 - (h) be closeable and be kept closed when the competent authority considers it necessary;
 - (i) have facilities to provide adequate water supplies satisfying the conditions laid down in paragraph 7 of Section I of Chapter III;
 - (j) have special watertight receptacles made of corrosion-resistant materials for fishery products which are unfit for human consumption;
 - (k) in so far as they do not have their own premises on-the-spot or in the immediate vicinity on the basis of the quantities displayed for sale, have, for the purposes of the competent authority, an adequately equipped lockable room and the equipment necessary for carrying out inspections.
- 4.** After lending or, where appropriate, after first sale, fishery products must be transported without delay under the conditions laid down in Chapter VIII to their place of destination.
- 5.** However, if the conditions laid down in paragraph 4 are not fulfilled, the markets in which fishery products may be stored before being displayed for sale or after being sold and pending transport to their place of destination must have sufficiently large cold rooms which satisfy the conditions laid down in paragraph 3 of Section I of Chapter III. In such cases, fishery products must be stored at a temperature approaching that of melting ice.
- 6.** The general conditions of hygiene laid down in Section II of Chapter III—with the exception of paragraph 1(a) of Section IIB—shall apply *mutatis mutandis* to the markets in which fishery products are displayed for sale or stored.
- 7.** The wholesale markets in which fishery products are displayed for sale or stored shall be subject to the same conditions as those laid down in paragraphs 3 and 5 of this Chapter and to those set out in paragraphs 4, 10 and 11 of Section I of Chapter III. The general conditions of hygiene laid down in Section II of Chapter III shall apply *mutatis mutandis* to wholesale markets.

CHAPTER III

GENERAL CONDITIONS FOR ESTABLISHMENTS ON LAND

Section I.

General conditions relating to premises and equipment

Each establishment shall afford at least the following facilities—

1. working areas of sufficient size for work to be carried out under adequate hygienic conditions. Their design and layout shall be such as to preclude contamination of the product and keep quite separate the clean and contaminated parts of the building;
2. in areas where products are handled, prepared and processed—
 - (a) waterproof flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of the water or provided with equipment to remove water;
 - (b) walls which have smooth surfaces and are easy to clean, durable and impermeable;
 - (c) ceilings or roof linings which are easy to clean;
 - (d) doors in durable materials which are easy to clean;
 - (e) adequate ventilation and, where necessary, good steam and water-vapour extraction facilities;
 - (f) adequate natural or artificial lighting;
 - (g) an adequate number of facilities for cleaning and disinfecting hands. In work rooms and lavatories, taps must not be hand-operable. These facilities must be provided with single use hand towels;
 - (h) facilities for cleaning plant, equipment and utensils;
3. in cold rooms where fishery products are stored—
 - the provisions set out under paragraph 2(a), (b), (c), (d) and (f);
 - where necessary, a sufficiently powerful refrigeration plant to keep products at temperatures prescribed in these Regulations;
4. appropriate facilities for protection against pests such as insects, rodents, birds etc.;
5. instruments and working equipment such as cutting tables, containers, conveyor belts and knives made of corrosion-resistant materials, easy to clean and disinfect;
6. special watertight, corrosion-resistant containers for fishery products not intended for human consumption and premises for the storage of such containers if they are not emptied at least at the end of each working day;
7. facilities to provide adequate supplies of potable water, or alternatively of clean seawater or seawater treated by an appropriate system, under pressure and in sufficient quantity. However, by way of exception, a supply of non-potable water is permissible for the production of steam, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products. Non-potable water pipes must be clearly distinguishable from those used for potable water or clean seawater;
8. hygienic waste water disposal system;
9. an adequate number of changing-rooms with smooth, water-proof, washable walls and floor, wash basins and flush lavatories. The latter may not open directly onto the work rooms. The wash basins must have materials for cleaning the hands and disposable towels; the wash basin taps must not be hand-operable;
10. if the volume of products treated requires regular or permanent presence an adequately equipped lockable room for the exclusive use of the inspection service;

11. adequate facilities for cleaning and disinfecting means of transport. However, such facilities are not compulsory if there is a requirement for the means of transport to be cleaned and disinfected at facilities officially authorised by the food authority;

12. establishments keeping live animals such as crustaceans and fish must have appropriate fittings ensuring the best survival conditions provided with water of a quality such that no harmful organisms or substances are transferred to the animals.

Section II

General conditions of hygiene

A. General conditions of hygiene applicable to premises and equipment

1. Floors, walls and partitions, ceilings and roof linings, equipment and instruments used for working on fishery products must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the products.

2. Rodents, insects and other vermin must be systematically exterminated in the premises or on the equipment; rodenticides, insecticides, disinfectants and any other potentially toxic substances must be stored in premises or cupboards which can be locked; their use must not present any risk of contamination of the products.

3. Working areas, instruments and working equipment must be used only for work on fishery products. However, following authorization by the food authority they may be used at the same time or other times for work on other foodstuffs.

4. Potable water or clean seawater must be used for all purposes. However, by way of an exception, non-potable water may be used for steam production, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products.

5. Detergents, disinfectants and similar substances must be acceptable to the food authority and used in such a way that they do not have adverse effects on the machinery, equipment and products.

B. General conditions of hygiene applicable to staff

1. The highest possible standard of cleanliness is required of staff. More specifically—

- (a) staff must wear suitable clean working clothes and headgear which completely encloses the hair. This applies particularly to persons handling exposed fishery products;
- (b) staff assigned to the handling and preparation of fishery products must be required to wash their hands at least each time work is resumed; wounds to the hands must be covered by a waterproof dressing;
- (c) smoking, spitting, eating and drinking in work and storage premises of fishery products must be prohibited.

2. The employer shall take all the requisite measures to prevent persons liable to contaminate fishery products from working on and handling them, until there is evidence that such persons can do so without risk. When recruited, any person working on and handling fishery products shall be required to prove, by a medical certificate, that there is no impediment to such employment.

CHAPTER IV

SPECIAL CONDITIONS FOR HANDLING FISHERY PRODUCTS ON SHORE

Section I

Conditions for fresh products

1. Where chilled, unpackaged products are not dispatched, prepared or processed immediately after reaching the establishment, they must be stored or displayed under ice in the establishment's cold room. Re-icing must be carried out as often as is necessary; the ice used, with or without salt, must be made from potable water or clean seawater and be stored under hygienic conditions in receptacles provided for the purpose; such receptacles must be kept clean and in a good state of repair. Pre-packed fresh products must be chilled with ice or mechanical refrigeration plant creating similar temperature conditions.

2. If they are not carried out on board, operations such as heading and gutting must be carried out hygienically. The products must be washed thoroughly with potable water or clean seawater immediately after such operations.

3. Operations such as filleting and slicing must be carried out in such a way as to avoid the contamination or spoilage of fillets and slices, and in a place other than that used for heading and gutting operations. Fillets and slices must not remain on work tables any longer than is necessary for their preparation and must be protected from contamination by appropriate packaging. Fillets and slices to be sold fresh must be chilled as quickly as possible after preparation.

4. Guts and parts that may constitute a danger to public health must be separated from and removed from the vicinity of products intended for human consumption.

5. Containers used for the dispatch or storage of fresh fishery products must be designed in such a way as to ensure both their protection from contamination and their preservation under sufficiently hygienic conditions and, more particularly, they must provide adequate drainage of melt water.

6. Unless special facilities are provided for the continuous disposal of waste, the latter must be placed in leakproof, covered containers which are easy to clean and disinfect. Waste must not be allowed to accumulate in working areas. It must be removed either continuously or as soon as the containers are full and at least at the end of each working day in the containers or to the premises referred to in paragraph 6 of Section I of Chapter III. The containers, receptacles and/or premises set aside for waste must always be thoroughly cleaned and, if appropriate, disinfected after use. Waste stored there must not constitute a source of contamination for the establishment or of pollution of its surroundings.

Section II

Conditions for frozen products

1. Plants must have—

- (a) freezing equipment sufficiently powerful to achieve a rapid reduction in the temperature so that the temperature laid down in these Regulations can be obtained in the product;
- (b) freezing equipment sufficiently powerful to keep products in storage rooms at a temperature not exceeding those laid down in these Regulations, whatever the ambient temperature may be,

however, for technical reasons related to the method of freezing and to the handling of such products, for whole fish frozen in brine and intended for canning, higher temperatures than those laid down in these Regulations are acceptable, although they may not exceed -9°C .

2. Fresh products to be frozen or quick-frozen must comply with the requirements of Section I of this Chapter.

3.—(1) Storage rooms must have a temperature recording device in a place where it can easily be read. The temperature sensor of the recorder must be located in the area furthest away from the cold source, i.e. where the temperature in the storage room is the highest.

(2) Temperature charts must be available for inspection by the supervisory authorities at least during the period in which the products are stored.

Section III

Conditions for thawing products

Establishments that carry out thawing operations must comply with the following requirements—

1. fishery products must be thawed under hygienic conditions; their contamination must be avoided and there must be adequate drainage for any melt water produced. During thawing, the temperature of the products must not increase excessively;

2. after thawing, fishery products must be handled in accordance with the requirements of these Regulations. When they are prepared or processed, these operations must be carried out without delay. If they are put directly onto the market, particulars as to the thawed state of the fish must be clearly marked on the packaging in accordance with the Food Labelling Regulations 1996.

Section IV

Conditions for processed products

1. Fresh, frozen and thawed products used for processing must comply with the requirements set out in Sections I, II or III of this Chapter.

2.—(1) Where the processing treatment is carried out to inhibit the development of pathogenic micro-organisms, or if it is a significant factor in the preservation of the product, the treatment must be a scientific process which produces safe food, or in the case of a treatment of products referred to in Parts II and III of Chapter I of Schedule 2 which have not been relayed or purified, such treatment must be a form of treatment mentioned in the Annex to Commission Decision [93/25/EEC](#) approving certain treatments to inhibit the development of pathogenic micro-organisms in bivalve molluscs and marine gastropods.

2. The person responsible for an establishment must keep a register of the processing carried out. Depending on the type of process employed, details such as heating time and temperature, salt content, pH, water content, etc. must be monitored and controlled. Records must be kept at least for the expected storage life of the products and be available to the food authority.

3. For products which are preserved for a limited period by a treatment such as salting, smoking, drying or marinating, the appropriate conditions for storage must be clearly marked on the packaging, in accordance with the Food Labelling Regulations 1996.

Canning

4. In the case of fishery products which have been subjected to sterilisation in hermetically sealed containers—

- (a) the water used for the preparation of cans must be potable water;
- (b) the process used for the heat treatment must be appropriate, having regard to such major criteria as the heating time, temperature, filling, size of containers etc., a record of which must be kept; the heat treatment must be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms. The heating equipment must be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment. Potable water must be used to cool containers after heat treatment, without prejudice to the presence of any chemical additives used in accordance with good technological practice to prevent corrosion of the equipment and containers;

- (c) further checks must be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment, *viz*—
 - incubation tests: incubation must be carried out at 37°C for seven days or at 35°C for ten days, or at any other equivalent combination;
 - microbiological examination of contents and containers in the establishment's laboratory or in a laboratory recognised by the food authority;
- (d) samples must be taken of production each day at predetermined intervals, to ensure the efficacy of sealing or of any other method of hermetic closure. For that purpose, appropriate equipment must be available for the examination of cross-sections of the can-seams;
- (e) checks are carried out in order to ensure that containers are not damaged;
- (f) all containers which have undergone heat treatment under practically identical conditions must be given a batch identification mark, in accordance with the Food (Lot Marking) Regulations 1996(72).

Smoking

5. Smoking must be carried out in separate premises or a special place equipped, if necessary, with a ventilation system to prevent the smoke and heat from the combustion from affecting other premises or places where fishery products are prepared, processed or stored—

- (a) materials used to produce smoke for the smoking of fish must be stored away from the place of smoking and must be used in such a way that they do not contaminate the products;
- (b) materials used to produce smoke by burning wood that has been painted, varnished, glued or has undergone any chemical preservation treatment must be prohibited;
- (c) after smoking, products must be cooled rapidly to the temperature required for their preservation before being packaged.

Salting

6. As regards salting—

- (a) salting operations must take place in different premises and sufficiently removed from the premises where the other operations are carried out;
- (b) salt used in the treatment of fishery products must be clean and stored in such a way as to preclude contamination. It must not be re-used;
- (c) any container used for salting or brining must be constructed in such a way as to preclude contamination during the salting or brining process;
- (d) containers or areas used for salting or brining must be cleaned before use.

Cooked crustacean and molluscan shellfish

7. Crustaceans and molluscan shellfish must be cooked as follows—

- (a) any cooking must be followed by rapid cooling. Water used for this purpose must be potable water or clean seawater. If no other method of preservation is used, cooling must continue until the temperature approaching that of melting ice is reached;
- (b) shelling or shucking must be carried out under hygienic conditions avoiding the contamination of the product. Where such operations are done by hand, workers must pay particular attention to the washing of their hands and all working surfaces must be cleaned

(72) S.I. 1996/1502.

thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected after each working day. After shelling or shucking, cooked products must immediately be frozen or kept chilled at a temperature which will preclude the growth of pathogens, and be stored in appropriate premises;

- (c) every manufacturer must carry out microbiological checks at regular intervals, complying with the standards and other obligations set out in Commission Decision [93/51/EEC](#) on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish, but for the purposes of that Commission Decision—
 - (i) the reference in article 3(1) to the requirements of article 6 of the Council Directive shall be treated as if it were a reference to regulation 28, and
 - (ii) the reference in the first indented paragraph of article 3(2) to competent authorities shall be treated as a reference to the food authority which approved the establishment in question.

Mechanically recovered fish flesh

- 8. The mechanical recovery of fish flesh must be carried out under the following conditions—
 - (a) mechanical recovery of gutted fish must take place without undue delay after filleting, using raw materials free of guts. Where whole fish are used, they must be gutted and washed beforehand;
 - (b) the machinery must be cleaned at frequent intervals and at least every two hours;
 - (c) after recovery, mechanically recovered flesh must be frozen as quickly as possible or incorporated in a product intended for freezing or stabilising treatment.

Section V

Conditions concerning parasites

1.—(1) During production and before they are released for human consumption, fish and fish products must be subject to a visual inspection for the purpose of detecting and removing any parasites that are visible.

(2) Fish or parts of fish which are obviously infested with parasites, and which are removed, must not be placed on the market for human consumption.

(3) This inspection must be carried out in accordance with the rules set out in the Commission Decision [93/140/EEC](#) laying down the detailed rules relating to the visual inspection for the purpose of detecting parasites in fishery products, but for the purposes of that Commission Decision—

- (a) the competent authority to which article 4 of that Decision refers is the food authority; and
- (b) the provisions referred to in that article (the provisions in accordance with which a sampling plan must be drawn up) are those specified in regulation 28(4).

2. The fish and fish products referred to in paragraph 1(1) of this Section which are to be consumed as they are must, in addition, be subjected to freezing at a temperature of not more than -20°C in all parts of the product for not less than 24 hours. Products subjected to this freezing process must be either raw or finished.

3. Fish and fish products which are subject to the conditions in paragraph 2 are—

- (a) fish to be consumed raw or almost raw, e.g. raw herring 'maatje';
- (b) the following species, if they are to undergo a cold smoking process at which the internal temperature of the fish is less than 60°C —
 - herring;

- mackerel;
 - sprat;
 - (wild) Atlantic and Pacific salmon;
- (c) marinated and/or salted herring where this process is insufficient to kill the larvae of nematodes.
4. Manufacturers must ensure that fish and fish products listed in paragraph 3, or the raw materials for use in their manufacture, are subjected to the treatment described in paragraph 2 prior to their release for consumption.
5. The fishery products listed in paragraph 3 must, when they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have undergone.

CHAPTER V

HEALTH CONTROL AND MONITORING OF PRODUCTION CONDITIONS

Section I

General monitoring

Each food authority shall establish the following arrangements in order to establish whether the requirements laid down in the Regulations are complied with, and such arrangements will include, in particular—

1. a check on the fishing vessels, on the understanding that such a check may be carried out during the stay in port;
2. a check on the conditions of landing and first sale;
3. an inspection at regular intervals of establishments and factory vessels (wherever registered) to check in particular—
 - (a) whether the conditions for approval (where applicable) are still fulfilled;
 - (b) whether the fishery products are handled correctly;
 - (c) the cleanliness of the premises, facilities and instruments and staff hygiene;
 - (d) whether any necessary identification marks are put on correctly;
4. an inspection of the wholesale and auction markets;
5. a check on storage and transport conditions.

Section II

Special Checks

Organoleptic checks

1.—(1) Without prejudice to the derogations provided for by Council Regulation (EEC) No. 103/76⁽⁷³⁾ laying down common marketing standards for certain fresh or chilled fish, as amended⁽⁷⁴⁾, each batch of fishery products must be submitted for inspection by the food authority at the time of landing or before first sale to check whether they are fit for human consumption. This inspection comprises an organoleptic check carried out by sampling.

⁽⁷³⁾ OJ No. L20, 28.1.76, p.29.

⁽⁷⁴⁾ The Regulation was last amended by Council Regulation (EEC) No. 1935/93 (OJ No. L176, 20.7.93, p.3).

(2) Fishery products complying, as far as the freshness criteria are concerned, with the common marketing standards already laid down pursuant to article 2 of Council Regulation (EEC) No. 3759/92⁽⁷⁵⁾ on the common organisation of the market in fishery products, as amended⁽⁷⁶⁾, are considered to fulfil the organoleptic requirements necessary for compliance with the provisions of these Regulations.

(3) The organoleptic examinations must be repeated after the first sale of fishery products, if it is found that the requirements of these Regulations have not been complied with or when considered necessary. After the first sale, fishery products must at least comply with the minimum freshness requirements of Regulation (EEC) No. 3687/91⁽⁷⁷⁾, as amended.

(4) If the organoleptic examination reveals that the fishery products are not fit for human consumption, measures must be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption.

(5) If the organoleptic examination reveals any doubt as to the freshness of the fishery products, use may be made of chemical checks or microbiological analysis.

Parasite checks

2.—(1) Before they are released for human consumption, fish and fish products must be subject to a visual inspection on behalf of the food authority, by way of sample, for the purpose of detecting any parasites that are visible.

(2) Fish or parts of fish which are obviously infested with parasites must not be placed on the market for human consumption.

Chemical checks

3A. When the chemical checks are to be carried out by the food authority samples must be taken and subjected to laboratory analysis for the control of the following parameters—

(a) TVB-N (Total Volatile Basic-Nitrogen), in respect of which—

(i) the following TVB-N limits must not be exceeded—

— 25 milligrams of nitrogen per 100 grams of flesh for the following species:

- *Sebastes* spp.;
- *Helicolenus dactylopterus*;
- *Sebastichthys capensis*;

— 30 milligrams of nitrogen per 100 grams of flesh for the following species:

- all species belonging to the *Pleuronectidae* family (with the exception of halibut: *Hippoglossus* spp.);

— 35 milligrams of nitrogen per 100 grams of flesh for the following species:

- *Salmo salar*;
- species belonging to the *Merlucciidae* family;
- species belonging to the *Gadidae* family;

(ii) the reference method to be used for checking the TVB-N limit is the method involving distillation of an extract deproteinized by perchloric acid as set out in

⁽⁷⁵⁾ OJ No. L388, 31.12.92, p.10.

⁽⁷⁶⁾ The Regulation was last amended by Council Regulation (EC) No. 3318/94 (OJ No. L350, 31.12.94, p.15).

⁽⁷⁷⁾ OJ No. L354, 23.12.91, p.1.

- Annexes II and III of Commission Decision [95/149/EC](#) of 8th March 1995(78) (“the Decision”) read together with article 3 of the Decision;
- (iii) the routine methods which may be used to check the TVB-N limit are those specified in article 2(3) of the Decision;
 - (iv) the sample must consist of about 100 grams of flesh, taken from at least 3 different points and mixed together by grinding;
- (b) TMA-N (Trimethylamine-Nitrogen);
- (c) Histamine, in respect of which—
- (i) nine samples must be taken from each batch; these must fulfil the following requirements—
 - the mean value must not exceed 100 parts per million (“ppm”);
 - two samples may have a value of more than 100 ppm but less than 200 ppm;
 - no sample may have a value exceeding 200 ppm;
 - (ii) these limits apply only to fish species of the following families: Scombridae, Clupeidae, Engraulidae and Coryphaenidae; however, fish belonging to these families which have undergone enzyme ripening treatment in brine may have higher histamine levels but not more than twice the above values; examinations must be carried out in accordance with reliable, scientifically recognised methods, such as high-performance liquid chromatography (HPLC).

Contaminants present in the aquatic environment

3B.—(1) Without prejudice to the Community rules concerning water protection and management, and in particular those concerning pollution of the aquatic environment, fishery products must not contain in their edible parts contaminants present in the aquatic environment such as heavy metals and organochlorinated substances at such a level that the calculated dietary intake exceeds the acceptable daily or weekly intake for humans.

(2) The Ministers shall establish a monitoring system to check the levels of such contamination of fishery products.

Microbiological analyses

4.—(1) Subject to sub-paragraph (2), the microbiological standards applicable to the production of cooked crustaceans and molluscan shellfish are those set out in Commission Decision [93/51/EEC](#) on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish.

(2) For the purposes of sub-paragraph (1), the reference in article 2 of Commission Decision [93/51/EEC](#) to a processing plant shall be treated as if it were a reference to an approved establishment or factory vessel.

5.—(1) The sampling programme to be established in accordance with article 3 of Commission Decision [93/51/EEC](#), as provided for in—

- (a) paragraph 8(1)(b) of Section II of Chapter I; and
- (b) paragraph 7(c) of Section IV of Chapter IV,

shall be monitored by the food authority which approved the establishment or factory vessel in question.

(78) OJ No. L97, 29.4.95, p.84.

- (2) For the purposes of sub-paragraph (1)—
- (a) the reference in article 3(1) of Commission Decision [93/51/EEC](#) to the requirements of article 6 of the Fishery Products Directive shall be treated as if it were a reference to the requirements of regulation 28; and
 - (b) the reference in the first indented paragraph of article 3(2) of that Commission Decision of competent authorities shall be treated as if it were a reference to the food authority mentioned in sub-paragraph (1).

CHAPTER VI

PACKAGING

1. Packaging must be carried out under satisfactory conditions of hygiene, to preclude contamination of the fishery products.
2. Packaging materials and products liable to enter into contact with fishery products must comply with all the rules of hygiene, and in particular—
 - they must not be such as to impair the organoleptic characteristics of the fishery product;
 - they must not be capable of transmitting to the fishery products substances harmful to human health;
 - they must be strong enough to protect the fishery products adequately.
3. With the exception of certain containers made of impervious, smooth and corrosion-resist ant material which are easy to clean and disinfect, which may be re-used after cleaning and disinfecting, packaging materials may not be re-used. Packaging materials used for fresh fishery products which are held under ice must provide adequate drainage for melt water.
4. Unused packaging materials must be stored in places away from the production area and be protected from dust and contamination.

CHAPTER VII

IDENTIFICATION MARKS

PART I

PRODUCTS PREPARED ON OR AFTER 29 APRIL 1998

1. This Part of this Chapter shall apply to all products other than those which were prepared before these Regulations come into force and in respect of which the conditions set out in Part II of this Chapter are satisfied.
- 2.—(1) Without prejudice to the provisions of the Food Labelling Regulations 1996, it must be possible to trace for inspection purposes the establishment of dispatch of consignments of fishery products, by means either of the labelling or of the accompanying documents. For that purpose, the following information must appear on the packaging or, in the case of a non-packaged product, in the accompanying documents—
 - the country of dispatch, which may be written out in full or shown as an abbreviation, using capital letters, e.g. for the member States of the European Community, one of the following:
 - B—DK—D—EL—E—F—IRL—I—L—NL—P—UK—AT—FI—SE;
 - identification of—

- (i) the establishment or factory vessel by its official approval number,
 - (ii) in the case of marketing from a freezer vessel covered by, as respects Great Britain, paragraph 7 of Part II of Schedule 4 or, as respects any other part of the European Economic Area, point 7 of Annex II to the Fishing Vessels Directive, the identification number of the vessel, or
 - (iii) the registered wholesale or auction market by its registration number, from which the products were dispatched;
- one of the following abbreviations:
- CE—EC—EG—EK—EF—EY.
- (2) All the letters and figures must be fully legible and grouped together on the packaging in a place where they are visible from the outside without any need to open the packaging.

PART II

PRODUCTS PREPARED BEFORE 29 APRIL 1998

1. This Part of this Chapter applies to products which were prepared before these Regulations come into force and in respect of which the conditions set out Part I of this Chapter are not satisfied, but only if the conditions set out in this Part of this Chapter are satisfied in relation to those products.

2. Without prejudice to the requirements of the Food Labelling Regulations 1996, it must be possible to trace for inspection purposes the establishment of dispatch of consignments of fishery products, by means of either labelling or the accompanying documents. For that purpose, in respect of each consignment of fishery products the following information must appear on the packaging or in the accompanying documents—

- the country of dispatch;
- identification of the establishment or factory vessel of dispatch by its approval number or, in the case of separate registering of auction or wholesale markets, the registration number of the auction or wholesale market.

CHAPTER VIII

STORAGE AND TRANSPORT

1. Fishery products must, during storage and transport, be kept at the temperatures laid down in these Regulations, and in particular—

- (a) fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products must be kept at a temperature approaching that of melting ice;
- (b) frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned foods, must be kept at an even temperature of -18°C or less in all parts of the product, after temperature stabilisation, and allowing for the possibility of brief upward fluctuations of not more than 3°C , during transport.

2. Where frozen fishery products are transported from a cold storage plant to an approved establishment to be thawed on arrival for the purposes of either preparation or processing and where the distance to be covered does not exceed 50 km or, if the distance is greater, the anticipated duration of the journey is less than one hour, the food authority may grant a derogation from the conditions laid down in paragraph 1(b).

3. Products may not be stored or transported with other products which may contaminate them or affect their hygiene, unless they are packaged in such a way as to provide satisfactory protection.

4. Vehicles used for the transport of fishery products must be constructed and equipped in such a way that the temperatures laid down in these Regulations can be maintained throughout the period of transport. If ice is used to chill the fishery products, adequate drainage must be provided in order to ensure that water from melted ice does not stay in contact with the products. The inside surfaces of the means of transport must be finished in such a way that they do not adversely affect the fishery products. They must be smooth and easy to clean and disinfect.

5. Means of transport used for fishery products may not be used for transporting other products likely to impair or contaminate fishery products, except where the fishery products can be safeguarded against contamination by such transport being thoroughly cleaned and disinfected immediately prior to each occasion it is used for fishery products.

6. Fishery products may not be transported in a vehicle or container which is not clean or which should have been disinfected.

7. The transport conditions of fishery products to be placed on the market alive must not adversely affect the fishery products.

SCHEDULE 4

Regulations 22(1), (2) and (4) and 36(1)(a)

(i)

HYGIENE CONDITIONS FOR FISHING VESSELS (BASED ON THE CORRESPONDING PROVISIONS OF THE ANNEXES TO THE FISHING VESSELS DIRECTIVE)

PART I

General hygiene conditions applicable to fishery products on board fishing vessels

1. The sections of vessels or the containers reserved for the storage of fishery products must not contain objects or products liable to transmit harmful properties or abnormal characteristics to the foodstuffs. These sections or containers must be so designed as to allow them to be cleaned easily and to ensure that melt water cannot remain in contact with the fishery products.

2. When used, the sections of vessels or the containers reserved for the storage of fishery products must be completely clean and, in particular, must not be capable of being contaminated by the fuel used for the propulsion of the vessel or by bilge water.

3. As soon as they are taken on board, the fishery products must be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, the water used must be either fresh water complying with the parameters set out in—

- (a) in England and Wales, Tables B and C of Schedule 2 to the Water Supply (Water Quality) Regulations 1989(79); or
- (b) in Scotland, Tables B and C of Schedule 2 to the Water Supply (Water Quality) (Scotland) Regulations 1990(80),

or clean seawater, so as not to impair their quality or wholesomeness.

(79) S.I. 1989/1147; there are no relevant amending instruments.

(80) S.I. 1990/119; there are no relevant amending instruments.

4. The fishery products shall be handled and stored in such a way as to prevent bruising. The use of spiked instruments shall be tolerated for the moving of large fish or fish which might injure the handler, provided the flesh of these products is not damaged.

5. Fishery products other than those kept alive must undergo cold treatment as soon as possible after loading. However, in the case of fishing vessels where cooling is not possible from a practicable point of view, the fishery products must not be kept on board for more than 8 hours.

6. Ice used for the chilling of products must be made from potable water or clean seawater. Before use, it must be stored under conditions which prevent its contamination.

7. After the fishery products have been unloaded, the containers, equipment and sections of vessels which are directly in contact with the fishery products must be cleaned with potable water or clean seawater.

8. Where fish is headed and/or gutted on board, such operations must be carried out hygienically and the products must be washed immediately and thoroughly with potable water or clean seawater. The viscera and parts which may pose a threat to public health must be removed and set apart from products intended for human consumption. Livers and roes intended for human consumption must be refrigerated or frozen.

9. Equipment used for gutting, heading and the removal of fins, and containers and equipment in contact with the fishery products, must be made of or coated with a material which is waterproof, resistant to decay, smooth and easy to clean and disinfect. When used they must be completely clean.

10. Staff assigned to the handling of fishery products shall be required to maintain a high standard of cleanliness for themselves and their clothes.

PART II

Additional hygiene conditions applicable to article 1.2 fishing vessels

1. Fishing vessels must be equipped with holds, tanks or containers for the storage of refrigerated or frozen fishery products at the temperature laid down by these Regulations. These holds shall be separated from the machinery space and the quarters reserved for the crew by partitions which are sufficiently impervious to prevent any contamination of the stored fishery products.

2. The inside surface of the holds, tanks or containers shall be waterproof and easy to wash and disinfect. It shall consist of a smooth material or, failing that, smooth paint maintained in good condition, not being capable of transmitting to the fishery products substances harmful to human health.

3. The holds shall be designed to ensure that melt water cannot remain in contact with the fishery products.

4. Containers used for the storage of products must ensure their preservation under satisfactory conditions of hygiene and, in particular, allow drainage of melt water. When used they must be completely clean.

5. The working decks, the equipment and the holds, tanks and containers shall be cleaned each time they are used. Potable water or clean seawater shall be used for this purpose. Disinfection, the removal of insects or rat extermination shall be carried out whenever necessary.

6. Cleaning products, disinfectants, insecticides and all potentially toxic substances shall be stored in locked premises or cupboards. Their use must not present any risk of contamination of the fishery products.

7. If fishery products are frozen on board, this operation must be carried out in accordance with the conditions laid down in paragraphs 1 and 3 of Section II of Chapter IV of Schedule 3. Where freezing in brine is used, the brine shall not be a source of contamination for the fish.

8. Vessels equipped for chilling of fishery products in cooled seawater, either chilled by ice (CSW) or refrigerated by mechanical means (RSW), shall comply with the following requirements—

- (a) tanks must be equipped with adequate seawater filling and drainage installations and must incorporate devices for achieving uniform temperature throughout the tanks;
- (b) tanks must have a means of recording temperature connected to a temperature sensor positioned in the section of the tank where temperatures are highest;
- (c) the operation of the tank or container system must secure a chilling rate which ensures the mix of fish and seawater reaches 3°C at the most 6 hours after loading and 0°C at the most after 16 hours;
- (d) after each unloading, the tanks, circulation systems and containers must be completely emptied and thoroughly cleaned using potable water or clean seawater. They should only be filled with clean seawater;
- (e) the date and the number of the tank must be clearly indicated on the temperature recordings which must be kept available for the control authorities.

SCHEDULE 5

Regulation 59(1)

REVOCATIONS

<i>Column (1)</i>	<i>Column (2)</i>	<i>Column (3)</i>
The Food Safety (Fishery Products) (Derogations) Regulations 1992	S.I. 1992/1507	The whole Regulations
The Food Safety (Live Bivalve Molluscs) (Derogations) Regulations 1992	S.I. 1992/1508	The whole Regulations
The Food Safety (Fishery Products) Regulations 1992	S.I. 1992/3163	The whole Regulations
The Food Safety (Live Bivalve Molluscs and Other Shellfish) Regulations 1992	S.I. 1992/3164	The whole Regulations
The Food Safety (Fishery Products on Fishing Vessels) Regulations 1992	S.I. 1992/3165	The whole Regulations
The Food Safety (Live Bivalve Molluscs and Other Shellfish) (Import Conditions and Miscellaneous Amendments) Regulations 1994	S.I. 1994/2782	The whole Regulations
The Food Safety (Fishery Products) (Import Conditions and Miscellaneous	S.I. 1994/2783	The whole Regulations

<i>Column (1)</i>	<i>Column (2)</i>	<i>Column (3)</i>
Amendments) Regulations 1994		
The Food Safety (General Food Hygiene) Regulations 1995	S.I. 1995/1763	Paragraphs 3 to 7 of Schedule 2
The Food Safety (Fishery Products and Live Bivalve Molluscs and Other Shellfish) (Miscellaneous Amendments) Regulations 1996	S.I. 1996/1547	The whole Regulations
The Products of Animal Origin (Import and Export) Regulations 1996	S.I. 1996/3124	Paragraphs 4 and 5 of Schedule 6

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations consolidate with amendments the regulations which were made to give effect to the provisions of Council Directive [91/492/EEC](#) laying down the health conditions for the production and placing on the market of live bivalve molluscs, as adapted for the purposes of the EEA Agreement and as amended, and Council Directive [91/493/EEC](#) laying down the health conditions for the production and placing on the market of fishery products, as adapted and as amended, together with a number of Commission Decisions made under these two Council Directives. These Regulations also consolidate with amendments the regulations which were made to give effect to the provisions of Council Directive [92/48/EEC](#) laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with article 3.1(a)(i) of Council Directive [91/493/EEC](#), and to the measures set out in paragraph 1 of Section II of Chapter III of the Annex to Council Directive [85/73/EEC](#) on the financing of veterinary inspections and controls covered by Directives [89/662/EEC](#), [90/425/EEC](#), [90/675/EEC](#) and [91/496/EEC](#), which is annexed to Council Directive [96/43/EC](#) amending and consolidating Directive [85/73/EEC](#) in order to ensure financing of veterinary inspections and controls on live animals and certain animal products and amending Directives [90/675/EEC](#) and [91/496/EEC](#) (OJ No. L162, 1.7.96, p.1). In addition, these Regulations give effect to the amendments made by Council Directive [95/71/EC](#) to the Annex to Directive [91/493/EEC](#) (health conditions for the production and placing on the market of fishery products; *see* Schedule 3 to these Regulations).

The Regulations are made under the Food Safety Act 1990, except for Part V which is made under section 2(2) of the European Communities Act 1972. Part V implements the amendments made by Council Directive [96/43/EC](#) to which reference is made above.

Part I of the Regulations contains general provisions relating to citation, commencement and interpretation (regulations 1 and 2).

Part II contains the provisions relating to the production and placing on the market of live shellfish (defined as live bivalve molluscs, echinoderms, tunicates and marine gastropods, and so excluding

crustaceans) in Great Britain. The Ministers have the power to designate certain areas as designated production areas for live bivalve molluscs; relaying areas (areas where bivalve molluscs may be relaid after harvesting to remove contamination) are designated by food authorities (regulation 3). The Ministers may also designate certain areas as prohibited areas for live shellfish production of various kinds (regulation 4) and food authorities may make temporary prohibitions concerning layings (regulation 7). Collecting shellfish from areas subject to a relevant prohibition is an offence (regulation 8). The Ministers may vary and revoke their designations of production and prohibited areas, and food authorities may vary and revoke their designations of relaying areas (regulation 5). The Ministers have an obligation to keep an up-to-date list of designated production and relaying areas (regulation 6).

Part II also contains special requirements relating to the harvesting, transporting and relaying of live shellfish (regulation 9), and to the operation of dispatch and purification centres, which need to be approved by the local food authority (regulations 10 to 13). There are also special rules for the variation and revocation of approvals of such centres (regulation 14 and 15).

Part II also contains special rules for the wrapping, unwrapping, repackaging, storage and transportation of live shellfish within Great Britain (regulations 16 to 18), and detailed obligations relating to the placing on the market of live shellfish (regulation 19). There is, however, an exemption scheme from most of the requirements of this Part which relates to local sales of small quantities of live shellfish (regulation 20).

Part III of the Regulations deals with the production and placing on the market of fishery products. There is a registration scheme for fishing vessels on board which shrimps and molluscs are cooked, there are hygiene rules for all fishing vessels, and there are special additional rules for certain longer range vessels (regulations 21 and 22). Factory vessels and establishments on land which are involved in the production of fishery products both have to be approved by the local food authority (regulations 23 and 24), and their proprietors have to comply with various specified requirements (regulation 28). Masters of third country factory vessels also have an additional obligation to give the food authority at their port of arrival at least 24 hours notice before they arrive (regulation 29). Auction and wholesale markets also have to be registered, again by the food authority (regulations 25 and 26), and their proprietors also have to comply with certain specified requirements (regulation 30). Provision is also made for appeals against decisions to refuse to approve or register, or to grant approvals but only subject to conditions (regulation 27), and there are procedures (including appeals procedures) relating to the variation and revocation of approvals and the cancellation of market registrations (regulations 31 and 32).

Part III also contains a special rule relating to the timing of gutting of fishery products (regulation 33), and rules relating to the packaging, storage and transportation of fishery products within Great Britain (regulations 34 and 35). There are also detailed obligations relating to the placing on the market of all types of fishery products (regulation 36), with special additional rules relating to the placing on the market of aquaculture products (regulation 37), processed shellfish (regulation 38) and live fish and other aquatic animals (regulation 39). There is, however, a prohibition on selling or supplying in the course of a business certain poisonous fishery products (regulation 40). As with live shellfish, there is an exemption scheme from most of the requirements of this Part which relates essentially to local sales of small quantities of products (regulation 41).

Part IV of the Regulation deals with the import conditions for fishery products and live shellfish (regulations 42 to 45), but there is an exemption from this Part for certain private consignments (regulation 46).

Part V deals with inspection charges for third country direct landings (products landed from third country vessels which have or had not been on land prior to their importation into the European Community). The charge is paid by the first purchaser to the vendor, and an equivalent amount is then passed by the vendor to the food authority (regulations 48 and 49). Some reductions are available in relation to part of this charge where checks are facilitated by specified factors (regulation 50).

The vendor is also under an obligation to make a written return in respect of his weekly sales (regulation 51).

Part VI contains more general provisions. These include provisions relating to the health control responsibilities of the Ministers and food authorities (regulation 52), enforcement responsibilities (regulations 54 and 56), certification of shellfish and fishery products as failing to comply with food safety requirements (regulation 57), amendments to other Regulations (regulation 58), and revocations (regulation 59). Regulation 59 also contains a transitional provision.

An assessment of the cost to business of complying with these Regulations has been prepared and copies may be obtained from the Department of Health, Room 501A, Skipton House, 80 London Road, London SE1 6LW, or the Scottish Office Agriculture, Environment and Fisheries Department, Room 358, Pentland House, 47 Robb's Loan, Edinburgh EH14 1TW. A copy has also been placed in the library of each of the Houses of Parliament.