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STATUTORY INSTRUMENTS

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**1998 No. 994**

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

**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.

**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<sup>(1)</sup>) 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;

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<sup>(1)</sup> See regulation 55(4).

(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](#)(2), 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—

(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(3) as adjusted by the Protocol signed at Brussels on 17th March 1993(4);

“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

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(2) OJNo. L281, 10.11.79, p.47; this Directive was last amended by Council Directive [91/692/EEC](#) (OJNo. L377, 31.12.91, p.48).

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

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

(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](#)(**5**) 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(**6**) and as amended(**7**);

“the Fishing Vessels Directive” means Council Directive [92/48/EEC](#)(**8**) 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—
    - (aa) if it is situated in a port health district, the port health authority for that district, or
    - (bb) 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(**9**) in whose area that part is situated;

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

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

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

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

(9) [1994 c. 39](#).

“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](#)(10) 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(11);

“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](#)(12) 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(13) and as amended(14);

“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,

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

(11) “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 \(c. 30\)](#).

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

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

(14) 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.

- (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;
- (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(15);

“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—

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

- (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;

“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(16);

“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.