

- or restrictions which may be attached to a licence, and the variation of such conditions;
- (e) the information to be supplied and documents to be produced in connection with an application for a licence, or for the removal or variation of any condition or restriction attaching to a licence;
  - (f) fees to be charged in respect of anything required or permitted to be done under this Ordinance;
  - (g) responsibilities of operators of fishery enterprises with respect to health conditions and requirements relating to the preparation, processing, packaging, storage, transport or distribution of fishery products;
  - (h) the inspection by the Authority, member of the Authority or public officers of any regulated units of persons licensed under this Ordinance and the arrangements for the hygiene thereof;
  - (j) the implementation of any directive, regulation or other law of the Council of the European Communities affecting the health conditions for the production and the placing on either the local or export market of fish or fish products, or which in any manner concerns or affects the objects of this Ordinance.

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## **FISH AND FISH PRODUCTS ORDINANCE (TRISTAN DA CUNHA), 2012**

### **FISH AND FISH PRODUCTS (TRISTAN DA CUNHA) REGULATIONS, 2012**

(Section 13)

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## **PART A PRELIMINARY**

### **Citation and commencement**

1. These Regulations may be cited as the Fish and Fish Products (Tristan Da Cunha) Regulations, 2012, and come into operation on 1 June 2012.

### **Interpretation**

2. In these Regulations, unless the context otherwise indicates, any word or expression to which a meaning has been assigned in the Ordinance bears the meaning so assigned, and—

“**batch**” means a quantity of fish or fishery products of the same species and collected from the same production area during the same fishing or harvesting operation;

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

“**clean sea water**” means sea water or brackish water which is free from microbiological contamination and toxic or objectionable substances occurring naturally or as a result of discharge into the environment;

“**disinfection**” means the application of hygienically satisfactory chemical or physical agents and processes to clean surfaces with the intention of eliminating micro-organisms;

“**fish landing site**” means a place at which fishing or transport vessels discharge a catch of fish to land;

“**fishery enterprise**” means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of fishery products for human consumption;

“**fresh products**” means any fishery product whether whole or prepared, including live fishery products and fishery products packaged under vacuum or in a modified

atmosphere, which have not undergone any treatment to ensure preservation other than chilling;

“**hazard**” means biological, chemical or physical agent in, or condition of, fishery products with the potential to cause an adverse effect on human health;

“**hermetically sealed container**” means a container that is designed and intended to be secure against the entry of hazards;

“**marine biotoxins**” mean poisonous substances accumulated by fish and bivalve molluscs which feed on plankton containing toxin;

“**means of transport**” means the parts set aside for fishery products in road vehicles, holds of vessels and containers for transport of fishery products by land, sea or air, and includes means of transport used for conveying products to their destination market;

“**monitoring**” means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with the requirements of these Regulations and the laws on food hygiene and public health which relate to fishery products;

“**official control**” means any form of control performed by the Authority for the verification of compliance with the Ordinance and Regulations made under it, and the laws on food hygiene and public health which relate to fishery products;

“**operator**”, in relation to a fishery enterprise, means the natural or legal persons responsible for ensuring that the requirements of food laws are met within the fishery business under their control;

“**own checks system**” means all those actions undertaken by a fishery enterprise aimed at ensuring and demonstrating that a fishery product satisfies the requirements of product safety as laid down in these Regulations;

“**placing on the market**” means the holding of food for the purpose of export from Tristan da Cunha, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer from Tristan da Cunha;

“**risk**” means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

“**potable water**” means water which complies with the specification set out in Schedule 15 to these Regulations;

“**processed products**” means any chilled or frozen fishery products which have undergone a chemical or physical process of heating, smoking, salting, dehydration or marinating or a combination of processes, whether or not mixed with other foodstuffs;

“**preservation**” 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 therein are destroyed or inactivated, irrespective of the temperature at which the product is to be stored;

“**the Ordinance**” means the Fish and Fish Products (Tristan da Cunha) Ordinance 2012, and where applicable, includes these Regulations.

“**traceability**” means the ability to trace and follow a fishery product, or other substance intended, or expected to be incorporated into a fishery product, through all stages of production, processing and distribution;

“**viscera**” means the internal organs of fish or fishery products and includes the heads of crustaceans.

## **PART B CONTROL AND MONITORING OF FISHERY ENTERPRISES**

### **Responsibilities of operator of fishery enterprise**

**3. (1)** Every operator of a fishery enterprise must ensure that the fishery products under the operator's control satisfy the requirements of these Regulations at all stages of preparation, processing, packaging, storage and distribution, and must verify that those requirements are met.

**(2)** If an operator of a fishery enterprise considers or has reason to believe that any fishery product which the enterprise has imported, produced, processed or distributed is not in compliance with the requirements of these Regulations or that it may be injurious to human health, and such fishery product has left the immediate control of such operator, the operator must immediately initiate procedures to withdraw the fishery product in question from the market and must inform the Authority of the fact.

**(3)** Every operator of a fishery enterprise must collaborate with the Authority on actions taken to investigate, avoid or reduce risks posed by a fishery product which the operator supplies or has supplied.

### **Application and granting of licence**

**4. (1)** Any person who wishes to apply for a licence in respect of a regulated unit must submit to the Authority an application in the form set out in Form A in Schedule 1 accompanied by the fee prescribed in Regulation 14.

**(2)** In considering whether to grant a licence, the Authority must inspect the regulated unit in which the processing, packaging or storage is intended to be carried on.

**(3)** If the Authority is satisfied that the regulated unit complies with the requirements set out in these Regulations, the Authority may issue a licence in the form set out in Form B in Schedule 1, subject to any conditions the Authority thinks appropriate taking into account the nature of the licence applied for.

### **Official control of fishery products**

**5. (1)** The Authority must undertake official control and monitoring of food safety conditions in all fishery enterprises and in respect of imports of fishery products for re-export in order to establish whether they comply with requirements laid down in these Regulations.

**(2)** The official control must include the checks set out in Regulation 6.

**(3)** Official control of fishery products must be carried out—

*(a)* regularly and according to priorities determined by risk assessment;

*(b)* in any case where non-compliance is suspected;

*(c)* when required for the purpose of granting a licence or providing a certificate.

(4) Official control must be carried out using means proportionate to the end to be attained.

(5) Official control must cover all stages of preparation, production, processing, storage, transport and distribution related to fishery products, including imported raw materials where appropriate.

(6) Measures applied by the Authority under these Regulations must be applied in a non-discriminatory manner and be based on an assessment of the food safety risks, except where this is not appropriate to the circumstances or the nature of the measure; and these measures must be effective, equitable and proportionate to the risk.

(7) Assessment of the food safety risks must be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

(8) Where there are reasonable grounds to suspect that any fishery product subject to these Regulations may present a risk to human health, the Authority must, depending on the nature, seriousness and extent of that risk, take steps to identify the fishery product concerned and implement appropriate measures to prevent, reduce or eliminate that risk.

### **General principles of inspection**

6. (1) Official control of the food safety conditions must comprise one or more of the following checks and, where necessary, be followed by consequential actions:

- (a) periodic inspection of vessels, landing sites, fish processing establishments and means of transport (including transport vessels and other vehicles used to consign fishery products to export markets), and monitoring of compliance with licence conditions;
- (b) examination of any control systems put in place by operators of a regulated unit in respect of which a licence has been granted and the results obtained;
- (c) inspection of—
  - (i) raw materials, ingredients, processing aids and other products used for the preparation and production of fishery products, their sources (including fishing vessels and landing sites) and the conditions under which they are produced;
  - (ii) semi-finished and finished products;
  - (iii) materials and articles intended to come into contact with fishery products;
  - (iv) cleaning and maintenance products and processes;
  - (v) labelling, presentation and advertising;
- (d) assessment of procedures on good manufacturing practices, good hygiene practices, and hazard analysis and critical control points as required in the laws relating to food safety and public health which apply in respect of fishery products;
- (e) examination of written material and other records which may be relevant to the assessment of compliance with the Ordinance;
- (f) interviews with fishery enterprise operators in the supply chain and with their staff;
- (g) the reading of values recorded by measuring instruments;
- (h) controls carried out with the Authority's own instruments to verify measurements taken by the fishery enterprise operator;

- (i) any other activity required to ensure that the objectives of the Ordinance are met;
- (j) certifying, on request in writing, the health conditions relating to any batch of fishery products.

(2) Whenever practicable, inspections for official control must be carried out without prior warning.

(3) Inspection of fishery products must include an examination of the following characteristics in a sample of the relevant fishery product at each stage of production and distribution:

- (a) organoleptic characteristics;
- (b) freshness indicators in cases of doubt regarding freshness of fishery products;
- (c) level of histamine in susceptible species;
- (d) level of residues and contaminants;
- (e) level of permitted additives;
- (f) microbiological contamination;
- (g) visual presence of parasites;
- (h) presence of poisonous fish species or fish products.

### **Imported fishery products for re-export**

7. (1) The Authority must undertake official control of food safety conditions in relation to fishery products which are imported with the intention of processing in Tristan da Cunha for subsequent re-export.

- (2) The official controls described in paragraph (1) may include checks on—
- (a) the import conditions including the territory of origin;
  - (b) the conditions aboard freezer or factory vessels flying the flag of another country, to confirm compliance with the requirements prescribed in these Regulations and the laws relating to food safety and public health which apply in respect of fishery products;
  - (c) the health certification issued by the regulating body of the country of origin which has powers and functions similar to those of the Authority.

(3) In considering a request for certification for export of fishery products referred to in paragraph (1) to a territory which applies restrictions on the country of origin of fishery products, the Authority must—

- (a) be satisfied that the provisions relating to traceability and recall procedures, as prescribed in Schedule 15, are applied; and
- (b) confirm compliance with any such restrictions regarding country of origin that are in place at the time.

### **Inspection reports**

8. (1) The Authority must draw up reports on the inspections for official control that it has carried out, which must include—

- (a) a description of the purpose of the official control;
- (b) the control methods applied;
- (c) the results of the official control; and
- (d) where appropriate, the action that an operator of a fishery enterprise must take.

(2) The Authority must provide the operator concerned with a copy of the report referred to in paragraph (1).

(3) If the inspection report identifies a case of non-compliance and any corrective actions are required, they must be specified in the report, along with a time limit for their implementation.

### **Laboratory analysis of samples**

9. (1) Samples collected under these Regulations for analysis for the purpose of official control must be selected and transmitted by the Authority to the official testing laboratory nominated under Regulation 10.

(2) The costs of the analyses will be borne by the Authority.

### **Accreditation of official testing laboratories**

10. (1) The Authority must nominate the official testing laboratory to analyse samples collected under these Regulations for analysis for the purpose of official control.

(2) The official testing laboratories nominated under paragraph (1) must comply with the *General Requirements for the Competence of Calibration and Testing Laboratories* laid down by the International Organization for Standardization in ISO Standard 17025 in respect of the tests to be conducted.

(3) The accreditation and assessment of testing laboratories referred to in these Regulations may relate to individual tests or groups of tests.

(4) The testing laboratories nominated for the purposes of analysis in support of official controls must participate in appropriate proficiency testing schemes.

### **Certification of fishery products**

11. (1) In relation to any defined batch of fishery products, the Authority may issue a certificate attesting to—

- (a) the conditions in which that batch was produced, processed, stored, packed, transported or placed on the market;
- (b) the compliance of that batch with any standard;
- (c) the fitness of that batch for any particular purpose.

(2) Applications for the issue of a certificate must be made on a standard form to be prescribed by the Authority.

(3) In relation to certification of direct exports from a freezer vessel or factory vessel for which the Authority has no jurisdiction under the Ordinance to determine the facts attested by the certificate, the Authority may undertake one or more of the following measures to determine the facts to be attested as a condition of issue of the certificate:

- (a) inspect the vessel;

- (b) inspect the consignment of fishery products, including taking samples for laboratory testing;
- (c) consult with the Authority of the flag state regarding the food safety conditions onboard the vessel and its approval status.

### **Annual inspection programme and annual report**

**12. (1)** The Authority must prepare and publish an annual programme of official control activities, specifying—

- (a) the number and type of inspections to be carried out; and
- (b) the criteria applied in drawing up the programme.

**(2)** The Authority must prepare and publish an annual report on official control activities, specifying—

- (a) the number and type of inspections carried out in relation to the programme;
- (b) the number and type of infringements identified; and
- (c) actions taken in the case of non-compliance.

### **Annual monitoring programmes**

**13. (1)** The Authority must design and cause to be implemented an annual monitoring programme with the objective of assessing the nature and extent of the food safety hazards associated with fishery products produced in Tristan da Cunha.

**(2)** The monitoring programme referred to in paragraph (1) must take into account the risks of different food safety hazards in fishery products and the criteria and conditions prescribed in these regulations, and shall include the following parameters:

- (a) heavy metals;
- (b) residues of organochlorine and organophosphate contaminants of the environment;
- (c) residues of pesticides and organic pollutants;
- (d) visible parasites in fish;
- (e) other hazards in fishery products which are identified as relevant to food safety conditions of fishery products;
- (f) water supplies used by fishery enterprises.

**(3)** The monitoring programme must specify the sampling plan and the methods of analysis to be used.

**(4)** The Authority must prepare an annual report describing the monitoring programme and the results, which must be presented to the Island Council.

### **Fees**

**14. (1)** The fees set out in Schedule 2 are payable in respect of the several matters set out in that Schedule.

**(2)** The Administrator may in consultation with the Island Council amend the fees in Schedule 2 from time to time by notice affixed to the public notice board at the Office of the Administrator.

**PART C**  
**HEALTH CONDITIONS AND REQUIREMENTS FOR FISHERY ENTERPRISES**

**Health conditions and requirements for fishery enterprises**

**15. (1)** Every operator of a fishery enterprise must, with respect to any vessel, premises, establishment, site or means of transport, comply with the health conditions and requirement as prescribed in the following Schedules:

Fishing vessels	Schedule 3
Factory vessels	Schedules 3,4,5,11,12,13
Freezer vessels	Schedules 3,4,11, 12, 13
Landing sites, auctions and wholesale markets	Schedule 6
Vehicles and means of transport	Schedule 7
Processing establishments	Schedules 7 to 15 inclusive

**(2)** These Regulations apply in addition to any other legislation relating to food hygiene and in the event of any inconsistency between these Regulations and any other subsidiary legislation relating to the same matter, these Regulations prevail.

**Unfit fishery products**

**16. (1)** Fishery products are to be considered unfit for human consumption if—

- (a) organoleptic, chemical, physical or microbiological checks or checks for parasites have shown that they are not compliant with standards set out in these Regulations;
- (b) they contain in their edible parts contaminants or residues in excess of the limits laid down in relevant Schedules to these Regulation and other applicable legislation, or at levels where the calculated dietary intake would exceed the acceptable daily or weekly intake for humans;
- (c) they derive from—
  - (i) prohibited fish species described in Regulation 17; or
  - (ii) fishery products not complying with Schedule 11; or
- (d) the Authority considers that they may constitute a risk to public or are for any other reason considered to be not suitable for human consumption.

**(2)** Unfit fishery products may be subject to seizure under the powers granted to an authorised officer by section 9 of the Ordinance.

**Prohibited species**

**17.** The retention on board by a freezer vessel or factory vessel, or the possession by an operator or a fishery enterprise of the following fishery products is prohibited:

- (a) Fish of the families *Tetradontidae*, *Molidae*, *Diodontidae*, *Canthigasteridae*, *Gempylidae*;
- (b) Fish products commonly containing biotoxins of marine origin, such as *ciguatera* or other toxins dangerous to human health;

- (c) Bivalve and gastropod molluscs, tunicates, and echinoderms harvested from areas in which such animals may become contaminated with marine biotoxins, unless production and harvest is subject to a monitoring plan approved by the Authority.
- 

**SCHEDULE 1**

**FORMS**

**FORM A**  
(Regulation 4(1))

**FISH AND FISH PRODUCTS (TRISTAN DA CUNHA) ORDINANCE, 2012**

**APPLICATION FOR LICENCE FOR  
FISH PROCESSING ESTABLISHMENT, FACTORY AND FREEZER VESSELS**  
(Section 5(2))

To: The Regulatory Authority

Name of Applicant (Title and Full Names):

Postal Address:

Telephone Number:                      Fax:                      E-mail:  
Trading name and postal address of business:

Location and name of premises where business will be carried on or details of freezer or factory vessel in respect of which application is being made:

Full names of other persons in control of the business (including titles):

State purpose for which licence is applied (Full details of activities and specific products to be handled, e.g. whether to process, package or store fish or fish products and include details of fish species):

Specify where product will be sold (for local or export market):

Which of the following will be supplied with products from the establishment or vessel (tick all that apply)?

- Other businesses that manufacture or process food
- Wholesale packers
- Cold stores that are not part of the establishment to which this application relates
- Warehouses that are not part of the establishment to which this application relates
- Restaurants, hotels, canteens or similar catering businesses
- Take-away businesses
- Retail shops, supermarkets, stalls, or mobile vendors that you own

- Retail shops, supermarkets, stalls, or mobile vendors that you do not own
- Members of the public direct from the establishment to which this application relates
- Other (please specify)

Specify how products will be transport from the establishment or vessel (own vehicle, contract/ private haulier):

*The following information is required in order to process your application and should be sent with this application form if possible. Please indicate which information you are sending now. (N.B. Information that is not sent now will still be required before your application can be determined.)*

- A detailed scale plan of the (proposed) establishment showing the location of rooms and other areas to be used for the storage and processing of raw materials, product and waste, and the layout of facilities and equipment
- A description of the (proposed) food safety management system based on HACCP principles
- A description of the (proposed) establishment and equipment maintenance arrangements
- A description of the (proposed) establishment, equipment , and transport cleaning arrangements
- A description of the (proposed) waste collection and disposal arrangements
- A description of the (proposed) water supply
- A description of the (proposed) water supply quality testing arrangements
- A description of the (proposed) arrangements for product testing
- A description of the (proposed) pest control arrangements
- A description of the (proposed) monitoring arrangements for staff health
- A description of the (proposed) staff hygiene training arrangements
- A description of the (proposed) arrangements for record keeping
- A description of the (proposed) arrangements for applying the identification mark to product packaging or wrapping

In the case of an application with respect to any freezer or factory vessel, which of the following activities will be carried out on the product whilst on board such vessel:

Chilling  
Freezing  
Gutting  
Filleting  
Slicing  
Skinning  
Shelling  
Shucking  
Mincing  
Processing  
Wrapping  
Packing  
Heading  
Cooking

Add any further information that you consider may be relevant for purposes of determining this application:

I hereby apply for a licence in respect of the above and I hereby certify the foregoing particulars to be correct.

Signature:

Date:

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FORM B  
(Regulation 4(1))

FISH AND FISH PRODUCTS (TRISTAN DA CUNHA) ORDINANCE, 2012  
(Section 5(2))

**APPLICATION FOR LICENCE FOR  
VESSELS OTHER THAN FACTORY VESSELS AND FREEZER VESSELS**

To: The Regulating Authority

Name of Applicant (Title and Full Names):

Postal Address:

Telephone Number:

Fax:

E-mail:

Name of Vessel:

Registration No:

Specify where product will be sold (For local or export market)

Specify which of the following activities will be carried out on board the vessel:

Chilling  
Heading  
Gutting  
Other

I hereby apply for a licence in respect of the above and I hereby certify the foregoing particulars to be correct.

Signature:

Date:

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FORM C  
(Regulation 4)

FISH AND FISH PRODUCTS (TRISTAN DA CUNHA) ORDINANCE, 2012  
(Section 5)

**LICENCE**

THIS LICENCE is granted to:

in respect of the following establishment or vessel:

to *(set out nature of licence, e.g., to process, package or store fish or fish products and set out species of fish)*:

at the premises or on the vessel known as:

for the period *(state duration of licence)*:

SUBJECT to the following conditions: *(Insert appropriate conditions)*

Signed:

Date:

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**SCHEDULE 2**  
(Regulation 14)

**FEES**

1.	Application for a licence (non-refundable)	£100
2.	Grant of licence for an establishment (other than an establishment in respect of which item 5 applies)	£100
3.	Grant of licence for a freezer or factory vessel	£1000
4.	Grant of licence for a vessel other than a freezer or factory vessel	£15
5.	Grant of licence for an establishment approved for the purposes of export	£5,000

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**SCHEDULE 3**  
(Regulation 15(1))

**HEALTH CONDITIONS FOR FISHING VESSELS**

**PART I**

**STRUCTURAL AND EQUIPMENT REQUIREMENTS**

**A. Requirements for all vessels**

1. All vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, must comply with the structural and equipment requirements laid down in this Schedule.
2. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.

3. Vessels must be equipped with suitable holds, tanks or containers for the preservation of fishery products on ice or under refrigerated conditions.
4. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.
5. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.
6. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.

**B. Requirements for vessels designed and equipped to preserve fresh fish and fish products for more than 24 hours**

1. Vessels designed and equipped for voyages of more than 24 hours duration must be equipped with suitable sanitary facilities for the crew, including a flushing water closet and hand wash basin.
2. Holds in which fishery products are stored must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the fishery products.
3. Holds tanks, or containers used for the storage of fishery products must be so designed and constructed as to ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products.
4. Holds, tanks or containers used for the storage of fishery products comprising fish species which are susceptible to the production of histamine must be equipped with a device for continuous automatic recording of the temperature inside each hold, tank or container.

**PART II  
HYGIENE REQUIREMENTS**

1. Fishing vessels owners or their representatives must ensure that persons employed on board his fishing vessel who handle fisheries products—
  - (a) undergo an annual medical examination and possess a certificate of good health issued by a medical officer in the form approved by the Senior Medical Officer/Clinical Director; and
  - (b) are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.
2. When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in good repair and condition. In particular, they must not be contaminated by fuel or bilge water.
3. As soon as possible after they are taken on board, 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 potable water or, where appropriate, clean sea water.

4. Fishery products must be handled and stored so as to prevent bruising. Handlers may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products suffers no damage.
5. Fishery products, other than those kept alive, must be chilled immediately after harvest, so that the core temperature of the product is reduced to a temperature to as near as possible to 0°C as soon as possible after being caught.
6. Ice used to chill fishery products must be made from potable water or clean seawater.
7. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after harvest, and the products must be washed immediately and thoroughly with potable water or clean seawater.
8. If not to be used for human consumption, the viscera must be removed as soon as possible, and discarded or kept apart from products intended for human consumption.
9. Livers, roes and other viscera intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.
10. Where vessels undertake fishing voyages of duration greater than 24 hours, they must have a programme for the systematic extermination of rodents, insects and any other pests.

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**SCHEDULE 4**  
(Regulation 15(1))

**HEALTH CONDITIONS FOR FACTORY AND FREEZER VESSELS**

1. Freezer vessels and factory vessels must meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours laid down in Part IB in Schedule 3.
2. Freezer vessels must have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of -18°C or less.
3. In the case of brine freezing of whole fish intended for canning, the vessel must have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -9°C. The brine must not be a source of contamination for the fish.
4. Freezer vessels and factory vessels must have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18°C. Storage holds must be equipped with a temperature-recording device

in a place where it can be easily read. The temperature sensor must be located in the area furthest away from the cold source where the temperature in the storage room is the highest.

5. Rodents, insects and any other pests must be systematically exterminated in the vessel.
6. Vessels must apply a systematic hygiene and sanitation plan which covers all areas where fish is handled, and equipment, tables, fish boxes, knives and other items with which fish comes into contact. A copy of the plan, and evidence of its implementation, must be available to inspectors during inspections.

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**SCHEDULE 5**  
(Regulation 15(1))

**HEALTH CONDITIONS FOR FACTORY VESSELS**

1. Factory vessels must comply with the requirements of Schedule 4.
2. Factory vessels must have at least—
  - (a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the elements and from any source of contamination;
  - (b) a hygienic system for conveying fishery products from the receiving area to the work area;
  - (c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean and disinfect and 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 by products;
  - (e) a place for storing packaging materials that is separate from the product preparation and processing areas;
  - (f) suitable equipment for disposing of waste or fishery products that are unfit for human consumption 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 its sanitation, separate areas must be allocated for that purpose;
  - (g) a water intake situated in a position that avoids contamination of the water supply; and
  - (h) hand-washing equipment for use by the staff engaged in handling exposed fishery products with taps designed to prevent the spread of contamination.
3. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Schedule 4.

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**SCHEDULE 6**

(Regulation 15(1))

## **GENERAL HEALTH CONDITIONS FOR FISH LANDING SITES**

### **PART A DESIGN AND LAYOUT**

1. Fish landing sites must provide working areas which are of sufficient size for work to be carried out under adequate hygienic conditions.
2. The location, design and layout must be such as to preclude contamination of the products and to allow separation of activities which might give rise to contamination of the fish during landing.
3. In areas where fishery products are landed, the operator of the fisheries enterprise responsible should take measures to—
  - (a) exclude the entry of animals where fishery products are landed;
  - (b) exclude the entry of unauthorized persons to areas when fishery products are landed;
  - (c) ensure unloading and landing operations are carried out rapidly;
  - (d) prevent the fishery products from being exposed to direct sunlight;
  - (e) ensure waterproof non-slip flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of water;
  - (f) provide adequate artificial lighting when work is conducted at night;
  - (g) provide an adequate supply of water under pressure and in sufficient quantities to aid cleaning and disinfecting tools, equipment and fittings when necessary.
4. For purposes of paragraph 3(a), the operator of a fisheries enterprise may, notwithstanding the fact that a landing site may be a public place, display a notice during any period that fish is being landed or handled, prohibiting members of the public from entering such landing site for that period.
5. Equipment used for unloading and landing that comes into contact with fishery products must be made of corrosion-resistant materials which are easy to clean and disinfect.
6. Suitable water-tight, corrosion-resistant, containers must be provided for fishery products not intended for human consumption. Separate premises must be provided for the storage of such containers if they are not emptied at the end of each working day.

### **PART B GENERAL CONDITIONS OF HYGIENE**

1. The fish landing site must be kept in a satisfactory state of cleanliness and repair, in order not to constitute a source of contamination for the products.
2. Rodents, insects and any other vermin must be systematically exterminated in the area of the fish landing site.

3. The operator of the fisheries enterprise must apply a systematic hygiene and sanitation plan for the landing site to cover all areas where fish is handled, and equipment, and other items with which fish comes into contact. A copy of the plan and evidence of its implementation must be made available to inspectors during inspections.
4. Potable water or clean seawater must be used for cleaning purposes.
5. Detergents, disinfectants and similar substances must be approved by the Authority and be used in such a way that they do not have an adverse effect on the machinery, equipment and fishery products.
6. A high standard of cleanliness is required of staff working in the area of the fish landing site, auction or wholesale market areas. In particular—
  - (a) staff assigned to the handling of fishery products must wash their hands at least each time work is resumed;
  - (b) staff assigned to the handling of fishery products must refrain from wearing jewellery, nail polish and other personal items which may contaminate the product;
  - (c) wounds to the hands must be covered by a water proof dressing;
  - (d) smoking, spitting, eating and drinking in the area of the fish landing site, are prohibited.
7. The operator of a fisheries enterprise must—
  - (a) take all the necessary measures to prevent persons liable to contaminate fishery products from handling such products;
  - (b) nominate a person to be responsible for ensuring that the condition set down in this schedule are applied during working hours.
8. All fishery products must undergo further chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.

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**SCHEDULE 7**  
(Regulation 15(1))

**REQUIREMENTS FOR STORAGE AND MEANS OF TRANSPORT**

1. Fishery products must, during storage and transport, be kept at the prescribed temperature, and in particular—
  - (a) fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products must be kept at the temperature 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  $-18^{\circ}\text{C}$  or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than  $3^{\circ}\text{C}$ , during transport;
  - (c) processed products must be kept at the temperature specified by the manufacturer.

2. Paragraph 1(*b*) must not apply where frozen fishery products are transported from a cold storage plant to an approved processing plant to be thawed on arrival for the purpose of preparation or processing.
3. Means of transport used to transport fishery products may never be used for the transport of products other than food fit for human consumption. Products may not be stored or transported together with other fishery products or with any other goods which may contaminate them or affect their quality, unless they are packaged in such a way as to provide adequate protection.
4. Vehicles and vessels and other means of transport used for fishery products must be constructed and equipped in such a way that the prescribed temperatures can be maintained through the period of transport. If ice is used to chill the products, adequate drainage must be provided in order to ensure that water from melted ice does not stay in contact with the products.
5. The inside surfaces of the means of transport must be smooth and easy to clean and disinfect, and must be kept in clean condition so as to avoid contaminating the product during transport.

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**SCHEDULE 8**  
(Regulation 15(1))

**GENERAL HEALTH CONDITIONS FOR FISH PROCESSING ESTABLISHMENTS**

**PART A**

**GENERAL CONDITIONS RELATING TO PREMISES AND EQUIPMENT**

1. Each establishment must provide working areas which are of sufficient size for work to be carried out under adequate hygienic conditions. The location, design and layout must be such as to preclude contamination of the products and to separate the clean parts of the building from the contaminated areas.
2. In areas where products are handled, prepared and processed there must be—
  - (*a*) water-proof non-slip flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of water;
  - (*b*) walls which have smooth surfaces and which are easy to clean, durable and impermeable;
  - (*c*) ceilings or roof linings which are easy to clean and designed to avoid the accumulation of dust;
  - (*d*) adequate natural or artificial lighting;
  - (*e*) doors made of durable materials which are easy to clean;
  - (*f*) an adequate ventilation and, where necessary proper vapour extraction facilities; airflow from a contaminated area to a clean area is to be avoided and ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible;
  - (*g*) an adequate number of wash hand basins with taps that are not hand-operable and an adequate supply of soap and single use towels or appliances for drying the hands;

- (h) facilities for cleaning and disinfecting tools, equipment and fittings.
3. Appropriate measures must be taken for protection against the entry of pests such as insects, rodents and birds. Areas surrounding premises must be maintained and protected from access and harbourage of pests.
  4. Instruments and equipment such as fish processing machinery, cutting boards, work-tables, containers, conveyor belts and knives must be made of smooth, corrosion-resistant materials which are easy to clean and disinfect.
  5. Suitable water-tight, corrosion-resistant containers must be provided for fishery products not intended for human consumption. They must be easily distinguishable from containers used for fishery products for human consumption. Separate premises must be provided for the storage of such containers if they are not emptied at the end of each working day.
  6. Facilities must be provided to ensure adequate supplies of potable water or clean sea water, under pressure and in sufficient quantities for processing and cleaning operations. Clean seawater may only be used in contact with whole bivalve molluscs and whole fish and for washing of plant and equipment.
  7. Where a non-potable water supply is provided for the production of steam, fire fighting or the cooling of refrigeration equipment, the pipes installed for the purpose must preclude the use of such water for any other purpose and present no risk of contamination of the products. Water pipes for non-potable water must be clearly distinguished from those used for potable water or clean seawater.
  8. There must be provided an adequate hygienic waste water disposal system. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area.
  9. There must be provided adequate facilities in a separate room for staff to change their clothes. This must have smooth, waterproof, washable walls and floors.
  10. The establishment must have an adequate number of flush toilets, the latter not opening directly onto areas where fishery products are prepared, processed or stored. There must be an adequate number of wash basins, and an adequate supply of soap and single use towels or appliances for drying the hands. The wash basin taps must not be hand operable.
  11. If the volume of products treated requires their regular or permanent presence, there must be provided an adequately equipped lockable room for the exclusive use of the authorized fish inspectors.
  12. There must be adequate facilities for cleaning and disinfecting the means of transport delivering raw material to, or taking final products from, the establishment.

13. Establishments keeping live animals such as crustaceans and fish must be provided with water supply of a quality such that no harmful organisms or substances are transferred to the animals.

**PART B  
GENERAL CONDITIONS OF HYGIENE**

1. Floors, walls and partitions, ceilings and roof linings and equipment and instruments used for working on fishery products must be kept in a satisfactory state of cleanliness and repair, in order not to constitute a source of contamination for the products.
2. Rodents, insects and any other vermin in the premises or on the equipment must be systematically exterminated.
3. The establishment must apply a systematic hygiene and sanitation plan which covers all areas where fish is handled, and equipment, tables, fish boxes, knives and other items with which fish comes into contact. A copy of the plan, and evidence of its implementation must be available to inspectors.
4. Equipment used in the processing areas must be used only for work on fishery products.
5. Potable water or clean seawater must be used for cleaning purposes.
6. Detergents, disinfectants and similar substances must be approved by the Authority and be used in such a way that they do not have an adverse effect on the machinery, equipment and fishery products.
7. Rodenticides, insecticides, disinfectants and any other potentially toxic substances must be stored in locked premises or cupboards in order not to present any risk of contamination of the product.

**PART C  
STAFF HYGIENE AND TRAINING**

1. A high standard of cleanliness is required of staff working in processing areas. In particular—
  - (a) staff must wear suitable working clothes, and headgear which completely covers the hair;
  - (b) staff assigned to the handling and preparation of fishery products must refrain from wearing jewellery and nail polish and must wash their hands at least each time work is resumed;
  - (c) wounds to the hands must be covered by a suitable waterproof dressing;
  - (d) smoking, spitting, eating and drinking in work and storage premises of fishery products are prohibited.
2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted with infected wounds, skin infections, sores or diarrhoea may be permitted to handle fishery products or enter any an area where fishery

products are handled in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a establishment and who is likely to come into contact with fishery products must report immediately the illness or symptoms, and if possible their causes, to the fishery enterprise operator.

3. Employers must take all the necessary measures to prevent persons liable to contaminate fishery products from handling and working on such products until there is evidence that such persons can do so without risk.
4. Operators of fish processing establishments must ensure that—
  - (a) persons handling fishery products undergo an annual medical examination and possess a certificate of good health issued by a medical officer in the form approved by the Senior medical officer/Clinical Director; and
  - (b) persons handling fishery products are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.

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**SCHEDULE 9**  
(Regulation 15(1))

**SPECIAL CONDITIONS FOR HANDLING FISHERY PRODUCTS ON SHORE**

**PART A**  
**CONDITIONS FOR FRESH PRODUCTS**

1. If chilled and packaged products are not dispatched, prepared or processed immediately after reaching a processing establishment they must be stored or preserved with adequate quantities of ice to ensure that temperature does not rise above the temperature of melting ice. Packaged fresh fishery products may alternatively be chilled by mechanical refrigeration.
2. Re-icing must be carried out as often as is necessary; Ice must be made from potable water or clean seawater and be stored under suitable conditions in receptacles or an area provided for the purpose; such facilities must be kept clean and in a good state of repair.
3. Preparation of products on shore must be carried out in hygienic conditions, and the products must be washed thoroughly with potable water or clean seawater immediately after such operations. Clean seawater used for washing fishery products may only be used to wash whole fish, fish from which viscera have been removed, and whole live bivalve molluscs, echinoderms, tunicates and marine gastropods.
4. 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 space 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. Fillets and slices to be sold fresh must be chilled as quickly as possible after preparation.

5. Guts and other parts which may constitute a danger to public health must be separated from, and removed from the vicinity of, products intended for human consumption.
6. Containers used for dispatch or storage of fresh fishery products must be designed in such a way as to ensure both the protection from contamination and their preservation under sufficiently hygienic conditions and, more particularly, they must provide adequate drainage of melt water.
7. Unless special facilities are provided for the continuous disposal of waste, the latter must be placed in leak proof, 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 premises specifically set aside for that purpose. Care must be taken to ensure that waste stored as provided for in this paragraph does not constitute a source of contamination or pollution.
8. The containers, receptacles and/or premises set aside for waste must be always thoroughly cleaned and disinfected after use.

**PART B**  
**CONDITIONS FOR FROZEN PRODUCTS**

1. Except as provided in paragraph 2 below, all establishments producing frozen fishery products must have—
  - (a) refrigeration equipment sufficiently powerful to achieve a rapid reduction in the product temperature to  $-18^{\circ}\text{C}$  or below;
  - (b) refrigeration equipment sufficiently powerful to keep products in the storage rooms at  $-18^{\circ}\text{C}$  or below irrespective of the ambient temperature.
2. Whole fish frozen in brine must be stored at temperatures not higher than  $-9^{\circ}\text{C}$ .
3. Storage rooms for frozen fish must have a temperature recording device in a place where it can easily be read. The temperature sensor must be located in the area where the temperature in the storage room is the highest.
4. Temperature charts must be available for inspection by the Authority during the period in which the products are stored.

**PART C**  
**CONDITIONS FOR THAWED PRODUCTS**

1. If establishments carry out thawing operations they must ensure that—
  - (a) fishery products must be thawed under hygienic conditions; their contamination must be avoided and there must be adequate drainage for any melt water produced;
  - (b) during thawing the temperature of the product must not be increased excessively.

2. After thawing the fishery products must be handled in accordance with the requirements of these Regulations.

**PART D**  
**GENERAL CONDITIONS FOR PROCESSED PRODUCTS**

1. Fresh, frozen and thawed products used for processing must comply with the requirements of Parts A, B and C of this Schedule.
2. The person responsible for a fish processing establishment must keep a register of the processing operations carried out and the associated processing conditions. Depending on the type of process employed, heating time and temperature, salt content, pH, water content etc. must be monitored and controlled. Records must be kept at least two years and be available to the 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 kept clearly marked on the packaging.

**PART E**  
**CONDITIONS FOR CANNED PRODUCTS**

1. Fish products which have been subjected to sterilisation in hermetically sealed containers must comply with the requirements of this Part.
2. The water used must be potable.
3. 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 and such like, 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.
4. Further checks must be carried out at random to ensure that the processed products have undergone appropriate heat treatment, namely—
  - (a) incubation tests, which must be carried out at thirty seven degrees centigrade for seven days, or at thirty-five degrees centigrade for ten days, or at any other equivalent combination; and
  - (b) microbiological examination of the contents and the containers in either the establishment's laboratory or in another laboratory approved by the competent authority.
5. Samples must be taken of production each day at predetermined intervals, to ensure the efficiency of sealing. For that purpose, appropriate equipment must be available for the examination of cross-sections of the can seams.

6. Checks must be carried out to ensure that containers are not damaged.
7. All containers, which have undergone heat treatment under practically identical conditions, must be given a batch identification mark, in accordance with any law for the time being in force concerning indications or marks identifying the lot to which a foodstuff belongs.

#### **PART F CONDITIONS FOR SMOKED PRODUCTS**

1. Smoking must be carried out in a separate premises or area used specifically for this purpose, equipped if necessary, with a ventilation system to prevent the smoke and heat from affecting other premises or places where fishery products are prepared, processed or stored.
2. 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 produce.
3. Smoking by burning wood that is painted, varnished, or glued or has undergone any chemical preservation treatment is prohibited.
4. After smoking products must be cooled rapidly to the temperature required for their preservation. Cooling must take place in an area with adequate protection against contamination with insects, their larvae or eggs.
5. Smoked fish must be packed in adequate cartons, which provide a suitable degree of protection from contamination with insects, their larvae or eggs. Cardboard cartons must be lined with waxed paper.

#### **PART G CONDITIONS FOR DRIED PRODUCTS**

1. Drying of fishery products must be carried out in a premises or area used specifically for this purpose.
2. Areas in which fish is dried must be adequately protected against the entry of animals and unauthorised persons.
3. Fish may not be dried on the ground unless the ground is covered with a smooth impermeable surface which is capable of being easily cleaned.
4. Dried fish must be packed in adequate cartons, which provide a suitable degree of protection from contamination with insects, their larvae or eggs. Cardboard cartons must be lined with waxed paper.

#### **PART H CONDITIONS FOR SALTED PRODUCTS**

1. Salting operations must be carried out in a premises or area used specifically for this purpose.
2. Salt used in treatment of fishery products must be clean and stored in such a way as to preclude contamination. Salt must not be re-used.
3. Any container used for salting or brining must be constructed in such a way as to preclude contamination during the salting or brining process.
4. Containers or areas used for salting or brining must be cleaned before use.

**PART I**  
**CONDITIONS FOR COOKED CRUSTACEAN AND MOLLUSCAN SHELLFISH PRODUCTS**

1. Only potable water or clean sea water must be used for the cooking of crustaceans and molluscan shellfish.
2. Cooking must be followed by rapid cooling. If no other method of preservation is used, cooling must continue until the temperature approaching that of melting ice is reached.
3. Shelling or shucking of cooked products must be carried out under hygienic conditions avoiding 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 thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected after each working day.
4. After shelling or shucking, cooked products must immediately be frozen or kept chilled at a temperature which precludes the growth of pathogens, and be stored in appropriate conditions.

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**SCHEDULE 10**  
(Regulation 15(1))

**PACKAGING REQUIREMENTS FOR FISHERY PRODUCTS**

1. Packaging of fish and fishery products must be carried out under satisfactory conditions of hygiene, to preclude contamination.
2. Packaging materials and products liable to enter into contact with fishery products must comply with all the rules of hygiene, and in particular—
  - (a) they must not be such as to impair the organoleptic characteristics of the fishery products;
  - (b) they must not be capable of transmitting to the fishery products substances harmful to human health;
  - (c) they must be strong enough to protect the fishery products adequately.

3. With the exception of containers made of impervious, smooth and corrosion-resistant durable material which may be re-used after cleaning and disinfecting, packaging materials must not be re-used.
  4. Packaging materials used for fresh products held under ice must provide adequate drainage for melt water.
  5. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.
  6. Packaging materials must be stored in areas separate to the area in which fishery products are processed or handled and must be protected from dust and contamination.
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**SCHEDULE 11**  
(Regulation 15(1))

**FOOD SAFETY CONDITIONS FOR FISHERY PRODUCTS**

**Spoilage**

Fish and fishery products intended for sale for human consumption must have organoleptic and chemical characteristics consistent with fitness for human consumption

**Conditions concerning parasites**

Fish and fishery products must be free from visible parasites and visible manifestations of parasitic infections.

**Histamine**

1. A consignment of fishery products comprising a fish species which is susceptible to the production of histamine must not be placed on the market if the level of histamine in nine samples selected at random from the consignment exceeds the minimum levels specified in below.
2. The results of the analysis must fulfill the following requirements:
  - (a) the mean value must not exceed 100 ppm;
  - (b) two samples may have a value of more than 100 ppm but less than 200 ppm;
  - (c) no sample may have a value exceeding 200 ppm.
3. Fish which have undergone enzyme-ripening treatment in brine are permitted higher histamine levels, but not more than twice the above values.

4. Examinations for official control must be carried out in accordance with the high-performance liquid chromatography (HPLC) method described in the following publications:
- (a) Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49; and
  - (b) Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangus merlangus*). J. AOAC Internat. 1999, 82, 1097-1101.

### Heavy metal contaminants present in the aquatic environment

1. Batches of fishery products in which the levels of heavy metal contaminants exceed the maximum limits indicated in the following table must be regarded as unfit for human consumption.

Substrate	Maximum Limit (ppm)		
	Lead	Cadmium	Mercury
Muscle meat of all fish except where indicated below:	0.3	0.05	0.5
Little tuna ( <i>Euthynnus</i> spp.) Marlin ( <i>Makaira</i> spp.) Sail fish ( <i>Istiophorus platypterus</i> ) Rays ( <i>Raja</i> species) Shark and dogfish (all species) Tunas ( <i>Thunnus</i> spp, and <i>Katsuwonus pelamis</i> .)		0.1	1.0
Bullet tuna ( <i>Auxis</i> species)		0.2	
Swordfish ( <i>Xiphias gladius</i> )		0.3	1.0
Crustaceans (excluding brown meat of crabs and thorax meat of lobsters of the genus <i>Palinuridae</i> )	0.5	0.5	0.5
Bivalve Molluscs	1.5	1.0	0.5
Cephalopods (without viscera)	1.0	1.0	0.5

2. Sampling and analysis must be conducted in accordance with European Committee for Standardization (CEN) Standard 'Foodstuffs — Determination of trace elements — Performance criteria and general consideration' or other equivalent recognised methodology.

- Laboratories must use a validated analytical method with a detection limit at least one tenth of the MRL indicated in the above Table. The validation must include a certified reference material in the collaborative trial test materials.

### Microbiological standards

- Batches of ready to eat fishery products which do not meet the following criteria must be considered to be unfit for human consumption.

Type of bacteria	Standard
Salmonella	Absent in 25g n=5 c=0
Coagulase positive Staphylococci	m=100 cfu/g M=1000 cfu/g n=5 c=2
E.coli (on solid medium)	m=1 cfu/g M=10 cfu/g n=5 c=2
Listeria monocytogenes (in samples taken before the product has left the establishment)	Absent in 25g n=5 c=0

Where:

*m* = limit below which all results are considered satisfactory

*M* = acceptability limit beyond which the results are considered unsatisfactory

*n* = no. of units comprising the sample

*c* = number of sample units giving bacterial counts between *m* and *M*

- In determining compliance with the above microbiological specifications, examinations for official control must employ the testing methodologies referred to in the following standards published by the International Organisation for Standardization:
  - In the case of Salmonella: EN/ISO 6579
  - In the case of Listeria monocytogenes: EN/ISO 11290-1
  - In the case of E.coli: ISO TS 16649-2
  - In the case of coagulase positive staphylococci: EN/ISO 6888-1 Or 2

### Organochlorine contaminants present in the aquatic environment

- Batches of fishery products in which the levels of dioxins and dioxin like PCBs and their congeners exceed the limits indicated in the following table must be regarded as unfit for human consumption.

Substrate	Maximum level	

	Sum of dioxins (WHO PCDD/F-TEQ) <sup>1</sup>	Sum of dioxins and dioxin like PCBs (WHO PCDD/F-TEQ)
Muscle meat of fishery products, including crustaceans (excluding brown meat of crabs and head and thorax meat of lobsters of the genus <i>Palinuridae</i> )	4.0 pg/g wet weight	8.0 pg/g wet weight
Fish liver	n/a	25 pg/g wet weight <sup>2</sup>
Marine oils for human consumption	2.0 pg/g fat	10.0 pg/g fat

<sup>1</sup> Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent using the WHO-toxic equivalency factors (WHO-TEFs)) and sum of dioxins and dioxin-like PCBs (sum of PCDDs, PCDFs and polychlorinated biphenyls (PCBs), expressed as WHO toxic equivalent using the WHO-TEFs), as described in the WHO-TEFs for human risk assessment based on the conclusions of the WHO meeting in Stockholm, Sweden, 15 to 18 June 1997 (Van den Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and for Wildlife. Environmental Health Perspectives, 106 (12), 775)

<sup>2</sup> In the case of canned fish liver, the maximum level applies to the whole edible content of the can.

2. Methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in fishery products must follow established international practices where they are available.

### Permitted Additives

1. The additives listed in Table 1 are permitted in fishery products, insofar as they may be added to fishery products listed in Tables 2 and 3 providing that the maximum limits in the final product are not exceeded.

Table 1: List of permitted additives

Sulphur dioxide
Sodium sulphite
Sodium hydrogen sulphite
Sodium metabisulphite
Potassium metabisulphite
Calcium sulphite
Calcium hydrogen sulphite
Potassium hydrogen sulphite
Triphosphates of sodium and potassium
Polyphosphates of sodium, potassium and calcium

Table 2: Maximum limits of SO<sub>2</sub>

<b>Fishery products</b>	<b>Maximum level (mg/kg) expressed as SO<sub>2</sub></b>
Fresh, frozen crustacean and cephalopods	150
Cooked crustacean	50

Table 3: Maximum limits of tri-phosphates and polyphosphates

<b>Fishery products</b>	<b>Maximum level (g/kg)</b>
Frozen fishery products	5

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**SCHEDULE 12**  
(Regulation 15(1))

**IDENTIFICATION MARKS FOR FISHERY PRODUCTS**

1. Fishery products which are packed and consigned to market by an establishment must bear the following information on the packaging:
  - (a) The name of the country of origin of the products.
  - (b) The name and official registration number of the establishment in which the products were processed or packed.
  - (c) A description of the product, including the common name and the Latin name of the species and its state (fresh, frozen), weight and grade.
  - (d) Packaging method (chilled/frozen/canned etc).
  - (e) The date on which it was packed by the establishment and the Batch identification number.
  - (f) Any special storage instructions required to maintain the safety and quality of the fishery product, including storage temperature.
  - (g) Production method (capture fisheries or aquaculture).
  - (h) If capture fisheries, the catch area (according to the Food and Agriculture Organization of the United Nations (FAO) Areas).
  - (i) Name of any food additives administered to the product and code number if appropriate.

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**SCHEDULE 13**  
(Regulation 15(1))

## REQUIREMENT FOR HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM

1. Fishery enterprise operators must implement a system of own checks based on the principles of Hazard Analysis and Critical Control Point System, which must include the following actions:
  - (a) identification of fish and fishery product safety hazards associated with their products and processes, and identification of critical points in their establishment on the basis of the manufacturing processes used;
  - (b) establishing and implementing methods for monitoring and checking such critical points, and for taking corrective actions to prevent or minimize the risk of hazards arising;
  - (c) taking samples for analysis for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the fish and fishery product safety requirements established by these Regulations;
  - (d) keeping a written record or a record registered in an indelible fashion of the preceding points with a view to making them available to the relevant regulatory authority. The results of the different checks and tests will be kept for a period of at least two years.
2. The Authority must by notice in the *Gazette* publish guidelines on the specific requirements for the own checks system.
3. The persons responsible for the establishment must prepare a sampling and testing programme and submit it for the approval of the Authority. The sampling programme, though not concerning systematically every production batch, must allow—
  - (a) validation of the system of own checks when first set up;
  - (b) if necessary, revalidation of the system in case of a change to the characteristics of the product or to the manufacturing process;
  - (c) verification, at specified intervals, that all provisions are still appropriate and properly applied.
4. If the results of the own checks referred to in this Schedule reveal the existence of a significantly elevated risk to the health of consumers in respect of a batch of fish or fishery products, then the products concerned will be considered to be injurious to health and therefore not in compliance with the requirements of the Ordinance. Should they be offered for sale for human consumption, the Authority may consider that an offence has been committed and such products may also be subject to seizure and/or destruction following the procedures laid down in section 9 of the Ordinance or section 18 of the Food Safety Ordinance, 2016.
5. In order to keep a written record or a record registered in an indelible fashion, as referred to in paragraph 1(d), the persons responsible for the establishment must document all information relating to the implementation of own checks system and its verification.

6. The documentation referred to in paragraph 1(*d*) must include two types of information to be kept for submission to the Authority on request:
  - (*a*) a detailed and comprehensive document including—
    - (i) description of the product;
    - (ii) description of the manufacturing process indicating critical points;
    - (iii) for each critical point, identified hazards, assessment of risks and control measures;
    - (iv) procedures for monitoring and checking at each such critical point, with indication of critical limits for parameters that need to be controlled and corrective action to be taken in case of loss of control;
    - (v) procedures for verification and review;
  - (*b*) records of the observations and/or measurements referred to in paragraph 1(*b*), results of the verification activities referred to in paragraph 3, plus reports and written accounts of decisions relating to corrective action when taken. An appropriate document management system must provide, in particular, for the easy retrieval of all documents relating to an identified production batch.
  
7. Operators of fish processing establishments are to ensure that those responsible for the development and maintenance of the procedures referred to in this Schedule have received adequate training in the application of the Hazard Analysis and Critical Control Point principles.

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**SCHEDULE 14**  
(Regulation 15(1))

**REQUIREMENT FOR TRACEABILITY AND RECALL PROCEDURES**

1. The traceability of fish and fishery products and any substance intended to be, or expected to be, incorporated into a fish or fishery product must be established at all stages of production, processing and distribution.
2. Operators of fishery enterprises must be able to identify any person from whom they have been supplied with a fish or fishery product, or any substance intended to be, or expected to be, incorporated into a fishery product. To this end, such operators must have in place systems and procedures which allow for this information to be made available to the Authority on demand.
3. Operators of fishery enterprises must have in place systems and procedures to identify the other businesses to which their products have been supplied. This information must be made available to the Authority on demand.
4. Fish and fishery product which is placed on the market or is likely to be placed on the market must be labelled or otherwise identified through relevant documentation or other information to ensure its traceability.
5. Each operator of a fishery enterprise must prepare a written recall plan detailing the procedures to be followed in the case that a batch of fish or fishery products which

has left the possession of the operator must be withdrawn from being placed on the market.

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**SCHEDULE 15**  
(Regulation 15(1))

**REQUIREMENTS FOR POTABLE WATER**

1. Operators of fish processing establishments must be in a position to demonstrate with a distribution diagram the distribution of potable water and other water within the establishment. This must show all sources, pipework, tanks and cisterns and outlets of water within the establishments. Outlets must be numbered and identifiable on the plan.
2. Where water is treated with a process of chlorination, and the fishery enterprise operator relies on that treatment to comply with the microbiological standards set out in Table 1, then the level of residual chlorination will be monitored at least on a daily basis.
3. At least once every month, water samples from each source must be submitted for a microbiological analysis, to ensure that there is no contamination of the water supply. If numbers of microbes exceed the specifications, then action must be taken to identify the source and stop the contamination.
4. At least once every year, a sample must be submitted for analysis of other parameters. Samples of water taken to test for compliance with standards set out in this Schedule must be taken from various outlets within the establishment in rotation. Ice must also be subject to regular testing. The results of the examinations must bear the identification of the outlet from which the sample is taken.
5. Potable water must comply with the microbiological standards set out in Table1, and the chemical parameters of Table 2 where practical.

**Table 1: Microbiological parameters**

Parameter	Parametric value (Number/100ml)
<i>Escherichia coli (E.Coli)</i>	0
Enterococci	0

**Table 2: Chemical Parameters**

Parameter	Parametric value	Unit	Note
Acrylamide	0.1	$\mu\text{g/l}$	1

Antimony	5.0	$\mu\text{g}/\text{l}$	
Arsenic	10	$\mu\text{g}/\text{l}$	
Benzene	1.0	$\mu\text{g}/\text{l}$	
Benzylpyrene	0.01	$\mu\text{g}/\text{l}$	
Boron	1.0	$\text{mg}/\text{l}$	
Benzoate	10	$\mu\text{g}/\text{l}$	2
Cadmium	5	$\mu\text{g}/\text{l}$	
Chromium	50	$\mu\text{g}/\text{l}$	
Copper	2	$\text{mg}/\text{l}$	3
Cyanide	50	$\mu\text{g}/\text{l}$	
1,2 dichloroethane	3.0	$\mu\text{g}/\text{l}$	
Epichlorhydrine	0.1	$\mu\text{g}/\text{l}$	1
Fluoride	1.5	$\text{mg}/\text{l}$	
Lead	10	$\mu\text{g}/\text{l}$	3,4
Mercury	1	$\mu\text{g}/\text{l}$	
Nickel	20	$\mu\text{g}/\text{l}$	3
Nitrate	50	$\text{mg}/\text{l}$	
Nitrite	0.5	$\text{mg}/\text{l}$	
Pesticides	0.1	$\mu\text{g}/\text{l}$	4,5
Pesticides total	0.5	$\mu\text{g}/\text{l}$	4,6

Polycyclic aromatic hydrocarbons	0.1	$\mu\text{g}/\text{l}$	Sum of concentration of specified compounds Note 7
Selenium	10	$\mu\text{g}/\text{l}$	
Tetrachloroethane and trichloroethane	10	$\mu\text{g}/\text{l}$	Sum of concentration of specified compounds
Trihalomethanes	100	$\mu\text{g}/\text{l}$	Sum of concentration of specified compounds Note 8
Vinyl chloride	0.5	$\mu\text{g}/\text{l}$	1

Note 1: The parametric value refers to the residual monomer concentration in the water as calculated according to specifications of the maximum release from the corresponding polymer in contact with the water.

Note 2: Where possible, without compromising disinfection, a lower value must be aimed for.

Note 3: The value applies to a sample of water intended for human consumption obtained by an adequate sampling method at the tap. Where appropriate the sampling and monitoring methods must be applied to take account of the occurrence of peak levels that may cause adverse effects on human health.

Note 4: 'Pesticides' means:

- organic insecticides,
- organic herbicides,
- organic fungicides,
- organic nematocides,
- organic acaricides,
- organic algicides,
- organic rodenticides
- organic slimicides,
- related products (inter alia, growth regulators)

and their relevant metabolites, degradation and reaction products.

Only those pesticides which are likely to be present in a given supply need be monitored.

Note 5: The parametric value applies to each individual pesticide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the parametric value is 0,030  $\mu\text{g}/\text{l}$ .

Note 6: 'Pesticides — Total' means the sum of all individual pesticides detected and quantified in the monitoring procedure.

Note 7: The specified compounds are:

- benzo(b)fluoranthene,
- benzo(k)fluoranthene,
- benzo(ghi)perylene,
- indeno(1,2,3-cd)pyrene.

Note 8: Where possible, without compromising disinfection, a lower level must be aimed for. The specified compounds are: chloroform, bromoform, dibromochloromethane, bromodichloromethane.