Tuvalu

FOOD SAFETY (FISHERY PRODUCTS) REGULATIONS 2022

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Arrangement of Sections

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MADE UNDER SECTION 41 OF THE FOOD SAFETY ACT 2007 AND SECTION 96 OF THE MARINE RESOURCES ACT 2006

1 Objectives and Scope

The objective of this Regulation is the protection of consumer health in relation to fishery products supplied for export for human consumption.

This Regulation establishes:

(a) Obligations of fishery business operators in respect of general conditions for compliance with the Food Safety Act of 2007;

(b) The specific food safety conditions required for production and distribution of fishery products to export markets;

(c) Detailed arrangements for the implementation of the Food Safety Act 2007, including a system for the official control of exported fishery products to ensure compliance with the prescribed requirements;

(d) Powers and responsibilities of government institutions involved.

2 Citation

These Regulations shall be cited as the Food Safety (Fishery Products) Regulations 2022.

3 Interpretation

In these Regulations:

"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 from toxic or objectionable substances occurring naturally, or as a result of discharge into the environment.

"competent authority" means the body nominated under Regulation 4.

"disinfection" means the application of hygienically satisfactory chemical or physical agents and processes to clean surfaces with the intention of eliminating micro-organisms.

"establishment" means any premises where fishery products intended for human consumption are prepared, processed, chilled, frozen, packaged or stored, but does not include any auction or wholesale market where fishery products are only displayed and sold by wholesale.

"export" means commercial trade with a natural or legal person outside the territory of Tuvalu.

"factory vessel" means any vessel on which fishery products undergo any one or more of the following operations, namely, filleting, slicing, skinning, mincing or processing, followed by packaging, chilling, or freezing.

"fish landing site" means place at which fishing or transport vessels discharge a catch of fish to land.

"fishery business operator" means any person 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.

"fishery products" means any cold blooded aquatic animal, or part or product derived therefrom, intended as food for human consumption. This includes any fish, crustacean, mollusc, echinoderm, holothurian or aquatic reptile, but does not include live fish other than shellfish.

"freezer vessel" means any vessel on which freezing of fishery products is carried out, including after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, wrapping and packaging.

"hazard" means biological, chemical or physical agent, or condition of fishery products with the potential to cause an adverse effect on human health.

"own checks system" means all those actions undertaken by a fishery business aimed at ensuring and demonstrating that a fishery product satisfies the requirements of product safety, as laid down in these Regulations.

"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 fish in road vehicles and rail and aircraft, holds of vessels and containers for transport of fish 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 this Regulation.

"official control" means any form of control that the competent authority performs for the verification of compliance with the Act and regulations made thereunder.

"packaging" means the procedure of protecting fishery products by a wrapper, a container or any other suitable material or device.

"potable water" means water which complies with the specification set out in Schedule 9 of these Regulations.

"risk" means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

"the Act" means the Food Safety Act 2008.

'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.

4 Nomination of the Competent Authority

The Ministry responsible for Fisheries shall be the Competent Authority responsible for the discharge of the functions under this Regulation.

5 General responsibilities of fishery business operators

(1) All fishery business operators shall ensure that fishery products under their control satisfy the requirements of the Food Safety Act at all stages of production, processing, and distribution, and shall verify that such requirements are met.

(2) If a fishery business operator considers or has reason to believe that a fishery product which it has produced, processed, manufactured or distributed, is not in compliance with the requirements of this Regulation or may be injurious to human health, it shall immediately initiate procedures to withdraw the food in question from the market, whether or not the fishery product has left the immediate control of the operator.

(3) In cases where a fishery business operator determines the existence of a non-compliance situation described in subsection 2 of this Regulation, he shall without delay inform the Competent Authority thereof.

(4) Fishery business operators shall collaborate with the Competent Authorities on actions taken to investigate, avoid or reduce risks posed by a food which they supply or have supplied.

6 Conditions for fishery business operators supplying the export market

(1) No person shall export fishery products for human consumption from Tuvalu or from a Tuvalu flagged vessel, unless they are prepared, processed, or packed in an establishment, a freezer vessel, or a factory vessel subject to a permit granted under Section 13 of the Act and in accordance with this Regulation.

(2) Every establishment or vessel requiring a permit under subsection 1 shall be subject to conditions regarding the specific food safety requirements as prescribed in Schedule 1A or 1B.

(3) The Competent Authority shall publish from time to time in the Official Gazette the list of establishments, freezer vessels and factory vessels subject to a permit granted in accordance with Subsection 1.

(4) The applicable Schedules and their content may be amended by order of the Minister responsible for fisheries.

7 Conditions for fishery business operators supplying the domestic market

(1) Fishery business operators which exclusively supply the domestic market shall meet the specific food safety requirements as prescribed in Schedule 1C.

(2) The applicable Schedules and their content may be amended by order of the Minister responsible for fisheries.

8 Prohibited species

(1) The retention by a fishery business operator subject to this Regulation of the following fishery products is hereby prohibited.

(a) Fish of the families Tetradontidae, Molidae. Diodontidae, Canthigasteridae.

(b) Fishery products commonly containing biotoxins of marine origin, such as ciguatera or other toxins dangerous to human health.

9 Principles to be applied in official control

(1) Measures applied by the Competent Authority under this Regulation shall be applied in a non-discriminatory manner, and shall be based on an

assessment of the food safety risks, except where this is not appropriate to the circumstances. The nature of the measure and these measures shall be effective, equitable, and proportionate to the risk.

(2) Where there are reasonable grounds to suspect that a fishery product subject to this Regulation may present a risk to human health then, depending on the nature, seriousness and extent of that risk, the Competent Authority shall take steps to identify the fishery product concerned, and to implement appropriate measures to prevent, reduce or eliminate that risk.

10 Official control of fishery products

(1) The Competent Authority shall undertake official control and monitoring of food safety conditions in establishments and vessels, in order to establish whether the requirements laid down are complied with.

(2) The official controls shall, at a minimum, include the checks set out in Regulation 11.

(3) Official control of fishery product shall be carried out:

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

(b) where non-compliance is suspected;

(c) when required for the purpose of issue of permits and certificates.

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

(5) Official control shall cover all stages of production, manufacture, processing, storage, transport, distribution, and export of fishery products from Tuvalu, including imported raw materials where appropriate.

11 General principles of official control

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

(a) periodic inspection of vessels and transport vessels within the jurisdiction of the Government of Tuvalu, and monitoring of compliance with permit conditions;

(b) periodic inspection of landing sites and shore facilities used to consign fishery products to markets;

(c) examination of any control systems that fishery business operators have put in place, and the results obtained;

(d) 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;

(e) assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), and HACCP, as set out in the Schedules to this regulation;

(f) examination of written material and other records which may be relevant to the assessment of compliance with the Act;

(g) interviews with fishery business operators in the supply chain and with their staff;

(h) the reading of values recorded by measuring instruments;

(i) controls carried out with the competent authority's own instruments to verify measurements taken by the operator;

(j) any other activity required to ensure that the objectives of the Act and this Regulation are met;

(k) Certifying, on request in writing, the health conditions relating to any batch of fishery products.

(2) Whenever practicable, inspections for the purposes of official control shall be carried out without prior warning.

(3) Inspection of fishery products shall include an examination of the following characteristics in a sample of fishery products 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 additives;

(f) microbiological contamination;

(g) visual presence of parasites;

(h) presence of poisonous fish species or fishery products.

12 Inspection reports

(1) The Competent Authority shall draw up reports on the inspections for official controls that it has carried out.

(2) These reports shall include a description of the purpose of the official controls, the control methods applied, the results of the official controls and, where appropriate, the action that the fishery business operator subject to official control should take.

(3) The Competent Authority shall provide the operator concerned with a copy of the report referred to in paragraph 2.

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

13 Unfit fishery products

(1) Fishery products are to be considered unfit for human consumption under Section 10 of the Act if:

(a) they have not been produced in accordance with the requirements of the Food Safety 2008 and Regulations made thereunder;

(b) organoleptic, chemical, physical, or microbiological checks or checks for parasites have shown that they are not compliant with standards set out in the Schedule 6 to this Regulation;

(c) they derive from prohibited fish species described in Regulation 8;

(d) the Competent Authority considers that they may constitute a risk to public health or, for any other reason, are considered to be not suitable for human consumption.

(2) Possession for sale or for the purpose of sale of fishery products which are unfit for human consumption shall be considered to be an offence under the Food Safety Act 2008.

14 Laboratory analysis of samples

(1) Samples collected under these Regulations for analysis for the purpose of official control shall be analysed by the official testing laboratories nominated by the Competent Authority and Gazetted by the Minister under Section 28 of the Food Safety Act 2008.

(2) Samples collected under these Regulations for analysis for the purpose of official control shall be selected and transmitted to the official laboratory by an authorised officer of the Competent Authority.

(3) The costs of the analyses will be borne by the Competent Authority except where the provisions of Section 31 of the Act are applied by the court.

15 Accreditation of official testing laboratories

(1) The official testing laboratories nominated for the purposes of analysis in support of official control shall comply with the *General Requirements for the Competence of Calibration and Testing Laboratories* laid down in ISO/IEC Standard 17025 in respect of the tests to be conducted.

(2) The accreditation and assessment of testing laboratories referred to in this Regulation may relate to individual tests or groups of tests.

(3) The testing laboratories nominated for the purposes of analysis in support of official control shall participate in appropriate proficiency testing schemes.

16 Certification of fishery products

(1) In relation to any defined batch of fishery products the Competent Authority may issue a certificate attesting to the:

(a) conditions in which that batch was produced, processed, stored, packed, transported, or placed on the market;

(b) compliance of that batch with any standard or regulation;

(c) fitness of that batch for any particular purpose.

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

(3) In relation to certification of direct exports from a freezer or factory vessel for which the Competent Authority has jurisdiction under the Act, the Competent Authority may delegate the responsibility for the issue of health certificates to the Master of the vessel.

(4) In relation to certification of direct exports from a freezer or factory vessel, for which the Competent Authority has no jurisdiction under the Act to determine the facts attested by the certificate, the Competent 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 Competent Authority of the flag state regarding the food safety conditions on board the vessel and its approval status.

17 Annual monitoring programmes

(1) The Competent Authority shall 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 Tuvalu.

(2) The monitoring programmes described in paragraph (1) will take into account the risks of different food safety hazards in fishery products, and the criteria described in Schedule 10 of this Regulation, and shall include the following parameters:

(a) heavy metals;

(b) residues of organochlorine and organophosphate contaminants of the environment;

(c) visible parasites in fish;

(d) histamine;

(e) marine biotoxins;

(f) other hazards in fishery products which are identified as relevant to food safety conditions of exported fishery products.

(3) The monitoring programmes will specify the sampling plan and the methods of analysis to be used.

(4) The Competent Authority shall prepare an annual report describing the monitoring programme and the results, which will be published by the Competent Authority.

18 Annual inspection programme and annual report

(1) The Competent Authority shall prepare an annual programme of official control activities, specifying:

(a) the number and type of inspections to be carried out;

(b) the criteria applied in drawing up the programme.

(2) The Competent Authority shall prepare 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;

(c) actions taken in the case of non-compliance.

(3) The annual programme and report on official control of safety of fishery products will be subject to the approval of the Minister.

(4) The annual inspection programme and the annual report shall be published by the Competent Authority.

19 Authorised officers

(1) The Competent Authority specified by the Ministers under Regulation 4 may nominate public officers under its control as food inspectors under Section 23(1) of the Act.

(2) Authorised officers acting in the course of their duties shall at all-time act with integrity, transparency and confidentiality.

(3) Information relating to any individual business which is obtained by an officer during the course of official controls or other activities under this Regulation shall not be disclosed without the consent in writing of the person carrying on the business, except:

(i) in accordance with directions of the Minister, so far as may be necessary for the purposes of this Regulation; or

(ii) for the purposes of any proceedings for an offence against the order or any report of those proceedings.

20 Offences

A person who contravenes this Regulation commits an offence, and where there is no specific penalty provided under the Food Safety Act 2007 or the Marine Resources Act 2006, including any subsidiary legislation or subsequent amendments, shall be liable to a fine not exceeding $2000 or imprisonment for a term up to 12 months or both.

SCHEDULE 1

COMPLIANCE CONDITIONS FOR FISHERY BUSINESS OPERATORS

1A. Operators supplying the European Union Market

Fishery business operators supplying the European Union Market shall comply with all Schedules applicable to their operations.

1B. Operators Supplying Other Export Markets

Fishery business operators supplying export markets other than the European Union shall comply with such Schedules as are required to meet the conditions applicable to their operations, as set by the Competent Authority of the importing country.

1C. Operator Supplying the Domestic Market

Fishery business operators supplying the domestic market shall comply with Schedules 2 and 5.

Schedule 2

HEALTH CONDITIONS FOR ALL FISHING VESSELS

1 Structural and Equipment Requirements

A. Requirement 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 should 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 fishery products for more than 24 hours:

1. Vessels designed and equipped for voyages of more than 24 hours duration should 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 ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products, notwithstanding that storage of fish in an ice-water slurry is an acceptable practice.

4. Holds, tanks or containers used for the storage of fishery products comprising fish species which are susceptible to the production of histamine should be equipped with a device for continuous automatic recording of the temperature inside each hold, tank, or container.

2 Hygiene Requirements

1. 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.

2. 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 seawater.

3. 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.

4. Fishery products comprising fish species which are susceptible to the production of histamine must be chilled immediately after harvest, so that the core temperature of the product reaches a maximum of 0°C within 12 hours.

5. Fishery products other than fishery products comprising fish species which are susceptible to the production of histamine, and other than those kept alive, must undergo chilling as soon as possible after harvest. However, when chilling is not possible, fishery products must be landed as soon as possible.

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. Where fish are headed and/or gutted on board, 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 shall have a programme for the systematic extermination of rodents, insects and any other pests.

Schedule 3

HEALTH CONDITIONS FOR 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 Schedule 2.
2. Freezer vessels must have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18°C.
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. In the case of brine freezing of whole fish intended for canning, the vessel operator should ensure that systems are in place to ensure that no tank which is used for the storage of fuel may also be used for the freezing or storage of fish.
5. Freezer 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 shall be located in the area furthest away from the cold source i.e. where the temperature in the storage room is the highest.
6. Rodents, insects, and any other pests shall be systematically exterminated in the vessel.
7. Vessels shall 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, shall be available to inspectors during inspections.

Schedule 4

HEALTH CONDITIONS FOR FACTORY VESSELS

1. Factory vessels should comply with the requirements of schedules 2 and 3.
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. special 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;
   h. hand-washing equipment for use by the staff engaged in handling exposed fishery products to have 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 3.

Schedule 5

REQUIREMENT FOR STORAGE AND MEANS OF TRANSPORT INCLUDING TRANSPORT VESSELS

1. Fishery products shall 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, shall 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, shall be kept at an even temperature of –18°C or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than 3°C during transport.
   c. Processed products shall be kept at the temperature specified by the manufacturer.
2. Means of transport used to transport fishery products should never be used for the transport of products other than food fit for human consumption.
3. 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 shall 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 shall 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 shall be smooth and easy to clean and disinfect, and shall be kept in clean condition so as to avoid contaminating the product during transport.

Schedule 6

FOOD SAFETY CONDITIONS FOR FISHERY PRODUCTS

1 Spoilage

Fish and fishery products intended for sale for human consumption shall possess organoleptic, chemical, and microbiological characteristics consistent with fitness for human consumption.

2 Conditions concerning parasites

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

3 Histamine

1. A consignment of fishery products comprising a fish species which is susceptible to the production of histamine shall 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 shall fulfil the following requirements:

   a. the mean value shall 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. Examinations for official control shall be carried out in accordance with EN ISO 19343.

4 Heavy metal contaminants

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

Table 1: Maximum Limits for lead concentration in fishery products

Substrate	MRL Pb (mg/kg wet weight)
Edible portion of all fishery products except were indicated below	0.3

Table 2: Maximum Limits for cadmium concentration in fishery products

Substrate	MRL Cd (mg/kg wet weight)
Edible portion of all fishery products except were indicated below:	0.05
Mackerel (*Scomber* species), tuna (*Thunnus* species, *Katsuwonus pelamis*, *Euthynnus* species)	0.1
Muscle meat of bullet tuna (*Auxis* species)	0.15
Muscle meat of Swordfish (*Xiphias* gladius)	0.25

Table 3: Maximum Limits for mercury concentration in fishery products

Substrate	MRL Hg (mg/kg wet weight)
Fishery products (26) and muscle meat of fish, excluding species listed below	0.5
Muscle meat of the following fish (25): Bonito (*Sarda sarda*) Marlin (*Makaira species*) Sail Fish (*Istiophorus platypterus*) Swordfish (*Xiphias gladius*) Tuna (*Thunnus species, Euthynnus species, Katsuwonus pelamis*)	1.0

2. Sampling and analysis should be conducted in accordance with CEN Standard 'Foodstuffs — Determination of trace elements — Performance criteria and general consideration' or other equivalent recognised methodology.

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

5 Organochlorine contaminants

1. 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, shall be regarded as unfit for human consumption.

Table 4: Maximum Limits for concentration of dioxin and dioxin-like PCBS in fishery products

Foodstuffs	Maximum levels		
	Sum of dioxins (WHO-PCDD/F-TEQ) (32)	Sum of dioxins and dioxin-like PCBS (WHO-PCDD/F-PCB-TEQ) (32)	Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180 (ICES – 6) (32)
Muscle meat of fish and fishery products and products thereof, with the exemption of marine oils	3,5 pg/g wet weight	6,5 pg/g wet weight	75 ng/g wet weight
Marine oils (fish body oil, fish liver oil and oils of other marine organisms intended for human consumption)	1,75 pg/g fat	6,0 pg/g fat	200 ng/g fat

2. Sampling methods, preparation and analytical requirements should follow internationally specified protocols

6 Additives

1. The additives listed in this section may be applied to the fishery products indicated providing that the maximum limits in the final product are not exceeded.

2. Salts taken up by fish during brine freezing in clean seawater shall not be considered additives.

Additive	Permitted Fishery products	Maximum level (g/kg)
Tri-phosphates and polyphosphates of sodium, potassium and calcium	Frozen fishery products	5

7 Marine biotoxins

Fishery products should be free of marine biotoxins at levels likely to render it unfit for human consumption

Schedule 7

IDENTIFICATION MARKS FOR FISHERY PRODUCTS

1. Fishery products which are consigned to market shall bear the following information on the packaging or associated documentation.
   a. The name of the country of origin of the products.
   b. The name and official registration number of the vessel 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 grade.
   d. Packaging method (chilled/frozen/canned/bulk etc)
   e. The date on which it was processed or packed 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)
   h. The catch area (according to FAO Areas)
   i. Name of any food additives administered to the product and code number if appropriate.

Schedule 8

REQUIREMENT FOR HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM

GENERAL REQUIREMENTS

1. Fishery business operators subject to this Schedule shall implement a system of own checks, based on the principles of Hazard Analysis and Critical Control Point System, which shall 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 operations 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 this Regulation

   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 competent authority. The results of the different checks and tests will be kept for a period of at least two years.

2. Fishery business operators subject to this Schedule must make provision for a sampling programme which, though not concerning systematically every production batch, nevertheless allows:

   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

   c. product or to the manufacturing process;

   d. verification, at specified intervals, that all provisions are still appropriate and properly applied.

3. 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 fishery products, then the products concerned will be considered to be not in compliance with the requirements of Section 10 of the Food Act and shall be treated accordingly.

4. In order to keep a written record or a record registered in an indelible fashion, as referred to paragraph 1(d) of this Part of the schedule, the fishery business operators must document all information relating to the implementation of own checks system and its verification.

5. The documentation referred to in paragraph 1 (d) must include two types of information to be kept for submission to the competent 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 2, plus reports and written accounts of decisions relating to corrective action when taken. An appropriate document management system must provide for the easy retrieval of all documents relating to an identified production batch.
6. The documentation referred to in paragraph 1 (d) must be kept available for inspection at all times at the location of the fishery business activity.
7. Fishery business operators should 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 HACCP principles.

SPECIFIC REQUIREMENT FOR THE OWN CHECKS SYSTEM

1. The own checks system will represent an approach internal to the operation, developed and implemented by the fishery business operator.
2. As part of the internal approach referred to in paragraph 1 of this part of the Schedule, fishery business operators may use guides of good manufacturing practice drawn up by appropriate professional organizations and acceptable to the Competent Authority.
3. In the design of any system for own-checks the following general approach should be adopted:
   a. identification of hazards, analysis of risks and determination of measures to control them.
   b. identification of critical points
   c. establishing critical limits for each critical point
   d. establishing monitoring and checking procedures
   e. establishing corrective action to be taken when necessary

f. establishing verification procedures

g. validation of the own-checks system

h. documentation of the system and maintaining records of results.

4. This general approach should be used with flexibility appropriate to each situation.

IDENTIFICATION OF CRITICAL POINTS

1 General principles

1. "Critical point" means any point, step or procedure at which control can be applied and when a food safety hazard can be prevented, eliminated or reduced to acceptable levels.

2. All critical points should first be identified by a detailed review of the process (applying knowledge of microbiological and other hazards which may potentially arise). This should be undertaken by a person with specialised knowledge, and by reference to existing codes of practice.

3. The information thus generated is used as the basis of the own-checks system to ensure compliance with the hygiene and safety requirements of the process, including those specified in any relevant code of practice.

4. The critical points are specific to each fishery business operation depending on the raw materials it uses and on its manufacturing processes, structure and equipment, end products and marketing system.

5. The sequential steps described below may be followed in order to identify and characterise the critical points in the process.

2 Assembly of a multidisciplinary team

1. A multi-disciplinary team should be drawn from all parts of the fishery business operator concerned with the product, and should include a wide range of specific knowledge and expertise appropriate to the product under consideration, its production (manufacture, storage, and distribution), its consumption, and the associated potential hazards.

2. The team may consist of one or more of:

    a. a quality control specialist who understands the biological, chemical, or physical hazards connected with a particular product group.

    b. a production specialist who has responsibility for, or is closely involved with, the technical process of manufacturing the product under study,

c. a technician who has a working knowledge of the hygiene and operation of the process plant and equipment,

d. any other person with specialist knowledge of microbiology, hygiene, and food technology.

3. One person may fulfil several, or all, of these roles. The most important factors are that all relevant information should be available to the team and that they are applied effectively to ensure that the own-checks system developed is valid and reliable.

4. Where necessary, the team may be assisted by external specialists who will contribute technical knowledge in areas not adequately covered by the establishment's own personnel. Such advice may be obtained from sources such as consultants or government inspectors.

3 Description of the product

1. The end product should then be described in terms of:

   a. composition (e.g. species, raw materials, ingredients, additives)

   b. structure and physio-chemical characteristics (e.g. whole, portion, Aw, pH,),

   c. nature and extent of processing (e.g. heating, freezing, drying, salting, smoking and respective process conditions)

   d. packaging (e.g. hermetic, vacuum, modified atmosphere)

   e. storage and distribution conditions (temperature control)

   f. required shelf life (e.g. sell by date and best before date)

   g. instruction for use

   h. any microbiological or chemical criteria applicable to the final product

4 Identification of intended use

The multi-disciplinary team should also define the normal or expected use of the product by the customer and by the consumer target groups for which the product is intended. In specific cases, the suitability of the product for particular groups of consumers with special needs may have to be considered (whether target market segments or not).

5 Construction of a flow diagram (description of manufacturing process)

1. All steps involved in the process, including delays during or between steps, from receiving the raw materials to placing the end product on the market, through preparation, processing, storage and distribution, should be studied in sequence,

and presented in a detailed flow diagram with technical data to describe process conditions at each stage.

2. Types of data may include but are not limited to:
   a. plan of working premises and ancillary premises.
   b. equipment layout and characteristics
   c. sequence of all process steps (including the incorporation of raw materials)
   d. ingredients or additives and delays during or between steps)
   e. technical parameters of operations (in particular, time and temperature, including delays, and concentrations of solutions)
   f. flow of products (including potential cross-contamination)
   g. segregation of clean and dirty areas (or high/low risk areas)
   h. cleaning and disinfection procedures
   i. hygienic environment of the establishment
   j. personnel routes and hygiene practices
   k. product storage and distribution conditions

6 On-site confirmation of flow diagram

After the flow diagram has been drawn up, the multi-disciplinary team should confirm it on site during operating hours. Any observed deviation should result in an amendment of the original flow diagram to make it accurate.

7 Listing of hazards and control measures

1. A hazard is a potential to cause harm to health, and is anything covered by the hygiene objectives of legislation and codes of practice relating to the storage, processing, and packaging of fishery products.
2. Specifically, a hazard may include any of the following:
   a. unacceptable contamination (or recontamination) of a biological, chemical, or physical nature of raw materials, intermediate products, or final products
   b. unacceptable survival or multiplication of pathogenic micro-organisms, and unacceptable generation of chemicals in intermediate products, final products, production line or line environment,
   c. unacceptable production or persistence of toxins or other undesirable products of microbial metabolism.
3. For inclusion in the list, hazards must be of a nature such that their elimination or reduction to acceptable levels is essential to the production of safe food.

4. Using the confirmed flow diagram as a guide, the team should then:
   a. list all potential biological, chemical, or physical hazards that may be reasonably expected to occur at each process step (including those resulting from acquisition and storage of raw materials and ingredients and delays during manufacture and any other foreseeable eventuality).
   b. consider and describe what control measures, if any, exist which can be applied for each hazard.
5. Control measures are those actions and activities that can be used to prevent hazards, eliminate them, or reduce their impact or occurrence to acceptable levels.
6. More than one control measure may be required to control an identified hazard, and more than one hazard may be controlled by a single control measure.
7. Control measures need to be supported by detailed procedures and specifications to ensure their effective implementation. For instance, this may include detailed cleaning schedules, precise heat treatment specifications (time and temperature combinations), concentrations, and quantities of preservatives used.

8 Methods for identification of critical points

1. The identification of a critical point for the control of a hazard requires a logical approach. Such an approach can be facilitated by the use of the decision tree in Figure 1. Other methods can be used by the team, according to their knowledge and experience.
2. For the application of the decision tree, each process step identified in the flow diagram should be considered in sequence. At each step, the decision tree must be applied to each hazard that may be reasonably expected to occur or be introduced, and each control measure identified.
3. The decision as to which stages of the process are to be regarded as critical points requires a flexible and common sense approach. In particular, there is a need to apply a pragmatic view of the causes of given hazardous effects to avoid, whenever possible, the listing of unnecessary critical points.

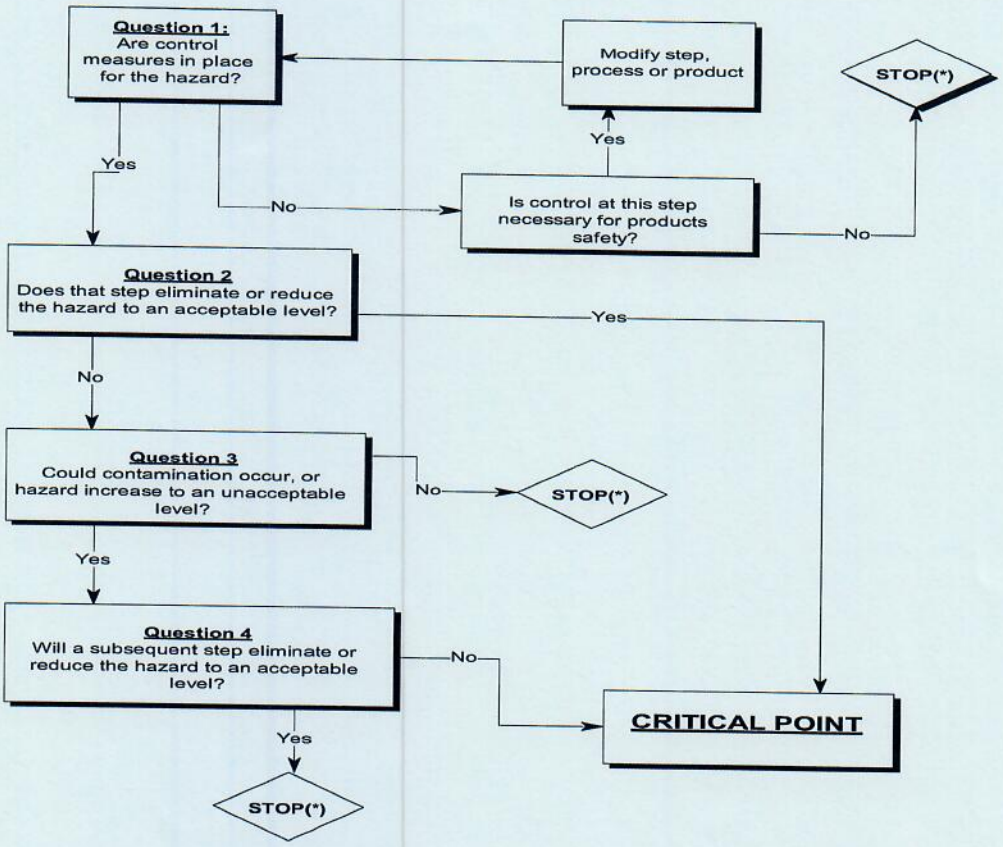

Figure 1: Decision Tree for the Identification of Critical Points

(NB. * indicates that point is not critical; proceed to the next stage of the process)

9 Action to be taken following identification of a critical point

1. The identification of critical points has two consequences for the multi-disciplinary team which should then:

   a. ensure that appropriate control measures are effectively designed and implemented. In particular, if a hazard has been identified at a step where control is necessary for product safety and no control measure exists at that step or at any other, then the product or process should be modified at that step, or at an earlier or later stage, to include a control measure.

   b. establish and implement a monitoring and checking system at each critical point.

MONITORING AND CHECKING OF CRITICAL POINTS

1 General principles

1. An appropriate monitoring and checking system is essential to ensure the effective control of each critical point.
2. Monitoring and checking of critical points includes all those observations and/or measurements necessary to ensure that the key process variables at critical points are kept under control.
3. The following steps are suggested as an appropriate framework for the design of a suitable system for of monitoring and checking.

2 Establishing critical limits

1. Each control measure associated with a critical point should give rise to the specification of critical limits.
2. Those critical limits should correspond to the extreme values acceptable with regard to product safety. They separate acceptability from unacceptability. They are determined for observable or measurable parameters which can readily demonstrate whether the critical point is under control; they should be based on substantiated evidence that the chosen values will result in elimination of the hazard.
3. Examples of such parameters include temperature, time, pH, moisture level, additive, preservative or salt level, and sensory parameters such as visual appearance or texture.
4. In some cases, to reduce the risk of exceeding a critical limit due to naturally occurring process variations, it may be necessary to specify more stringent target levels than are necessary to eliminate the hazard, to ensure that process variables remain within the critical limits in a reasonable majority of cases.
5. Critical limits may be derived from a variety of sources. They may be defined by regulatory standards or from existing and validated guides of good manufacturing practices. In all cases the team should ascertain their validity relative to the control of the identified hazards at the critical points.

3 Establishing a monitoring and checking system

1. An essential part of own-checks is a programme of observations or measurements performed at each critical point to ensure compliance with specified critical limits. The programme should describe the methods of measurement, the frequency of observations or measurements and the recording procedures to be followed.
2. Observations or measurements must be able to detect loss of control at critical points and provide information in sufficient time for corrective action to be taken.
3. Observations or measurements may be made continuously or discontinuously.
4. When observations or measurements are not continuous, it is necessary to establish a frequency of observations, or measurements (in terms of a defined sampling plan), which provides information which can be validly used for extrapolation of the resulting measurement data to the behaviour of critical variables between observations.
5. Any decision on the periods between discontinuous observations of critical variables at critical points should therefore be based on a detailed knowledge of the behaviour of those variables (and in particular their rate of change under all foreseeable circumstances).
6. A written programme of observations or measurements should properly identify for each critical point:
   a. Who is to perform monitoring and checking.
   b. When monitoring and checking is performed.
   c. How monitoring and checking is performed.

4 Establishing a corrective action plan

1. Observations or measurements may indicate:
   a. that the parameter monitored is tending towards, although not exceeding, its specified critical limits, indicating a trend toward loss of control. Appropriate corrective action to maintain control must be taken before the occurrence of a hazard.
   b. that the parameter monitored has exceeded its specified critical limits, indicating a loss of control. It is necessary to take appropriate corrective action to regain control, and to decide on an appropriate action with respect to the products subject to the process conditions exceeding the critical limits.

2. Corrective action must therefore be planned and documented in advance by the multi-disciplinary team, for each critical point and for each of the above scenarios, so that the necessary action can be taken without hesitation when the event is observed.
3. The corrective action plan should include:
    a. proper identification of the person(s) responsible for the implementation of the corrective action
    b. description of means and action required to correct the observed deviation.
    c. action to be taken with regard to products that have been manufactured.
    d. the period when the process was out of control.
    e. written records of measures taken.

5 Validation

1. "Validation" refers to those actions taken to confirm that the HACCP system is working effectively in reducing or eliminating the identified hazards
2. The multidisciplinary team should specify the methods and procedures to be used for the periodic validation of the own-checks system.
3. The validation procedure may include:
    a. a reinforced sampling and analysis (both more intensive and extensive than the systems established for the routine application of own-checks) of intermediate or final products, and at critical points
    b. surveys on actual conditions and product characteristics during storage, distribution, and sale, and at the point of actual use of the product
4. Validation procedures may also include:
    a. inspection of operations
    b. confirmation of effectiveness of critical limits
    c. review of deviations and corrective action and measures taken
    d. additional confirmatory sampling and measurements
    e. audits of the HACCP system and its records
5. The person responsible for the establishment should implement the validation programme at specified intervals.
6. On a basic level, verification will entail an audit of the own-checks system and its records. This may include random sampling and analysis, to confirm that own checks are being made, and that sampling, measurement and recording of results are being carried out correctly.

7. In addition it is necessary to review the HACCP system to ensure that it is still valid in case of changes made. Changes in the system of own-checks may arise as a result of:
   a. change in raw material or in product, processing conditions (factory layout and environment, process equipment, cleaning, and disinfection programme).
   b. change in packaging, storage, or distribution conditions.
   c. change in consumer use.
   d. receipt of any information on a new hazard associated with the product, or any new information on an old hazard.
8. Any amendments to the own-checks system should be fully incorporated into the documentation and record-keeping system, in order to ensure that accurate up-to-date information is available.

6 Documentation

1. A written record of the complete documentation relating to the design and operation of the system of own-checks, should be kept at the establishment, or on board the vessel, and be permanently available for inspection.
2. The written record should include:
   a. own checks system definition
      i. detailed physical, chemical and microbiological description of the product
      ii. description of the process (including process flow diagrams)
      iii. identification and definition of hazards
      iv. identification of critical points
      v. definition of critical limits to key variables at critical points
      vi. definition of sampling periods and frequency for measurement of key variables
      vii. description of measurement methods and procedures for measurement of key variables
      viii. description of corrective actions in case critical limits are exceeded.
      ix. definition of validation procedures
      x. results of the validation activities
   b. results of own checks
      i. results of all monitoring and checking actions

ii. written accounts of any decisions made relating to corrective action when critical limits have been exceeded

iii. results of the validation activities.

3. Data retrieval should allow identification of the monitoring data applicable to each batch of fishery products.

4. Results of monitoring and checking actions should be maintained for a period of at least two years.

5. The own checks data management system must provide, in particular, for the easy retrieval of all documents relating to an identified production batch.

Schedule 9

REQUIREMENT FOR POTABLE WATER

1. Where this Regulation refers to potable water, it shall mean water which complies with the specifications set out in this Schedule.
2. Fishery business operators should be in a position to demonstrate with a distribution diagram the distribution of potable water and other water within the establishment or vessel. This should show all sources, pipework, tanks and cisterns and outlets of water within the establishment or vessel. Outlets should be numbered and identifiable on the plan.
3. Where potable water is treated with a process of chlorination or other means of ensuring microbiological safety, and the fishery business operator relies on that treatment to comply with the microbiological standards set out in Table 1, then the effectiveness of the process should be monitored by the operator on a regular basis by submitting water samples from each source for a microbiological analysis. If numbers of microbes exceed the specifications, then action must be taken to identify the source and correct the situation causing the contamination.
4. Samples of potable water taken to test for compliance with standards set out in this schedule should be taken from various outlets within the establishment or vessel in rotation. Where used, ice shall 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 shall comply with the microbiological standards set out in Table 1, and the chemical parameters of Table 2.

Table 1: Microbiological parameters

Parameter	Parametric value (Number/100ml)
Escherichia coli (E.Coli)	0
Enterococci	0
Clostridium perfringens (including spores)*	0

*This parameter should be tested if the water originates from or is influenced by surface water.

Table 2: Chemical Parameters

Parameter	Parametric value	Unit	Note
Acrylamide	0.1	µg/l	1
Antimony	10	µg/l	
Arsenic	10	µg/l	
Benzene	1.0	µg/l	
Benzylpyrene	0.010	µg/l	
Boron	1.5	mg/l	
Benzoate	10	µg/l	2
Cadmium	5	µg/l	
Chromium	25	µg/l	
Copper	2	mg/l	3
Cyanide	50	µg/l	
1,2 dichloroethane	3.0	µg/l	
Epichlorhydrine	0.1	µg/l	1
Fluoride	1.5	mg/l	
Lead	5	µg/l	3,4
Mercury	1	µg/l	
Nickel	20	µg/l	3
Nitrate	50	mg/l	
Nitrite	0.5	mg/l	
Pesticides	0.1	µg/l	4,5
Pesticides total	0.5	µg/l	4,6
Polycyclic aromatic hydrocarbons	0.1	µg/l	Sum of concentration of specified compounds Note 7
Selenium	20	µg/l	
Tetrachloroetchane and trichloroethane	10	µg/l	Sum of concentration of specified compounds
Trihalomethanes	100	µg/l	Sum of concentration of specified compounds Note 8
Vinyl chloride	0.5	µg/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 should 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 µg/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 should be aimed for. The specified compounds are: chloroform, bromoform, dibromochloromethane, bromodichloromethane.

Made under my hand this 1st day of November, 2022.

HON. ISAIA TAAPE

Minister for Health, Social Welfare and Gender Affairs

And under my hand this 1st day of November, 2022.

HON. REV. DR. KITIONA TAUSI

Minister for Fisheries and Trade

Published at the Government Notice Board this 1st day of November, 2022 at Funafuti.

DR. TAPUGAO FALEFOU

Secretary to Government