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REPUBLIC OF MARSHALL ISLANDS

Marshall Islands Marine Resources Authority

Industry Standards

For the offering of official guarantees in terms of fish and fishery product exports to General Markets, United States of America, China and the European Union

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SEAFOOD INDUSTRY STANDARDS

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Issue no.1, Revised Version.02

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BERRY MULLER
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Supported by

NEW ZEALAND
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1 Contents

REGULATORY STATEMENT

These standards:

- Are issued pursuant to the the Fish Processing and the Fish Export Regulations 2020, under Title 51 Marshall Island Resource Code.
- May be referred to as Industry Standards.
- Apply to operators of fish processing establishments and applicants for licences in respect of fish processing establishments and landing sites, transporters, ice plants, cool stores and vessels with product destined for all markets in general and for the European Union (EU) in particular.

2 Amendments

Section Title	Page/ s	Date	Version No.	Details of amendment	Approval
6.3.5	45	6/22/22	02, revised	Amended from: 5) The operators shall hold records on file for at least TWO years from date of production to read "The operator shall hold records on file for at least 3-5 years depending on the shelf life of the products date from production, taking into consideration products destined for canning purposes.	approved
Appendix 5	106	6/22/22	02, revised	Amended to include; 3. refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18ºC. Storage holds must be equipped with automated temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest. 4.. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Part C, points 1, 2, 3, 4 and 5.	approved
7.5.5.1 (1) 6.	64	6/22/22	02, revised	Requirements of the EU Health Certificate 1), point 6, Removal of Article 3 and 4 of Commission Implementing Regulation 2019/628 and replaced with Regulation 2020/2035.	approved
Sampling plan listeria monocytogenes	118	6/22/22	02, revised	iii) Fresh/frozen fish- Ready to eat, sampling plan for listeria monocytogenes- reference method EN/ISO 6579 is amended to EN/ISO 11290-1 method	approved

3 General terms and interpretations

3.1 General Terms

The following terms shall be considered when reading this Standard:

3.2 Authority

Throughout this Standard, the Authority refers to Director and the Marshall Island Marine Resource Authority and or the authority for the implementing of the fish/food safety, verification and certification aspects of that Authority.

3.3 Alternative Standards

In situations where these Standards do not cover a specific requirement, but which becomes a requirement from importing country and/or fitness for purpose needs, MIMRA as the CA reserve the right to adopt the principles of any of the following international standards without the need to amend these Standards:

a) Fish and Fishery Product standards and codes of practice Volume 9 of the Codex Alimentarius, Fish and Fishery Products Standards
b) USFDA Low Acid Canned Foods Code Federal Regulation Title 21 Chapter 113

3.3.1 Legislation

Where legislation is referenced throughout this Standard it should be noted that the requirements includes the title of the primary legislation and secondary legislation and any subsequent amendments.

3.4 Legislation

Title 51- of the Marshall Island Marine Resource Code - MRA 1997 (Primary)

The Marine Resource Act, Fisheries Act and subsequent Legislation relevant to this standard provides for:

1. The controls on licensing local and foreign flagged vessels fishing vessels
2. The controls on licensing fish processing establishments
3. The powers of authorised officers (in general all officers licensed under the Act)
4. The offences relating to authorised officers and observers
5. The setting of fees, charges and levies.
6. The penalties pursuant to the breach of the license conditions
7. Powers to make regulations, set standards
8. Setting out powers to regulate the processing, marketing, certification and export of fish and fishery products.
9. The duties of the Fish Processing Establishments and Operators
10. The provision of powers of entry and search of any place believed to be in breach of the requirements of RMI legislation
11. The seizure and confiscation of fish and fish products.

3.4.1 The Fish Processing and Export Regulations 2020.

Subject to Title 51 of the Marshall Island Revised Code, these Regulation enables;

1. the regulation of the commercial processing of fish and fish products,
2. the commercial export of such fish and fish products,
3. prohibits the commercial processing and export of fish and fish products without authorization from the Authority
4. the setting of standards for the processing and exports of fish and or establishment and related activities.

5. provides for an application process for licenses to conduct such activities;
6. provides for the appointment of fish inspectors
7. provides offenses for the violation of the Regulation;
8. and prescribes the penalties.

3.4.2 Food Safety Act and Environmental Protection Act

Subject to the above legislations' exporters will adhere to requirements pertaining to manufacture and domestic trade where public health is concern and meeting certain requirements under local legislations.

The operator must make it his or her business to understand the requirements of those legislations.

Operator may be subjected to these laws when required by the RMI Authorities

3.5 Application

The Industry Standards (ISs) outline requirements to be met at an operational level by fish processing establishments, vessels and other activities requiring controls.

These Industry Standards are intended to provide further detail to legislation and provide an auditable standard for both CA and industry personnel alike.

Facilities that are not in substantial compliance with the Fish Processing and Export Regulation 2020 and the requirement of the ISs may not be permitted to export seafood products from RMI in particular those intending to export to the European Union.

This Standards sets additional requirements for:

1. European Union:
    a. Ice plants
    b. Cold Stores
    c. Offshore vessels
    d. Coastal vessels
    e. Landing sites
    f. Transporters
2. China
3. United States of America

3.6 Interpretation

Approved	Approved by the Director.
Batch	A number of lots from the same facility submitted for inspection simultaneously.
Competent Authority	Marshall Island Marine Resource Authority (MIMRA) is the competent authority for fish and fishery products, whilst the implementation function of food safety verification and certification for exports is carried out by the fish inspectors or CA officers, authorised under Tittle 51- Marine Resource code.
Clean seawater	Sea-water that is free of excess turbidity, colour, offensive odours and other contaminating substances, and which meets other approved requirements.
Container	Includes any box, bag, can, carton, crate, jar, wrapper, packaging material used for packing fish but does not include shipping containers.

Contaminant	Any biological or chemical agent, foreign matter, or other substances not intentionally added to fish and fishery product that may compromise food safety or suitability.
Contamination	The introduction or occurrence of a contaminant in food or food environment.
Control (verb)	To take all necessary actions to ensure and maintain compliance with criteria established in a HACCP plan or support programme.
Control (noun)	the state wherein correct procedures are being followed and criteria are being met.
Control measure	any action and activity that can be used or put in place to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
Control Point	any point, step or procedures at which biological, chemical or physical factors can be controlled
Corrective Action	Any action to be taken when the results of monitoring at the Critical Control Point indicate a loss of compliance with criteria established in a HACCP plan, support programme or any other approved programme.
Critical Control Point (CCP).	A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level
Critical Limit	A criterion, which separates acceptability from unacceptability.
Director	of the Marshall Islands Marine Resource Authority of the Ministry of National Resources and Development
Facility	Any building or vessel or area in which food is handled, prepared and stored, including the surroundings under the control of the same management.
Fishing Vessel	Vessels which bleed, head, gut or remove fins of fish into a chilled or for preserved fish in brine or refrigerated sea water. It can also have the capacity for frozen storage for less and or more than 24 hours.
Fish	Any water dwelling, aquatic or marine animal or plant, live or dead, and includes the egg, spawn, spat and juvenile stages, and any of their parts but does not include any species of whales.
Fitness for purpose	Suitable for intended use
Flow diagram	a systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item
Food safety	Assurance that food will not cause harm to the consumer when it is prepared or eaten according to its intended use.
Foreign matter	Any organic or inorganic matter that is not permitted in these standards, not indigenous to fish, detrimentally affects the quality of the fish or fitness for human consumption, and is included in or adheres to any part of the fish.
Good Manufacturing Practice -	Compliance with the structural and operational requirements of Sections 3 and 4 of these standards.
HACCP	Hazard Analysis Critical Control Point – a preventative measure system that identifies, evaluates, and controls hazards that are significant for food safety.
HACCP Plan	A document prepared in accordance with the principles of HACCP as defined by Codex Alimentarius Commission to ensure control of hazards that are

	significant for food safety in the segment of the food chain under consideration.
Hazard	A biological, chemical or physical agent in, or condition of, food which has the potential to: a) Affect food safety; or b) Cause an adverse health effect.
Hazard Analysis	The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP Plan.
Ingredient	Any substance (including a food additive) used in the processing of fish that is included in or part of the final fish product.
Label	Any wording, tag, brand, symbol, picture, or other descriptive matter written, printed, stencilled, marked, embossed, impressed on, appearing on, attached to, or enclosed within any fish or fish product.
Lot	A quantity of fish of the same type produced under the same conditions during a particular time interval generally not exceeding 24 hours and from an identifiable processing line.
Monitor	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP or other control point, is under control.
National Control Plan	A document intended for CA personnel use and outlining the organisation, legality & procedures that define how a CA performs their obligated duties.
Official analysis	Analysis carried out by an approved laboratory or on behalf the CA, at an accredited laboratory.
Operator	The natural or legal persons responsible for ensuring that the requirements of 'Fish Processing and Export Regulations 2020'are met within the food business under their control". The types of business entity are defined may include incorporations, partnerships, sole traders and other specialised types of organisation. A legal person has a legal name and has rights, protections, privileges, responsibilities, and liabilities under law, just as natural persons (humans) do.
Packing	The placement of fish into a container and includes sorting and grading.
Packaging	Any material that comes into immediate contact with the product that is intended to protect, encase, cover, enclose, contain or pack. Includes rigid materials such as cartons and containers where product is filled directly into the carton or container
Pre-requisite programme	See Support Programme
Potable water	Water that is fit for human consumption as prescribed according to RMI Environmental Protection Act seen equivalent to WHO standards for drinking water
Processing	Includes dismembering, cleaning, chilling, treating, freezing, drying, smoking, cooking, canning, packing of live fish or other preservation or further processing techniques
Refrigerated seawater	Clean seawater cooled by a suitable refrigerated system.

Sanitary design	In relation to any licensed facility, internal structure, equipment, or conveyance, means designed, constructed, and located so that it minimises the risk of contamination.
Sanitise	adequate treatment of surfaces by approved processes that are effective in reducing microbial contamination to a level that will not give rise to a health hazard.
Sample unit	one container and its contents, or individual fish, drawn at random from a batch.
Shall	Denotes a mandatory requirement.
Shipping containers	those containers used to store or otherwise contain raw materials and/or finished product under conditions that will prevent deterioration
Should	Denotes a recommended or advisory procedure.
Sound	In a state that will not contribute to contamination, directly or indirectly, of a food product
Suitable	Meeting the requirements of this standard and which will contribute to food safety
Support programme	A documented system that underpins or supports a recognised HACCP plan or a recognised hazard identification and analysis process (for example a good manufacturing or good hygiene practice (GMP or GHP) programme or schedule relating to cleaning, staff training, document management or other matters). Also known as pre-requisite programme, standard operating procedure (SOP), standard sanitary operating procedure (SSOP).
Validation	Obtaining evidence that a programme (HACCP plan or other documented programme required under these standards) is complete and meets the requirements of the legislation, and when implemented, will consistently achieve the required outcomes of the programme.
Verification	The application of methods, procedures, tests and other checks, in addition to monitoring, to confirm on-going compliance with the HACCP plan and other programmes.
Operator verification	Activities undertaken by the company, External verification – activities carried out by an external organisation (including Fisheries Division, overseas government reviewers, and customers).

3.7 Acronyms

CAC	Codex Alimentarius Commission
CCP	Critical Control Point
CA	Competent Authority (otherwise known as the MIMRA)
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organisation
FDA	Food and Drug Administration
FVO	Authorised Fisheries Verification Officer
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Points

IS	Industry Standards
IQF	Individually Quick Frozen
ISO	International Standards Organisation
MIMRA	Marshall Islands Marine Resource Authority
MPN	Most probable number
OMAR's	Overseas Market Access Requirements
QA	Quality Assurance
QC	Quality Control
Ppm	Parts per million
SSOP	Standard Sanitation Operating Procedure
TVB-N	Total volatile base - nitrogen
US or USA	United States of America
WHO	World Health Organisation

3.8 Document Control

3.8.1 Approval

These Industry Standards (ISs) will not become valid until approved by the Director of MIMRA through signing page 3 of this document.

3.8.2 Review

The IS will be reviewed at least annually, but more often if required.

Review may take place if one of these factors arises but is not limited to:

1. A requirement by overseas importing countries
2. Following a significant food safety occurrence
3. On request from the Director
4. Discussions in the CA of various market and industry requirements
5. The comments from the operators in response to these IS or any market requirements.

When there is a need to make alterations to any part of these ISs, the proposed change will be presented to the CA Advisor and the CA officer approval.

Request for any changes will be discussed by the CA team and record of such discussions be held on file as records.

3.8.3 Amendments

Once CA approval has been gained the appropriate section or page of the IS will be changed.

Each person with responsibility for maintaining a copy of the ISs will record any amendments in the amendment sheet of each IS.

Amendment Sheet:

Name:	Page:	Amendment date	Details of amendment	Approval

4 Export Requirements

4.1 Conditions and Restrictions

4.2 General

The export of fish and fish products processed in RMI is prohibited unless the conditions and restrictions in these Industry Standards, RMI legislation and subsequent amendments have been fully met.

4.3 Licensing

RMI legislation requires the licensing of land-based establishments and vessels and other facilities required by market access requirements.

4.4 Conditions

A licensed fish processing facility shall operate:

a. In accordance with the Fish Processing and Fish Export Regulation 2020.
b. In accordance with these ISs for exports to the European Union.
c. In a clean and hygienic state which will not contaminate the product being handled at all times during catching, processing, packaging and transportation
d. With an effective means of fish storage to prevent deterioration
e. Under an approved HACCP plans as detailed in these standards
f. To meet importing country requirements

4.5 Procedure

4.5.1 Pre-Inspection Meeting

Before the management of an establishment start to build, rebuild or adapt an establishment, acting on their own initiative or on the initiative of the Competent Authority, the applicant may request a pre-inspection visit to discuss the requirements the operator is required to meet.

The Competent Authority may visit the establishment or meet with company representatives to view and discuss their plans in more detail.

4.5.1 Application

The business operator of an establishment proposing to prepare fish or fish products for export shall make an application on an approved form as given in Appendix Two.

Such an application must be accompanied by:

1. An adequate plan and description of the premises and process
2. A license fee set by the Authority
3. A copy of the HACCP plan and or supporting documents and or declaration as requested by the Authority from time to time
4. Further Information in line with *the Fish Processing and Fish Export Regulation 2020* may be requested by the Authority.

Similarly, vessels wishing to handle fish intended for export to the EU or vessel wishing to gain CA Health Certification for their products shall make an application on an approved form.

Such an application must be accompanied by:

1. A copy of the vessel plans
2. The prescribed licence fees.
3. A copy of the vessel's HACCP plan(s) and any supporting programmes (pre-requisite programmes or SSOPs)

4.5.1.1 Plans: Land based Facilities

Plans for land-based facilities shall include:

1. A locality map showing the physical boundaries of the site;
2. A site plan detail showing:
    a. The layout of the entire facility including roads and all prominent features,
    b. North compass point,
    c. Adjoining and location of neighbours;
3. A product flow diagram and main features of product flow;
4. Detailed information on major equipment used in fish processing including refrigeration equipment and capacities;
5. A water reticulation plan including all pipe work and fittings and identification of potable and non-potable water supply as applicable;
6. Identification of any factories or other hazardous premises that may affect the safety of the fish or fish products being processed, packed or stored within or next to the radius of the facility.
7. Specifications that must accompany plans include the following details in relation to the premises to be licensed /approved:
    a. Construction materials of the facility to be approved;
    b. Construction materials of equipment used in fish handling;

c. Construction materials and finishing for product contact surfaces;
d. Details of essential services, pest control, waste storage;
e. Details of waste treatment (if any) and disposal systems for sewerage, waste water and wash water
f. For cold stores, the method of refrigeration, capacity in kilograms and holding temperature;
g. For freezers, the method of refrigeration, capacity in kilograms, time required for a full load to reach -18°C (or -9C) from a stated initial temperature;
h. For refrigerated rooms, operating temperatures and size;

4.5.1.2 Plans: Vessels for EU Approval

Plans for EU approved vessels shall include:

1. A schematic or layout diagram of all areas where fish are to be handled and the flow of product
2. Details of water inlets for processing water in the hull
3. Detailed information on major equipment and surfaces used in fish handling on board the vessel including refrigeration equipment and capacities;
4. Details of the RMI registration and ownership of the vessel.
5. Specifications that must accompany plans include the following details in relation to the vessel to be licensed /approved
    a. Where there is more than one room, tank or hold having a similar function, the rooms, tank or hold shall be individually identified;
    b. Maximum number of processing personnel or crew.
    c. For vessels, the type of preservation and the number and location of holds or wells

4.5.2 Changes in Licence Details

When company information held on file by the MIMRA CA changes, for example, a change in factory or EU vessel layout, processing techniques, markets, ownership or company name, the company is to complete the application form for Amendments to Approval Details as given in Appendix Two. Additional and relevant information shall be attached to this form and submitted to the CA Advisor or to the CA Officer of the MIMRA

4.6 Rejection of Product

4.6.1 Within the Licensed Facility

Where product is found to be unfit for human consumption within the premises of the licensed facility or an EU vessel or establishment, this product must be clearly identified and isolated until an appropriate disposition is agreed.

The operator must ensure that all actions taken are documented and held on file. This action should be brought to the attention of a CA during officer in their next visit or port call.

4.6.2 Rejection from an Importing Country

Where product is found to be unfit for human consumption anywhere from distribution, an importing country, the operator must notify a CA inspector within 24 hours.

All affected product must be traced, identified, isolated and held pending agreement between the officer and the operator on disposition. The operator must ensure that all actions are recorded and that evidence is gathered to show actions were taken as agreed with a CA inspector within the agreed timeframe.

The operator must carry out an investigation into the cause of the problem. Corrective action must be taken to prevent recurrence of a similar problem. All such actions are to be documented and kept on file.

Penalties for not informing the authorities may include cancellation of license if in very serious scenarios.

Companies will be expected to follow their documented and approved Product Recall procedure when an importing country or customer rejects product as unfit for human consumption.

4.7 Container Refrigeration Unit Malfunction

Should the operation of the refrigeration unit of a shipping container fail or malfunction during transit from RMI to any foreign port destination the following procedure is to be followed:

1. The company is to advise the CA in writing, within 24 hours of the issue, with initial details of the malfunction including (where possible):
    a. Details of the malfunction including date, time and location of the container
    b. Intended actions to be taken to rectify the situation
    c. Condition of the product
2. Within 1 week of this advice the company is to provide the following information:
    a. Copies of the container automatic temperature recording chart showing container air temperatures up until the time of malfunction.
    b. Photos of the product being loaded into the new container
    c. Confirmation of product temperatures both on the day of the malfunction and temperatures once placed in the new operational container.
    d. At least 30 product temperatures evenly spread across the front, back and middle of the container shall be taken per container.
    e. At least 9 histamine test results with samples evenly spread across the front, back and middle of the container and tested using either:
        i. For product destined for the EU: an ISO 17025 accredited, independent laboratory, OR
        ii. For non-EU product: a reputable quantitative rapid test for histamine
3. In order to gain a new health certificate from the CA, test results must confirm that the histamine levels are acceptable to both the receiving market and according to RMI Industry Standards.
4. Confirmation of seal number and container number in which the product will be placed to rectify the situation.
5. A report detailing all actions taken to rectify the situation and maintain the integrity of the product. This should include:
    a. Dates and times of malfunction, date product is moved to another container or storage awaiting container repair and, date the problem is rectified, and
    b. Sufficient information to back up the condition of the product, and
    c. A conclusion as to product “fitness for purpose” following analysis of the histamine test results, and
    d. A decision on the recommended disposition of the product.
    e. Any other information requested by the CA
6. The CA will consider the information and provide the response. Upon satisfactory evaluation the CA will issue a new certificate for the product that is to be sent on to its final destination.
7. The CA must follow the procedure in the National Control & Export Protocol for the issuance of a replacement certificate.
8. The CA will provide a summary report for file purposes covering:
    a. Actions they have taken, and
    b. Decisions made, and
    c. The final outcome of the investigation
9. Any notes or other evidence kept or gathered during the course of the investigation.

10. Please note:
    a. The cost of any testing is to be covered by the company concerned and NOT the Competent Authority.
    b. The CA reserves the right to elect to visit the location of the affected product and sight the product in situations where they believe the information provided is incorrect or incomplete. The cost of CA travel and associated costs to be covered by the company concerned.

4.8 Export Clearance

4.8.1 General

Any persons seeking to export must meet the requirements of these standards. Furthermore, those intending to export to the European Union shall only export if they have been approved and meet the requirements given in Appendix 5.

4.8.2 Loading for Export

Loading for export shall take place in accordance with the following:

1. Where fish is being loaded for export, whether into a container, the hold of a ship or an aircraft, or otherwise, a CA officer shall be afforded a reasonable opportunity to inspect the loading of the fish, and
2. Any person involved in the loading operations shall assist the CA Officer in this inspection

For markets requiring a seal to be placed on containers prior to shipment, a CA will ensure seals are placed securely on containers and seal numbers recorded.

4.8.3 Refusal to Issue Certificate/Re-examination of Fish

In situations where an operator fails to meet the requirements of these Standards, the CA officer may refuse to issue an export or health certificate (refer section 6.5). Alternatively, the CA Officer may request to inspect or examine the fish and/or take samples for testing.

4.9 CA Inspection and Auditing

4.9.1 General

All facilities wishing to export fish or fish product must be audited by a CA officer as prescribed in this standard. Failure to undergo audits according to these standards will result in penalties.

This section details audit protocols to be followed when auditing a licensed facility's ability to ensure the following:

1. Structural and operational requirements of these standards are met;
2. Compliance with documented and approved HACCP plans;
3. Corrective actions are being followed and allow for the production of safe food;
4. Any relevant overseas market access requirements are met.

4.9.2 Documentation Requirements

Documents required by these standards shall be controlled and held on file by the operator.

Such documentation shall be made readily available to any CA officer or other authorised personnel within 24 hours of the request.

4.9.3 Rating of fish handling and processing establishments

Rating of the Establishment	**Number of minor deficiencies**	**Number of major deficiencies**	**Number of serious deficiencies**	**Number of critical deficiencies**
A	0 to 6	0 to 5	0	0

B	7 or more	6 to 10	1 to 2	0
C	NA	11 or more	3 to 4	0
D **(not approved)**	NA	NA	5 or more	1

*NA: Not applicable in this case.

4.9.4 Verification Frequency

4.9.4.1 Processing Establishments – External List

Based on the outcomes of verification the following variations will apply:

CATEGORY	STATUS	FOLLOW UP INSPECTION/VERIFICATION FREQUENCY
A	Very Good	Every 6 months
B	Good	Every 3 months
C	Acceptable	Every month (depend on risk)
D	Deficient	No processing until non-compliances rectified
Action to be taken by the CA	1. Record on Compliance database 2. Verification reports evaluated and it decided if there is need for special action to be taken, and compliance database 3. The CA decides if there is need for an immediate suspension or if a short time to correct the noncompliance can be given.	

4.9.4.2 Processing Establishments – Internal List

Based on the outcomes of verification the following variations will apply:

CATEGORY	STATUS	FOLLOW UP INSPECTION/VERIFICATION FREQUENCY
A	Very Good	Every 6 months
B	Good	Every 3 months
C	Acceptable	Every month (depend on risk)
D	Deficient	No processing until non-compliances rectified
Action to be taken by the CA	1. Record on Compliance database 2. Verification reports evaluated and it decided if there is need for special action to be taken, and compliance database 3. The CA decides if there is need for an immediate suspension or if a short time to correct the noncompliance can be given.	

4.9.4.3 EU Vessels

Based on the outcomes of verification the following variations will apply:

CATEGORY	STATUS	FOLLOW UP INSPECTION/VERIFICATION FREQUENCY
A	Very Good	Next verification on 1st unload after 6 months +/- 15 days.
B	Good	Next verification on 1st unload after 3-month days +/- 10 days.
C	Acceptable	Next verification on 1st unload after 1-month days +/- 5 days.

D	Deficient	Continuous inspection to up-grade once the critical deficiencies are corrected
Action to be taken by the CA	Record on Compliance database Verification reports evaluated and it decided if there is need for special action to be taken, and compliance database The CA decides if there is need for an immediate suspension or if a short time to correct the noncompliance can be given.	

4.9.4.4 Cold Stores, Landing Sites, Ice Plants or Transporters.

Cold stores, landing sites, ice plants or transporters will be subject to external verification every quarter (3 monthly)

4.9.4.5 New Operators

Any new operators (whether it be land-based premises or EU vessels, cold stores, landing sites, ice plants or transporters will commence inspections at the most frequent verification frequency and future frequencies will be dependent on the outcome of the initial inspection.

4.9.4.6 HACCP Plan, SSOP/GMP and Infrastructure Reviews

These are to be completed before an establishment commences operation and again annually after this.

4.9.4.7 Suppliers to EU exporters

The frequency of regulatory verification for establishments in full compliance will be fixed at four annual visits.

Time granted for completion of corrective actions or suspension of EU supplier status will be decided on case-by-case basis.

4.9.4.8 Traceability Checks

The frequency of checks on traceability should be at least monthly for exporters of fishery products to the EU.

4.9.4.9 Organoleptic Checks

The frequency of organoleptic checks should be at least monthly for exporters of fishery products to the EU.

4.9.4.10 Parasite Checks

The frequency of parasite checks should be at least monthly for exporters of fishery products to the EU.

4.9.5 Corrective actions

Whenever a deficiency is noted as a result of a CA inspector's audit, the officer will discuss each deficiency with the operator (or his or her representative) prior to leaving the premises. In discussing each deficiency, the officer and the operator shall agree actions to be taken and timeframes allowed to rectify the deficiency. The CA Inspector will then complete a corrective action form as shown in Appendix Six and return this with the completed audit report.

5 Design and Construction

5.1 Site and Layout

5.1.1 Location

1. The licensed facility shall be sited so that neighbouring buildings, operations or land-use present no source of potential contamination for the hygienic operation of the facility. It shall also be located in an area away from objectionable odours, smoke, dust, other contaminants and flooding.

5.1.2 Surrounds

1. Immediately surrounding buildings, roads, pathways and other areas serving the licensed facility shall be kept clean and tidy at all times and be suitably paved, graded, grassed, or landscaped to avoid the risk of dust, pests or other contaminants from entering food handling and storage areas.
2. Product load in or load out areas shall be suitably covered to protect the product from dust and environmental exposure (sun, rain, etc.) in situations where the product is unpackaged. There shall be adequate drainage of the surrounds including roads, access ways and pathways and provision shall be made to allow for their cleaning. Where vehicles are cleaned on the premises a paved and drained area shall be provided for this purpose
3. The processing facility and associated amenities and storage areas shall be adequately separated from other parts of the building that are not directly associated with fish processing or packing. Separation may be by wall, ceiling or self-closing door.
4. Guard dogs shall not be used unless there is no risk of contamination to the establishment and/or product.
5. If the plants' grounds are bordered by property not under the operator's control and not maintained in the manner described in this section, extra care shall be taken to inspect, exterminate or other methods to exclude pests, dirt and filth that may be a source of food contaminations.

5.1.3 Layout

1. Layout of factory precludes contamination and provides adequate working area. There should be separation by walls, physical separation or other effective means to separate:
    a. between clean and dirty areas
    b. between dry and wet areas
    c. between hot and cold areas
    d. between areas that may cause contamination to the product being processed.
2. The layout shall be such that equipment and processing activities facilitates the rapid processing of fish and that fish is not exposed to unnecessary contamination at any point in the process.
3. All possible preventative measures and provisions must be taken during design and construction:
    a. to avoid cross-contamination during production between final and raw products;
    b. to minimize the risk of food contamination by contact surfaces, packing materials, offal, drainage systems etc.;
    c. to minimize maintenance;
    d. to facilitate cleaning and disinfection;
    e. to build in the passive pest-control systems;
    f. to minimize airborne contamination;
    g. to guarantee safety and a healthy work environment to the workers; to provide adequate working space to allow for satisfactory performance of all operations connected with the preparation and or processing of food;

h. to hygienically dispose of all liquid and solid waste, storm-water and sewerage;
i. to install an adequate potable water supply; it may be necessary to install an in-plant chlorination system to ensure the potability of water at all times
j. to install an adequate electrical supply to maintain normal and efficient operation of all electrically powered equipment and lighting
k. to ensure that:
    i. product flow takes place from dirty areas to clean areas (raw final with no cross over)
    ii. drains flow from clean to dirty areas, away from clean to dirty areas, away from food handling areas
    iii. airflow is directed from clean to dirty areas.
l. to avoid that dripping or condensation from fixtures, ducts, pipes and ceilings contaminates food, food-contact surfaces or food packing materials.

5.2 Reception Area

1. The receiving area should be kept clean and in good repair to prevent contamination.
2. The floors, walls and ceiling should be made of materials that are easy to clean.
3. There should be adequate supply of potable water and the area should be adequately separated from the outside environs to prevent contamination.

5.3 Plant and Equipment to be of Sanitary Design

5.3.1 Buildings and Facilities

1. Buildings and facilities shall be of **sound construction and maintained in good repair.** All construction materials shall be of a type that will not transmit any undesirable substances to the food.
2. Adequate **working space** shall be provided to allow for satisfactory performance of all operations connected with the preparation of food.
3. The design of buildings and facilities shall permit **easy and adequate cleaning** to allow the hygienic preparation of food.
4. Buildings and facilities shall be designed to **prevent the entrance** and harbourage of pests and contaminants.
5. Buildings and facilities shall be designed to **provide separation** by partition, location or other effective means between operations (including waste disposal), which may cause cross contamination of food. ***Note:*** *To meet this requirement the following areas namely, areas for processing by-products, offices, engineering workshop, equipment, spare parts store, canteen and garages shall be separate from areas handling fish*.
6. Buildings and facilities shall be **designed** to facilitate hygienic production, by means of an orderly flow of ingredients, food, packaging, and removal of waste products in the preparation process, from the arrival of the raw materials at the licensed facility through to the final product. Crossover in production between final and raw product shall be avoided.
7. Areas where raw materials are **received or stored** shall be separated from areas in which final product preparation or packing is conducted to prevent contamination of the final product. Areas and compartments used for storage, manufacture or handling of edible products shall be separated and distinct from those used for inedible materials.
8. The main processing area in which fish is handled should have only one entrance for personnel being independent and separate from any entrances and exits used for raw materials, finished products and other materials used during processing.

9. An adequate potable **water supply** shall be made available. Where necessary an in-house treatment system should be installed to ensure the potability of water at all times.
10. The **electrical supply** shall be adequate to maintain normal and efficient operation of all electrically powered equipment and lighting.
11. Provision shall be made for all **liquid and solid waste** to be disposed of hygienically. Wastes shall be disposed in a way that cannot contaminate water and food supplies and cannot offer harbourage or breeding places for rodents, insects or other vermin.
12. **Drainage** facilities shall include:
    a. Disposal of processing and sewerage effluent; storm-water and site drainage; and
    b. Shall be large enough to carry peak loads and constructed to avoid contamination of potable water supplies.

5.3.2 Food handling Areas

5.3.2.1 General Requirements

1. Areas handling and processing fish shall be designed and constructed to:
    a. Allow efficient handling of the product;
    b. Be separated by partition, location or other effective means so that operations will not cause cross-contamination of food or food handling surfaces;
    c. Provide separate storage of raw material, final product and waste processing material;
    d. Protect raw material and final product from risk of contamination;
    e. Prevent product deterioration due to exposure to the elements.
2. Facilities shall be designed so that:
    a. Product flow takes place from dirty areas to clean areas (raw to final with no cross over);
    b. All areas and equipment are easily accessible for inspection and cleaning.

5.3.2.2 Ceilings

1. Ceilings shall be designed, constructed, sealed and finished so as to:
    a. Provide a height of at least 2.2 meters in all rooms where fish is handled;
    b. Be lightly coloured, smooth and impervious to moisture;
    c. Where sheeting is used, joints to be sealed so that they are impervious to moisture;
    d. Prevent dirt accumulating and be capable of being effectively cleaned;
    e. Have all overhead machinery and pipes located above ceiling unless covered by a regular and effective cleaning regime
    f. Minimise condensation, mould development and flaking.
2. In buildings in which the roof frame is exposed, the installation of a suspended ceiling should be considered. Otherwise all parts of the structure must be smooth and painted a light colour. There should be easy access to all parts of the roof structure to facilitate cleaning.

5.3.2.3 Floors

1. Floors shall be constructed of dense waterproof concrete or another impact resistant impervious surface that has a smooth, non-slip finish and is easily cleaned. The floor must be constructed so that it slopes towards drains (as a guide a minimum slope of 1:50 is recommended) and does not allow pooling. If pooling of water occurs companies must ensure this is squeegeed away at regular intervals.
2. All floor joints shall be:

a. Sealed with impervious materials;
b. Finished flush with the surface.

3. Junctions between the floor and walls shall be adequately coved facilitate cleaning.

5.3.2.4 Floor Drains

1. In any area that involves “wet" operations:
    a. Floors shall be sufficiently graded (at least 1:50 gradient) for liquids to drain to trapped outlets;
    b. Floor drains shall be adequate in size, number and location to cope with the maximum flow of water under normal working conditions.
2. All drains shall:
    a. Be effectively sealed by a trap or similar device;
    b. Have adequate access for cleaning;
    c. Where necessary, be adequately vented to the exterior of the building.
    d. Be rodent proof.
    e. Be covered with suitable removable grills or covers.
    f. Allow the rapid removal of all liquid wastes arising from all processing operations
    g. Be able to cope with the maximum flow of water under normal working conditions but also to carry peak loads.
    h. prevent the return of gases and odours from the drainage system
3. Solid traps installed in conjunction with floor drains shall be designed to enable adequate cleaning.
4. Where necessary back flow preventers should be fitted to prevent the back flow of water from an undesirable source.
5. Drains shall flow away from food handling areas.

5.3.2.5 Internal Walls and Partitions

1. Internal walls and partitions shall:
    a. Be constructed of water-proof, non-absorbent and washable materials;
    b. Be smooth, lightly coloured and free from gaps;
    c. Have all joints sealed that might allow the ingress of water, pests or contaminants;
    d. Be impact resistant or protected from impact;
    e. Be easy to clean and disinfect.
2. In areas where “wet” operations are carried out, angles between walls and floors shall be sealed and coved to facilitate cleaning unless adequate cleaning and sanitising can be demonstrated without the need for coving.
3. Where walls do not touch the ceiling, their tops shall be capped at approximately 45 degrees.
4. Where internal walls are painted or surface coated, the surface shall:
    a. Be non-toxic;
    b. Withstand hosing with hot water and detergents;
    c. Withstand reasonable impact.
5. If any room (including a cold store) is built within a food handling room, inaccessible cavities formed between the walls or ceilings of the inner and outer rooms shall be made pest and dust proof.

6. Any piping or tubing should be located either within the wall or fixed at least 4 cm from the wall, in order to permit easy cleaning behind.

5.3.2.6 Windows, Doors, Hatches, Vents and Internal Walls

1. All external and ventilation openings shall be proofed against the entry of pests.
2. Windows that open to the outside are not permitted in areas where food is exposed, processed or packed.
3. Open-able windows and vents shall be fitted with insect-proof screens kept in good repair that are easily removed for cleaning. Such screens shall have a mesh of no more than 1 mm.
4. Doors and hatches shall:
    a. Have smooth and non-absorbent surfaces;
    b. Be close fitting;
    c. Be impact resistant or protected from impact damage.
5. Doors, hatches and other openings to the outside of the building, or where physical separation is required, shall be constructed to render the opening pest proof (deemed to be less than 3 mm between the edge of the door and the outer surface). These doors should possess either plastic curtains or air curtains or a self-closing curtain or a self-closing device, in order to minimize the entry of flying insects, when they are opened.
6. The doors and hatches inside the factory shall:
    a. be well constructed, using suitable, durable materials which are easy to clean;
    b. have smooth, impermeable and non-absorbent surfaces;
    c. be close fitted; and
    d. be impact resistance or protected from impact damage.
7. Where doors are painted or surface coated:
    a. any paint materials applied to the doors shall be non-toxic, durable and of light colour; and
    b. the surface shall withstand hosing with hot water and detergent, and withstand a reasonable impact.
8. If air locks are installed they shall be designed to minimize movement of air into or between areas where food is exposed, processed or packed.
9. Window frames shall be made of a smooth impermeable material and window sills shall be as small as possible and inclined in order to prevent the accumulation of dust, and their use for the storage of articles.
10. Where there is a likelihood of breakage of glass windows that could result in the contamination of food, the windows are constructed of alternative materials or adequately protected. Windows without pest-proofing that open are not permitted in areas where food is exposed, processed or packed. ***Note:*** *This requirement may be met by effectively employing one or more of these methods: - a self-closing curtain, strip curtain or an air curtain; a pest proof annex; a self-closing device*
11. If airlocks are installed they shall be designed to minimise movement of air into or between areas where food is exposed, processed or packed. ***Note:*** *A low-pressure airlock vented to the exterior with doors that cannot be opened simultaneously will meet this requirement*.
12. If any services, chutes, conveyors or the like pass through external walls, the gap where they pass through, if any, must be sealed against the entry of pests and dust.

5.3.2.7 Stairs, Platforms and Stands

1. Stairs, catwalks, platforms, stands, ladders and the like in processing areas shall be:

a. Of a construction and material that is impervious, non-slip, non-corroding, easy to clean and impact resistant;
b. Situated and constructed so as not to cause contamination of food processing areas, equipment and product by allowing potential contamination items to fall onto them.

5.3.2.8 Hoses

1. Hoses used in fish processing areas must be of a sanitary design. Hose nozzles should be cleaned and sanitised on a regular basis.
2. Hoses shall be fitted with a hose reel or a similar system to prevent hoses from touching the floor when not in use.

5.3.2.9 Footbaths

1. Personnel entranceways into the factory must be fitted with an appropriate footbath that contains an approved sanitiser used at the strength and conditions of use as advised by the manufacturer.
2. The footbath must be fitted with drainage facilities or suitable mechanism to dispose of the sanitiser solution. The footbath shall not pose a risk of contamination and must be in use at all times the premises is operational.

5.3.3 Equipment

5.3.3.1 Equipment, Utensils, and Services: Design, Construction, and Installation

1. All equipment and utensils shall be designed, constructed, installed, operated and maintained so as to prevent contamination and adulteration of products and permit easy and thorough cleaning and sanitising and where necessary be accessible for inspection.
    a. All equipment and utensils (except non-returnable items) including tubs and bins that are food contact surfaces shall be:
        i. Smooth, non-absorbent and resistant to corrosion;
        ii. Free from pits, crevices and loose scale;
        iii. Made of materials which do not transmit odour, taste and are non-toxic;
        iv. Unaffected by food products;
        v. Designed to prevent the contamination and adulteration of the products with toxic materials, lubricants, fuel, metal fragments, contaminated water or other contaminants;
        vi. Avoid the accumulation of dirt which could contaminate the product and be the source of hygiene hazards;
        vii. Permit easy and thorough cleaning and disinfection;
        viii. Allow accessibility for inspection where necessary;
        ix. Capable of withstanding repeated cleaning and disinfecting.
2. Supporting framework for machinery, benches, sinks, worktables, foot-stands, etc. shall be constructed of smooth, impervious materials free from openings, ledges or crevices in which pests or potential contaminants may accumulate. ***Note:*** *Racks and shelving may accommodate this requirement with a minimum floor clearance of 300mm.*
3. Welds created in the manufacture or repair of equipment shall be smooth and of sanitary design to prevent build-up of contamination and facilitate cleaning.
4. Equipment or fittings adjacent to wall or other equipment shall have any gaps sealed to prevent entry of moisture and dirt or have sufficient space to permit cleaning.
5. Equipment standing directly on the floor shall be installed:

a. By sealing directly to the floor to prevent the entry of moisture;
b. On a raised plinth coved at the junction of the floor and plinth; OR
c. On legs with a minimum of 300 mm clearance between the underside of the equipment and the floor.

6. Chutes and other enclosed transport systems shall be:
    a. Constructed with inspection and cleaning hatches;
    b. Easily dismantled for cleaning.
    c. Sorting trays, chutes, conveyors and bins may be made of high-density nylon, aluminium, stainless steel or fibreglass, free of crevices and with all internal junctions rounded out.
7. All overhead structures, services and fittings including lighting shall be easy to clean and:
    a. Installed so as to avoid contamination either directly or indirectly of food by condensation;
    b. Installed so as not to hamper cleaning operations;
    c. Insulated where appropriate and be designed and finished as to prevent the accumulation of dirt, minimise condensation, mould development and flaking.
    d. Note: May be met by locating all pipes and machinery above the ceiling. Ducts, conduits and pipes may be recessed into the wall or mounted at least 25mm clear. Long runs of exposed pipes should be avoided.
8. Racks for gloves and aprons shall be provided within or adjacent to the processing area.
9. Storage areas shall be provided for knives and other utensils when not in use.
10. Hose points shall be provided together with hose racks made of rust resistant material.

5.3.3.2 Product Handling and Conveying Equipment

1. Fish boxes, sufficient in number, shall be provided for the needs of the process. They must only be used within the plant, not for external transport of fish.
2. Fish boxes, which are used to transport product to the plant, and for the movement of fish within the plant, shall be constructed of a high-density plastic and be of a light colour. They shall have a smooth finish and their design shall avoid areas that could retain particles of product, grease and dirt. The boxes should be designed to permit drainage of any liquid.
3. Trolleys or similar equipment used to carry large fish or to feed blast freezers or chillers, they shall be made of non-corrodible material and have a smooth finish.
4. Ice shovels should be made of a light-coloured plastic, or of stainless steel. Wood is not permitted in any part of the construction.

5.3.3.3 Compressed Air

1. Where compressed air is used, the compressed air or other gases that come into direct contact with product or equipment surfaces or mechanically introduced into food or used to clean food-contact surfaces or equipment shall have a filtered air intake located in a clean place, contain no oil or substances hazardous to health or shall be treated or otherwise controlled in such a way that food is not contaminated with unlawful indirect food additives.

5.3.3.4 Use of Timber

1. Timber shall not be permitted for use in the following areas of an establishment:
    a. Product contact surfaces;
    b. Processing areas;
    c. Ice rooms, freezers, cold stores and chillers.

d. Anywhere fish and fishery products are exposed

2. This also applies in particular to knife-handles, spades for ice handling and filleting or cutting boards.
3. However, timber is permitted in the following circumstances:
    a. Doors, door jambs, windows in processing areas but must be sealed by a durable non-toxic surface coating (e.g. gloss enamel, epoxy or polyurethane paint).
    b. Clean sound and dry wooden pallets are permitted for the carriage of enclosed raw material or processed food in dry areas of processing only.
    c. Racks and storage systems in cold stores used to store packed products can be made of clean and sound timber provide they are sealed by a durable non-toxic coating is preferable.

5.3.3.5 Containers

Containers used to store fish must be maintained in good repair and not present a source of contamination. Containers used to store unpackaged fish must be designed so that the melt water does not pose a risk of contamination.

5.3.3.6 Equipment for Inedible Products

1. All equipment used for the disposal, storage and treatment of wastes or inedible material shall be:
    a. Clearly identified as such;
    b. Leak proof and impervious;
    c. Easy to clean or disposable;
    d. Able to be closed securely if stored externally
    e. Stored separately and not used for edible material.

5.3.4 Cleaning and Sanitising Facilities

1. Adequate facilities for cleaning and sanitising utensils and equipment shall be provided, where required, in the factory.
2. These facilities shall be constructed of corrosion resistant, non-absorbent materials capable of being cleaned effectively and be:
    a. fitted with hot and cold-water points, with hoses where necessary;
    b. fitted with sinks with hot and cold water for the washing of the movable equipment and fish boxes; and
    c. where applicable, provided with high-pressure cleaning and disinfecting systems.

5.3.5 Hand washing Facilities

1. All main personnel entrances to any processing area shall be equipped with hand washing facilities that meet the following criteria:
    a. Sufficient in number and provided in accessible locations throughout the processing areas for all staff to wash their hands both on entering the processing area and during processing;
    b. Located adjacent to personnel access areas;
    c. Provide suitably pressured potable water supply over a sink;
    d. Provided with taps that are non-hand operated;
    e. Provided with liquid soap contained with a dispenser;
    f. Provided with single use paper towels held in a dispenser with a sufficient number of receptacles for disposing of used towels or with other hygienic means of hand drying;
    g. Fitted with properly trapped waste pipes leading to drains.
    h. Only used for the purpose of hand washing

2. Additional hand washing facilities provided in addition to those at the main processing area should also meet the above criteria unless it can be proven that minimal facilities do not pose a risk of contamination to the product.
3. Signs advising persons to wash their hands on entering or re-entering food handling areas shall be provided in a prominent position near food handling area entrances

5.3.6 Cold Storage and Support Areas

5.3.6.1 Refrigerated Storage

1. Every refrigeration facility shall:
    a. Have floors, walls, ceilings, doors and hatches that are constructed, installed and maintained according to the requirements for food handling areas as detailed in section 4.3.2;
    b. Lighting that meets the requirements for food handling areas as detailed in section 4.4.3
    c. Have other internal structures constructed of smooth, impervious and corrosion resistant material;
    d. Those parties that are exposed to impact damage adequately protected.
    e. Facilities designed to allow for adequate drainage of water away from the refrigeration until.
    f. Be capable of reducing or maintaining the temperature of any food as required;
    g. Be checked against a standardised thermometer and must record within +/- 1□C;
    h. Have its temperature taken and recorded at least once every 24 hours while it is in operation;
    i. Be designed to allow for adequate drainage of defrosted water away from the refrigeration unit.
    j. Have adequate capacity to store all the raw material arriving at the establishment and which is not processed immediately and to ensure adequate protection from contamination.
2. Where refrigeration equipment is installed in a processing or packing area sufficient space shall be allowed for cleaning around and between the equipment.
3. Plastic strip curtains or similar shall be installed to assist in air retention when cold store doors are open.
4. Facilities processing product that is eligible for export to the EU must equip their cold stores with an automatic temperature recording device where it can be easily read. The temperature probe must be positioned at furthest away from the cold source. The records must be readily available for the CA inspectors.
5. Where under-floor ventilation pipes are provided they shall be proofed against pests. The design and construction of ice rooms and storage facilities shall be such that ice can be stored and removed in an efficient, hygienic manner and the ice protected from contamination at all times.
6. Container system units that are used, as cold stores shall:
    a. Be soundly constructed to meet the requirement of refrigeration chambers as given above with no internal or external damage to cladding;
    b. Have door seals that are sound;
    c. Be installed on a paved area suitably kerbed, graded and drained with all access to the area sealed;
    d. Have access provided on all sides to permit cleaning and avoid the harbourage of pests.

5.3.6.2 Ice Making Facilities

1. Ice plants and ice storage rooms should at least meet the following requirements:
    a. Able to produce ice in quantities adequate to satisfy the needs of the processing including:

i. transport of raw material from the wharf
ii. storage of raw material before processing
iii. chilling of fish during processing

b. Meet the requirements of Storage and Support areas as given previously in this section.

5.3.6.3 Dry Storage Areas

1. Non-refrigerated storage shall be:
    a. Have floors, walls, ceilings, doors and hatches that are constructed, installed and maintained according to the requirements for food handling areas;
    b. Have other internal structures constructed of smooth, impervious and corrosion resistant material;
    c. Designed and maintained so as to prevent undesirable physical, microbial and chemical changes to processed food and its packaging, which could affect the suitability of the processed food.
2. Cartons, Wrapping Materials and Food Containers Stores shall:
    a. Be dust and pest proof.
    b. Be designed and maintained to prevent undesirable physical, microbiological, biochemical contamination.
    c. Be stored on shelving or racks constructed to minimise damage and the risk of contamination.
    d. Have lined walls if exposed packaging it so be stored within the storage area.
3. **Stores for chemicals and maintenance compounds** shall be secure (lockable and locked when not in use) and separate from product areas, support areas or other stores.

5.4 Services

5.4.1 Changing Facilities, Living Areas, Toilets and Hand Washing Facilities

1. Suitable, adequate in number and conveniently located changing facilities, toilets and hand washing facilities shall be provided.
2. These facilities shall not be used for the storage of any processing ingredients or food.
3. The construction of the floors, walls, ceilings, doors and windows of the social amenities shall be of the same standard specified for the processing areas.
4. Living areas shall be completely separated from food handling areas and not open directly onto these areas.
5. Toilet and toilet areas should be adjacent to but separate from change rooms and shall be:
    a. Completely separated from food handling areas and not open directly onto these areas;
    b. Designed to ensure hygienic removal of waste matter:
    c. Well lit, ventilated and maintained in a clean and tidy condition.
6. There should be sufficient toilets for the number of persons employed at the facility to reduce congestion during staff breaks.
7. All toilets and urinals must be of the flushing variety. They should be constructed of materials that are easy to clean.
8. Hand wash facilities shall be provided near toilets and shall follow the requirements for **hand washing facilities** in section 4.3.5.
9. Notices shall be prominently posted in toilet areas directing persons to wash their hands after use.

10. An area for undressing out of day clothes and shoes shall also be provided.
    a. This room should contain a locker (or a hanger) for each person to store (or hang) the city clothes and racks for the shoes.
    b. The surfaces of the lockers or hangers and racks shall be smooth, non-absorbent and resistant to corrosion.
    c. The use of uncoated timber is prohibited for the construction of lockers, hangers and racks.

5.4.2 Effluent and Waste Disposal

1. Facilities shall have an efficient effluent and waste disposal system maintained in good order and repair to prevent the contamination of fishery products with bacteria from residues and wastes by:
    a. treating by-products in an appropriate way in the event that by-products are destined for human consumption
    b. separating and removing guts and other waste that may constitute a danger to public health from the vicinity of products intended for human consumption
    c. draining liquid waste water and treat sewerage
2. Effluent lines (sewerage, storm water, processing) must be large enough to carry peak loads and constructed so as to avoid contamination of the potable water supply.
3. Sanitary drainage shall not be connected with any other drains within the licensed facility and be directed to a septic tank or sewerage system.
4. Septic tanks and waste trap systems shall be located so as to avoid a hygiene hazard to the product and located away from any processing area or entrance to the building.
5. The storm-water drainage system shall not to be connected to the effluent treatment system.
6. They are to be designed and constructed to avoid the risk of contamination.
7. Where drainage channels are fully or partially open, they must be so designed as to ensure that waste does not flow from a contaminated area towards a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.

5.4.3 Lighting

1. Lighting of sufficient intensity and quality shall be provided throughout the factory to allow for production and inspection activities.
2. Lighting shall not distort colourings and be shadow free at work and inspection surfaces.
3. Light fittings shall be:
    a. Equipped with a protective cover or other means so that breakage will not contaminate the product;
    b. Readily accessible for cleaning purposes.
    c. Wherever possible, recessed into or flush fitted against the ceiling so that no exposed ledge is created. However, if this is not possible light fittings can protrude passed the ceiling provided there is no chance for dirt and dust accumulation.
4. Where light fittings cannot be installed in accordance with the requirements above they may be suspended from the ceiling by cables provided that the top of the fitting is sloped at approximately 45 degrees.

5.4.4 Ventilation

1. Adequate ventilation shall be provided to prevent excessive build-up of heat, steam, condensation and other undesirable hazards.

2. Where cooking, canning or boiling operations are carried out extractor fans and canopies shall be installed and have capture velocities capable of conveying all heat, fumes and other aerosols through the exhaust canopy opening.
3. Airflow shall always be directed from clean areas to dirty areas.
4. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.
5. Where fans, air conditioning systems and other air-blowing equipment are located and operated:
    a. it shall be done in a manner that minimizes the potential for contaminating food, packing materials and food-contact surfaces; and,
    b. all extraction fans, blowing fans and air conditioners shall be protected with filters and meshes to prevent the entry of dust, insects and birds.

5.4.5 Water, Ice and Steam Supply

1. Facilities shall be required to provide a permanent supply of potable water or alternatively of clean seawater as given below.
2. Potable water and clean seawater must meet the following parameters (as suggested by Reg (EC) Council Directive: 98/83 EC of 3 November 1998- on Quality of water intended for human consumption):

Microbiological Parameters and Limits.

Parameter	Volume of the sample in ml	Guide Level (GL)	Maximum Admissible Concentration (MAC)
Total Coliform bacteria	100	0	0 (number/100 ml)
Escherichia coli	100	0	0 (number/100 ml)
Clostridium perfringens (including spores)[1]	100	0	0 (number/100 ml)

[1]This parameter need not be measured unless the water originates from or is influenced by surface water

3. An ample supply of potable water shall:
    a. Be available under adequate pressure and suitable temperature;
    b. Be provided with adequate facilities for its storage where necessary and distribution;
    c. Be provided with adequate protection against contamination.
    d. If used in food handling areas meet the parameters given above.
4. Operators of establishments shall ensure the water is adequately chlorinated, or otherwise treated, to ensure the on-going potability of any water used.
5. Chlorine shall be added in-line by dosing or injection (gas or liquid) prior to intermediary storage to permit sufficient contact time with the water in order to allow the chlorine to react with the organic matter. The retention tank shall have to retain water together with the chlorine added for 30 minutes;
6. If chlorine is used a free residual chlorine reading of 0.5 - 2 ppm should be available at points of use within the establishment.

7. If the water used in the establishment receives additional treatment prior to use, this must be done in accordance with the instructions of the manufacturer of any equipment or chemicals utilized and under supervision of the management of the establishment.
8. Non-potable water may be used for steam production, refrigeration, fire control and other similar purposes not connected with food and shall be carried in completely separate identifiable lines (preferably by colour) with no cross-connections or back-flow into potable water lines.
9. Non-potable water outlets in processing areas shall be clearly identified.
10. Potable water shall only be used for the following:
    a. contact with fish or fish-contact surfaces;
    b. the manufacture of ice; and
    c. cleaning and sanitising in the establishment.
11. All pipe-work in the water distribution system shall be impermeable, well-constructed and in good condition.
12. There shall be provision to prevent backflow or cross-contaminations between potable and non-potable water within the establishment.
13. Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.
14. Clean seawater that does not contain any micro-organisms at levels exceeding those for the WHO Drinking Water Standards may be used in food handling areas provided it is also free from excessive turbidity, offensive odours, colour and other contaminating substances.
15. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination
16. All storage tanks, cooling towers and pipes used in handling water shall be constructed to facilitate cleaning and inspection.
17. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.
18. Adequate storage tanks shall be provided, where necessary, with sufficient capacity to supply the requirements of the establishment when operating at maximum capacity and to allow sufficient contact time for chlorine where necessary.
19. The tanks must be made of smooth, impermeable, easily cleaned surfaces and be fitted with an inspection hatch. The tanks shall prevent the entry of pests, rain or ground water and any process water that may flow out of the establishment. The area surrounding the tank must be kept clean and free of rubbish, dirt or water.
20. The licensed facility shall document the complete procedure for the control and treatment of sea and potable water used, including treatment and analytical results.
21. The documented programme must cover:
    a. The source(s) of the water supply(ies) used within the facility
    b. What treatment, if any, is applied to the water on-site
    c. Checks to be carried out to determine potability of the water supply including frequency of checks, parameters to be measured and limits to be met
    d. Where town supply water is used, a copy of the water test results from the local water authority renewed every 6 months

e. A reticulation plan showing potable and non-potable supplies (where applicable) and taps used for water sampling tests
f. Testing parameters to be used
g. Corrective actions to be followed in the event of a non-compliance with the documented programme

22. The operator must implement a reticulation management plan for potable water used within a premise including:
    a. Systems to ensure that reticulation of water throughout the premises is not adversely affected and that the intended water quality is delivered at point of use; and
    b. Systems to ensure that there is no unintentional mixing of water of different standards
    c. An action plan with appropriate sanitation procedures to be implemented in the event of non-compliance with the reticulation plan

5.4.5.1 Water Testing

1. Companies shall test their water to prove the water they use at point of use is potable and meet the parameters given in the previous section. Such testing shall involve:
    a. Gaining a copy water test results from an approved laboratory at least 6 monthly and holding these on file.
    b. Completing or obtaining point-of-use tests on a 6-monthly basis (or more frequently) for the presence of total coliforms and Escherichia coli. If any 100 ml sample tests positive for any of these tests then a re-test shall be performed immediately. If two consecutive samples show the presence of coliform bacteria or E. coli the source must not be used until the contamination is removed.
2. Water samples shall be taken from outlets within the establishment on a rotational basis.
    a. The tap to be sampled shall be run for 2 – 3 minutes to flush out the pipe.
    b. The top of the bottle shall be flamed before the sample is collected.
    c. The sample shall be refrigerated to below 4 degrees Celsius after taking and sent to the laboratory with testing to commence within 24 hours of the sample being taken.
3. To neutralise any chlorine used in the bottle sodium thiosulphate is to be introduced into the water sampling bottle prior to sterilisation.
4. In addition, if the company is chlorinating their water, they must complete daily chlorine checks to meet the standard given earlier in this section. Records shall be retained on file for CA inspection.

5.4.6 Laundry

1. A licensed facility may contract out its laundry services for protective clothing and other laundry. If contracted out the transportation of laundered clothing must perform this in a hygienic manner.
2. If performed internally the laundry must have sufficient capacity for the number of employees and carry the task in a hygienic manner from washing through to final delivery back to the storage area awaiting use.
    a. Internal laundries must have access to both hot and cold water.
    b. Drying must be performed mechanically or in enclosed hygienic environments.

5.5 Landing Sites/Loading/Unloading Docks

1. The landing site shall be kept clean and tidy at all times especially when landing of fish is taking place.

2. Unloading and landing equipment must be constructed of corrosive resistant material that is easy to clean, disinfect and kept in a good state of repair and cleanliness. Unloading and loading equipment must ensure that damage to fish is prohibited.
3. Where the load has to be assembled prior to loading the marshalling area shall be protected from the elements either through use of a cover or shade or through speedy marshalling that minimises any risk of contamination.
4. Both the loading dock and associated marshalling areas shall have sufficient lighting.
5. The area nominated for truck movement shall be finished with a well-drained surface that is impervious and durable.
6. Road access ways and storage areas for container system units shall be maintained to minimise the risk of contamination to product.
7. On-site or easily accessible wash facilities shall be made available for container system units.
8. If other activities are taking place while fish is unloaded, these operations are to be controlled by the operator as to minimise the risk of cross contamination.

5.6 Fishing Vessels

1. Fishing vessels intending on exporting product directly or indirectly to the European Union will be subject to these Industry Standards and subsequent inspections by the CA.

5.7 Transporters of Fish Products and Ice

1. Transporters carrying ice or fish products destined for the EU must be approved by the CA. Also, personnel operating transport must be trained in good hygienic practices and records held on file.

6 Operational Requirements

6.1 Hygiene and Sanitation

6.1.1 General Maintenance

1. Buildings, vessels, equipment, utensils, refrigeration and all other physical aspects of a licensed facility including drains shall be kept in good repair, in a clean and orderly condition and operated in accordance with these standards.
2. All licensed facilities shall have a documented programme for repairs and maintenance, including a record of all repairs and maintenance activities that are scheduled for completion, with appropriate target dates for completion
3. Repairs shall be carried out as soon as possible without interference to handling and processing and may cause the facilities closure during certain repairs.
4. All chemical compounds used as cleaners, sanitisers, soaps, detergents, lubricants or pesticides shall be suitable for use in food processing premises and the following information provided:
    a. Trade name and type of chemical compound (active ingredient);
    b. Purpose (e.g. detergent, sanitiser, hand wash, etc.) and, if available;
    c. Classification
5. The operator shall maintain a register of chemicals that are used in the facility, their purpose and food grade status.

6.1.2 Cleaning and Sanitising

1. A documented cleaning and sanitation programme shall be in place at each licensed facility and all cleaning personnel shall be suitably trained in cleaning and sanitising techniques. All cleaning and sanitation procedures shall be monitored and records maintained.
2. The programme shall cover the cleaning and sanitising of the fish premises, including product areas, appliances, support areas and stores. The programme shall be documented and contain the following elements:
    a. Areas/appliances to be cleaned;
    b. Detergents/sanitisers that are to be used;
    c. Frequency of cleaning;
    d. Procedures and work instructions for the various cleaning and sanitising operations;
    e. Monitoring/checks of the cleaning
    f. Recording of cleaning procedures;
    g. Personnel responsible;
3. To prevent the contamination of food, equipment, utensils and surfaces that contact food shall be:
    a. Cleaned as frequently as necessary either immediately after the end of each working day or at such times as may be appropriate to maintain hygienic conditions;
    b. Sanitised when there is a risk of contamination but not less than daily.
4. Surfaces contacting food must be adequately rinsed after the use of any detergents prior to handling of the food unless the detergent or sanitiser is deemed by the manufacturer to be a “non-rinse” variety.
5. Adequate precautions shall be taken to prevent food from being contaminated during cleaning or sanitising of rooms, equipment or utensils.
6. Staff changing facilities, toilets and lunchrooms shall be kept clean at all times. Roadways, yards and other areas in the immediate vicinity of the licensed facility shall be kept clean.

6.1.3 Inedible By-products

1. Inedible by-products and other inedible material shall:
    a. Be stored so as to avoid contaminating food for human consumption;
    b. Be removed from the food preparation area as often as necessary to avoid contamination.
2. All equipment used for the disposal, storage and treatment of wastes or inedible material shall be clearly identified, stored separately and not used for edible material.
3. Waste containers used for the disposal, storage and treatment of wastes or inedible material shall comply with the following requirements as to hygiene, and unless special facilities are provided for the continuous disposal of waste, waste must be placed in leak proof, impermeable containers:
    a. that are provided with tight fitting lids to prevent the entry of insects, rodents and other animals if outside;
    b. that are designed to facilities cleaning and disinfection;
    c. that are clearly marked for that purpose only or be of a different colour to boxes used for fish for human consumption;
    d. that, when used for temporary storage of viscera and offal in the work room, should be kept below the level of the work tables to avoid splashing and contamination of the fishery products;
    e. that must be always thoroughly cleaned and disinfected after use.
4. Sanitising of edible materials and equipment used for the disposal, storage and treatment of wastes shall not take place together but in a physically separate environment.
5. Waste shall be removed from the vicinity of the establishment at regular intervals in order to ensure that the waste does not constitute a source of contamination of the establishment or of pollution of its surroundings by the development of smells and the presence of insects and rodents.

6.1.4 Disposal of Waste

1. Waste shall be removed from food handling areas and other working areas as often as necessary to avoid potential contamination sources.
2. Immediately after the disposal of waste, receptacles used for the storage and any equipment, which has come into contact with the waste, shall be cleaned and sanitised.
3. Waste stored in a fish premises must not constitute a source of contamination for the establishment or of pollution of its surroundings. The waste storage area shall be kept clean.
4. All outside waste disposal bins shall be fitted with close-fitting lids that are kept closed and which are easy to clean and sanitise.

6.1.5 Domestic Animals

1. Domestic animals are not permitted on the premises unless they are guard dogs in which case their area of activity will be limited to outside use only.

6.1.6 Pest Control

1. The establishment:
    a. shall afford appropriate facilities against pests such as insects, rodents, birds, or other animals;
    b. shall take effective measures to exclude pests and animals from the processing areas and to protect products against contamination by pests and animals, with exception of live animals such as crustaceans and fish to be placed on the market alive or not admitted.

2. There shall be an effective and continuous schedule for the detection, control and eradication of pests.
3. Pest control measures undertaken shall not constitute a hazard to human health and product safety.
4. Control measures involving treatment with chemicals, shall only be undertaken by personnel who have a complete understanding of the health hazards these chemicals may pose to the product. Chemicals used for pest control shall be approved for use in food processing facilities.
5. Any units used to kill flying insects shall be positioned away from the main processing lines or protected in such a way as to not present a risk.
6. Companies shall document a vermin control programme and this programme shall cover:
    a. vermin considered on site
    b. actions to prevent vermin breeding or entering the facility
    c. actions taken to eliminate vermin
    d. vermin control chemicals to be CA approved
    e. details of bait stations and their location
    f. checks carried out to demonstrate effectiveness
7. Accurate and legible records of the location and frequency of servicing bait stations at a licensed facility shall be kept.

6.1.7 Hazardous Substances

1. Cleaning and sanitation, maintenance and vermin control chemicals must be of a type approved for use in food processing areas. Companies shall hold on file written confirmation of this from the supplier.
2. Pesticides, cleaning agents or other substances, which could represent a hazard to health, shall be suitably labelled with the product name and a warning about their toxicity and use and extreme care taken to avoid the chemicals contaminating food, food contact surfaces and ingredients.
3. Hazardous substances shall be stored in rooms or cabinets used only for that purpose, separate from the main processing area and handled only by authorised and properly trained persons.
4. Except when necessary for hygienic or preparation purposes no substances which could contaminate food may be used or stored in food handling areas or be stored with any product, ingredients or product packaging materials.
5. Companies shall document a Chemical or Hazardous Goods programme and this programme is to cover:
    a. A list of chemicals used on site (cleaning and sanitation, maintenance and vermin control chemicals used within the processing area vicinity)
    b. That chemicals will only be stored in secure, separate designated areas
    c. Only trained persons shall handle chemicals.
    d. Requiring all chemicals to be labelled.

6.1.8 Door management policy

1. Companies shall document a door management procedure that details the controls on door closure in the following areas:
    a. Processing areas
    b. Chillers
    c. Freezers

6.2 Personnel Hygiene

6.2.1 Documented Programme

1. The establishment must document a programme detailing how personal hygiene and hygienic work practice will be controlled and, in particular:
    a. What protective clothing is to be worn.
    b. Controls on personal conduct e.g. smoking, spitting etc.
    c. A hand washing procedure.
    d. Controls on jewellery
    e. Controls on communicable diseases, illness, sores and wounds.
    f. Controls on visitors and contractors.

6.2.2 Personal Effects and Clothing

1. Personal effects and clothing shall not be worn in food handling areas.

6.2.3 Hygiene Training

1. The manager of a licensed facility shall arrange for adequate and continuous training of all food handlers in personal hygiene and hygienic handling of food to ensure that the precautions necessary to prevent contamination of food are understood. Training shall include reference to relevant parts of these standards.
2. Training records for each person trained shall be maintained.

6.2.4 Communicable Diseases

1. No person who:
    a. Is suffering from or a carrier of a communicable disease;
    b. Is suffering from a condition causing a discharge of pus or serum (e.g. weeping sore, infected cuts, boils) from any part of the head, neck, hands or arms;
    c. Has reason to suspect there is a chance of transmitting a disease producing organism to the product
    d. Is suffering from vomiting or diarrhoea
2. shall prepare, pack, or handle any material likely to be used in constructing the product.
3. If the manager of a fish processing establishment has reason to suspect that any person is likely to transmit a disease producing organism to the product, the manager shall ensure, the person does not enter the licensed facility until he/she produces a certificate from a medical practitioner indicating that they are free from infection and are non-infectious.

6.2.5 Injuries

1. Any person with an uninfected wound or cut shall discontinue working with food or being in contact with any food contact surfaces until the wound is covered with a clean waterproof dressing that is securely attached.

6.2.6 Personal Cleanliness and Conduct

1. All staff while on duty in food handling areas should maintain a high degree of personal cleanliness.
2. Fingernail polish is not permitted by those persons handling fish with bare hands.
3. Jewellery including watches, earrings, and rings (other than wedding bands which must be covered by a glove) shall not be worn in a fish processing area.
4. Any behaviour, which could result in the contamination of food products such as chewing, eating, spitting, smoking, and other unhygienic behaviour shall be prohibited in food handling areas.

5. All personnel shall wash their hands frequently and:
    a. On entering product processing areas;
    b. Immediately after using the toilet;
    c. After handling dirty or contaminated materials such as rubbish;
    d. After chewing, eating, smoking or drinking;
    e. After cleaning procedures, handling sanitisers and similar cleaning chemicals.
    f. Whenever contaminated.
6. Persons handling food, ingredients and items used in food handling shall wash and sanitise their hands immediately after handling any material that might be capable of transmitting contaminants.
7. Where necessary to minimise microbiological contamination, employees must use disinfectant hand dips.
8. The wearing of clean gloves does not exempt the wearer from having thoroughly washed their hands.

6.2.7 Protective Clothing

1. All personnel and visitors entering the processing area shall at all times:
    a. Wear suitable protective clothing and impermeable footwear;
    b. Wear a head-covering that encloses all hair;
    c. A waterproof, impermeable apron;
    d. If the person is wearing gloves, shall ensure that the gloves are non-absorbent and, in a sound, clean and sanitary condition;
    e. If the person has a beard, wear a suitable beard mask
2. If a person wears disposable gloves or other disposable protective in the food handling area the disposable clothing shall be discarded after use and not be reused.
3. Protective clothing worn by persons in food handling areas shall:
    a. Be clean and lightly coloured;
    b. Be either washable or disposable;
    c. Not have an outer breast pocket or sewed on buttons.
4. Protective clothing including hats, hairnets, boots, coats, aprons and gloves shall be maintained in a clean condition and in good repair.
5. Protective outer clothing including footwear, aprons, headgear and gloves used in the processing area shall only be worn within the area approved within the site boundaries or thoroughly cleaned and sanitised before use.

6.2.8 Visitors

1. Precautions shall be taken to prevent visitors to food handling areas from contaminating food.
2. This shall include the use of protective clothing. Visitors shall comply with provisions of this Standard.

6.2.9 Supervision

1. The operator of a licensed facility shall allocate responsibility for ensuring personnel comply with the above requirements to competent supervisory personnel.

6.3 Processing

6.3.1 Raw Materials

1. A food business operator must have a documented programme that covers the inspection, handling and storage procedures for all raw materials and ingredients.

2. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.
3. Fish and fishery products shall be subject to a temperature and organoleptic (smell and appearance) check on arrival. Records shall be kept and made available to the CA officer on request.
4. Chilled products temperature should be downwards to the temperature of melted ice; brine frozen product shall not be warmer than - 9 C and frozen product shall not be warmer than -18 C. If these temperatures are exceeded the raw material shall be placed on hold and submitted to sensory evaluation and/or testing.
5. Fishery products which are not processed immediately upon arrival at the establishment shall be washed with clean water and stored with ice in suitable reception tanks or put in fish-bins, iced and stored in a chill room.
6. Raw materials, ingredients and packaging stored in a licensed facility shall be:
    a. Maintained under conditions that will prevent spoilage;
    b. Protected against contamination;
    c. Protected against damage.
    d. Not processed if there are signs of contamination or deterioration.
7. Stocks of raw materials and ingredients shall be used so as to ensure that the oldest stock is used first.
8. Suitable provision shall be made for the washing of raw materials as necessary.
9. Ink used to apply information such as marks in direct contact with the fish, shall not contain any of the following substances:
    a. Antimony
    b. Arsenic
    c. Cadmium
    d. Chromium
    e. Lead
    f. Mercury
    g. Other toxic compounds
    h. Fluorescent brighteners of carcinogens, teratogens and mutagens
10. Lacquer applied to the inner surface or part of the inner surface of packaging shall:
    a. cover the inner surface in continuous film
    b. be uniform in thickness
    c. leave no area of the surface uncoated
    d. firmly adhere to the covering
    e. be compatible and non-toxic with the food being packed.

6.3.2 Prevention of Cross Contamination

1. Effective measures shall be taken to prevent cross contamination of food.
2. Effective measures shall be taken to prevent raw material or semi-processed material coming into contact with and contaminating the end product.

3. Companies will be required to identify risks within their processing facility, and for each risk demonstrate adequate control.
4. The following areas should be considered as part of the risk assessment:
    a. Personnel
    b. Equipment
    c. Water splash
    d. Use of hoses
    e. Condensation
    f. Construction of plant and equipment etc.
    g. Packaging and incoming materials
    h. Waste material
    i. Chemicals and maintenance compounds
    j. Pests

6.3.3 Processing Requirements

1. All steps in the production process including packing shall be performed without unnecessary delay and under conditions that will minimise the possibility of contamination, deterioration and growth of microorganisms. **NOTE:** *If frozen food is thawed or tempered for the purpose of use in production, it shall be done under hygienic conditions that avoid contamination*.
2. Melted water produced shall be adequately drained and temperature rises kept to a minimum. It shall be brought to its thawed state as quickly as possible without causing undesirable physical, biochemical and microbial changes to the food.
3. The company shall document process controls used to maintain the safety and quality of the product in particular times and temperatures.
4. Operating practices shall be designed to avoid contamination of product, product surfaces and packaging materials.
5. Where chilled, unpackaged fishery products (raw material) are not dispatched, prepared or processed immediately after reaching the establishment, they must be stored or kept under ice in a chill store. Re-icing must be carried out as often as necessary.
6. Ice used, with or without salt, must be made from potable water or clean seawater and be stored under hygienic conditions in containers provided for the purpose, such containers must be kept cleans and in a good state of repair.
7. Pre-packed chilled products must be chilled with ice or kept in a chill store.
8. Operations such as heading and gutting shall be carried out quickly and hygienically. Products must be washed thoroughly with potable water or clean seawater immediately after such operations.
9. The quantities of fish on work tables at any one time should be kept to a minimum. If there are delays in processing fish on tables should be adequately iced.
10. During work breaks, products shall not be left on the worktables. Processing of fish already on the tables shall be completed before line workers leave their posts.
11. Operations such as filleting and slicing shall be carried out quickly and in such a way as to avoid contamination or spoilage, and in a place other than that used for heading and gutting operations. Fillets and slices must not remain on worktables any longer than is necessary for their preparation. Fillets and slices to be sold fresh must be chilled as quickly as possible after preparation.
12. If fillets are not immediately packed or frozen they shall be stored at 0°C with adequate quantities of ice, or in a chill store.

6.3.4 Separation of EU eligible and EU-ineligible product

1. To be eligible for export to the EU, seafood products must have been produced or handled in an EU approved establishment (either from the internal CA list or the official EU approved list) at all stages of processing, handling and storage.
2. Operators must ensure the physical separation of EU-eligible from seafood products ineligible for the EU. **NOTE:** *Physical separation means allocation of a separate store or separate areas within a store for EU and non-EU eligible product*.
3. Operators must have procedures and methods to distinguish ineligible seafood products from EU-eligible seafood products.
4. Where any alleged EU-eligible seafood products are indistinguishable from ineligible seafood products then the former are deemed to be ineligible and must be dealt with accordingly.
5. Packaged products may be separated per pallet.
6. Vertical stacks of pallets should not mix EU and non-EU market eligibility.
7. The CA shall perform checks on the adequate separation of EU and non-EU eligible product.

6.3.5 Processing and Production Records

1. The operator shall keep, for audit by a CA inspector, records of each lot of fish processed.
2. Records shall show evidence that fish has been processed in accordance with these standards.
3. Records shall be signed and dated by the operator or the person delegated this responsibility by the operator.
4. Records should also show the time the measurement was taken.
5. The operator shall hold records on file for at least 3-5 years depending on the shelf life of the products from date of production, taking into consideration products destined for canning purposes.
6. All records used as evidence to demonstrate compliance with these Standards must be:
    a. Complete
    b. Accurate
    c. Of sufficient quality
    d. Appropriately stored and accessible to the request by an CA officer
7. Records shall enable the operator, the Director or an authorised person to readily ascertain the nature, quantity and source of any fish or fish product handled in the fish premises.

6.3.6 Storage

1. Food including raw materials, ingredients and finished product shall be stored under conditions that will:
    a. Minimise contamination and growth of micro-organisms;
    b. Protect the food against deterioration and damage.
2. No materials other than those used for immediate processing shall be stored in an area in use or processing.
3. Vehicles not designed for use in the licensed facility shall be garaged in an area not used for processing.
4. Storage areas must be adequately pest proofed.
5. Dry ingredients shall be stored in a closed, well ventilated, pest proof and clean area with the required room temperature and humidity. The products shall be protected against spoilage, damage and contamination.

6. Packaging materials shall be stored in a closed, well ventilated, pest proof, dust-free and clean area with the required room temperature and humidity.

6.3.7 Calibration of Measuring Equipment

1. All measuring equipment, gauges and devices used in connection with food shall be:
    a. graduated so as to be easily read
    b. be checked to ensure their accuracy is sufficient for the task in hand.
    c. be adequate in number for their designated uses and adequately maintained
2. Where measurements are critical to the maintenance of food safety and management of hazards, the equipment shall be calibrated so as to be accurate.
3. Frequency of calibration shall be determined by the type of equipment and its ability to measure accurately over time.
4. Hand held thermometers used to measure product temperatures should be calibrated monthly using ice water to compare 0 C and boiling water to compare 100 C.
5. Temperature measuring devices for chillers and freezers should be calibrated against a standard thermometer at least annually.
6. A calibration system shall be applied either in-house or by an external authority. The results of the calibration shall be recorded and records kept for 2 years.

6.3.8 Loading and Unloading

1. Unloading and landing equipment must be constructed of material which is easy to clean and disinfect and must be kept in a good state of repair and cleanliness.
2. During unloading and loading, contamination of fishery products must be avoided. It must in particular be ensured that:
    a. unloading and landing operations proceed rapidly;
    b. fishery products are placed without unnecessary delay in a protected environment at the temperature required on the basis of the nature of the product and, where necessary, in ice in transport, storage or market facilities, or in an establishment;
    c. equipment and handling practices that cause unnecessary damage to the edible parts of the fishery products are not permitted.
3. After landing or, where appropriate, after first sale, fishery products must be transported without delay, under the conditions laid down in section 5.4.3 and 5.4.4 of this Standard, to their place of destination.

6.4 Freezing, Chilling, Storage and Transport

6.4.1 Chilling Fish and Fish Products

1. The chilling of fish shall be performed with sufficient rapidity to prevent undesirable physical, biochemical and microbiological deterioration.
2. The temperature of fish that has been chilled shall that of melting ice
3. Cool room or brine tank facilities or the provision for sufficient ice may be provided in the licensed facility for the purpose of cooling product to within the temperature range of melting ice. These facilities shall be adequate to cool and maintain the product within that range until the product is removed for further processing.
4. A chill store used to store chilled fish should be operated at a temperature between -1 C and +4 C.

6.4.2 Freezing Fish and Fish Products

1. The term freezing is applied to the continuous process of reducing the thermal core temperature of fish or fish product from an ambient temperature to -18 C or colder.
2. The freezing process shall be carried out in a way that minimises undesirable, biochemical and microbiological changes.
3. Fish shall be frozen in a room or chamber specifically designed for this purpose and as rapidly as possible.
4. The freezing process shall be carried out in one chamber except that fish cooled to -10 C or colder may be transferred to a second freezer for continuation of the process provided the transfer causes only a minimal rise in temperature

6.4.2.1 Freezing Capability

1. Freezing equipment must have the capability to reduce the internal temperature of the fish or fish product to -18 C within 24 hours.
2. Freezing equipment, when utilized for the initial freezing of unfrozen fish or fishery products should reduce the product temperature through the zone of maximum water crystallization (usually between -1°C to -5°C) preferably within 4 hours, but not exceeding 6 hours, from the commencement of the refrigeration process.
3. The process shall not be regarded as completed unless and until the product temperature has reached -18 C as core product temperature. An exception is brine frozen fish to be used for canning, which may be frozen at higher temperature, although not exceeding -9°C (≤-9ºC).
4. Where the refrigeration process is continued in order to reduce the thermal core temperature to -18°C or colder, the whole refrigeration process should preferably be completed within 8 hours, but not exceeding 12 hours.
5. Effective measures shall be taken to keep temperature rises to a minimum after the freezing process and during handling and transport.
6. The freezing of fish shall be carried out in a freezer capable of reducing the internal core temperature of fish to -18 C or colder within 24 hours and must not be carried out in a cold store without blast capacity.
7. Blast freezers shall not be loaded with fish in excess of the design capacity of the equipment. Reference should be made to specifications of the supplier of the refrigeration equipment in order to determine the recommended capacity, but generally loading should not exceed 70% of the internal volume.
8. After freezing, cold stores shall be operated to maintain fish in a frozen state with the product temperature maintained at -18 C or colder except at times when the freezer is on a defrost cycle.
9. A record of cold store temperatures shall be maintained by either:
    a. A continuous monitoring system that shall be checked at least once a day, or,
    b. Manual readings taken at least daily. In situations where the cold store temperature is found to be above -18 C product shall be placed on hold pending further assessment. Temperatures are to be re-checked on an hourly basis until acceptable. Air velocity in cold stores shall be moderate and no higher than necessary to achieve uniform temperatures within the rooms.
10. Product should be stacked so that air circulation within the storage room is not impaired. Except in jacketed rooms no direct contact with ceilings and floors shall be allowed.
11. Transport of frozen fish shall be done so as to ensure the fish remain frozen
12. Rises in temperature of frozen fish that occurs during storage or processing shall be reduced to -18ºC or colder as quickly as possible.

13. The temperature of frozen fish for export shall not go above -18 C with only a brief upward fluctuation of 3ºC allowed for no longer than 2 hours.

6.4.3 Storage and Transport

6.4.3.1 General

Companies shall document storage and transport controls including:

- Controls in storage areas (chilled, frozen and dry store areas) to prevent contamination
- Temperatures to be maintained in refrigerated storage areas
- Controls on transport operated by the company to prevent contamination and ensure temperatures (if necessary) are maintained

6.4.3.2 Food Carriers

1. The company shall verify that carriers of food products are suitable for the transportation of food. This shall include:
    a. Inspection of carriers to ensure they are free from contamination and suitable for the transportation of food.
    b. Carriers are loaded, arranged and unloaded in a manner that prevents damage and contamination of food and packaging materials.
    c. Incoming materials (food, non-food, and packaging) are received in an area separate from the processing area.

6.4.3.3 Non-food Chemicals Receiving and Storage

1. Chemicals shall be received and stored in a dry, well-ventilated area.
2. Non-food chemicals shall be stored in designated areas such that there is no possibility for cross contamination of food or food contact surfaces.
3. Where required for on-going use in food handling areas chemicals shall be stored in a manner that prevents contamination of food, food contact surfaces or packaging materials.
4. Chemicals shall be stored and mixed in clean, correctly labelled containers.
5. Chemicals shall be dispensed and handled only by trained personnel.

6.4.4 Transportation

1. Vehicles used for the transportation of chilled or frozen fish shall:
    a. Be clean and maintained in a state that will prevent contamination;
    b. Be covered during the transporting of the product in order to prevent exposure to dust, birds, insects and sunlight;
    c. Be of adequate size
    d. Be constructed and equipped in such a way that the temperature requirements laid down in these Standards can be maintained throughout the period of transport
    e. For journeys exceeding one hour, vehicles shall be insulated, designed and equipped to maintain fish in a chilled or frozen state;
    f. Keep fish products for animal consumption clearly separate from fish and fish products and so that any risk of contamination is minimised;
    g. Have internal surfaces of the cargo area constructed from smooth, corrosion resistant, impervious materials free from cracks and crevices. The use of wood is not permitted unless it is painted with gloss paint of a light colour and the fish are carried in fish boxes;

h. Have internal surface joints that are smooth or flush and sealed to prevent the entry of moisture;
i. Be proofed against pests and dust;
j. Have adequate drainage if ice is used to chill the products, in order to ensure that water from melted ice does not stay in contact with the products
k. Ramps, if provided, shall not be stowed in the cargo area;
l. If lighting is supplied, the light source shall be covered by a shatterproof shield;
m. Never carry animals in the cargo area.
n. Where applicable, seafood products shall not be transported with other goods that may cause a risk of contamination.

6.5 Repairs and Maintenance

1. All facilities should have in place a documented repair and maintenance programme to ensure that regular preventative maintenance is carried out and faulty or broken plant and equipment is fixed in a suitable timeframe.
2. The repairs and maintenance programme could include a register that shows identification of the problem, details of how the item is to be fixed, the target date for completion and actual completion date.
3. Repairs shall be carried out as soon as possible without interference to handling or processing and may cause the facilities closure during certain repairs.
4. Planned actions shall be scheduled in a timetable to demonstrate the commitment to future actions.
5. Responsibilities and authorities have to be established for implementing, maintaining, monitoring and verifying the maintenance plan.
6. Procedures must be established to ensure that maintenance will be done in such a way that the risk of contamination of the products is eliminated. A regular preventative maintenance programme must be implemented, whereby equipment, utensils and premises are regularly reviewed for signs of wear and tear and where deficiencies are detected prior to a problem occurring.
7. These schedules and timetables shall be available to the Competent Authority and checked for execution during on-site CA verifications.
8. Defective plant and equipment that is likely to cause contamination of plant and/or equipment should be rectified immediately whereas plant/equipment that is not likely to cause contamination of product will be allowed more time.
9. In all instances contamination of product should be avoided and corrective action taken to ensure that recurrence does not occur.

6.6 HACCP

6.6.1 General

1. All fish and fish products produced for export from land-based establishments and EU approved vessels shall be produced in accordance with an approved and documented HACCP programme.
    a. It is a requirement that a logical approach for food safety be followed based on the seven principles of HACCP. These principles are:
        i. identification of hazards, analysis of risks and determination of measures necessary to control them;
        ii. identification of Critical Control Points;
        iii. establishment of Critical Limits for each Critical Control Point;

iv. establishment of Monitoring procedures;
v. establishment of Corrective Action to be taken when Monitoring indicates that there is a deviation in control parameters;
vi. establishment of Verification and review procedures
vii. establishment of Documentation concerning all procedures and records.

6.6.2 Contents of HACCP Plan

1. The HACCP plan shall be developed for each product manufactured by the establishment.
2. Such a programme should include the following as a minimum:
    a. Company description including company name, address, overall person responsible, phone number.
    b. Scope of the HACCP plan. Namely what products/processes are covered and where the processes start and finish
    c. A company organisation chart or information covering personnel with key responsibilities under the HACCP plan.
    d. A company HACCP policy signed by an authorised company representative.
    e. HACCP team members, their responsibilities and background.
    f. References used to develop or support the HACCP plan.
    g. Product description or specification including method of preparation and storage, intended use, product characteristics, target consumer group, packaging, additives and ingredients and method of distribution or storage.
    h. Process flow clearly showing all steps in the process as well as inputs (either in the flow or elsewhere in the HACCP plan) and process variations as applicable to each step. The flow shall be verified by an authorised company person.
    i. Identification of any hazards (raw material and process) that must be prevented, eliminated or reduced to acceptable levels;
    j. Identification of biological, chemical and physical hazards for process steps.
    k. Analysis of hazards for significance (likelihood and severity).
    l. Identification of appropriate critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels
    m. Establishment of critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards. Limits must be scientific or validated, measurable and allow adequate control of the hazard.
    n. Documentation of effective monitoring procedures at critical control points covering who, what, how and when for each aspect monitored. Monitoring frequency should allow adequate control of the hazard.
    o. Documentation of corrective actions when monitoring indicates that a critical control point is not under control. Corrective action to cover action taken to rectify the cause as well as product disposition and responsibilities. Actions to prevent recurrence also covered where possible.
    p. Documentation of procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (i) are working effectively. The procedure must cover record review, internal audit, annual review, product testing and calibration with “who, what, how and when being covered for each element of verification.

q. Establishment of a document and records procedure commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (h). Documents and records must include date and/or version number for document control. Records must record date and time of observation and the signature of the person performing the check.

6.6.3 Approval of HACCP Plans

1. The HACCP programme must be signed and dated by an authorised company representative and an authorised CA officer. When the HACCP plan is signed by the company representative it represents management's acceptance and commitment implementing the plan.
2. HACCP programmes shall also be subject to annual review, or more frequently if changes occur in the product or process.
3. The annual review shall consider the following:
    a. Review of records pertaining to the HACCP plan including monitoring records, corrective action records, supporting system records and product test results to demonstrate compliance and production of safe product.
    b. Review of non-conformances in particular recurring non-conformances
    c. Review of customer complaints for food safety reasons
    d. Consideration of any food safety recalls in the past 12 months
    e. Review of legislative requirements to identify legal requirements that may have changed since the HACCP plan was written.
    f. Review of the process to determine any changes made since the HACCP plan was written.
4. Should changes be made to the approved HACCP plan, these changes must be notified to the CA for approval.

6.6.4 Hazard Information

Hazards can be:

a. Biological hazards, such as:

i. Pathogenic micro-organisms (e.g. harmful bacteria, viruses)

ii. Parasites

b. Chemical hazards, such as:

i. natural toxins

ii. pesticides

iii. veterinary drug residues

iv. unapproved food and colour additives

c. Physical hazards, such as metal, glass, etc.

Hazards can be:

- *unacceptable contamination (or recontamination) of a biological (micro-organisms, parasites), chemical or physical nature of raw materials, intermediate or final products;*
- *unacceptable survival or multiplication of generation of chemicals in intermediate products, final products, production line or environment; and*
- unacceptable production or persistence of toxins or other undesirable products of microbial metabolism.

- *Species related hazards that are potential hazards associated with specific species of fishery products. Species related hazards are:*
    - *i) chemical contamination*
    - *ii) mercury*
    - *iii) natural toxins*
        - *Paralytic Shellfish Poisoning (PSP)*
        - *Neurotoxic Shellfish Poisoning (NSP)*
        - *Diarrheic Shellfish Poisoning (DSP)*
        - *Amnesic Shellfish Poisoning (ASP)*
        - *Ciguatera Food Poisoning (CFP)*
        - *Clupeotoxin*
        - *Chondrichthytoxin*
        - *Tetrodotoxin (Puffer fish)*
        - *Gempylotoxin (esolar)*
    - *iv) histamine*
    - *v) parasites*
    - *vi) veterinary / aquaculture drugs*

- *Process related hazards are potential hazards that are associated with food handling, preparation or processing. Examples of process related hazards are:*
    - *i) Inadequate drying, pathogen growth, toxin formation as a result of inadequate salt, sugar, and/or nitrite concentration:*
    - *ii) Pathogen survival through cooking;*
    - *iii) Cross-contamination;*
    - *iv) Temperature abuse during processing of cooked products;*
    - *v) Temperature abuse during processing of chilled products;*
    - *vi) Microbiological growth in batters;*
    - *vii) Pathogen survival through pasteurization;*
    - *viii) Recontamination after pasteurization;*
    - *ix) Temperature abuse during final cooling;*
    - *x) Temperature abuse during finished product storage;*
    - *xi) Temperature abuse during distribution;*
    - *xii) Excessive amounts of food and colour additive; and*
    - *xiii) Important physical hazards.*

6.7 Specific Processing Requirements

6.7.1 Checks on Incoming Raw Material and Other Inputs

6.7.1.1 Packaging

1. Packaging shall be checked before use for cleanliness and absence of contamination.

6.7.1.2 Ice

1. Ice shall be made from potable water or clean seawater and be free from contamination at the point of use.

6.7.2 Ingredients

1. Ingredients shall be food grade, free from contamination and meet importing country requirements.

6.7.3 Fish

1. Premises shall receive fish according to a documented and approved “Reception of Fish” programme. This programme shall cover checks, and resulting records, for each incoming batch of fish as follows:
    a. Evidence of spoilage, contamination or other deterioration
    b. Evidence that the fish has been adequately chilled or frozen from the time of catching or harvesting to the time of arrival at the processing premises
    c. Labelling of each incoming batch of fish to allow trace back where required
    d. Action to be taken whenever non-compliances occur against the documented programme
    e. Records to be kept
    f. Responsibilities under the programme

6.7.4 Canning

1. Premises operating low acid canned foods production must meet the following criteria:
    a. Supervision of the canning process is under a person who has successfully completed an approved Low Acid Canned Foods Supervisors course (or equivalent)
    b. A scheduled process for low acid canned foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low acid canned foods packed in hermetically sealed containers. A “Standard Operating Procedure” Manual (or equivalent title) shall be documented and cover the following:
        i. Establishment of the thermal process with heat penetration and distribution studies and data
        ii. The process control system covering a description of the equipment and monitoring requirements
        iii. Container integrity checks and documentation including incoming containers, seaming machines, double seam integrity, cooling water monitoring, can cooling controls, post-process handling of containers
        iv. Documentation and records covering processing and production records, management review of records and process deviation records.
        v. The scheduled process must be approved by the CA and follow the requirements as laid down in Title 21 of the US Food and Drug Administration Code of Federal Regulations Part 113
        vi. Canning conditions shall comply with the following requirements:
            - The water used for the preparation of cans must be potable water
            - The process used for heat treatment must be appropriate having regard to heating time, temperature, can filling, size of containers with records being kept of each
            - The heat treatment must be capable of killing or inactivating pathogenic micro-organisms and their spores

- The heating equipment must be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment
- Can cooling water must contain residual chlorine of at least 5 ppm
- The following checks must be carried out to verify the canning process:

vii. Incubation test studies at either 37 C for seven days or 35 C for ten days or any other equivalent combination
viii. Tear downs or similar tests to confirm the integrity of the double seam
ix. Checks on cans to ensure the can seam is not damaged or jeopardised
x. That all cans are traceable to an individual batch that relates to individual retort batches processed

c. The HACCP plan must include as CCPs:
   i. Check weighing
   ii. Seaming (as per can manufacturers recommendations)
   iii. Retorting (with parameters and limits meeting scientific requirements and the manufacturers recommendations for the retort used)
   iv. Cooling

2. Unless otherwise accounted for:
   a. The critical limits for each of the CCPs must be scientifically valid and data kept on site to prove this
   b. Retort equipment must be of an approved type
   c. The mercury-in-glass thermometer, retort gauges and any other critical measuring equipment must be calibrated at least annually
   d. Heat sensor cards must be used in every retort basket or unit processed and must be held on file as part of the production records
   e. The cannery shall be designed in such a way as to prevent retort baskets inadvertently missing the retort process
   f. Cooling cans must be held in an area away from the main processing and people movement to prevent contamination
3. The provision of a documented scheduled process and Standard Operating Procedure Manual established by a qualified person having expert knowledge of the thermal processing for low acid canned foods packed in hermetically sealed containers and covering the following:
   a. Establishment of the thermal process with
      i. heat penetration and
      ii. heat distribution study
   b. Process control system with:
      i. equipment description
      ii. monitoring system
      iii. general operations in thermal process room
      iv. Container integrity checks:
      v. incoming containers
      vi. seaming machines
      vii. evaluation of double seam integrity

viii. cooling water monitoring
ix. cooling of containers
x. post-process handling of containers

c. Documentation and records:
i. processing and production records
ii. management review of records
iii. process deviation records

4. and shall be approved by the Competent Authority.
5. The Standard Operating Procedures Manual shall be based on the requirements laid down in Title 21 Food and Drugs, Code of Federal Regulations, Chapter 1, Food and Drug Administration, Department of Health and Human Services, Part 113, Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers (21 CFR p.113).
6. Canning conditions shall comply with following requirements:
   a. The water used for the preparation of cans must be potable water;
   b. The process used for the heat treatment must be appropriate, having regard to such major criteria as the heating time, temperature, filling, size of containers, etc., a record of which must be kept;
   c. The heat treatment must be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms;
   d. The heating equipment must be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment; and
   e. 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.
7. The following checks must be carried out to verify the canning process:
   a. Checks must be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment:
      i. incubation test: incubation must be carried at 37°C for seven days or at 35°C for ten days, or at any other equivalent combination.
      ii. microbiological examination of the content of the containers in the establishment's laboratory or in another approved laboratory.
   b. Samples must be taken of production each day at predetermined intervals, to ensure the efficiency of sealing or of any other method of hermetic closure. For that purpose, appropriate equipment must be available for the examination of cross-seams.
   c. Checks are carried out in order to ensure that containers are not damaged.
8. All containers that have undergone that treatment under practically identical conditions during the same period of time must be given a batch identification mark.

6.7.5 Salting/Smoking

1. Premises salting fish must provide a salting area separate from other processing areas and must meet the following criteria:
   a. Salt used in the treatment of fishery products must be clean and stored in such a way as to preclude contamination. It must not be re-used

b. Any container used for salting or brining must be constructed in such a way as to preclude contamination during the salting or brining process.
c. Containers or areas used for salting or brining must be cleaned before use

2. Smoking must be carried out in separate premises or a special place equipped with a ventilation system to prevent the smoke and heat from affecting other premises or places where fishery products are prepared, processed or stored.
3. Premises smoking fish on site must meet the following criteria:
    a. Materials used 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 products.
    b. Wood that has been painted, varnished, glued or undergone any chemical preservation treatment must not be used for fish smoking.
    c. The process is to be carried out under an approved HACCP plan that has the following CCPs:
        i. Brining
        ii. Smoking
        iii. Cooling
    d. Provides for adequate separation of the smoking units from the packing and other processing areas.
    e. The critical limits for brining, smoking and cooling are scientifically valid
    f. After smoking products must be cooled rapidly to the temperature required for their preservation before being packaged

6.7.6 Thawing

1. Where thawing is carried out:
    a. Fishery products must be thawed under hygienic and controlled time / temperature conditions. During thawing, the temperature of products must not increase excessively and must be monitored;
    b. Fishery products shall be brought to their thawed state as quickly as possible without causing undesirable physical, biochemical and microbial changes to the food;
2. Thawing must be carried out so that product reaches a maximum temperature of 4.4 degrees or cooler.

6.7.7 Cooking of fish, shellfish and crustaceans

1. Where cooking of fishery products is carried out the following criteria shall be met:
    a. Where products are being heated in any way, such as blanching or retorting, there shall be adequate control to ensure that the correct temperature / time regime is used to achieves the desired functionality and shelf-life without jeopardising consumer health.
    b. Any cooking must be followed by rapid cooling. Water used for this purpose must be potable water or clean seawater. If no other method of preservation is used, cooling must continue until the temperature approaches that of melting ice.
    c. Shelling, shucking or filleting must be carried out under hygienic conditions to avoid the contamination of product. Where such operations are done by hand, workers must pay particular attention to proper hand washing 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.
    d. Cooked products must immediately be frozen or kept chilled at a temperature that will preclude the growth of pathogens, and be stored in appropriate premises.

e. Every manufacturer must carry out microbiological checks on its production at regular intervals as follows:

Pathogens

Type of pathogen	**Standard**
Salmonella spp.	Absent in 25 g n = 5 c = 0
Listeria monocytogenes	Absent in 25 g n = 5 c = 0

6.7.8 Packing

1. Packing must be carried out under satisfactory conditions of hygiene, to preclude contamination of the fishery products.
2. The time that elapses between processing and packaging shall not cause the food to suffer any undesirable physical, chemical or microbiological deterioration.
3. Labels, tags and adhesives used in packaging shall not contaminate food and a container of food for export shall not contain any foreign objects except the food.
4. Unused packaging materials must be stored in premises connected with the production area and protected from dust and contamination

6.7.9 In house Laboratory

1. For premises operating a laboratory on site the laboratory must be physically separated from processing areas with restricted access to approved persons only.

6.8 Training

1. All personnel who handle seafood shall undertake induction training (or training at commencement of employment) in the following areas:
    a. Personal hygiene and hygienic work practices
    b. Seafood safety and seafood spoilage
2. Refresher training on these topics shall be conducted on a regular basis for employees. Employees in key positions may also be required to complete specialised training. For example, personnel developing, verifying or amending the documented HACCP plan must have attended a HACCP training programme.
3. Records of training must be kept on file for each employee and records are to include the date of training, details of the training completed and any results or certificates.
4. Companies shall have a documented training programme that outlines:
    a. What training is required and by whom
    b. Frequency of training
    c. Who will conduct the training
    d. Who is responsible for identifying training needs
5. The operator, or a person delegated by the operator should review training requirements at least annually and keep a copy of this review on file.

6.9 Recall

1. Operators must document a Recall programme in the event that product is found to be non-compliant or injurious to health in the market place.
2. The documented Recall programme must cover:
    a. Personnel responsible for the recall.

b. The situations in which a recall will be necessary.
c. Notification of the CA in the event of a recall (within 24 hours of deciding a recall in necessary)
d. The steps in the recall process from initial notification through to and including a review of recall effectiveness. The steps must ensure adequate control and separation of affected product throughout.
e. The need for a review of recall effectiveness.

6.10 Inventory Control and Traceability

Operators must be able to demonstrate one-up and one-down traceability for all products processed as follows:

1. Operators must be able to trace all products being receipted, processed, stored and dispatched both physically and by record (electronic or hard copy) from source to final sale.

2. The following traceability requirements apply for all fish and fishery products receipted, stored and processed onsite:

a. Operators must be able to demonstrate traceability of entire lots received onto site from receipt to dispatch. This will require operators to be able to trace lots both physically and by records from receipt, through storage, through processing and subsequent storage to dispatch.

When lots are divided e.g. some is processed, some continues to be held in storage or is processed into a different end product. Operators must still ensure they can trace the destination and quantity of that product.

Similarly, operators must maintain traceability of reworked products the same as product from normal production.

3. The following table can be used as a guide to the type of information that can be used to assist with meeting traceability requirements:

Step	***Record Type***	***Inventory Records***	***Description***
Product received from catching vessel	Reception records	Reception check sheets Unloading documentation Vessel records	Record date, supplier details e.g. vessel name, voyage number, fish species, fish form e.g. whole, G&G and quantity
Product received from other establishments		Purchasing records Reception check sheets	Record date received, details of the product received including species, form, lot details from the supplier
Imported fish		Purchasing records Overseas authority records such as Health Certificate	
Reception weighing, grading	Processing records	Reception check sheets Delivery dockets Unloading dockets Weigh sheets	Date received, quantity, species
Processing			Product id, pack date or lot number, species, quantity
Storage	Cold store Inventory	Store records	Product id, species, quantity
Dispatch	Dispatch records	Sales invoices Health certificate information Dispatch record	Date of dispatch, customer, product id, pack date or lot number, quantity

1. Operators must be conducting a review of their ability to trace fish and fishery products in entirety from source to sale at least every 3 months. They must retain evidence of this review and make this available to CA Officers on request.
2. EU-listed land-based establishments must use a proven e-traceability system to provide traceability for the purposes of this section.

6.11 Internal Audit and Compliance

6.11.1 Internal Audit and Compliance System

1. Companies are required to conduct their own internal audits and compliance checks to demonstrate compliance with these Standards, their own HACCP plans, GMP's, SSOP or other pre-requisite programmes as well as any other requirements for export of seafood products from RMI.

2. Companies can develop their own monitoring system and records but companies must cover the following as a minimum:

Pre-requisite programme checks

AREA/ITEM	DETAILS
Building Exterior	Clean, tidy, good drainage etc.
Building Interior	Design, construction, maintenance, lighting, ventilation, waste disposal
Sanitary facilities	Employee facilities including hand washing & equipment cleaning and sanitising facilities
Water/Steam/Ice	Quality & supply
Transportation and Storage	Food carriers Temperature control Incoming Material Storage Non-food Chemical receiving & storage Finished Product storage
Equipment	Design & installation Food contact surfaces Equipment maintenance & calibration Maintenance records
Personnel	Training: general & specialised Health and hygiene
Sanitation and Pest Control	Sanitation programme & records Pest control programme & records
Product recall	Programme & records
Labelling	Correct & complete
Traceability	Traceability of products one step forward and one step back
Records	Clear, complete, accurate, legible, signed & dated
HACCP Plan	Current & complete Monitoring records available and as for records above Corrective actions taken as required Verification activities completed as required & showing production of safe food

A suggested format is given in Appendix Four.

6.11.2 Records

1. Records from any Internal Audit and Compliance activities must be kept on file and made available to CA inspector on request.
2. Companies must not use twink/white out or red pen in completing such records.

7 Product Standards and Export

7.1 Labelling

All fish and fish products intended for export shall be labelled with the following information:

7.1.1 Inner Cartons to be sold as Individual Items

1. Product common name
2. Date of production (may be in code)
3. Country of origin (unless in the name and address of the licensed facility below)
4. Name and address of licensed facility who produced the product
5. Ingredient statement (if applicable)

7.1.2 Outer Cartons or Packaging and Inner Cartons

1. Product common name
2. Scientific name
3. Date of production (may be in code)
4. Country of origin (unless in the name and address of the licensed facility below)
5. Name and address of licensed facility who produced the product
6. Ingredient statement (if applicable)

7.1.3 Market Specifics

1. The operator shall also take account of any overseas country requirements for labelling.
2. All the letters and figures must be fully legible and grouped together on the packaging in a place where they are visible from the outside without any need to open the said packaging.

7.2 Residues and contaminants

All residues (pesticides, antibiotics or other) and metals where applicable shall not exceed the limits as specified by importing country requirements. In particular the requirements for residue and contaminant monitoring for products destined for the EU and Chinese markets are given in Appendix Five.

Where no standard exists, the requirements given in Codex Standard 193-1995 “Codex General Standard for Contaminants and Toxins in Food and Feed” shall be used.

7.3 Ingredients and Additives

1. All ingredients and additives added to fish shall be prepared so as not to present a risk to consumers.
2. Fishery products, intended to be placed on the market, must not contain sweeteners, colours, food additives others such as preservatives, antioxidant and phosphates other than those approved by national legislations, Codex Alimentarius and the relevant market requirement per intended products and are not in excess of the permitted levels. any maximum quantity or proportion permitted by these Standards.
3. Ingredients and additives shall also meet the relevant overseas country requirements (documented evidence is required)
4. Storage and handling of ingredients or additives shall be according to manufacturer recommendations and also protect from contamination. They shall be labelled at all times.

7.4 Sampling and Testing

- **Histamine:**

Test	*No. of samples*	*Sampling requirements*	*Method of analysis*	*Frequency*
Histamine	9 samples per species per company exporting	n = 9 c = 2 m = 100ppm M = 200ppm	HPLC	bi-annually per species per existing company exporting and 4 - monthly for new companies

Note- All new establishment histamine sampling frequency will be reviewed at the end of their 2nd year purely based on compliance.

- **Ciguatera:** it is an offence to export fish and fishery product from RMI that has the presence of ciguatoxin.

1. In addition to this an operator is required to meet any overseas country sampling and testing requirements BEFORE export to that country. Refer to Appendix Five for Overseas Country Requirements.

7.5 Certification

7.5.1 General Provisions in Issuing Certificates

1. An export certificate as described by these Standards shall accompany all products destined for export.
2. Export certificates shall be issued by a CA officer provided the requirements of any relevant legislation and any overseas market access requirements have been met.
3. Only licensed exporters may apply for export certificates.
4. Export certificates shall not be issued unless:
    a. The person has first-hand knowledge of the on-site operation to state that the information used in the export certificate is complete and accurate.
    b. The information provided by the exporter in incomplete, inaccurate, or otherwise, not in accordance with any requirement of the NCP.
    c. The authorised person is satisfied that the information provided is correct and complete.
5. The Competent Authority may only issue one type of certificate for each consignment or lot.

7.5.2 Requirements of Operators

1. An operator intending to produce fish or fish product for export shall give at least 48 hours warning to the CA officer of their need for certification so that any necessary verification can be performed and export is not delayed unnecessarily.
2. An operator intending to produce fish or fish product for export is required to take all reasonable steps to ensure that the fish or fish product is not mixed with product that is not intended for export.
3. An operator intending to export fish or fish product must:
    a) Carry out specific checks of the received fish or fish product against the market access requirements of the intended market(s), including transport conditions, product item marks, labels and any other identifying features;

b) Have a system of clear separation, and identification or traceability of fish or fish product during receipt, processing and subsequent storage,

c) Keep records of these matters to enable the usage and movement of the fish or fish product to be traced

d) Have a written programme that describes how these requirements will be met.

7.5.3 Requirements on Exporters

1. If different form the exporter must ensure that the fish or fish product for export meets the requirements of both the importing country as well as RMI export standards.

7.5.4 Export Health Certificates

1. Export health certificates must be issued for every export of seafood from RMI by the authorised CA officers of the MIMRA
2. MIMRA CA will issue different types of certificates depending on the source of the product and the intended destination.:
    a. An EU Health Certificate
    b. A non-EU Health Certificate (General)
    c. Hygienic Handling Certificate.
    d. A Chinese Health Certificate
    e. A fishmeal health certificate

    as shown in Appendix Three

1. It is the exporters' responsibility to request export certificates. The request must be made at least48 hours prior to the shipment being dispatched otherwise the exporter will be refused certification.
2. Only export certificates, produced on official MIMCA CA stationery, may be used.
3. The certificate must provide an accurate description of the identity of the approved processor of the goods, the type of fish being shipped, the quantity of product being shipped, and the final destination of the goods.
4. Export health certificates remain the property of Director of MIMRA until received by a foreign country.
5. The MIMRA (CA) has the right to refuse to issue an export health certificate in the following circumstances:
    a. The request for the certificate from the exporter is made more than 24 hours after the shipment left.
    b. The information supplied by the exporter is incomplete or inaccurate
    c. If the product fails to meet the requirements of these Standards or any other relevant RMI legislation
    d. If the inspector has any reason to doubt the information being supplied or the condition of the product
6. Certifying officers, issuing export certificates, must enter the actual date the export certificate is issued in the designated box clearly. The date entered must be the actual date of issue of the export certificate and not any other.
7. The export certificates must be dated and stamped prior to date of shipment and before the consignment leaves the control of the competent authority.
8. Certifying officers may issue only one export certificate set per consignment.

9. Additional sets of export certificates to cover alternative destinations for the same consignment will not be issued.

7.5.5 EU Certification

1. All EU Health Certification uses the EU TRACES system. All the procedures pertaining to this uses the EU TRACES Manual for completing the electronic certification.
2. The developer and administrator are the EU and any issues concerning IT and certification pertaining to online system are addressed to the relevant personal in the EU TRACES.
3. The local contact administration is the RMI CA and contact point will be the CA advisor and the Senior CA officer who will enable users both from the industry and the CA to have access to validate and certify the Health Certificate.
4. Any updates in EU TRACES. will be communicated to the relevant contact point.
5. EU Health certificates will only be issued for product processed in establishments that are listed on the EU Approved External Establishment list.
6. Certificate format is to be identical with that of Regulation (EC) 1012/2012. A single, original, fully completed EU Health certificate must accompany each shipment.
7. The certificate provides the *official guarantees* from the MIMRA CA and the Republic of the Marshall Islands to the EU regarding the relevant provisions of EC Regulations.

7.5.5.1 Requirements of the EU Health Certificate

1. **Only listed exporters may apply for official assurances regarding their products.**
2. The certificate must provide an accurate description of the identity of the approved processor/establishment of the products, the type of fish being shipped, the quantity of product being shipped, and the final destination of the goods.
3. Information published on the EU List must match the information about the exporting establishment that is listed on the certificate and the product labels.
4. RMI exporters should ensure that their products are accompanied by the proper EU documentation prior to being exported out of RMI and if transhipped via another country.
5. Certificates will be signed and stamped in ink that is a different colour than the remaining text on the certificate.
6. EU Health certificates will only be issued for product obtained and processed in establishments that are listed on the EU Approved Establishment list and meets the certification requirement under *Article 126 of EU Regulation 2017/625 and Regulation 2020/2035.*
7. EU Health Certificates are obtained online via EU Trade Control and Expert Systems (TRACES) web-based 'online' system through their website https://webgate.ec.europa.eu/sanco/traces/.
8. Online TRACES registered user criteria;
    a. Only MIMRA EU TRACES registered fish business operators i.e. those on the EU approved establishment list, exporters and their registered authorized users are allowed to access online e-health certificate through their login account.
    b. CA officers whose names are registered in the TRACES system have access to the online e-health certificate using their login accounts.
    c. The CA EU TRACES National Administrator is responsible for approval and registration of the CA Officers and the Operators.
    d. Process on new account creation, approval and activation are all detailed out in the *EU TRACES User Manual Import Certificates, Part 1 intended for economic operators.*

7.5.5.2 Preparation of the EU Health Certificate

It is the exporters' responsibility to login to the EU TRACES System, complete the online certificate and submit on line for verification and validation by the authorized CA officer.

i. The completed HC is to be lodged online and other supporting documents to be manually lodged with the CA for cross referencing and approval. If need be on site verification will be carried out.

ii. Exporters must ensure that the information completed one online is correct prior to it being lodged for validation by the CA officer.

iii. The certificate will be completed in an official language of the country where the shipment will be subject to import controls. (Port of first entry).

iv. The information to be completed on the Health Certificate must comply accordingly to the descriptions (next section) identified for each of the respective boxes shown in the HC.

v. In the event that the exporter is unable to access online certificate due to system break down or disaster, CA Officer shall assist in preparation of the certificate on-line and validation of the same.

vi. As a requirement under the EU TRACES rule, the e-certificate must be prepared within or on the 10th day from the tentative date of export. TRACES System will not accept new certificates prepared prior to the 10th day or after the shipment date.

vii. In accordance with Now Article 126 EU Reg 2017/625 and Articles 3 and 4 of Commission Implementing Reg 2019/628on Health Certificate requirements;

a. Health Certificate will be issued only for products processed in EU approved and listed facility.

b. Health Certificate be drawn up in the official language of the third country (exporting country) and the first port of entry in which the boarder inspection takes place, or be accompanied by a certified translation into that language.

c. The certificate must be signed and must bear the official stamp on all pages if more than one page. ONLY ONE hand signed copy.

d. **Certificate stamped in colour different from the colour of the certificate using CA Official Stamp** at the bottom of each certificate page and within the crossed-out section. *The CA uses the Red Ink as the official colour for the stamp. The certificate is prepared and validated online, but still needs to be printed out as hard copy for stamping and signature.*

e. Certificate must be signed using colour different from the colour of the certificate. CA can use **red ink biro** except advice by the exporter to use other ink biro as the official ink colour.

f. The original version of the certificate must accompany consignments into EU

g. Certificate must consist of sequences of pages numbered so as to indicate that it is a particular page in a finite sequence.

h. Health Certificate must bear a unique reference number. Certificate consist of more than one page. Each page must indicate this number. The EU TRACES System automatically generate unique reference numbers.

i. The certificate must be issued before the consignment leaves the control of the competent authority of the third country.

j. Each Health Certificate is issued per Invoice therefore list of container numbers and seal shall be stated clearly on the HC with product description including other required information. Additional sets of export certificates to cover alternative destinations for the same consignment is not allowed.

7.5.5.3 Additional exporter declarations, endorsements, etc.

An export certificate, once produced, must not be modified with alterations, deletions, additional declarations or endorsements.

Commercial information such as contract numbers and bank arrangements must not be entered on an export certificate.

Commercial inventory references to products, including product item numbers, are valid product identifications. The references may be placed with the product description on the export certificate and are verifiable.

7.5.6 Certification rulings on unloading from fishing vessels

7.5.6.1 EU and Non-EU listed RMI flagged (Vessels and Carrier Vessels)

7.5.6.1.1 Fish landed and loaded into Containers

Fish loaded onto containers and/or landed for handling on shore and containerized and/or for further processing and loading for export.

In this instance the CA is afforded the opportunity to view and inspect the unloading and perform related verifications and when all is satisfactory the CA issues

i. EU HC is issued to fish and fish products that come from the EU listed vessel only as assessed and deemed in compliant to EU rules and approved by the CA.
ii. Non- EU HC is issued to fish that come from non-EU approved vessel

7.5.6.1.2 Fish landed for further processing

EU Eligibility by approval status of the catching vessels into the processing establishments and their separation from non-EU products will be followed under the 0perator's traceability system

7.5.6.2 Foreign flagged (Vessels & Carrier Vessels)

7.5.6.2.1 Fish landed and loaded into Containers

i. Fish loaded on an approved landing site onto containers and or landed for handling on shore and re - containerized and or for further processing and loading for export, is not eligible for RMI EU HC. A Hygienic Handling Certificate can be issued on request
ii. Yet the fish will be deemed eligible by the processing state based on the EU authorization status of the flag state and the approval of the vessel as well as the EU authorization status of RMI and approval of the landing site and or cool stores if used.

7.5.6.2.2 Fish landed for further processing

i. Fish from non RMI vessels landed for further handling, process and export will be eligible for EU Health Certificate after processing in an RMI EU listed establishment, only if the harvesting vessel and/or carriers are EU approved and listed by the flag state.
ii. In case that the vessels are not EU approved by its flag state, the fish unloaded, nor any products thereof can qualify for a non-EU HC after processed.

7.5.6.3 Domestically based foreign flagged vessels

Foreign vessels in charter arrangements with domestic companies are not eligible for the EU market independent of the approval status of the processing establishment. Unless an MOU is established by the CA of the flag state and MIMRA for inspection on behalf for the maintenance of the EU listing, and this acknowledged by DG SANTE

7.5.7 Records and Storage of Certificates

1. The operator must keep a record of the serial numbers of completed certificates.

2. A copy of the original signed certificate must be held by the KSVA for a minimum of FOUR years after the date of signing.
3. All copies and originals of certificates must be securely stored to prevent loss or damage.

7.6 Re-issue of Export Certificate(s)

i. Formal CA involvement with the export of any product ceases when the consignment leaves RMI.
ii. The CA will assist with problems that occur during the voyage, or at the border post of the country for which the export certificate has been given. Replacement export certificates are sometimes required for changes to consignor or destination en-route or for inaccuracies in the export certificates discovered by the border inspectors or other parties.
iii. Replacement of incorrect official assurances for any reason is not an automatic event and each case is evaluated individually.
iv. To obtain a replacement export certificate, the exporter must provide, to the original signing officer, a signed statement detailing the reasons for replacement of the original signed export certificate. If satisfied with the declaration and explanation provided, certifying officers may issue a replacement export certificate. The original issued export certificate or any corrected documentation to support the issue of the replacement certificate must be presented to the certifying officer.
v. The certifying officer must keep the original export certificate attached to the new file copy.
vi. Replacement of an EU Health Certificate is done automatically via TRACES system by using the functional tab "copy as replacement" if satisfied with the declaration and explanation provided by the exporter. The replacement certificate automatically replaces the previously validated certificate and the new TRACES Import Number and version is displayed referring to the old number and version which is also displayed on the certificate**.**

NB. The EU HC does not have an expiry date. Once validated it is considered as valid and amendments can be made months later through the TRACES functional tabs of "copy as replacement" so long as the certificate was initially validated.

7.6.1 Incorrectly Prepared Export Certificates

MIMRA CA is not required, nor obliged, to provide replacement certificates where the reason for the replacement results from an error made during the preparation of the information or in the preparation of the consignment. Many of these errors are preventable and could be avoided by an effective quality system.

However, this section sets out the procedure for the reissue of an export certificate where the reissue is required due to the detection of an error, other than by the EU or Member State.

The exporter must request a replacement export certificate. The Certifying Officer will endorse the replacement export certificate set in the body of each document with the statement: "*Replacement of certificate No …... Dated …… which is cancelled."*

The exporter must complete a signed statement:

i. Outlining the reasons for replacement.
ii. Stating that no authorities of foreign governments are involved in the need to replace the original issued export certificate.
iii. Where the error is a consequence of an unintentional change of destination or method of conveyance of the consignment, the exporter must provide details of the circumstances, and whether the consignment has been discharged in another country.
iv. The exporter must present the request for replacement export certificate sent to the signing office, where the original export certificate was issued along with:
v. The original issued export certificate or

vi. Any corrected documentation to support the issue of the replacement certificate.

The exporter must ensure the details entered on the replacement export certificate are consistent with the corrected documentation provided to the certifying officer to support the issue of the replacement export certificate.

Replacement export certificates must be issued with a new unique shoulder number. Certifying officers must record on the replaced original certificate and its file copies that the certificate has been cancelled and replaced, and record the new shoulder number of the replacement certificate.

The certifying officer must attach the original of the replaced export certificate to the file copy of the new certificate.

7.6.2 Foreign governments involvement

This section sets out the procedure for the reissue of an export certificate where the reissue is as a result of a foreign government detecting an error on the original issued certificate. The original issued certificate may be returned to the original signing office, retained by that foreign government for destruction**.**

i. If the CA authorizes the reissue of the export certificate, it will endorse the replacement export certificates in the body of the document with the statement:
   - "Replacement of certificate No ……. Dated …… which is cancelled."

ii. The exporter must ensure the details entered on the replacement export certificate are consistent with the supporting documentation, and the inventory records if appropriate, supplied to the certifying officer for the issue of the original issued export certificate.

iii. The certifying officer must compare the details entered on the replacement certificate with the corrected documentation provided to support the issue of the replacement certificate. The official assurance verifier at the originating premises must verify any inconsistencies before the replacement certificate may be issued.

iv. Replacement export certificates must be issued with a new unique shoulder number.

v. Certifying officers must record on the original certificate and file copies of the original certificate that the certificate has been cancelled and replaced, and record the new shoulder number of the replacement certificate.

vi. The certifying officer must keep the original export certificate attached to the new file copy.

8 Overseas Market Access Requirements

Appendix Five gives individual country requirements for any seafood products. Exporters must meet these minimum requirements in addition to the remainder of these Standards in order to export to the chosen market.

9 Fishmeal

While fishmeal operations are not regularly inspected by the Competent Authority, if a company requests a health certificate to accompany any shipment the CA must sight records that confirm compliance with the following parameters:

Parameter	***Limit***
Moisture	10% maximum
Salmonella	Nil

10 Vessels

10.1 General

Where RMI flagged vessels require product processed on board that is for direct export to the market and not via

an approved land-based premises then those vessels shall meet the requirements laid down in these Standards

for EU vessels given in section 7 and Appendix Five.

11 Complaints, Appeals and Resolution of Disputes

10.2 Clarification Provisions for Exporters

11.1.1 First instance

The initial point of contact for operators/licensees seeking clarification of specifications, including overseas market access requirements, will be the CA officer responsible for the premises, or the signing officer dealing with export certification.

11.1.2 Second Instance

Where the CA officer is unable to provide the clarification sought by the operator/licensee, it will refer the query to the CA advisor.

11.1.3 International instances

Official communication with foreign governments and RMI diplomatic posts remains the responsibility of the CA.

Exporters seeking the CA's assistance with problem consignments must submit the relevant data and information to the CA, for an assessment and subsequent recommendation and clarification to border authorities and diplomatic missions.

11.2 Appeal Provisions for Exporters

Where any operator/licensee believes, **after following the suggestions of section 7.1** that information, clarification, or sanctioned is demonstrably unfair, inaccurate, or impinges on the operator/licensee's ability to conduct operations, they may contact MIMRA Management.

The operator/licensee is required to advise the CA directly involved first. The operator/licensee should be aware that the likely first action of MIMRA management will be to seek the views of the verification officer and MIMRA Legal officer.

APPENDIX ONE: Complaint or Appeal Form

FULL NAME OF COMPLAINANT………[1]

COMPANY OR LICENCE NO.………..

DATE OF COMPLAINT OR APPEAL………..

DESCRIPTION OF COMPLAINT OR APPEAL:

ACTIONS TAKEN TO DATE OVER COMPLAINT OR APPEAL:

REASONS FOR COMPLAINT OR APPEAL:

[1] Full name of complainant = person making complaint on behalf of company or individual

SUPPORTING INFORMATION OR DOCUMENTATION SUPPLIED:

FOR CA USE ONLY:

1. **Actions taken to resolve complaint or appeal:**

2. **Agreed Outcome to Complaint or Appeal:**

Signed:	**Signed:**
Complainant Name:	**CA Representative:**
Date:	**Date:**

APPENDIX TWO: Application Forms

A. Exporter registration and listing

Application Form: Exporter registration and listing (F25A)	**CA Verification**
1. Exporter Identification	
A unique identification will be assigned to each exporter. Refer form guidelines for criteria.	
Registration ID:	
2. Applicant Name:	
Registered company name or partnership names (including the trading name) or individual name.	
Full legal name:	
3. Business Address and Contact Details:	
Physical (for service/delivery of items):	
Phone No:	
Fax No:	
Postal (for communication):	
E-mail:	
4. Processing Establishment Address(es) and Contact Details:	
Only complete if the Processing establishment details are different from the business address in Section 3.	
Legally registered address:	
Phone No:	
Fax No:	
E-mail:	
5. Type of listing: Tick [.] as many product categories as are applicable	

Exporter	**Supplier**
[ ] Processing Establishment	[ ] Fishing Vessel [ ] *Coastal* [ ] *Off Shore* [ ] *Reefer*
[ ] Fishing Vessel	
[ ] Cold Store	[ ] Cold Store
	[ ] Ice Factory
	[ ] Transporters
Type of Product	
[ ] Wild Caught [ ] *Fresh/Frozen* [ ] *Smoked* [ ] *Conserved*	Others: *(specify)*
Markets sought: [ ] EU [ ] Other (see over)	Others: *(specify)*

6. Applicant Declaration: *To be completed by applicant*. I declare that:
(a) I am authorised to make this application as the exporter or person with legal authority to act on behalf of the exporter; and
(b) the information supplied in this application is truthful and accurate to the best of my knowledge; and
(c) the applicant is a RMI resident, and in within the meaning of applicable sections of company registrations and tax purposes legislation, and
(d) I accept that due to the voluntary basis of this registration, it would be expected from the company to comply with production and compliance standards, as well as verification frequency that could exceed the requirements of the prevailing RMI legislation, and
(e) I accept that verifications and control of Fish &Fishery Products processing establishments exporting fish and fishery products, will as be performed by MIMRA as the Competent Authority (CA), and
(f) I accept that the obtaining of this registration is conditional to a positive outcome of an Verification visit performed by Competent Authority against standards lay down under the relevant regulations and the contents of the National Control Plan issued and managed by the CA, and
(g) I accept that maintaining this registration as part of the listing of companies allowed to export of fish and fishery products, is dependent on continuous regulatory compliance and ongoing performance against standards lay down under the relevant legislation (including overseas market access requirements) and the contents of the National Control Plan issued and managed by the CA, and
(c) the applicant is an RMI resident, and in within the meaning of applicable sections of company registrations and tax purposes legislation, and
(d) I accept that due to the voluntary basis of this registration, it would be expected from the company to comply with production and compliance standards, as well as verification frequency that could exceed the requirements of the prevailing RMI legislation, and
(e) I accept that verifications and control of Fish &Fishery Products processing establishments exporting to the EU, will as be performed by MIMRA as the Competent Authority (CA), and
(f) I accept that the obtaining of this registration is conditional to a positive outcome of an Verification visit performed by Competent Authority against standards lay down under the relevant EU regulations and the contents of the National Control Plan issued and managed by the CA, and
(g) I accept that maintaining this registration as part of the listing of companies allowed to export to the EU, is dependent on continuous regulatory compliance and ongoing performance against standards lay down under the relevant EU regulations and the contents of the National Control Plan issued and managed by the CA, and
(h) I accept that receiving health certificates that this registration entitles me, is dependent on regulatory compliance and on-going performance against standards lay down under the relevant legislation (including overseas market access requirements) and the contents of the National Control Plan issued and managed by the CA

Name:	**Date:**
Designation:	**Signature:**
Attachments: Product flow diagram HACCP plan Equipment and Facilities details	 Site plan Supporting programmes Details of services (water, power etc.)

Notes Section 1:

A unique identification will be assigned to each exporter and must not be the same as any other identification used in regard to any other activity regulated under these regulations.

In case the applicant holds identification as an exporter to the EU under prior verification regimes, this ID would be maintained.

Official Use Only:

B. Amendments to Approval Details

Application Form: Exporter registration and listing	**F25B**
1. Exporter Identification	
Registration ID:	
2. Applicant Name:	
Registered company name or partnership names (including the trading name) or individual name.	
Full legal name:	
3. Business Address and Contact Details:	
Physical (for service/delivery of items):	
Phone No:	
Fax No:	
Postal (for communication):	
E-mail:	
4. Processing Establishment Address(es) and Contact Details:	
Only complete if the Processing establishment details are different from the business address in Section 3.	
Legally registered address:	
Phone No:	
Fax No:	
E-mail:	

5. Type of listing: Tick [.] as many product categories as are applicable	
Exporter	**Supplier**
[ ] Processing Establishment	[ ] Fishing Vessel [ ] *Coastal* [ ] *Off Shore* [ ] *Reefer*
[ ] Fishing Vessel	
[ ] Cold Store	[ ] Cold Store
	[ ] Ice Factory
	[ ] Transporters
Type of Product	
[ ] Wild Caught [ ] *Fresh/Frozen* [ ] *Smoked* [ ] *Conserved*	Others: *(specify)*
Markets sought: [ ] EU [ ] Other (see over)	Others: *(specify)*

6. Details of change: Tick [.] as many categories as are applicable	
(a) Change in HACCP plan information	
(b) Change in SSOP/pre-requisite programme information	
(c) Change in market destination	
(d) Change in products, species, processing categories	
(e) Change in processing plant or EU vessel layout, design or construction	
(f) Change in legal ownership or company name	
(g) Other: please specify in the space below:	
7. Company Information Supplied: Tick [.] as many product categories as are applicable	
(a) Amended documentation including, as relevant, HACCP plan, SSOPs or pre-requisite programmes	
(b) Amended factory or vessel layout or design and construction details	
(c) Amended approval information (from page 1 of this form) including change in ownership, change in market destination, species being processed or processes carried out	
(d) Other information: please specify in the space below	
8. Operator Statement	
(a) I am authorised to make this application as the exporter or person with legal authority to act on behalf of the exporter; and	
(b) the information supplied in this application is truthful and accurate to the best of my knowledge; and	
(c) I request the update of my company file within the Competent Authority	
Name:	**Date:**
Designation:	**Signature:**
Official Use Only:	

Please complete return to
E mail:

C. Vessel Data Sheet

Vessel Data Sheet				**F26**
Date:		Inspection Place:		
Time Spent on Inspection		From:	To:	Hours:

Vessel Details			
Vessel Name:		Registration Number:	
Flag Country:		Inspection Ref.:	
Vessel Approval Reference Number:		Vessel Approval Date:	
Vessel Owner:			
Name:		Telephone:	
Address:			
Quality Manager:			
Name:		Number of Crew:	
Vessel Type	[ ] Transport [ ] Factory [ ] RSW [ ] Ice [ ] Brine [ ] Freezer		
Fishing Methods	(A vessel can have multiple fishing methods)		
	Type 1: Trawler		
	Type 2: Long line		
	Type 3: Pole and line		
	Type 4: Purse seiners		
	Type 5: Gill netting		
	Type 6: Deep Sea Fishing		
	Type 7: Other (Please specify):		

D. Transport Data Sheet

Transport Data Sheet				**F27**
Date: _____	Inspection Place	_____		
Inspectors Name: _____		Inspection Ref	_____	
Time spent for on Inspection; From_____		To _____	Hours_____	

Vehicle Details

Vehicle Registration Number	_____	Approval Reference Number:	_____
Vehicle Make	_____		_____
Vehicle Model	_____	Year of registration	_____
Vehicle Owners Name	_____	Tel:	_____
Company	_____	Company Approval No.	_____
Address:	_____		

Vehicle Type

A	Flat-bed or pickup truck with removal insulated Ice Box.	☐	
B	Truck with fixed insulated and closed cargo area for use with iced, open fish boxes.	☐	
C	"Reefer" Truck with fixed insulated and closed cargo area with mechanical refrigeration unit.	☐	
D	Tractor Unit for transportation of shipping (freezer)containers	☐	
E	Other.	☐	

Vehicle approved for transport of:			
	Iced fresh fish / ice	☐	
	Fresh packed fishery products.	☐	
	Frozen packed fish and fishery products	☐	
	Waste for disposal	☐	
	Other (Please State)	☐	_____

Inspectors Signature	. . . . .	Date	. . . . .

APPENDIX THREE: Forms and Certificates for Seafood Product Exports

1. Health Certificate Export Information form (F29)

Please complete the following form in MS Word software so that the CA) has all the necessary information to complete your Health Certificate. Please send the file by e-mail to the nearest CA office (ADD DETAILS OF EMAIL CONTACT(S).

Destination of Export (please tick): European Union ☐ Non-European Union ☐

I.1. Consignor Name Address Postal code Tel. No.			I.2. Certificate reference number	I.2a
			I.3. Central Competent Authority **MIMRA**	
			I.4. Local Competent Authority **Not applicable (N/A)**	
I.5. Consignee Name Address /Postal Code Tel. No.			I.6.	
I.7. Country of origin ISO Code		1.8. *Region of origin* Code	I.9. Country of destination ISO Code	I.10.
I.11. Place of origin Name: Approval number: Address:			I.12.	
I.13. Place of loading			I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references			I.16. Entry BIP in EU I.17.	
I.18. Description of commodity			I.19. Commodity code (HS code) I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages	
I.23. Identification of container and seal number			I.24. Type of packaging	

I.25. Commodities certified for: Human consumption ☐	
I.26.	I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Specie (Scientific name)	Nature of commodity	Treatment type	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

2. Request to Change Export Health Certificate Information

Application Form: Health Certificate Information		**F30**
Original Health Certificate Ref. No.:		
Change Required: **(please be as specific as possible giving actual replacement information required). CA reserves the right to refuse a**		
Company Justification for Change:		
FOR ICU USE ONLY:		
Request approved or denied: (circle as appropriate): APPROVED DENIED		
Reasons:		
Replacement Certificate No.:		
Signature of certifying officer:		
Name of certifying officer:		
Date:		

3. Non-EU Health Certificate

FISHERIES PRODUCTS HEALTH CERTIFICATE

Marshall Islands Marine Resource Authority

PO BOX 860 – Majuro +692 625 8262

Export certificate ID no.		Date	

Section 1. Consignor

Port of exportation	***Consignor***	***Contact Details***	***Name of container vessel or carrier***

Section 2. Consignee

Country	***Consignee***	***Contact Details***	***Date of exportation***

Section 3. Products Exported

Line #	Species	Product type	Product weight in kg	Containers ID or Bulk Carrier
1				
2				
3				
4				
Totals				*Number of containers*

Section 3 Attestation

It is hereby certified that the above captioned product:

1. *The fish were processed in a premise approved by and under the control of the RMI Competent Authority;*
2. *Have been caught, landed, where appropriate packaged, handled, marked, prepared, processed, frozen, thawed, stored and transported under conditions laid down under the Fish Export Regulations 2012.*
3. *Do not come from toxic species or species containing biotoxins;*
4. *The products have been handled, processed, identified, stored and transported under an approved HACCP (Hazard Analysis and Critical Control Point) consistently implemented and in accordance with the requirements laid down by Competent Authority.*
5. *The fish were wild caught and not grown or harvested in an aquaculture system at any stage*

Section 4. Certification		*Stamp*
Certifying MIMRA Officer Name	*Validation date*	

4. FCA 9 - Hygienic Handling Certificate

HYGIENIC HANDLING CERTIFICATE

Marshall Islands Marine Resource Authority

PO BOX 860 – Majuro +692 625 8262

Hygienic Handling certificate no.		Date	

Section 1. Fishing vessel identity

Vessel name	Flag state	Fishing Authorization	Fishing licence validity	Licenced fishing areas	FFA Vessel Reg

Section 2. Products Exported

Line #	Species	Product type	Product weight in kg	Containers ID or Bulk Carrier
1				
2				
3				
Totals				*Number of containers*

Section 2. *Consignment details*

Export destination	***Consignee***	***Contact Details***	***Date of exportation***
Port of exportation	***Consignor***	***Contact Details***	***Name of container vessel or carrier***

Section 3 Attestation

It is hereby certified that the above captioned product:

a) Containerized product: The frozen fish was unloaded from the refrigerated cargo hold of a fishing vessel and landed, placing the frozen fish out of reach of any freestanding water, dirt and oil contamination. The frozen loose fish was immediately sorted and loaded into the above-identified pre-cooled containers that were found to be sound, clean and free of odours prior to loading.

b) Bulk Carrier: The frozen fish was unloaded from the refrigerated cargo hold of a fishing vessel and immediately transferred to the refrigerated cargo hold of a carrier

c) The product has been handled according to the standard Good Manufacturing Practices (GMP) for frozen seafood.

Section 4. Port State validation		*Stamp*
Certifying MIMRA Officer Name	*Validation date*	

5. Fishmeal Health Certificate

HEALTH CERTIFICATE

EXPORT OF FISHMEAL PRODUCTS

Certificate Reference N°: _____ _____

I. Details Identifying the fishery products

Description of fishery* / aquaculture* products (*delete where not applicable) .....

- species (scientific name): .....

- presentation of product and type of treatment: .....

Type of packaging: .....

Number of packages: .....

Net weight: .....

Temperature required during storage and transport: .....

II. Origin of the fishery products

Name(s) and official approval / registration number(s) of establishment(s), factory vessel(s), or cold store(s) approved or freezer vessel(s) registered by the competent authority authorized for export by MIMRA:

.....

III. Destination of the fishery products

The fishery products are to be dispatched: .....

from (place of dispatch): .....

to (country and place of destination): .....

by the following means of transport (registration number of containers, flight number or name of ship): .....

Name and address of dispatcher: .....

Name of consignee and address at place of destination**:**

……

……

Certificate Reference N$^{o.}$: _____

IV. Health Attestation

The official inspector hereby certifies that the fishmeal products specified above:

Meet the minimum standards for fishmeal as specified in the RMI Islands Industry Standards 2020

Done at: **_____** on: **_____**

(place) *(date)*

Signature CA Authorised Officer

Name in capital letters, capacity and qualifications of person signing

Official Seal (different colour to document print)

6. Health Certificate for Export of Fish and Fishery Products to the EU

COUNTRY							Official certificate to the EU	
Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No						I.2. Certificate reference No	I.2.a IMSOC reference No
							I.3. Central Competent Authority	
							I.4. Local Competent Authority	
	I.5. Consignee/Importer Name Address Postal code Tel. No						I.6. Operator responsible for the consignment Name Address Postal code	
	I.7. Country of origin	ISO	I.8. Region of origin	Code			I.9. Country of destination	ISO	I.10.
	I.11 Place of dispatch Name Address		Approval No				I.12. Place of destination Name Address	
	I.13. Place of loading						I.14. Date and time of departure	
	I.15. Means of transport Aeroplane ☐ Road vehicle ☐ Identification:		Vessel ☐ Railway ☐		Other ☐		I.16. Entry BCP	
							I.17. Accompanying documents Type No	
	I.18. Transport conditions Ambient ☐		Chilled ☐		Frozen ☐			
	I.19. Container No/Seal No							

COUNTRY **Official certificate to the EU**

I.20. Goods certified as Canning industry ☐ Animal feedingstuff ☐ Human consumption ☐ Breeding/production ☐ Game restocking ☐	Fattening ☐ Quarantine ☐ Further process ☐ Slaughter ☐ Artificial reproduction ☐	Technical use ☐ Pharmaceutical use ☐ Approved body ☐ Relaying ☐ Registered equidae ☐	Trade samples ☐ Circus/exhibition ☐ Pets ☐ Other ☐
I.21. For transit ☐ Third country ISO		I.22. For internal market ☐ Definitive import ☐ Re-entry ☐ Temporary admission ☐	
I.23. Total number of packages	I.24. Quantity Total number	Total net weight (Kg)	Total gross weight (Kg)
I.25. Description of goods No Code and CN title			
Species (scientific name) Age	Breed/Category Sex	Identification system Quantity	Identification No Test
Species (Scientific name) Zone Abattoir Final consumer Number of packages ☐	Nature of commodity Manufacturing plant Net weight Batch No		Treatment type Cold store Type of packaging
Stamp	Signature		

COUNTRY **Fishery products**

II. Health information	II.a. Certificate reference number	II.b.

Part II: Certification

II.1. (1) **Public health attestation**

I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)) and Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1) and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:

— come from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;

— have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004;

— satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1);

— have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII of Annex III to Regulation (EC) No 853/2004;

— have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004;

— fulfil the guarantees covering live animals and products thereof, if of aquaculture origin, provided by the residue plans submitted in accordance with Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10), and in particular Article 29 thereof; and

▸(1)— have satisfactorily undergone the official controls laid down in Articles 67 to 71 of Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).◂

II.2 (2) (4) **Animal health attestation for fish and crustaceans of aquaculture origin**

II.2.1 (3) (4) **[Requirements for species susceptible to epizootic haematopoietic necrosis (EHN), taura syndrome and yellowhead disease**

I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:

(5) originate from a country/territory, zone or compartment declared free from (4) [EHN] (4) [taura syndrome] (4) [yellowhead disease] in accordance with Chapter VII of Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14) or the relevant OIE Standard by the competent authority of my country,

(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,

(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and

COUNTRY **Fishery products**

II.	Health information	II.a. Certificate reference number	II.b.

(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases.]

II.2.2 ([3]) ([4]) **[Requirements for species susceptible to viral haemorrhagic septicaemia (VHS), infectious haematopoietic necrosis (IHN), infectious salmon anaemia (ISA), koi herpes virus (KHV) and white spot disease intended for a Member State, zone or compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease**

I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:

([6]) originate from a country/territory, zone or compartment declared free from ([4]) [VHS] ([4]) [IHN] ([4]) [ISA] ([4]) [KHV] ([4]) [White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,

(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,

(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and

(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases.]

II.2.3 Transport and labelling requirements

I, the undersigned official inspector, hereby certify that:

II.2.3.1 the aquaculture animals referred to above are placed under conditions in which the water quality does not alter their health status;

II.2.3.2. prior to loading the transport container or well boat is clean and disinfected or previously unused; and

II.2.3.3. the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.11 of Part I of this certificate, and the following statement:

'([4]) [Fish] ([4]) [Crustaceans] intended for human consumption in the Union'.

Notes

See notes in Annex II of Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101)

Part I:

— Box reference I.8: Region of origin: For frozen or processed bivalve molluscs, indicate the production area.

— Box reference I.20: Tick 'Canning industry' for whole fish initially frozen in brine at – 9 °C or at a temperature higher than – 18 °C and intended for canning in accordance with the requirements of Section VIII, Chapter I; point II(7) of annex III to Regulation (EC) No 853/2004. Tick 'Human consumption' for the other cases.

— Box reference I.25: Insert the appropriate Harmonised System (HS) code(s) using headings such as: 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 0511, 1504, 1516, 1518, 1603, 1604, 1605 or 2106.

— Box reference I.25: *Nature of commodity*: specify whether aquaculture or wild origin.

Treatment type: specify whether live, chilled, frozen or processed.

Manufacturing plant: includes factory vessel, freezer vessel, reefer vessels, cold store and processing plant.

Part II:

([1]) Part II.1 of this certificate does not apply to countries with special public health certification requirements laid down in equivalence agreements or other EU legislation.

COUNTRY **Fishery products**

II. Health information	II.a. Certificate reference number	II.b.

([2]) Part II.2 of this certificate does not apply to:

(a) non-viable crustaceans, meaning crustaceans that cannot survive as living animals if returned to the environment from which they were obtained,

(b) fish which are slaughtered and eviscerated before dispatch,

(c) aquaculture animals and products thereof, which are placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004,

(d) crustaceans destined for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system that inactivates the pathogens in question, or where the effluent undergoes other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level, and

(e) crustaceans which are intended for further processing before human consumption without temporary storage at the place of processing and packed and labelled for that purpose in accordance with Regulation (EC) No 853/2004.

([3]) Parts II.2.1 and II.2.2 of this certificate only apply to species susceptible to one or more of the diseases referred to in the heading of the point concerned. Susceptible species are listed in Annex IV to Directive 2006/88/EC.

([4]) Keep as appropriate.

([5]) For consignments of species susceptible to EHN, taura syndrome and/or yellowhead disease this statement must be kept for the consignment to be authorised into any part of the EU.

([6]) In order to be authorised into a Member State, zone or compartment (boxes I.9 and I.10 of Part I of the certificate) declared free from VHS, IHN, ISA, KHV or white spot disease or with a surveillance or eradication programme drawn up in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farm and mollusc farming area in the Union are accessible at http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm.

— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official inspector

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

7. Health Certificate for The People's Republic of China

Marshall Islands Marine Resource Authority

PO BOX 860 – Majuro +692 625 8262

密克罗尼西亚联邦向中华人民共和国出口水产品检验检疫证书

Health Certificate

For Fish and Fishery Products Intended for Export from the Republic of the Marshall Islands to The People's Republic of China

证书号 Num.Ref:

I.主管当局信息 Information of competent authority:	
输出国 Country of export：	
生产国 Country of production:	
主管当局 Competent authority：	
出证部门Department of certificate issuance：	
II 水产品信息 Identification of the fishery products	
商品名称 Commodity name：	
学名Scientific name：	
包装数量 Number of packages：	
净重 Net Weight：	
III.水产品来源Origin of the fishery products	
产地 Production Place：	
加工方式 Processing Type[1]：	
生产模式 Production Mode：	
养殖 Aquacultured： 是Yes□否No□	野生捕捞 Wild Caught 是 Yes □ 否 No □
养殖区域 Aquaculture area：	捕捞区域 Catch Area ：
	捕捞渔船船名及编号 Name & Number of Vessel for the catch

生产加工企业名称及注册号 Production and processing enterprise name and registration number	
生产日期 Production Date：	

IV运输信息 Information of Transport	
发货人名称及地址 Name and address of Consignor：	
收货人名称及地址 Name and address of Consignee：	
发货地 Place of dispatch production:	
目的地 Place of destination：	
运输工具信息 Means of transport：	
船只名称 Name of Vessel：	
航班号 Flight Number：	
其他运输工具信息other transport means：	
集装箱号 Container Number：	
封识号 Seal Number：	

V健康声明 Health Attestation

兹证明：This is to certify that:

1.上述产品来自主管当局注册的企业。The above fishery products came from the establishment approved by competent authority.

2. 该产品在卫生条件下生产、包装、储藏和运输，并置于主管当局监督之下。The products were produced, packed, stored, and transported under sanitary condition, which were under the supervision of competent authority.

3. 该产品经主管当局检验检疫，未发现中国规定的有害病菌、有毒有害物质和异物。The products were inspected and quarantined by competent authority and not found any pathogenic bacteria, harmful substances and foreign substances regulated in the P.R. China.

4. 该产品符合兽医卫生要求，适合人类食用。The products meet veterinary sanitary requirements and fit for human consumption.

签发地点 Place of issue	签发日期 Date of issue

官方印章 Official Stamp	官方兽医签字 Official Veterinary Signature
注释Note:1.冷藏、冷冻、干制、熏制、罐装等。/Refrigerated, Frozen, Dried, Smoked, Canned. 2.此证书内容不适用部分以***填充。/If any of the information required is not applicable, then the blank area must be filled with ***.	

8. Certification Ruling

Fishing Vessel	***EU Listed***	***Package***	***Transport (foreign flagged)***	***EU Listed***	***Additional Comments***	***Destination***	***Health Certificate Type***	***Comments***
RMI flagged	YES	Bulk (separation net)	Carrier	NO		Non-EU	National Health Certificate	
	YES	Bulk (separation net)	Carrier	NO	Not going direct to EU	EU	National Health Certificate	
	NO	Bulk (separation net)	Carrier	NO	Not currently relevant to RMI	Non-EU	National Health Certificate	If CA do inspection of trans-shipment in port
	NO	Bulk (separation net)	Carrier	NO	Not currently relevant to RMI Not going direct to EU	EU	National Health Certificate	If CA do inspection of trans-shipment in port
RMI flagged	YES	Container	Container Ship	NO	Going direct to non-EU	Non-EU	National Health Certificate	
	YES	Container	Container Ship	NO	Going direct to EU	EU	EU Health Certificate	
	NO	Container	Container Ship	NO	Currently irrelevant in RMI	Non-EU	National Health Certificate	Subject to inspection of vessel records and container loading
	NO	Container	Container Ship	NO	Currently irrelevant in RMI Going direct to EU	EU	Non-EU eligible because vessel not EU listed	

Fishing Vessel	*EU Listed*	*Package*	*Transport (foreign flagged)*	*EU Listed*	*Additional Comments*	*Destination*	*Health Certificate Type*	*Comments*
Foreign Flagged	YES	Bulk (separation net)	Carrier	Non-EU			No Health Certificate	
	YES	Bulk (separation net)	Carrier	EU			No Health Certificate	
	NO	Bulk (separation net)	Carrier	Non-EU			No Health Certificate	
	NO	Bulk (separation net)	Carrier	EU			No Health Certificate	
Foreign Flagged	YES	Container	Container Ship	NO		Non-EU	National Health Certificate	CA to sight unload from vessel and load into containers
	YES	Container	Container Ship	NO	Direct shipment to EU	EU	National Health Certificate	CA to sight unload from vessel and load into containers
	NO	Container	Container Ship	NO		Non-EU	Hygienic Handling Certificate	CA to sight unload from vessel and load into containers
	NO	Container	Container Ship	NO		EU	Ineligible for EU market	Ineligible for export to EU but could go to other markets with Hygienic Handling Certificate with CA inspection of container loading

VESSEL LANDINGS INTO LAND-BASED PREMISES:

EU approved land based premises:

For product being loaded into EU approved land-based premises for processing off:

1. RMI flagged, EU approved vessels: EU eligible
2. RMI flagged, non EU approved vessels: currently irrelevant but non-eligible for EU

3. Foreign flagged, EU approved vessels: EU eligible provided full land-based premises checks done.
4. Foreign flagged, non-EU approved: non eligible for EU but eligible for National Health Certificate post land-based premises

Non-EU approved land-based premises:

For product being loaded into non-EU approved land-based premises for processing off:

1. RMI flagged, EU approved vessels: eligible for National Health Certificate post land-based premises
2. RMI flagged, non-EU approved vessels: eligible for National Health Certificate post land-based premises
3. Foreign flagged, EU approved vessels: eligible for National Health Certificate post land-based premises
4. Foreign flagged, non-EU approved: eligible for National Health Certificate post land-based premises

APPENDIX FOUR: Internal Audit and Compliance Programme for RMI Seafood Exporters

Background

The RMI seafood exporters need to implement an internal audit programme in order to demonstrate compliance with the Industry Standards (ISs) and to complement CA external audits. This document outlines how a seafood exporter may set up an internal audit programme.

1. Details of Programme

Audit Checks

Audit checks will be divided up into checks of the following frequency:

- Daily
- Weekly
- Monthly
- 6-monthly

details of which are detailed in the attached forms.

i. Compliance, deficiency types and corrective action classification

For each item inspected the compliance results are defined as:

NC (Non-Compliance)

The non-compliance clearly does not meet the requirements of this standard or is subjecting the product to an unacceptable level of exposure to any food safety hazard that jeopardizes the fitness for purpose as food.

The non-compliance must be corrected immediately and the exposed product shall be dealt accordingly. If the exposure justifies it, production shall not resume until satisfactory control measures are put in place.

In the case of a non-compliance that causes direct contamination of the fish, this shall be further classified as a "CRITICAL" or noted as NC/C and production ceased immediately until the situation is rectified to the satisfaction of the inspector. Any affected product must be isolated and subject to further testing and only released in the case of satisfactory test results.

Partial Compliance (Compliance with observations)

The issue is under substantial compliance; however, there are particulars that if not controlled could subject the product to an unacceptable level of exposure to any food safety hazard that could jeopardize the fitness for purpose.

These non-compliances shall be corrected before next verification. If the issue under scrutiny is a usual recurrence, it may grant a NC result.

FC (Full Compliance)

The issue under regulatory verification is under full compliance.

2. Pre-Operation Check Sheet

Week Starting: _____

Item to Check	Mo	Tu	We	Th	Fr	Sa	Su
Fish processing room, floors, drains, walls, tables, equipment, scales etc. – all smell & look clean, and are tidy and ready for processing?							
Plenty of hand soap & hand towels in processing rooms, toilets etc.?							
Fly zappers clean?							
Premises free from any signs of vermin activity?							
Chlorine level in water not less than 0.3 ppm?							
Sanitisers made up & correct strength?							
Landing area & scales clean and tidy?							
Chiller – smell & look clean, no condensation, all product off the floor?							
Chiller temperature checked?							
Carton storage – area clean & tidy and packaging correctly stored?							
Personnel wearing correct protective clothing & following correct procedures?							
Other - ?							
Checker Sign							

Non-Compliance Record

Day	Non-compliance	Corrective Action Taken	Signed

SIGNED (INTERNAL AUDIT CHECK): _____ DATE: _____

3. Daily/Weekly Check Sheet

Week Starting: _____

Daily Checks	Requirements	Mo	Tue	We	Th	Fr	Sa	Su
Reception of product	Reception checks completed for each batch?							
Incoming Goods	Transported & arrived in a suitable condition?							
Premises	In good state of repair, generally clean and tidy, any maintenance required? No signs of vermin activity?							
Personnel Hygiene	All staff observing correct procedures (protective clothing, health, hand washing, hygienic work practices, etc.)?							
In-Process Product	Checked and ok – processed to company requirements, correct temp during processing?							
Contamination	Product not at risk of contamination from water splash, non-potable water, equipment, bins or containers, appliances, dropped product?							
Final product Packaging & Labelling	Packaging clean and undamaged, product packed & labelled correctly – correct information on the label and the correct label on the package? Final product meets customer/company specifications?							
Waste Removal	Waste removed regularly & not creating a risk of contamination?							
Clean & Sanitation Programme	Cleaning & sanitation at breaks and at end of processing appropriate and as per programme?							
Chemicals	Use in accordance with manufacturer's instructions?							
Chiller/Freezer	Clean & tidy, product not at risk of contamination? Temperature checked & OK?							
Transport Vehicles	All checked & OK prior to loading product (condition, cleanliness, temp. & refrigeration equipment)?							
Product Load out	Temperature of product checked & recorded on Temperature Monitoring Record?							
Amenities & Packaging Store	Checked - clean & tidy? Packaging protected from contamination, stored off the floor, etc.?							
	Company Checker's Signature							

Weekly/Monthly Checks	***Requirements***	***Company Checker***
Environs	Weekly check – area tidy and no risk of product contamination	
Chiller/Freezer	Cleaned and sanitised at least 2 x weekly	
Ice Room	Clean & tidy, cleaned & sanitised if empty?	
Maintenance	Check any problem areas for maintenance required, including equipment, leaks, hoses, sign off any work completed.	
Vermin	Is monthly check of bait stations, fly screens up to date?	
Water monitoring	Is monthly water test up to date?	

Certification/OMARS	Check any new requirements implemented.	
Chemicals	Chemicals (cleaning, maintenance, vermin control etc.) are stored and labelled correctly?	

SIGNED (INTERNAL AUDIT CHECK): _____ *DATE:* _____

4. Checkers Comments

Details of Non-Compliance	Corrective Action to be taken	To be completed by (time)	Completed - date/time? fixed?	Internal Audit check

5. 6-Monthly Internal Audit Checks

Have the following been done.....?	Yes/No Action
Internal verification activities up-to-date? Any continual problems?	
Any new legislative requirements incorporated into the HACCP plan and/or supporting systems?	
Review customer complaints, all complaint dealt with in an appropriate manner? Procedures/HACCP plan reviewed in light of complaints received? Any necessary corrective action/preventative procedures put in place?	
Chemical Register up to date?	
Packaging Register up to date?	
Regular training for all product handlers carried out 3 monthly, records completed?	
Calibration of Hand-held or permanent Thermometers up to date?	
Calibration of scales due?	
Maintenance review of premises, plant, equipment, appliances etc.?	
Annual check of water reticulation up to date?	
Protective clothing, etc. in good order	
Any additional cleaning required in amenities, carton room, processing room, chillers, freezers	

6. Internal Audit Checks

Records Review

Item to Check	Status	Period Checked	Date Checked
Pre-Op & Daily Records			

Temperature Monitoring			
Vermin Control Records			
Water Monitoring Records			
CCP Monitoring			

Cleaning Verification

Item to Check	**Status**	**Period Checked**	**Date Checked**
Records			
Observation of cleaning procedure – all OK and as per programme?			
	Auditor Sign		

7. Reality Check

Observation	**Status**	**Date Checked**
Observation of processing activities		
Observation of company checker		
Review the labelling of product in process		
	Auditor Sign	

APPENDIX FIVE: Overseas Market Access Requirements

European Commission

This section informs operators on requirements for different markets based on the best information available at the present, these market access do change with time, and while the CA attempts to keep track and update these standards. *This information is not to be taken as the official position or interpretation of the authorities at the receiving markets*

Compliance to the EU legislation referred to in this section is ultimately the responsibility of the EU approved operator or the EU Importer that is placing product on the market in the EU.

1.0 FISHING VESSELS

Food business operators must ensure that:

1. Vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, comply with the structural and equipment requirements laid down in Part 1.1.1; and
2. Operations carried out on board vessels take place in accordance with the rules laid down in Part 1.1.2.

1.1.1 STRUCTURAL AND EQUIPMENT REQUIREMENTS

A. Requirements for all vessels

1. Holds or other parts of the vessel where fishery products are stored must:
   i) be covered and self-draining
   ii) be well insulated
   iii) have provision for holding an acceptable quantity of ice or have alternative means of refrigeration
   iv) not contain objects or products liable to damage or transmit harmful properties and abnormal characteristics to the food.
2. Decks used for fish handling may be constructed of one or more of the following materials, namely surface-coated aluminium, fibreglass, timber coated with an epoxy (or similar non-toxic) finish.

   Where fish does not normally come into contact with the deck and the timber is clean, sound and well caulked, timber is allowed on exposed decks.
3. Water used at any stage of handling / processing shall comply with the parameters of potable water, laid down in section 3.4 of these Standards or of clean seawater. Seawater intakes for vessels shall be located forward of any toilet or bilge discharge.
4. Containers and equipment in contact with the fishery products must be made of or coated with a material that is waterproof, resistant to decay, smooth and easy to clean and disinfect. When used they must be completely clean. Surface coatings must be durable and non-toxic.
5. When used, the section of vessels or the containers reserved for the storage of fishery product must be completely cleaned and, in particular, must not be capable of being contaminated by fuel used for the propulsion or bilge water.
6. Dual use of fish holds for holding fuel is prohibited.

7. After the fishery products have been unloaded the containers, equipment and sections of vessel that are directly in contact with the fishery products must be cleaned with potable water or clean water.
8. As soon as 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, water used must be either potable water complying with the parameters set out in section 3.4 of these Standards or clean seawater, so as not to impair their quality or wholesomeness.
9. Fishery products shall be handled and stored in such a way as to prevent damage. The use of spiked instruments shall be tolerated for the moving of large fish or fish that might injure the handler, provided the flesh of the products is not damaged.
10. Fishery products other than those kept alive must undergo chilling or freezing as soon as possible after landing.
11. Where fish are headed and/or gutted on board such operation must be carried out hygienically and products must be washed immediately and thoroughly with potable water or clean seawater. The viscera and parts, which may pose a threat to public health, must be removed and set apart from products intended for human consumption. Livers and roes intended for human consumption must be chilled or frozen.
12. Staff assigned to handling fishery products shall maintain a high standard of cleanliness for themselves and all outer clothing.
13. 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.
14. Hydraulic circuits shall be protected in such a way as to ensure no oil leakage can contaminate products.
15. The working decks, the equipment and the holds, tanks and containers shall be cleaned and disinfected after each time they are used. Control and monitoring for the presence of pests shall carried out regularly.
16. Cleaning products, disinfectants, insecticides and all potentially toxic substances shall be stored in a locked store or cupboard physically separated from fish cartons and ship to shore containers. Their use must not present any risk of contamination of fishery products.
17. Ice for chilling of fishery products must be used in such a way and in such quantities, so that fishery products will attain the temperature of melting ice as quickly as possible.
18. Fishing vessels that use seawater to wash up and process shall do so in uncontaminated waters and whilst the vessel is moving in open waters.
19. Dual use of fish well shall not be allowed by any RMI flag vessels nor any EU listed foreign flag vessel supplying fish for further export to the EU by any RMI establishment.

B. Requirements for vessels designed and equipped to preserve fresh fishery products for more than twenty-four hours

1. Vessels designed and equipped to preserve fishery products for more than twenty-four hours must be equipped with holds, tanks or containers for the storage of fishery products as follows:

   Frozen fishery products must be kept at a temperature of not more than -18ºC in all parts of the product; however, whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of not more than -9ºC.
2. Holds must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products.

Holds and 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.

3. In vessels equipped for chilling fishery products in cooled clean seawater, tanks must incorporate devices for achieving a uniform temperature throughout the tanks. Such devices must achieve a chilling rate that ensures that the mix of fish and clean seawater reaches not more than 3ºC 6 hours after loading and not more than 0 °C after 16 hours and allow the monitoring and, where necessary, recording of temperatures.

   Tanks must be equipped with adequate seawater filling and drainage installations and must incorporate devices for achieving uniform temperature throughout the tanks;

   After each unloading the tank's circulation systems and containers must be completely emptied and thoroughly cleaned using potable or clean seawater and should only be re-filled with clean seawater; and,

   The date and reference number of the tank must be clearly indicated on the temperature records. These must be kept and made available to the inspectorate.

4. Sanitary facilities including toilet and shower facilities shall be sufficient in number for the normal complement of crew. Any toilet must be equipped with a non-hand, non-elbow operated wash basins located in the toilet room or immediately outside the door.

C. Requirements for freezer vessels

Freezer vessels must:

1. have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18ºC;
2. freeze whole fish in brine intended for canning at -9°C or less.
3. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18ºC. Storage holds must be equipped with automated temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest; and
4. have holds that are separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products.

   Holds and 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.
5. Freezing machinery shall be physically separated from the hold in which frozen product is stored.
6. When brine-freezing, the brine shall not be a source of contamination.

D. Requirements for factory vessels

1. 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 such waste;

(e) a place for storing packaging materials that is separate from the product preparation and processing areas;

(f) special equipment for disposing 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.

2. However, factory vessels on board which crustaceans and molluscs are cooked, chilled and wrapped, need not meet the requirements of paragraph 1 above if no other form of handling or processing takes place on board such vessels.
3. refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18ºC. Storage holds must be equipped with automated temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest.
4.. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Part C, points 1, 2, 3, 4 and 5.

1.1.2 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 water.
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 other than those kept alive must undergo chilling as soon as possible after loading. However, when chilling is not possible, fishery products must be landed as soon as possible.
5. Ice used to chill fishery products must be made from potable water or clean water.

6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly with potable water or clean water. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.
7. Where freezing in brine of whole fish intended for canning is practised, a temperature of not more than -9 °C must be achieved for the product. The brine must not be a source of contamination for the fish.

2.0 REQUIREMENTS DURING AND AFTER LANDING

1. Food business operators responsible for the unloading and landing of fishery products must:

(a) ensure that unloading and landing equipment that comes into contact with fishery products is constructed of material that is easy to clean and disinfect and maintained in a good state of repair and cleanliness; and

(b) avoid contamination of fishery products during unloading and landing, in particular by:

(i) carrying out unloading and landing operations rapidly;

(ii) placing fishery products without delay in a protected environment at the temperature specified in Section 7.0; and

(iii) not using equipment and practices that cause unnecessary damage to the edible parts of the fishery products.

2. Food business operators responsible for auction and wholesale markets or parts thereof where fishery products are displayed for sale must ensure compliance with the following requirements.

(a) (i) There must be lockable facilities for the refrigerated storage of detained fishery products and separate lockable facilities for the storage of fishery products declared unfit for human consumption.

(ii) If the competent authority so requires, there must be an adequately equipped lockable facility or, where needed, room for the exclusive use of the competent authority.

(b) At the time of display or storage of fishery products:

(i) the premises must not be used for other purposes;

(ii) vehicles emitting exhaust fumes likely to impair the quality of fishery products must not have access to the premises;

(iii) persons having access to the premises must not introduce other animals; and

(iv) the premises must be well lit to facilitate official controls.

3. When chilling was not possible on board the vessel, fresh fishery products, other than those kept alive, must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.
4. Food business operators must cooperate with relevant competent authorities so as to permit them to carry out official controls in accordance with the requirements given in the National Control Plan in particular as regards any notification procedures for the landing of fishery products that the competent authority of the Member State the flag of which the vessel is flying or the competent authority of the Member State where the fishery products are landed might consider necessary.

3.0 REQUIREMENTS FOR ESTABLISHMENTS, INCLUDING VESSELS, HANDLING FISHERY PRODUCTS

Food business operators must ensure compliance with the following requirements, where relevant, in establishments handling fishery products.

A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS

1. Where chilled, unpackaged products are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, they must be stored under ice in appropriate facilities. Re-icing must be carried out as often as necessary. Packaged fresh fishery products must be chilled to a temperature approaching that of melting ice.
2. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly with potable water or, on board vessels, clean water immediately after these operations.
3. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.
4. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water does not remain in contact with the products.
5. Whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from aquaculture establishments, until they arrive at the first establishment on land carrying out any activity other than transport or sorting.

B. REQUIREMENTS FOR FROZEN PRODUCTS

Establishments on land that freeze fishery products must have equipment that satisfies the requirements laid down for freezer vessels in Section 1.1.1, Part C, points 1, 2 and 3.

C. REQUIREMENTS FOR MECHANICALLY SEPARATED FISHERY PRODUCTS

Food business operators manufacturing mechanically separated fishery products must ensure compliance with the following requirements.

1. The raw materials used must satisfy the following requirements.
   (a) Only whole fish and bones after filleting may be used to produce mechanically separated fishery products;
   (b) All raw materials must be free from guts.
2. The manufacturing process must satisfy the following requirements:
   (a) Mechanical separation must take place without undue delay after filleting;
   (b) If whole fish are used, they must be gutted and washed beforehand;
   (c) After production, mechanically separated fishery products must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.

D. REQUIREMENTS CONCERNING PARASITES

1. The following fishery products must be frozen at a temperature of not more than -20 °C in all parts of the product for not less than 24 hours or -35°C for at least 15 hours; this treatment must be applied to the raw product or the finished product:

   (a) fishery products to be consumed raw or almost raw;

   and

   (b) marinated and/or salted fishery products, if the processing is insufficient to destroy the viable parasite.

2. Food business operators need not carry out the treatment required under paragraph 1 for fishery products:

   (a) that have undergone, or are intended to undergo a heat treatment that kills the viable parasite before consumption. In the case of parasites other than trematodes the product is heated to a core temperature of 60°C or more for at least one minute.

   (b) that have been preserved as frozen fishery products for a sufficiently long period to kill viable parasites.

   (a) from wild catches provided that:

      (i) epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and

      (ii) the competent authority so authorises.

3. A document from the manufacturer, stating the type of process they have undergone, must accompany fishery products referred to in paragraphs 1 and 2 when placed on the market, except when supplied to the final consumer.

4.0 REQUIREMENTS FOR PROCESSED FISHERY PRODUCTS

Food business operators cooking crustaceans and molluscs must ensure compliance with the following requirements.

1. Rapid cooling must follow cooking. Water used for this purpose must be potable water or, on board vessels, clean water. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.
2. Shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands.
3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature laid down in Section 7.0.

5.0 HEALTH STANDARDS FOR FISHERY PRODUCTS

Food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Section.

A. ORGANOLEPTIC PROPERTIES OF FISHERY PRODUCTS

Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.

B. HISTAMINE

Food business operators must ensure that the limits given in section 10.0 with regard to histamine are not exceeded.

C. PARASITES

Food business operators must ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market.

They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.

D. TOXINS HARMFUL TO HUMAN HEALTH

1. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.
2. Fish containing escolar or oilfish must not be placed on the market unless in wrapped/packaged form and labelled with information for the consumer including preparation/cooking instructions and a warning on the risk of gastrointestinal effects. The scientific name must accompany the common name on the label.
3. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market.

6.0 WRAPPING AND PACKAGING OF FISHERY PRODUCTS

1. Receptacles in which fresh fishery products are kept under ice must be water-resistant and ensure that melt water does not remain in contact with the products.
2. Frozen blocks prepared on board vessels must be adequately wrapped before landing.
3. When fishery products are wrapped on board fishing vessels, food business operators must ensure that wrapping material:

   (a) is not a source of contamination;

   (b) is stored in such a manner that it is not exposed to a risk of contamination;

   (c) intended for re-use is easy to clean and, where necessary, to disinfect.

7.0 STORAGE OF FISHERY PRODUCTS

Food business operators storing fishery products must ensure compliance with the following

Requirements:

1. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.
2. Frozen fishery products must be kept at a temperature of not more than -18ºC in all parts of the product; however, whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of not more than -9ºC.
3. Fishery products kept alive must be kept at a temperature and in a manner that does not adversely affect food safety or their viability.

8.0 TRANSPORT OF FISHERY PRODUCTS

Food business operators transporting fishery products must ensure compliance with the following requirements.

1. During transport, fishery products must be maintained at the required temperature.

   In particular:

(a) fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice;

(b) frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than -18ºC in all parts of the product, possibly with short upward fluctuations of not more than 3°C.

2. Food business operators need not comply with point 1(b) when frozen fishery products are transported from a cold store to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing, if the journey is short and the competent authority so permits.
3. If fishery products are kept under ice, melt water must not remain in contact with the products.
4. Fishery products to be placed on the market live must be transported in such a way as not adversely to affect food safety or their viability.

9.0 LABELLING OF SEAFOOD PRODUCTS

Requirements for labelling are to be based on EU Regulation 1169/2011 on labelling, presentation and advertising of foodstuffs to the final consumer, as is the main piece of EU legislation regarding the labelling of foodstuffs. Its aim is to ensure that the consumer gets all the essential information as regards the composition of the product, the manufacturer, methods of storage and preparation, etc.

Plastic packaging shall meet the requirements of Regulation 10/2011.

Reference and updates to be found at

http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/comm_legisl_en.htm

Please note the information supplied below is a summary only – the EU legislation should be referred to in entirety to provide further detailed information if required.

This section intended to be an outline of the current position but is in no way a definitive guide to the requirements of the law.

Notes

Mixed Product:

Where mixed product is offered for sale (to final consumer or mass caterer) that consists of the same species but which has been derived from different production methods, the method for each batch shall be stated.

Where mixed product is offered for sale (to final consumer or mass caterer) that consists of the same species but which has been derived from a variety of catch areas or fish-farming countries, at least the area of the batch which is most representative in terms of quantity shall be stated, together with an indication that the products also come from different catch or fish-farming areas.

The Category of Fishing Gear:

On a mandatory basis, if the product was caught by any of the 7 gear types listed in Annex III (Appendix 2 of this document), the gear type must be included on the label. You can add more detail as per column 2 and/or 4 of Annex III if you wish.

For other fishing techniques not covered by Annex III (e.g. hand gathering or diving), you are free to indicate the fishing technique used if you wish, provided that the information they provide is clear, unambiguous and verifiable.

Labelling or Information Requirements	Further Detail
Identification number of each lot	A unique number be allocated to each lot.
External identification number and name of fishing vessel or name of aquaculture production unit	Name and number of the vessel or the marine farm lease/licence/permit number
The FAO alpha-3 code of each species	This is a 3-letter code assigned by FAO. To find the correct code, there is a database which can be found here: http://termportal.fao.org/faoas/main/start.do Type the scientific name and click search, the 3-letter code can be found under Remarks
The date of catches or the date of production	This is the catch or harvest date, it can include several days or one period of time corresponding to several dates of catches.
Quantity	Usually expressed as the net weight or where appropriate the number of individuals
Name and address of suppliers	This information may be provided by way of the identification mark, i.e. the approval number of the establishment
The commercial designation of the species and its scientific name;	The Common Name and Scientific Name of the species
The production method, in particular by the following words "… caught …" or "… caught in freshwater…" or "farmed…"	This is to identify if the product is wild caught or aquaculture, etc. *i.e. wild caught; or farmed; or caught in freshwater*
The area where the product was caught or farmed, and the category of fishing gear used in capture of fisheries as laid down in the first column on Annex III to this regulation; See Appendix 2 (this guide) for further detail	This will most commonly be a reference to Pacific Ocean, FAO 81/71. If the product was caught by the act of fishing, information on the specified gear type is also required. It is possible to combine the production method, the area from which it was caught or farmed and the fishing gear in one sentence, e.g. • Wild Caught in Pacific Ocean, Area FAO 71 by Purse seine Note – Gear Types: On a mandatory basis, if the product was caught by any of the 7 gear types listed in Annex III (Appendix 2 of this document) The gear type must be included on the label. You can add more detail as per column 2 and/or 4 of Annex III if you wish. For other fishing techniques not covered by Annex III (e.g. hand gathering or diving), you are free to indicate the fishing technique used if you wish, provided that the information they provide is clear, unambiguous and verifiable.

Whether the product has been defrosted	This will only be relevant for any product that is sold to the EU in a chilled state that has previously been frozen and thawed
The date of minimum durability, where appropriate	This is likely to be a best before date for the majority of seafood products

1. Food Information for Consumers

In order to achieve a high level of health protection for consumers and to guarantee their right to information, Council Regulation (EU) 1169/2011, Provision of Food Information for Consumers was established. This regulation amends and repeals a number of existing regulations and is designed to provide a basis for consumers to make informed choices and to prevent practices that may mislead the consumer.

Labelling or Information Requirements	**Further Detail**
The name of the food	This shall be the legal name of the food – for seafood this requirement should be met by inclusion of the common and scientific name of the species on the pack. The name shall also be accompanied by the physical condition of the food or treatment it has undergone (e.g. powdered, freeze-dried, quick frozen, smoked, etc) where its omission could mis-lead the purchaser. There are additional naming requirements for fishery products containing added proteins, added water (if more than 5% by weight of final product), and for formed fishery products. See Annex VI of Regulation (EU) 1169/2011
The list of ingredients	The list of ingredients shall include all ingredients in the food, in descending order of in going weight (m/m) weight at the time of production/processing. It shall be headed up by a suitable heading, i.e. Ingredients List Specific rules are found in Annex VII
Any ingredient or processing aid listed in Annex II or derived from substances listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and is still present in the finished product	Annex II of Regulation (EU) 1169/2011 includes substances which are considered allergenic or intolerant and these must be declared on the label (e.g in the ingredients list) if used and present in the finished food.
The quantity of certain ingredients or categories of ingredients	The indication of the quantity of ingredient or category of ingredients is required if it appears in the name of the food, is usually associated with the name of the food, is emphasised on the labelling or is essential to characterise a food (unless it is a single ingredient food and that is included in its name) There are technical rules applying to this requirement and are found in Annex VIII of Regulation (EU) 1169/2011
The net quantity	Net quantity is to be expressed in the most appropriate units of volume for liquids or units of mass for other products (i.e. grams or kilograms)
The date of minimum durability or 'use by' date	The best before date shall be included unless food would be considered a danger to human health (i.e. unsafe) after a specified time in which case a 'use-by' date shall be applied. Annex X of Regulation (EU) 1169/2011 provides further detail
Any special storage conditions and/or conditions of use	In cases where foods require special storage conditions or conditions of use, e.g keep chilled, keep frozen, specific cooking instructions, or storage/use of food after opening, these shall be included as appropriate
The name or business name and address of the food business operator referred to in Article 8 (1)	Article 8 (1) Refers to the food business operator responsible for the food information, is the operator under whose name or business name the food is marketed, or if that operator is not established in the European Union, the importer into the EU market.

The country of origin or place of provenance where provided for in Article 26	This is mandatory where failure to indicate it might mislead the consumer, particularly if other labelling or information accompanying the food would imply a different origin or place of provenance. For example, PNG caught product that is sent to Philippines for processing prior to export to the EU. This should be identified as: Product of Philippines, Origin PNG (or similar wording). Product that is caught on a RMI flagged vessel, processed in RMI and then exported directly to the EU would be: Product of RMI
The instruction for use where it would be difficult to make appropriate use of the food in the absence of such instructions	The instructions for use shall be included if necessary to enable appropriate use of the food.
With respect to beverages containing more than 1.2 % alcohol, the alcoholic strength by volume	Not likely to apply to seafood
A nutrition declaration (note requirement applies from 13 December 2016)	The detailed requirements for nutrition declarations are outlined in Article 30 – 35, Annex I and Annex XIII of Regulation (EU) 1169/2011. These requirements come into force for products labelled on or after 13 December 2016. There are foods which are exempted from the mandatory nutrition declaration requirements, including unprocessed products that comprise a single ingredient. Details are found in Annex V.
With respect to frozen unprocessed fishery products	The date of freezing or the date of first freezing in cases where the product has been frozen more than once. The wording shall say: 'Frozen on ….' Followed by the date of first freezing, the date shall be dd/mm/yy in that order and in un-coded form.

ii. Traceability

Traceability refers to the ability to trace goods along the supply chain. It requires critical information to be linked with the physical flow of product. Traditionally this has been provided by a combination of physical labelling on the packaging and associated documentation supplied with the product.

The traceability system required depends on the reason for which you are implementing it. Traditionally traceability systems in the seafood industry have been required for food safety. This has meant that companies have systems in place to identify the source of the product and to whom it was supplied, i.e. the traditional one-up and one-down.

Introduction of new European legislation and with a number of other countries reviewing their own traceability requirements means that processors and exporters supplying seafood to the European market may need to reconsider the traceability systems used in practice – the EU will require product in market to be traceable back to its catching or harvesting event (although this is already in place for aquaculture shellfish).

European legislation, Council Regulation (EC) No 1224/2009, Article 58 (1) states that all lots of fisheries and aquaculture products shall be traceable at all stages of production, processing and distribution from catching or harvesting to retail stage.

While it is the EU FBO or EU Importer placing the product on the market that is ultimately responsible for complying with this new legislation, it is difficult to see how this can be done without its suppliers implementing traceability systems. Again, the advice is to check with your importer/agent to determine what they will require.

However, the following provides some guidance on how traceability systems can be introduced should seafood companies wish or need to do so.

1. Key Data Elements and Critical Tracking Events

Critical Tracking Events (CTEs) are described as those **events** that must be recorded in order to allow for effective traceability of products in the supply chain, these are the instances where product is moved between premises, is

transformed, or is otherwise determined to be a point where data capture is necessary to trace a product. Key Data Elements (KDEs) is the **information or data** that needs to be captured as part of the CTE and which is used to support product tracing. KDEs for seafood will include information such as:

- Identity of the vessel that caught the product
- Identity of the marine farm from where the product was harvested
- Dates of catch or harvest
- Lot numbers allocated to incoming product
- Identity of the premise that received, processed or stored the product
- Amounts of product processed or shipped

The traceability system described in this guide relies on a combination of human readable data (i.e. labelling), electronically encoded data, and standardised electronic exchange of information, provided across the supply chain.

2. Practical Considerations for Traceability

Companies will have various traceability systems already in place. The following is an outline of things that may need to be considered, if not already done so.

For most seafood products, details of the catch event may not be recorded on pack in sufficient detail to meet the new EU requirements. It is highly likely therefore that a lot or batch identification system will need to be introduced to meet the new traceability demands. Product will need to be allocated an individual lot number which is specific enough to allow traceability back to the catching event, this would either have allocated by vessel per trip (i.e all the species from one vessel, from one trip were allocated an individual lot number) or could be by the individual species per vessel per trip. This Lot Number would then be used on all packs of that product. Regardless, associated with the lot number, the following information will need to be captured:

- Species
- Vessel name and registration number; or marine farm number
- Catch or harvest date (or catch date range)
- Gear type (for wild catch)
- Catch Area
- Date of first freezing (for frozen product)

Consideration will need to be given to when and how lots are identified. For product caught by an inshore vessel (where only minimal processing and no packing occurs), it is likely that the 'lot' will be allocated by the first receiver or processor. For products that are caught by a Freezer Vessel, and are processed (either partly or fully) and packed on board – the lot identification may be allocated by the vessel or by the processor.

The EU legislation states the following regarding mixed product:

- In cases where fisheries and aquaculture products lots are merged (or split) and several fishing vessels or aquaculture production units are mixed, operators shall be able to identify each lot origin at least by means of their identification number (the lot ID) and be able to trace them back to the catching or harvesting stage.
- Where mixed product is offered for sale that consists of the same species but which has been derived from different production methods, the method for each batch shall be stated.
- Where mixed product is offered for sale that consists of the same species but which has been derived from a variety of catch areas or fish-farming countries, at least the area of the batch that is most representative in

terms of quantity shall be stated, together with an indication that the products also come from different catch or fish-farming areas.

It is therefore possible to mix lots of product providing the 3 conditions above are met. However, it is recommended that where possible – lots should be processed and packed so that lot separation is maintained.

10.0 SAMPLING AND TESTING OF FISH AND FISHERY PRODUCTS AND WATER/ICE

General

(I) ORGANOLEPTIC SAMPLING AND TESTING

Application. This section applies to white and blue fish as specified in EU Council Regulation No. 2406/96 and in particular albacore and bigeye tuna in whole/gutted form.

Criteria				
	Freshness Ratings			
Part of fish inspected	**3**	**2**	**1**	**0**
Appearance				
Skin	Bright pigmentation, bright, shining iridescent colours; clear distinction between dorsal and central surfaces	Loss of lustre and shine; duller colours; less difference between dorsal and ventral surfaces	Dull, lustreless, insipid colours; skin creased when fish curved	Very dull pigmentation; skin coming away from flesh
Skin mucus	Aqueous, transparent, mucus	Slightly cloudy mucus	Milky mucus	Yellowish grey, opaque mucus
Eyes	Convex, bulging; blue-black bright pupil, transparent 'eyelid'	Convex and slightly sunken; dark pupil; slightly opalescent cornea	Flat; blurred pupil; blood seepage around the eye	Concave in the centre; grey pupil; milky cornea
Gills	Uniformly dark red to purple. No mucus	Less bright colour, paler at edges. Transparent mucus	brown/grey and bleached; mucus opaque and thick	brown or bleached; mucus yellowish grey and clotted
Gills cover	Silvery,	Silvery, slightly red or	Brownish and extensive seepage of blood from vessels	Yellowish

Smell (of gills and abdominal cavity)	Seaweedy	No small of seaweed, neutral smell	Fermented slightly sour,	Rotten
Flesh (cut from abdomen)	Bluish, translucent, smooth, shining No change in original colour	Velvety, waxy, dull Colour slightly changed	Slightly opaque	Opaque
Flesh(texture)	Firm and elastic Smooth surface	Less elastic	Slightly soft (flaccid), less elastic Waxy (velvety) and dull surface	Soft (flaccid) Scales easily detached from skin, surface rather wrinkled, inclining to mealy

Operators shall develop a sampling plan to check the relevant species/products prior to export and demonstrate compliance with this requirement.

(II) HISTAMINE SAMPLING

Histamine	9 samples bi-annually per species per existing company exporting and 4-monthly for new companies	No more than 2 samples with results between 100 and 200 mg/kg and no results over 200 mg/kg	HPLC

Rejection

A batch will be rejected when it fails to meet the acceptance criteria given above. In this case the company will need to contact their competent authority office to agree an acceptable disposition or re-sampling regime.

(III) FRESH / FROZEN FISH

Ready-to-eat Fish:

Selection of Sampling Plans and Assessment of Sample Units

For every lot exported from RMI in 1 consignment the operator must take at least 5 samples per 100 tons being exported.

Acceptance

Ready-to-eat fish products

Tests	**Sample plan**
Listeria monocytogenes.	n= 5, c= 0, M= absence in 25 using EN/ISO 11290 method

Rejection

A batch will be rejected when it fails to meet the acceptance criteria given above. In this case the company will need to contact their CA to agree an acceptable disposition or re-sampling regime.

Environmental Contaminants

Test	***Sample Plan***	***Limit***
Lead	1 sample per species per annum	0.3 ppm muscle meat of fish and cephalopods 0.5 ppm crustaceans 1.5 ppm bivalve molluscan shellfish
Cadmium	1 sample per species per annum	0.1 ppm mackerel and tunas 0.25 ppm swordfish 0.5 ppm Crustaceans 1.0 ppm cephalopods and bivalve molluscan shellfish 0.05 ppm other species
Mercury	1 sample per species per annum	1.0 ppm tuna, swordfish, emperor, marlin, sailfish, shark 0.5 ppm other species
PCB's/Dioxins	1 sample per species per annum	3.5 pg/g dioxins (sum of dioxins) 6..5 pg/g wet weight dioxins and PCBs (sum of dioxins and dioxin-like PCBs) 75 ng/g wet weight (sum of PCB28, PCB52, PCB101, PCB138, PCB153, PCB180)

Other:

Test	***Sample Plan***	***Limit***
Inorganic tin	1 sample per species per annum	200 mg/kg
Benzo(a)pyrene SMOKED PRODUCT ONLY	1 sample per product type being exported per annum	Benzo(a)pyrene: 2.0 ug/kg smoked fish Sum of benzo(a)- pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene: 12.0 ug/kg

(V) WATER/ICE

Water/Ice	***Sample Plan***	***Limit***
Microbiology	1 sample for each of 4 sites rotated on a 3 monthly. Test for: • TPC • E. coli • Enterococci • Total coliform	TPC 22^{o}C No abnormal change E. coli nil per 100 ml Enterococci Nil per 100 ml Total Coliform 0 per 100 ml

2. United States of America

Please note the section references relate to this USA Appendix only.

A. Formal Listing

Before a premises can export seafood to the United States of America it must be listed and approved by Marshall Islands Marine Resource Authority (MIMRA) of the Ministry of Fisheries and Marine Resources.

MIMRA inspectors will ensure the premises meets the following requirements:

B. Hazard analysis and Hazard Analysis Critical Control Point (HACCP) plans:

(a)*Hazard analysis.* Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b)*The HACCP plan.* Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c)*The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives; and

(ix) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and

(ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;

(3) List the critical limits that must be met at each of the critical control points;

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with Section B (b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with Section C (a);

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(d)*Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher-level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification of the plan in accordance with Section C (a) (1).

(e)*Products subject to other regulations.* For low acid canned fish and fishery products, the HACCP plan need not list the food safety hazard associated with the formation of*Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

(f)*Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with section F (b) they need not be included in the HACCP plan, and vice versa.

(g)*Legal basis.* Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

B. Corrective actions.

(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with Section A (c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Section E;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Section e, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Section C(a)(3)(ii) and the recordkeeping requirements of Section D.

C. Verification.

(a)*Overall verification.* Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1)*Reassessment of the HACCP plan.* A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Section A(c).

(2) *Ongoing verification activities.* Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and,

(iii) At the option of the processor, the performing of periodic end-product or in-process testing.

(3) *Records review.* A review, including signing and dating, by an individual who has been trained in accordance with Section E, of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Section B. This review shall occur within 1 week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b)*Corrective actions.* Processors shall immediately follow the procedures in Section B whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c)*Reassessment of the hazard analysis.* Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Section E.

(d)*Recordkeeping.* The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of Section D.

D. Records.

(a)*General requirements.* All records required by this part shall include:

(1) The name and location of the processor or importer;

(2) The date and time of the activity that the record reflects;

(3) The signature or initials of the person performing the operation; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b)*Record retention.* (1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the

case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(c)*Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

(d)*Public disclosure.* (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information.

(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e) Tags (defined as a record of harvesting information attached to a container of shellstock by the harvester or processor) are not subject to the requirements of this section.

(e)*Records maintained on computers.* The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

E. Training.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Section A(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Section B(c)(5), the HACCP plan in accordance with the verification activities specified in Section C(a)(1), and the hazard analysis in accordance with the verification activities specified in Section C(c); and

(c) Performing the record review required by Section C(a)(3); The trained individual need not be an employee of the processor.

F. Sanitation control procedures.

(a)*Sanitation SOP.* Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b)*Sanitation monitoring.* Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in this Appendix that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

The processor shall correct in a timely manner, those conditions and practices that are not met.

(c)*Sanitation control records.* Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of section D.

(d)*Relationship to HACCP plan.* Sanitation controls may be included in the HACCP plan, required by Section A (b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

G. Special requirements for imported products.

This section sets forth specific requirements for imported fish and fishery products.

(a)*Importer verification.* Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,

(ii) Affirmative steps that may include any of the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b)*Competent third party.* An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c)*Records.* The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of Section D.

(d)*Determination of compliance.* There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

HISTAMINE SAMPLING

Selection of Sampling Plans and Assessment of Sample Units

For every lot exported from RMI in 1 consignment the operator must take at least 18 samples.

Note the definition of a lot:

A quantity of fish of the same type produced under the same conditions during a particular time interval generally not exceeding 24 hours and from an identifiable processing line. Note: this definition implies individual species of a fish could be considered a lot.

Acceptance

Tuna and families *Scombridae* and *Clupeidae* - Chilled or frozen: no single sample can exceed 50 ppm histamine

If composited in no more than 3 samples per composite the limit is 17 ppm histamine

Rejection

A batch will be rejected when it fails to meet the acceptance criteria given above. In this case the company will need to contact their CA inspector to agree an acceptable disposition or re-sampling regime.

METHYLMERCURY SAMPLING

Selection of Sampling Plans and Assessment of Sample Units

Once a year all exporters exporting seafood to the USA shall select one sample per species exported to test for methylmercury.

Acceptance

Test results must be less than 1.0 ppm methylmercury

Rejection

If the test result fails to meet the limit above the company is to contact the CA inspector to agree an acceptable disposition. However, a retest is to be performed immediately and if this too exceeds the limit above then that species must not be exported to the USA until an acceptable result is achieved.

LOW ACID CANNED FOODS

A. Personnel.

The operators of processing systems, retorts, aseptic processing and packaging systems and product formulating systems (including systems wherein water activity is used in conjunction with thermal processing) and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the CA of MIMRA.

B. Equipment and procedures.

(a)*Equipment and procedures for pressure processing in steam in still retorts* --(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National OR International Standard upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.

(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.

(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained.

(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.

(iv) A temperature-indicating device shall be accurate to 0.5 deg. C. The temperature range of a mercury-in-glass thermometer shall not exceed 4 deg. C per centimetre of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.

(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a 2 centimetre diameter opening and equipped with a 1.5 millimetre or larger bleeder opening so located as to provide a full flow of steam past the length of the temperature-indicating device sensor. The bleeders for external wells shall emit steam continuously during the entire processing period. The temperature-indicating device shall be the reference instrument for indicating the processing temperature.

(i)*Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 12 deg. C per centimetre within a range of 10 deg. C of the process temperature. Chart graduations shall not exceed 1 deg. C within a range of 5 deg.) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(ii)*Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.

(iii)*Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(iv)*Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a recorder-controller.

(3) *Pressure gauges.* Each retort should be equipped with a pressure gauge that is accurate to 13.8 kilopascals or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. The steam controller may be air-operated and actuated by a temperature sensor positioned near the temperature-indicating device in the retort. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.

(5) *Steam inlet.* The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort. Steam may enter either the top portion or the bottom portion of the retort but, in any

case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion.

(6) *Crate supports.* A bottom crate support shall be used in vertical still retorts. Baffle plates shall not be used in the bottom of still retorts.

(7) *Steam spreaders.* Steam spreaders are continuations of the steam inlet line inside the retort. Horizontal still retorts shall be equipped with steam spreaders that extend the length of the retort. For steam spreaders along the bottom of the retort, the perforations should be along the top 90deg. of the pipe, that is, within 45deg. on either side of the top center. Horizontal still retorts over 30 feet (9.1 meters) long should have two steam inlets connected to the spreader. In vertical still retorts, the steam spreaders, if used, should be perforated along the center line of the pipe facing the interior of the retort or along the sides of the pipe. The number of perforations should be such that the total cross-sectional area of the perforations is equal to 1.5 to 2 times the cross-sectional area of the smallest restriction in the steam inlet line.

(8) *Bleeders.* Bleeders, except those for temperature-indicating device wells, shall be 3 millimeters or larger and shall be wide open during the entire process, including the come-up time. For horizontal still retorts, bleeders shall be located within approximately 30.5 centimeters of the outermost locations of containers at each end along the top of the retort. Additional bleeders shall be located not more than 2.4 meter) apart along the top. Bleeders may be installed at positions other than those specified in this paragraph, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of steam within the retort. Vertical retorts shall have at least one bleeder opening located in that portion of the retort opposite the steam inlet. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged so that the operator can observe that they are functioning properly.

(9) *Stacking equipment and position of containers.* Crates, trays, gondolas,*etc.,* for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch (2.5 centimeters) holes on 5.1 centimeter centers. If dividers are used between the layers of containers, they should be perforated as stated in this paragraph. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process.

(10) *Air valves.* Retorts using air for pressure cooling shall be equipped with a suitable valve to prevent air leakage into the retort during processing.

(11) *Water valves.* Retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.

(12) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or

other adequate type of valve. The retort manifold shall be of a size that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The discharge shall not be directly connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall not begin until the retort has been properly vented and the processing temperature has been reached.

(13) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

C. Control of Components, Food Product Containers, Closures, and In-Process Materials

Containers.

(a)*Closures.* Regular observations shall be maintained during production runs for gross closure defects. Any such defects shall be recorded and corrective action taken and recorded. At intervals of sufficient frequency to ensure proper closure, the operator, closure supervisor, or other qualified container closure inspection person shall visually examine either the top seam of a can randomly selected from each seaming head or the closure of any other type of container being used and shall record the observations made. For double-seam cans, each can should be examined for cutover or sharpness, skidding or deadheading, false seam, droop at the crossover or lap, and condition of inside of countersink wall for evidence of broken chuck. Such measurements and recordings should be made at intervals not to exceed 30 minutes. Additional visual closure inspections shall be made immediately following a jam in a closing machine, after closing machine adjustment, or after startup of a machine following a prolonged shutdown. All pertinent observations shall be recorded. When irregularities are found, the corrective action shall be recorded.

(1) Teardown examinations for double-seam cans shall be performed by a qualified individual and the results therefrom shall be recorded at intervals of sufficient frequency on enough containers from each seaming station to ensure maintenance of seam integrity. Such examinations and recordings should be made at intervals not to exceed 4 hours. The results of the teardown examinations shall be recorded and the corrective action taken, if any, shall be noted.

(i) Required and optional can seam measurements:

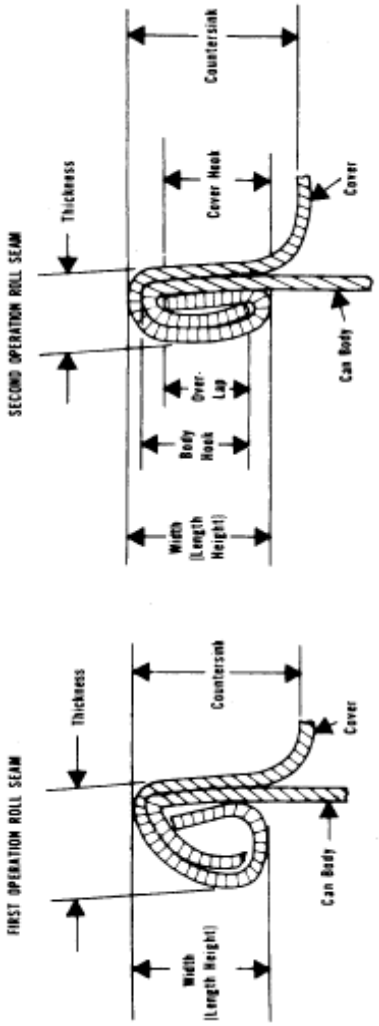
(*a*) Micrometer measurement system:

Required	**Optional**
Cover hook	Overlap (by calculation).
Body hook	Countersink.
Width (length, height)	
Tightness (observation for wrinkle)	
Thickness	

(*b*) Seam scope or projector:

Required	**Optional**
Body hook	Width (length, height).
Overlap	Cover hook.
Tightness (observation for wrinkle)	Countersink.
Thickness by micrometer	

(*c*) Can double seam terminology:



(*1*) "Crossover": The portion of a double seam at the lap.

(*2*) "Cutover": A fracture, sharp bend, or break in the metal at the top of the inside portion of the double seam.

(*3*) "Deadhead": A seam which is incomplete due to chuck spinning in the countersink.

(*4*) "Droop": Smooth projection of double seam below bottom of normal seam.

(*5*) "False seam": A small seam breakdown where the cover hook and the body hook are not overlapped.

(*6*) "Lap": Two thicknesses of material bonded together.

(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three measurements shall be made at points approximately 120deg. apart, excluding the side seam.

(iii) Overlap length can be calculated by the following formula:

The theoretical overlap length=CH+BH+T-W, where

CH=cover hook

BH=body hook

T=cover thickness, and

W=seam width (height, length)

(2) For glass containers with vacuum closures, capper efficiency must be checked by a measurement of the cold water vacuum. This shall be done before actual filling operations, and the results shall be recorded.

(3) For closures other than double seams and glass containers, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

(b)*Cooling water.* Container cooling water shall be chlorinated or otherwise sanitized as necessary for cooling canals and for recirculated water supplies. There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler.

(c)*Coding.* Each hermetically sealed container of low-acid processed food shall be marked with an identifying code that shall be permanently visible to the naked eye. When the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, if the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers that constitute the batch do not extend over a period of more than one personnel shift.

(d)*Post-process handling.* Container handling equipment used in handling filled containers shall be designed, constructed, and operated to preserve the can seam or other container closure integrity. Container handling equipment, including automated and non-automated equipment, shall be checked with sufficient frequency and repaired or replaced as necessary to prevent damage to containers and container closures. When cans are handled on belt conveyors, the conveyors should be constructed to minimize contact by the belt with the double seam,*i.e.,* cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions,*etc.* should be replaced with new nonporous material. All tracks and belts that come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination.

D. Production and Process Controls

Product preparation.

(a) Before using raw materials and ingredients susceptible to microbiological contamination, the processor shall ensure that those materials and ingredients are suitable for use in processing low-acid food. Compliance with this requirement may be accomplished by receiving the raw materials and ingredients under a supplier's guarantee that they are suitable for use, by examining them for their microbiological condition, or by other acceptable means.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. If the blanched food product is washed before filling, potable water should be used.

(c) The filling of containers, either mechanically or by hand, shall be controlled so as to ensure that the filling requirements specified in the scheduled process are met.

(d) The exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed. Compliance with the requirement may be accomplished by heat exhausting, mechanical exhausting, hot brining, or steam injection.

(e) When the maintenance of pH (above 4.6) of a normally low-acid food is a basis for a scheduled process, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets that of the scheduled process. The methodology described in 114.90 of the Code of Federal Regulations should be used.

(f) When the scheduled process sets forth critical factors to prevent the growth of microorganisms not destroyed by the thermal process, the factors shall be carefully controlled to ensure that the limits established in the scheduled process are not exceeded. When normally low-acid foods require sufficient solute to permit safe processing at low temperatures, such as in boiling water, there shall be careful supervision to ensure that the equilibrium water activity (aw) of the finished product meets that of the scheduled process. The scheduled thermal processes for foods having an aw greater than 0.85 and less than the aw that would allow the growth of spores of microorganisms of public health significance shall be sufficient to render the food free of microorganisms capable of reproducing in the food under normal non-refrigerated conditions of storage and distribution.

Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in

commercial production shall be adequately provided for in establishing the scheduled process. Variations include those that occur due to seasonal or growing fluctuations, variety differences, supplier processes, reprocessing, and mixing a batch of processed product with the same unprocessed product before it is processed. Critical factors, e.g., minimum headspace, consistency, maximum fill-in or drained weight, aw,*etc.,* that may affect the scheduled process, shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, but shall not be limited to, the use of microbial thermal death time data, process calculations based on product heat penetration data, and inoculated packs. Calculation shall be performed according to procedures recognized by competent processing authorities. If incubation tests are necessary for process confirmation, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for confirmation of the scheduled processes should include the containers from the test trials and a number of containers from each of four or more actual commercial production runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination.

Operations in the thermal processing room.

(a) Operating processes and retort venting procedures to be used for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or be made readily available to the retort or processing system operator and any duly authorized employee of the Food and Drug Administration. Scheduled processes must be made readily available to the supervisor and any duly authorized employee of the Food and Drug Administration.

(b) A system for product traffic control in the retort room shall be established to prevent unretorted product from bypassing the retort process. Each retort basket, truck, car, or crate used to hold containers in a retort, or one or more containers therein, shall, if it contains any retorted food product, be plainly and conspicuously marked with a heat-sensitive indicator, or by other effective means that will indicate visually, to thermal processing personnel, those units that have been retorted. A visual check shall be performed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator as a result of retorting for all retort baskets, trucks, cars, or crates, to ensure that each unit of product has been retorted. A record of these checks should be made.

(c) The initial temperature of the contents of the containers to be processed shall be accurately determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process. For those operations that use water during the filling of the retort or during processing, provision shall be made to ensure that the water will not, before the start of each thermal process, lower the initial temperature of the product below that specified in the scheduled process. The temperature-indicating device used to determine the initial temperature shall be tested for accuracy against a reference device for which the accuracy is traceable to a National OR International Standard with sufficient frequency to ensure that initial temperature measurements are accurate. Records of the

accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained.

(d) Timing devices used in recording thermal process time information shall be accurate to the extent needed to ensure that the processing time and venting time specified in the scheduled process are achieved. Pocket or wrist watches are not considered satisfactory for timing purposes. Digital clocks may be used if the operating process and the venting schedule have a 1-minute or greater safety factor over the scheduled process.

(e) Clock times on temperature-recording device records shall reasonably correspond to the time of day on the processing records to provide correlation of these records.

(f) The steam supply to the thermal processing system shall be adequate to the extent needed to ensure that sufficient steam pressure is maintained during thermal processing, regardless of other demands of steam by the plant.

(g) If mufflers are used on bleeders or vent systems, evidence that the bleeders or vents are operated in a manner that does not significantly impede the removal of air shall be kept on file. This evidence may be in the form of heat distribution data or other satisfactory evidence such as a letter from the manufacturer, the designer, or a competent processing authority.

Deviations in processing, venting, or control of critical factors.

Whenever any process is less than the scheduled process or when critical factors are out of control for any low-acid food or container system as disclosed from records by processor check or otherwise, the commercial processor of that low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, must set aside that portion of the product involved for further evaluation as to any potential public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless this evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside shall be either fully reprocessed to render it commercially sterile or destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commercial sterility or after the determination that no significant potential for public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved shall be destroyed. All process deviations involving a failure to satisfy the minimum requirements of the scheduled process, including emergencies arising from a jam or breakdown of a continuous agitating retort necessitating cooling the retort for repairs, shall be recorded and made the subject of a separate file (or a log identifying the appropriate data) detailing those deviations and the actions taken.

E. Records and Reports

Processing and production records.

(a) Processing and production information shall be entered at the time it is observed by the retort or processing system operator, or other designated person, on forms that include the product, the code number, the date, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the initial temperature, the actual processing time, the temperature-indicating device and temperature-recording device readings, and other appropriate processing data. Closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:

(1)*Still retorts.* Time steam on; time temperature up to processing temperature; time steam off; venting time and temperature to which vented.

(2)*Agitating retorts.* Functioning of condensate bleeder; retort speed; and, when specified in the scheduled process, headspace, consistency, maximum drained weight, minimum net weight, and percent solids.

(3)*Hydrostatic retorts.* The temperature in the steam chamber between the steam-water interface and the lowest container position; speed of the container conveyor chain; and, when the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, the temperatures near the top and the bottom of each hydrostatic water leg.

(b) Temperature-recording device records shall be identified by date, retort number, and other data as necessary, so they can be correlated with the record of process lots. Each entry on the processing and production records shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and this retort or processing system operator or other designated person shall sign or initial each record form. Not later than 1 working day after the actual process, and before shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness and to ensure that the product received the scheduled process. The records, including temperature-recording device records, shall be signed or initialled and dated by the reviewer.

(c) Records of the accuracy of a temperature-indicating device shall include:

(1) A reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device;

(2) The name of the manufacturer of the temperature-indicating device;

(3) The identity of the reference device, equipment, and procedures used for the accuracy test and to adjust the temperature-indicating device or, if an outside facility is used to conduct the accuracy test for the temperature-indicating device, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a National OR International standard;

(4) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device;

(5) The date and results of each accuracy test, including the amount of calibration adjustment; and

(6) The date on or before which the next accuracy test must be performed.

(d) Records of the accuracy of a reference device maintained by the processor shall include:

(1) A reference to the tag, seal, or other means of identity used by the processor to identify the reference device;

(2) The name of the manufacturer of the reference device;

(3) The identity of the equipment and reference to procedures used for the accuracy test and to adjust or calibrate the reference device or, if an outside facility is used to conduct the accuracy test for the reference device, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a national or international standard;

(4) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the reference device;

(5) The date and results of each accuracy test, including the amount of calibration adjustment; and

(6) The date on or before which the next accuracy test must be performed.

(e) Records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialled by the container closure inspector and reviewed by management with sufficient frequency to ensure that the containers are hermetically sealed. The records shall be signed or initialled and dated by the reviewer.

(f) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise rendered unfit for their intended use.

(g) Copies of all records provided for in this part, except those required to establish scheduled processes, shall be retained at the processing plant for a period of not less than 1 year from the date of manufacture, and at the processing plant or other reasonably accessible location for an additional 2 years. If, during the first year of the 3-year record-retention period, the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.

(h) Records of this part may be maintained electronically, provided they are password protected and backed up regularly.

3. The People's Republic of China

A. Formal Listing

A number of premises (as detailed below) require registration with the CA of MIMRA before they can export product to China.

The registration includes premises receiving, handling, processing or storing seafood products intended for export to China, and this applies to the following operations:

- Factory Vessels (FV),
- Freezing Vessels or transporting vessels (carriers) (ZV),
- Processing Premises (PP): including fish oil for human consumption and all aquaculture products,
- Cold Stores (CS): for all fish and fishery products (including all aquaculture products).

B. Sanitary Requirements

Before product can be exported to China the CA needs to be able to confirm fishery products exported from RMI meets the following parameters using the test frequencies indicated below:

Parameter	Product	Chinese legislation				Test Frequency	Method
Benzo(a)pyrene	Smoked fish	5 ug/kg				1 per product variant per year	GB5009.27
Lead	Fish	0.5 mg/kg fish and cephalopods 1.5 mg/kg Molluscs & Cephalopods				1 per species per year	GB5009.12
Cadmium	Fish	0.1 mg/kg 0.2 mg/kg (canned fish)				1 per species per year	GB5009.15
Mercury	Fish	1 mg/kg (Predatory fish) 0.5 mg/kg(non-predatory)				1 per species per year	GB5009.17
Tin	Canned foods	250 mg/kg				10 cans per product variant per year	GB5009.16
Chromium	Fish and crustaceans	2.0 mg/kg				1 per species per year	Gb5009.123
Inorganic Arsenic	Fish and crustaceans	0.1 mg/kg				1 per species per year	GB5009.11
N-nitrosamines	Aquatic fish (N-nitrosodimetilamine) (Ndietilnitrosamine)	4 µg/kg				1 per species per year	GB5009.26
PCBs	Aquatic Products	0.5 mg/kg				1 per species per year	GB5009.190
TVB-N	Marine fish	30 mg/100g				Only in cases that spoilage is suspected	
Colonies count	Aquatic products	n = 5	c = 2	≤5 x 10^4	≤10^5	5 samples per species per year	GB2733
Histamine	Scombroid species	40 mg/100g				1 per species per year	GB10136
Histamine	Non-scombroid species	20 mg/100g				1 per species per year	GB 2733
Coliforms (cfu/g)	Aquatic products	n = 5	c = 2	m = 10	M = 100	5 samples per species per year	GB 10136
Salmonella	Ready to eat products and dry products	Absence per 25g				5 samples per product type per year	GB 4798.4
S. aureus (cfu/g)	Ready to eat products and dry products	n = 5	c = 2	m = 100	M = 1000	5 samples per product type per year	GB 4798.10
V. parahaemolyticus (MPN/g)	Ready to eat products	n = 5	c = 2	m = 100	M = 1000	5 samples per product type per year	GB/T 4789.7

*** = Most Probable Number**

C. Certification Requirements

All products being exported to China must be accompanied by a Health Certificate specific to the Chinese market and signed by an authorised CAO. An example of the Chinese health certificate is given in Appendix 3 part 6.

D. Labelling Requirements

All products being exported to China must contain the following labelling on both the internal and external package and both in English and Chinese:

- Product name
- Date of production
- Batch number
- Storage conditions
- Production method (either marine caught or freshwater caught or cultured)
- Producing area (including the marine area caught)
- Name and registration number of the processing premises including vessels
- People's Republic of China must be shown clearly as the place of destination

E. Exporter Registration

Before exports are permitted, the exporting company must be registered with China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). Evidence of this registration or application for registration must be available to the CA inspector before they sign a health certificate.

APPENDIX SIX: F13 Corrective Action Request

3. F13 - Corrective Action Request

Name of the establishment:					**Approval Number:**					
CA Officers:					**Representatives of the establishment:**					
Source Verification Record:					**Date of Verification:**					
Mi/ma /Se/Cr	**Ref**	**IS Ref**	**Issue**	**Required action**	**Timeframe**	**Yes/No?**	**Extension? And reason**	**Comments**	**Signature**	**Date/Time**
Verifiers name and signature:					**Representative name and signature** [2]					
Date/Time:					**Date/Time:**					

[2] Representative of the establishment accepting results of evaluation