CELEBRATING 45 YEARS OF COOPERATION

FFA
PACIFIC ISLANDS FORUM FISHERIES AGENCY

EU SANITARY REQUIREMENTS FOR VESSELS - A GUIDE

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Disclaimer:

This manual was produced in May 2024 and does not replace the national legislation, nor the National Control Plans and Industry Standards of National Competent Authorities. It is a Guide to both National Competent Authorities and Industries on EU sanitary requirements for vessels.

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1.0 INTRODUCTION

The European Union (EU) market has become a sought-after market for tuna products from the Pacific. However, to access the EU operators and exporters must meet stringent sanitary standards set by the EU. These standards include but are not limited to:

- Design and construction
- Listings and approvals
- Operational requirements such as time/temperature controls and the need for HACCP/GMP
- Sampling and testing requirements
- The need for health certification

These guidelines are intended to provide operators of EU vessels with the information they need to ensure they meet EU requirements on a consistent basis.

2.0 DISCLAIMER

This guideline is intended as a guide only. While it summarises the key aspects a vessel operator needs to consider when accessing the EU market, it is not intended as a legal tool in the case of disputes and other matters where further detail is required. Operators should refer to the actual legislation and standards or seek further expert advice in this case.

3.0 OVERVIEW OF THE EU MARKET ACCESS REQUIREMENTS

3.1 General

The EU market sets some of the toughest standards for market access.

In summary, the EU market requires:

1. The country from which fish is exported needs to be authorised by the EU.
2. The establishments in the EU supply chain (including vessels, land-based establishments, landing sites, transporters, standalone cold stores and standalone ice plants) all need to be under CA control and listed by the CA. More detail is provided on this later in this guide.
3. Country food safety legislation that is deemed at least equivalent to that of the EU.

4. The establishment of a government-based Competent Authority (CA) to oversee the level of compliance at each establishment under their control.
5. Operators of establishments to operate under GMP/HACCP principles.
6. Minimum standards of design and construction and hygiene during catching, handling, processing, storage and transport to ensure the safety of the product produced.
7. Minimum residue and contaminant levels set by the EU.
8. Inventory Control and Traceability
9. Product recall systems and the Rapid Alert System

3.2 Terminology

The EU uses several terms that other markets do not use, including:

Establishment means the facility approved by the CA to catch, handle, process, store or transport food and includes:

- Vessels (fresh and frozen)
- Land-based establishments
- Landing sites
- Standalone cold stores
- Standalone ice plants
- Transporters

Competent Authority (CA) is the central authority of a country competent to ensure compliance with the requirements of EU legislation. The CA must be a government agency with sufficient legal power and authority to assume control in the event of a non-compliance with EU legislation.

National Control Plan is a document prepared by the CA containing information on the structure of the CA and the procedures it needs to perform to meet EU requirements.

Third country is a country outside the EU.

EU supply chain is the network of companies and people that are involved in the production of product for the EU market from catching through storage, handling, processing and transport .

Freezer vessel is any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging.

Reefer vessel means a vessel equipped to store and transport palletized or loose cargo (bulk) goods in temperature-controlled holds or chambers.

4.0 LEGISLATION

4.1 General

Operators of vessels need to meet both national legislation as well as that of their key trading partners. The focus of this guideline is on the EU market so here we will only identify the relevant national and EU legislation.

NOTE:

1. There may be other legislation operators need to meet for other markets.
2. The list of legislation provided.

4.2 National Legislation

National legislation will vary from country to country but will typically include an Act and a set of Regulations that control the catching, handling and export of fish and fishery products. For example, for the Federated States of Micronesia (FSM) the following legislation is applicable:

- FSM National Food Safety Act
- FSM Food Safety Regulation

In addition to this, countries will have additional standards that provide more detail of the standard to be met when processing and handling fish. This includes:

- The National Control Plan (designed for Competent Authority (CA) staff and the operation of the (CA)
- Industry Standards which detail the standards to be met by all approved establishments, (including vessels)

4.3 European Union

The main legal requirements are summarised below:

- Horizontal EU legislation including but not limited to:
  - Regulation (EC) 178/2002, Food Law
  - Regulation (EC) 852/2004, Food & feed hygiene
  - Regulation (EC) 853/2004, Specific Hygiene Rules for Products of Anima Origin
  - Regulation (EU) 2017/625, Official Controls
- Vertical EU legislation including but not limited to:
  - Regulation (EU) 1169/2011, Labelling
  - Regulation (EC) 2406/96, Common marketing standards
  - Directive 2020/2184 (EU), Quality of water for human consumption

- Regulation (EC) 2023/915, Maximum levels for certain contaminants
- Regulation (EC) 333/2007, Sampling methods & methods of analysis of heavy metals
- Decision 2002/657/EC, Performance of analytical methods & interpretation of results
- Commission Regulation (EU) 2016/582, Analysis of inorganic arsenic, lead and polycyclic aromatic hydrocarbons and certain performance criteria for analysis
- Regulation (EC) 2074/2005, Implementing measures for certain products
- Regulation (EC) 2073/2005, Microbiological criteria for foodstuffs
- EC Regulation 10/2011, Plastics and food contact surfaces
- Regulation (EU) 931/2011, Food Traceability requirements
- Regulation (EU) 1379/2013, Common Organisation of the Markets in Fishery
- Regulation (EU) 2022/2292, additional requirements for the entry into EU for certain goods intended for human consumption
- Regulation (EU) No 1019/2013, of 23 October 2013 amending Annex I to Regulation (EC) No 2073/2005, as regards histamine in fishery products

5.0 LISTINGS AND APPROVAL OF ESTABLISHMENTS

5.1 General

Establishments (including vessels) that wish to form part of the EU supply chain need to be under the control of the CA. Once an establishment has met the standard required by EU, it will be "listed" by the CA.

The CA maintains three different types of "lists" depending on the intended market:

1. General list for establishments: for all establishments exporting fish from a country EXCEPT THOSE in the EU supply chain.
2. Internal EU list: for those establishments handling, processing, storing or transporting product as part of the EU supply chain but NOT exporting directly to the EU. Includes fresh, chilled vessels, standalone ice plants, landing sites and transporters.
3. External EU list: for those establishments exporting directly to the EU. Includes land-based establishments, freezer vessels and standalone cold stores.

5.2 The Listing Process

An operator of a vessel wishing to gain EU approval and listing should first contact the CA. He/she will be required to submit an application form and associated documents e.g. a HACCP plan, the supporting programmes to the HACCP plan and details of the vessel (such as crew numbers, vessel type, vessel capacity, products, processes, freezing and/or chilling methods etc.).

The CA will review the information and may request amendments. Once satisfied the documentation is correct, the CA will then perform an onsite visit to the vessel to check compliance to EU standards.

Once satisfied both the documentation and vessel are acceptable, the CA will approve the establishment and list the vessel on the EU External list. The EU external list is maintained by the EC and published on their website so the CA must immediately notify the EC of the listing. Operators of vessels that have gained approval from the CA for an EU listing will be allowed to catch, handle or store fishery products from the date CA gives approval but will not be allowed to export this product until the EC has listed the establishment on their website.

5.3 Procedure Following Approval

Once a vessel is listed on the EU external list, it will be required to consistently meet the minimum standards laid out in the country's Industry Standards but also any specific EU requirements. The CA will perform regular verification audits of the vessel when it is alongside at the wharf (typically every 6 months) and require corrective action if the level of compliance is below the standard required.

6.0 DESIGN AND CONSTRUCTION

6.1 Requirements for all vessels

1. 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.
2. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.
3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.
4. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.
5. Vessels must be designed and constructed so as not to cause contamination of the fishery products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. Holds, tanks, or containers used for storing, cooling or freezing unprotected fishery products including those destined for the production of feed, shall not be used for other purposes than the storing, cooling or freezing those products, as well as ice or brine used for such purposes. In the case of reefer vessels, the provisions applicable to unprotected fishery products apply to all the products transported.

6.2 Additional Requirements for vessels designed and equipped to preserve fresh fishery products for more than 24 hours

In addition to the requirements for all vessels in section 6.1, vessels designed and equipped to preserve fishery products for more than 24 hours, must meet the following requirements:

1. Vessels designed and equipped to preserve fishery products for more than 24 hours must be equipped with holds, tanks or containers for the storage of fishery products at the temperatures below:
    a. Fresh fishery products must be maintained at a temperature approaching that of melting ice.
    b. Frozen fishery products must be kept at a temperature of not more than – 18 °C in all parts of the product; however, whole fish initially frozen in brine intended for the manufacture of canned food may be kept at a temperature of not more than – 9 °C. Once frozen in brine to -9 °C this fish MUST be destined for canning and cannot be used for any other purpose.

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 3 °C six hours after loading and not more than 0 °C after 16 hours and allow the monitoring and, where necessary, recording of temperatures.
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.

6.3 Additional Requirements for freezer vessels

In addition to the requirements in section 6.1, freezer vessels must also:

1. Have freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, to achieve a core temperature of not more than – 18 °C.
2. Have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than – 18 °C. Storage holds must not be used for freezing unless they fulfil the conditions laid down in the previous point, and must be equipped with a 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;
3. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.

6.4 Requirements for reefer vessels

Reefer vessels transporting and/or storing frozen fishery products in bulk must have equipment meeting the following requirements:

1. Have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than – 18 °C. Storage holds must not be used for freezing unless they have freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to achieve a core temperature of not more than – 18 °C,
2. They must be equipped with a 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.

6.5 Vessel 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. Even if it is subsequently frozen at a temperature of – 18 °C, the whole fish initially frozen in brine at a temperature of not more than – 9 °C must be destined for canning. The brine must not be a source of contamination for the fish.

7.0 GMP/HACCP

7.1 Introduction

HACCP is a technique that was initially used by the US space programme then the US military as a means to guarantee the safety of the product they were eating. It has since become a minimum requirement for entry into most of our major markets.

HACCP is a technique that identifies and analyses food safety hazards in processes and determines critical control points in the process where significant hazards can be controlled. Each establishment should operate under a documented HACCP plan(s) which is approved on an annual basis by the country's CA.

HACCP requires good manufacturing practices (GMPs) to be in place before HACCP is implemented. These GMPs provide a foundation for HACCP and focus on controlling the generic food safety hazards that are common to all processes being carried out on the vessel. For example control of cleaning and sanitation and personnel hygiene.

7.2 GMP

7.2.1 Overview of GMP

GMP (or sometimes called Good Hygiene Practices, GHP) are all practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

GMP/GHP should be documented and can also be called supporting or pre-requisite programmes.

A vessel should have the following documented programmes:

- Control of packaging, processing aids and chemicals
- Design and Construction of premises, facilities and equipment
- Maintenance
- Cleaning and Sanitation
- Pest Control
- Personal or Personnel Hygiene
- Water and ice (if used)
- Waste Management
- Inventory Control and Traceability
- Training

7.2.2 Control of packaging and processing aids

A vessel operator must ensure that any packaging and processing aids used onboard will not contaminate the product.

Packaging should be purchased from a reputable supplier and have supplier guarantees showing the packaging is suitable for use for product contact.

Processing aids such as antifoaming agents and salt should also have records to confirm the aids are suitable for use in food processing.

Packaging and processing aids should be stored in a manner that prevents contamination before use.

7.2.3 Hazardous Substances

1. Cleaning and sanitation, maintenance and pest 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.
3. Hazardous substances shall not pose a source of contamination to fish on board and handled only by properly trained persons.
4. 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 pest control chemicals used within the processing area vicinity)
    b. That chemicals will not pose a source of contamination to fish being handled or stored.
    c. Only trained persons shall handle chemicals.
    d. Requiring all chemicals to be labelled.

7.2.4 Maintenance

1. All EU approved vessels 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. Once completed repairs and maintenance activities should be signed off.
2. Repairs shall be carried out as soon as possible without interference to catching. Handling or storage of fish.

3. All chemical compounds used as detergents, sanitisers, lubricants or pesticides shall be suitable for use in food processing areas 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, ;
4. The operator shall maintain a register of chemicals used in the facility, their purpose, and their food-grade status.

7.2.5 Cleaning and Sanitising

1. A documented cleaning and sanitation programme shall be in place, and the crew 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 vessel, including areas where fish is handled and stored, equipment, tools and storage areas. The programme shall be documented and contain the following elements:
    a. Areas/equipment 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 fish, equipment, utensils and surfaces that come into contact with fish shall be:
    a. Cleaned as frequently as necessary, either immediately after the departure from ports, after fishing and handling, and prior to coming to port or at such times as may be appropriate to maintain hygienic conditions.

7.2.6 Pest Control

1. The establishment:
    a. shall take precautions to prevent pests such as insects, rodents, birds, or other animals;
    b. shall take effective measures to exclude pests and animals from the vessel and to protect products against contamination by pests.
2. There shall be an effective and continuous schedule for detecting, controlling and eradicating pests.
3. Pest control measures undertaken shall not constitute a hazard to human health and product safety.

4. Control measures involving chemical treatment shall only be undertaken by personnel who completely understand the health hazards these chemicals may pose to the product. Chemicals used for pest control shall be approved by the CA or authorised overseas agency.
5. Companies shall document a pest control programme and this programme shall cover:
    a. pests that may occur on the vessel
    b. actions to prevent pest breeding or entering the vessel
    c. actions taken to eliminate pest
    d. pest control chemicals to be CA approved
    e. checks carried out to demonstrate effectiveness
6. Accurate and legible records of the activities carried out to prevent pests are to be kept.

7.2.7 Personnel or Personal Hygiene

Documented Programme

1. The vessel must document a programme detailing how personnel 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.

Hygiene Training

1. The operator of a vessel shall arrange for adequate and continuous training of all food handlers in personal hygiene and hygienic handling of fish to ensure that the precautions necessary to prevent contamination of fish are understood.
2. Training records for each person trained shall be maintained.

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
    e. shall handle the fish.

Injuries

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

Personal Cleanliness and Conduct

1. While on duty with fish handling, all crew should maintain a high degree of personal cleanliness.
2. Any behaviour that could result in the contamination of fish, such as chewing, eating, spitting, smoking, and other unhygienic behaviour, shall be prohibited in fish handling areas.
3. All personnel shall wash their hands frequently to prevent contamination but especially after going to the toilet and after handling something that is contaminated.
4. Wearing clean gloves does not exempt the wearer from thoroughly washing their hands.

Protective Clothing

1. All crew entering the processing area shall at all times wear suitable protective clothing and impermeable footwear;
2. If a crew wears disposable gloves or other disposable protective while handling fish, the gloves shall be discarded after use and not be reused.

7.2.8 Water and Ice

Fresh Water

Fresh water used on board needs to be potable. Confirmation of potability can be demonstrated either by testing of the water on a biannual basis (6 monthly) for the following parameters or through provision of records confirming compliance with the parameters below (municipal supply/water authority records or similar):

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)
Intestinal Enterococci	100	0	0 (number/100 ml)

Seawater

Seawater used on board should be “clean” i.e. free from harmful contaminants including microorganisms. To ensure clean seawater vessels should take their seawater at distances of at least 1 kilometre offshore to prevent contamination from harbours and land runoff.

Ice

If ice is used onboard it must be made from potable water as detailed previously. If the company provides their own ice, evidence of potability of the water used must be provided by testing or from Water Authority records.

Once made ice should be stored and handled in a manner that prevents contamination.

7.2.9 Waste Management

1. Inedible by-products and other inedible material or waste shall:
    a. Be removed from the fish handling area(s) 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 facilitate cleaning and disinfection;
    c. that must be always thoroughly cleaned and sanitised after use.

7.3 Contents of a HACCP Plan

The HACCP plan shall be developed for each product manufactured by the establishment. 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. Including the method use to determining CCP.

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.

7.4 Approval of HACCP Plans

The HACCP programme must be signed and dated by an authorised company representative and an authorised CA inspector. When the HACCP plan is signed by the company representative it represents management's acceptance and commitment implementing the plan.

HACCP programmes shall also be subject to annual review, or more frequently if changes occur in the product or process. The review must be completed by company personnel who have completed a HACCP course approved by the CA.

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.

Should changes be made to the approved HACCP plan, these changes must be notified to the CA for approval.

8.0 OPERATIONAL REQUIREMENTS

8.1 Dual Use of Fish Wells for EU approved vessels

Dual use of fish wells (fuel and fish) is not allowed on any EU-listed vessel .

8.2 Requirements During and After Landing

1. 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.
        (iv) the premises must be well lit to facilitate official controls.
2. 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.
3. 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.

8.3 Labelling

Until the stage at which fish is used for further processing, operators must ensure that in the case of frozen fish intended for human consumption, the following information is made available to the food business operator to whom the food is supplied and, upon request, to the competent authority:

a. the date of production; and

b. the date of freezing, if different from the date of production.

Where a food is made from a batch of raw materials with different dates of production and of freezing, the oldest dates of production and/or of freezing, as appropriate, must be made available.

The appropriate form in which the information must be made available is up to the choice of the operator, as long as the date of production/freezing will be clearly and unequivocally available to and retrievable by the business operator to whom the food is supplied.

8.4 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.

8.5 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.
    b. 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.
    c. Similarly, operators must maintain traceability of reworked products the same as product from normal production.

8.6 Calibration

8.6.1 What is Calibration

Calibration is the process of checking a measuring instrument to see if it is accurate. All measuring equipment performing critical measurements on a vessel need regular calibration. This includes but is not limited to thermometer probes and temperature measuring devices in holds, wells etc.

8.6.2 The Calibration Procedure

Calibration should be carried out at least annually. This usually involves getting an accredited calibration organisation to visit the vessel to check the accuracy of items such as the temperature measuring equipment on wells and/or holds against a reference thermometer of known accuracy using internationally recognised methods. On completion the company performing the calibration will issue a calibration certificate confirming the accuracy of the equipment.

However, thermometer probes can be calibrated more easily and regularly using the ice point check. To perform the ice point check:

1. Fill a jug or similar container with ice (preferably chunk ice).
2. Fill the jug with water.
3. Let the water/ice mixture sit for a few minutes to allow the temperature to equilibrate.
4. Insert the probe into the middle of the jug being careful to check the probe tip is not sitting directly against the ice.
5. Wait for the temperature to settle.
6. Check whether the thermometer probe reads 0°C. If not record the number of degrees out from 0°C. If the probe cannot be replaced ensure any measurements taken with the probe are adjusted to take account of the discrepancy. For example, if you calibrate your thermometer using the ice point check and the probe reads 2°C instead of 0°C then any future measurements taken with the probe should have 2°C taken off the measurement. So a reading of 2°C should be recorded as 0°C.
7. Record the date of calibration, the time of equipment calibrated, the serial number or other means of identifying the equipment and the outcome from the calibration.
8. This simple form of calibration can be used whenever you suspect a discrepancy in the accuracy of your probe or on a weekly or monthly basis.

8.7 Internal Compliance

8.7.1 What is Internal Compliance?

Internal Compliance is the checks a vessel operator is expected to carry out to check that the documented HACCP plan and procedures being used to control food safety are being carried out and producing safe food.

8.7.2 Internal Compliance Activities

The following activities should be carried out as part of internal compliance:

1. Monitoring checks: the checks a company carries out to prove the procedures are being followed and to provide evidence on the safety of the product. For example, It is essential that a designated crew member conducts daily inspections to ensure the cleanliness of equipment and personnel, with proper documentation maintained. Additionally, regular reviews of the ATRD records should be carried out to verify that the fish holds and wells are consistently maintaining the required chilled or frozen temperatures.

2. Record review.

Records generated by the HACCP plan, especially CCP monitoring records, corrective action records and those relating to the supporting programmes should be reviewed on a regular basis. In the case of a vessel, this record review may be performed by someone onshore at the end of each voyage.

The record review should check that:

a. The required checks have been taken and records kept.
b. The measurements comply with the standard or limits pertaining to that check.
c. The checks have been taken as frequently as required by the HACCP plan or supporting programme.
d. Appropriate corrective action has been taken in the event of non-compliance.

Once the record review has been completed, the reviewer should initial and date each record reviewed as evidence of the review.

3. Internal audit:

An internal audit is a systematic and independent assessment of a company's food safety practices to ensure the company follows its documented procedures including HACCP and that they are producing safe food.

Internal audits should be carried out by trained company personnel (or a similarly trained external contractor, if the company doesn't have any trained personnel of their own).

An internal audit should be performed at least annually on the following:

a. The HACCP plan(s).
b. Supporting programmes e.g. Personnel Hygiene, Cleaning and Sanitation etc.

The internal audit should involve:

a. A document check where the document in question is checked for accuracy.
b. A reality check where the auditor checks whether the programme has been implemented as documented.
c. A record review to determine whether the records indicate any recurring non-compliances which would necessitate a change in the programme.
d. A check against legislation to determine whether any legislation or standards have changed since the last audit.

An audit report should be written documenting the findings from the audit and identifying any non-compliances and appropriate corrective action. These reports should be kept on file for future reference.

4. Annual HACCP review:

Companies are required to conduct an annual review of their HACCP plans and re-submit them to the CA for approval.

This review should cover:

a. A document check where the HACCP plan is checked for accuracy.
b. A reality check where the auditor checks whether the HACCP plan has been implemented as documented.
c. A record review to determine whether the records indicate any recurring non-compliances which would necessitate a change in the programme.
d. A check against legislation to determine whether any legislation or standards have changed since the last audit.
e. A check of product test results to confirm whether the product produced using the HACCP plan is safe to eat.
f. A check to see if there have been any product recalls and/or customer complaints relating to food safety.

An audit report should be written documenting the findings from the audit and identifying any non-compliances and appropriate corrective action. These reports should be kept on file for future reference.

8.8 Product Recall and Rapid Alert System

Product recall is the procedure carried out in the event product is found to be non-compliant in the market. This non-compliance may result from a discovery the company makes themselves but may also result from a market rejection or customer complaint.

No matter how the need for recall is identified, it is essential a company can act quickly to identify the affected product and recall this product to a place where that product can be assessed and future disposition determined.

A company must have a documented Product Recall programme the covers:

- When product will be recalled
- The people/positions in the Recall team
- The steps to be taken when carrying out a recall
- Communication within and outside the company: who and how
- Recall activity log
- A review of effectiveness of the recall
- Reconciliation of the lot(s) affected
- Product disposition once the product has been recalled
- A review of the effectiveness of the recall

Companies must conduct “dummy” recalls at least annually to check whether the procedure provides adequate control in the event of a recall. In a dummy recall a company should select a lot of product at random (from lots previously dispatched) and use the procedure to determine whether the company can recall that product (in a fictitious manner) in a timely and efficient manner.

9.0 SAMPLING AND TESTING

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

9.1 Organoleptic properties

9.1.1 General

Operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria if there are doubts regarding the organoleptic assessment.

9.1.2 Limits

No unacceptable signs of spoilage according to the criteria of the organoleptic assessment system.

9.1.3 Method

Organoleptic assessment using trained assessors.

9.1.4 Frequency

Every lot, every vessel unload.

9.2 Histamine

9.2.1 General

Operators will carry out their own in-house assessment for histamine at every unload. However in addition to this operators must ensure that they also carry out verification histamine testing on an annual basis. Both testing situations will be covered in this section.

9.2.2 Limits

Operators must ensure that the limits on histamine are not exceeded.
For the EU the following limits must be met:

n = 9
c = 2
m = 100 mg/kg
M = 200 mg/kg

The average of the 9 samples must not exceed 100 mg/kg
Where

'n'= the number of sample units;
'c'= the number of sample units that may exceed the limit 'm', and
'M' is the limit which no sample unit may exceed.

9.2.3 Method

In-house testing: ELISA Rapid test kit
Annual verification testing: ISO19343 using an ISO accredited testing laboratory

9.2.4 Frequency

In-house testing: Every lot, every unload where a lot is defined as "each species, each vessel unload."

Annual verification testing: ISO19343 using an ISO accredited testing laboratory

9.3 Total Volatile Nitrogen (TVB-N)

9.3.1 General

TVB-N tests only need to be conducted if a lot fails standard organoleptic testing. Fishery products must not be placed on the market if chemical tests reveal that the limits regarding TVB-N or TMA-N have been exceeded.

9.3.2 Limits

Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:

25 mg of nitrogen/100 g of flesh

9.3.3 Method

Not specified

9.3.4 Frequency

Only to be tested if the organoleptic assessment is unacceptable.

9.4 Parasites

9.4.1 General

Operators placing on the market fishery products intended to be consumed raw must ensure that the raw material or finished product undergo a freezing treatment in order to kill viable parasites that may be a risk to the health of the consumer.

9.4.2 Limits

The freezing treatment must consist of lowering the temperature in all parts of the product to at least:

(a) – 20 °C for not less than 24 hours; or
(b) – 35 °C for not less than 15 hours.

Unless:

(i) there are epidemiological data 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;

When placing on the market, except when supplied to the final consumer, fishery products must be accompanied by a document issued by the operator performing the freezing treatment, stating the type of freezing treatment that the products have undergone.

9.4.3 Method

Food business operators must ensure that fishery products have been visually examined to detect visible parasites before being placed on the market.

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

9.4.4 Frequency

Every lot every unload and done at the same time as the organoleptic assessment.

9.5 Toxins

9.5.1 General

Fishery product containing toxins from poisonous fish or biotoxins must not be placed on the market.

9.5.2 Limits

1. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.
2. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market.

3. Oilfish and escolar may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects.

9.5.3 Limits Method

Visual check

9.5.4 Frequency

Every fish to be checked for species and action taken according to the limits above.

10.0 CERTIFICATION

10.1 Requirements of Operators

An operator intending to produce fish or fish product for export and needing official CA assurances (certification) shall give at least 48 hours warning to the CA OF their need for certification so that any necessary verification can be performed and export is not delayed unnecessarily. A request for certification can be made by an exporter by completing the Health Certificate Export Information form given in Appendix Three of the Industry Standards.

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.

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.

10.2 Export Health Certificates

Export health certificates must be issued for every export of seafood from FSM by the authorised verification officers of the CA.

The CA will issue up to six different types of certificates depending on the source of the product:

1) An EU Health Certificate
2) A non-EU General Health Certificate
3) A Hygienic Handling Certificate
4) A Fishmeal/oil health certificate
5) A Chinese health certificate for fish and fishery products
6) Non-commercial consignment certificate

Examples of each of these certificates are given in Appendix Three of the Industry Standards.

10.3 EU Health Certificate

EU Health certificates will only be issued for product processed in establishments that are listed on the EU Approved Establishment list.

A single, original, fully completed EU Health certificate must accompany each shipment. A copy of the EU Health Certificate is given in Appendix 3 Part 5. The legal background and example certificate is given in the EU Commission Implementing Regulation 2020/2235.

The certificate provides the official guarantees from the CA to the EU regarding the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EC) No 2017/625 and Commission Implementing Regulation 2019/628 and certify that the fishery products described were produced in accordance with those requirements, and in particular that they:

- Have been obtained in the region(s) or countries which, at the date of issue of this certificate is/are authorised for entry into the Union of fishery products and listed by the Commission in accordance with Article 127(2) of Regulation (EU) 2017/625;
- Come from (an) establishment(s) applying general hygiene requirements and implementing a programme based on the HACCP principles in accordance with Article 5 of Regulation (EC) No 852/2004, regularly audited by the CA, and being listed as an EU approved establishment;
- 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;
- Have not been stored in holds, tanks or containers used for other purposes than the production and/or storage of fishery products;
- 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 Regulation (EC) No. 2073/2005;
- 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;
- Have been produced under conditions guaranteeing compliance with the maximum levels for contaminants laid down in Commission Regulation (EC) No. 1881/2006;
- Have satisfactorily undergone the official controls laid down in Articles 67 to 71 of Commission Implementing Regulation (EU) 2019/627.

11.0 IUU

11.1 About IUU

IUU stands for "Illegal, Unreported and Unregulated" catch.

The EU Regulation legislating IUU measures is Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing.

A fishing vessel shall be presumed to be engaged in IUU fishing if it has:

a) *fished without a valid licence, authorisation or permit issued by the flag State or the relevant coastal State; or*
b) *not fulfilled its obligations to record and report catch or catch related data, including data to be transmitted by satellite vessel monitoring system; or*
c) *fished in a closed area, during a closed season, without or after attainment of a quota or beyond a closed depth; or*
d) *engaged in directed fishing for a stock which is subject to a moratorium or for which fishing is prohibited; or*
e) *used prohibited or non-compliant fishing gear; or*
f) *falsified or concealed its markings, identity or registration; or*
g) *concealed, tampered with or disposed of evidence relating to an investigation; or*
h) *obstructed the work of officials in the exercise of their duties in inspecting for compliance with the applicable conservation and management measures; or the work of observers in the exercise of their duties of observing compliance with the applicable Community rules; or*
i) *taken on board, transhipped or landed undersized fish in contravention of the legislation in force; or*
j) *transhipped or participated in joint fishing operations with, supported or re-supplied other fishing vessels identified as having engaged in IUU fishing under this Regulation, in particular those included in the Community IUU vessel list or in the IUU vessel list of a regional fisheries management organisation; or*
k) *carried out fishing activities in the area of a regional fisheries management organisation in a manner inconsistent with or in contravention of the conservation and management measures of that organisation and is flagged to a State not party to that organisation, or not cooperating with that organisation as established by that organisation; or*
l) *no nationality and is therefore a stateless vessel, in accordance with international law.*

11.2 Control of IUU

The EU IUU Regulation applies to all landings and transhipments of EU and third-country fishing vessels in EU ports, and all trade of marine fishery products to and from the EU. It aims to make sure that no illegally caught fisheries products end up on the EU market.
To achieve this, the Regulation requires flag States to certify the origin and legality of the fish, thereby ensuring the full traceability of all marine fishery products traded from and into the EU.

The Regulation requires all exports of fishery products to the EU to be accompanied by a Catch Certificate using the format and details given in Annex II in Council Regulation (EC) No 1005/2008 of 29 September 2008.

11.3 IUU and Sanitary Controls

Therefore, to export to the EU vessel operators need to:

1) Ensure the country of origin is authorised by the EC for export of fishery products to EU.
2) Ensure the fishing vessel on which the product is caught is not involved in IUU activities.
3) Ensure the fishing vessel on which the product is caught is approved by the CA and listed on the CA EU External list and the relevant section of the EC website.

NOTES

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