Government of the People's Republic of Bangladesh
Ministry of Fisheries & Livestock

Edible Aquatic Animal Products Control Guideline

Department of Fisheries
Competent Authority

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This Guideline Comprises

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1. Introduction

This document becomes the compulsory manual to regulate the services and procedures of Competent Authority (CA) for official Controls in respect to the certification, approval, licensing, inspection, audit and ~~monitoring of~~monitoring of production and exports of edible aquatic animal products' operators: farms, vessels and processing establishments and related sub-sector activities of collection and landing ~~centres~~centers, distribution, transport, ice and feed production. It will function as compulsory guidance for Competent Authority Staff and as potential informative guidance of the establishments on how safety controls will be established and implemented.

This protocol is also developed for transparency purposes for transmitting a perception of the integrity and effectiveness of Edible aquatic animal products control operations and activities in Bangladesh, for both local and export markets.

2. Background

The development of this document "Edible Aquatic Animal Products Official Controls Protocol" is directly linked to the importance of Bangladeshi edible aquatic animal products' export to the P.R. China.

In this context it is important that the official guarantees in terms of compliance to Edible aquatic animal products' export requirements should be given by a competent authority, Department of Fisheries, Bangladesh which is officially ~~responsible for~~responsible for the organisation of official control of edible aquatic animals and products thereof. This statement has to be read in terms of the official controls as required in terms of food safety, production standards and others, as specified as per legislation of P. R. of Bangladesh and P.R. of China for Edible Aquatic Animal Products.

All methods, procedures and regulatory instruments to be used for conformity assessment, regulatory verification and official guarantees, are presented in this "Edible Aquatic Animal Products Official Controls Protocol".

3. Structure and Contents

Listing Guidelines

1. Objectives

This chapter has the objective to identify the listing process of edible aquatic animal products business operations.

2. Scope

The chapter establishes the mechanism for official listing to be applied by the Competent Authority and the potential possible scenarios arising in terms of offering of official assurances.

3. General principles

Establishments producing, handling and packaging of edible aquatic animal products must appear on the relevant establishments lists specified in this sub-part and which are maintained by the Bangladesh CA, as appropriate, before those edible aquatic animal products are produced at, or enter, the establishments. The CA will therefore maintain control over the complete production chain allowing the traceability of the products.

CA will notify the operator of the dates of CA's acceptance and importering country's listing.

The listing entitles registration and approval of establishments/ operators.

4. Types of listign

The CA manages two general types of lists as follows which have relation to the requirements for export to the P. R. China.

4.1. Internal **listing**

The operators of this type are listed as per rules and regulations of Bangladesh.

The operators under this type of listing may not export directly to the P. R. China but are part of the destined value chain.

Operators like fishing vessels, processing plants, packing centers will be allowed to export as per rules and regualtions and other operators provides raw materials and services to those establishments exporting edible aquatic animals to P. R. China directly.

The following types of establishments are listed under this category:

4.1.3 Farms

Independent aquaculture producers or part of a company production chain, which are part to the refereed export destined value chain (under DoF controls).

4.1.4 Vessels

Vessels providing to operators that are part of the referred export destined value chain are divided in three groups[1]:

Coastal: Fishing vessels that maintain raw materials in storage for less than 24 hours and preserve catch on Ice.

High seas: Fishing vessels that maintain raw materials on storage for more than 24 hours and preserve catch on Ice, RSW[2], or Brine.

Reefers: Vessels providing the service of storing and transporting frozen materials for vessels, and/or processing establishments, that are part the referred export destined value chain.

4.1.5 Depots, Landing Centres, Auction Centres, Packing Centres, Processing Plants etc.

Establishments where aquaculture edible aquatic animals are landed or collected or sold for further distribution; or dockyard on which product is landed; both destined to the referred export markets.

Packing Centres, processing plants etc. comprehend the collection of edible aquatic animals directly from suppliers and middlemen for export.

4.1.6 Cold storage

Independent establishment or of the company chain of facilities usually a part of packing centres that are part of the referred export destined value chain.

4.1.7 Ice Factories

Independent providers of ice (in any shape or form) to farms, depots, landing centres, auction and packing centres, vessels, and processing establishments, that are part of the referred export destined value chain.

4.1.8 Transport vehicles

Independent providers or part of the company chain of transport for edible aquatic animals products or ice/ or as transportation mean for that are part of the referred export destined value chain.

4.2. External listing

The operators under this type, subject to listing/approved by the General Administration of the Customs of P. R China (GACC), are **allowed to export to China**. In this case, the listing is maintained by the CA with the help of Embassy of Bangladesh in Beijing, China and presented to the GACC regularly for any addition or modification or deletion of the operators.

Operators having valid license under internal listing should apply to the concerned RCA of DoF for inclusion/approval in the list of GACC. DoF, as the Competent Authority, requests GACC for listing through the Embassy of Bangladesh in Beijing, China. As per request of the CA, GACC approves addition, modification or deletion of any operators and publishes in its website. Upon approval by the GACC as information provided through the Embassy of Bangladesh in Beijing, China, CA allows the operators/establishments to export edible aquatic animals and products thereof to China.

Operators like fishing vessels, processing plants, packing centers etc. under this listing are automatically part of the internal listing as well.

5. Mechanism for listing processing establishments

Initial listing procedure comprises the following steps:

a) Submission of application for approval

Edible aquatic animal products establishments operating a registered license or newly established, wishing to be included on the list shall, in the first instance, complete the application form for Producer / Exporter Registration and forward as instructed to the local CA. This is identified as the initial application for approval and will be submitted together with a set of documentation integrating the following:

1. Business Pre-requirements:
    - Tax Identification Number (TIN) registration and Value Added Tax (VAT) registration certificate.
    - Article of Memorandum from the processing establishment.
    - Chamber of Commerce Certificate.
    - Export Registration Certificate (ERC) and Import Registration Certificate (IRC) as required.

2. General description of the company, facilities (construction plants, layout), products and process, number of employees (by section, task, or processing line and shift, production capacity by product or processing line and the storage capacity.

3. The description of operations followed (SOP).

4. The documented prerequisite programmes (SSOP), including water/ice quality program (with test report from the Third party) and also waste water disposal system.

5. The HACCP plan (whenever necessary).

6. GACC refer FAO and WHO guidance for ensuring safety in food business which is not contaminated Corona virus.

7. The system to provide guarantees for the product traceability.

8. The documented and formalized withdrawal and recall procedures.

9. Brand registration certificate if necessary.

After receiving such documents the CA will carry out a desk audit to detect any missing element or requesting for revising or completion of the necessary documentation.

Where the CA is satisfied with the documentation received, a full regulatory visit - **Full Verification Audit-** will take place for approval of the establishment.

b) Full Verification/Evaluation Audit of the factory

Takes place when is in full operation. It includes an in depth full verification / audit of physical settings, operational conditions and control strategies, concerning the entire production process, following the Procedure of Regulatory Verification and specific application of the respective verification / audit forms.

Documentation received previously will be confirmed on-site. Verification / Audit will include checking and evaluation of all pre-requisite programmes, including:

1. The general hygiene requirements and conditions of infrastructure (building and surroundings) and equipment.
2. Water supply and water quality management system, detailing the internal distribution net, treatment if any, quality monitoring plan and related data filing.
3. Ice production or storing, internal distribution and quality monitoring
4. The absence of cross contamination / air currents risks / separation between dirty-clean areas or wet-dry areas (lay-out considerations).
5. Personnel health and hygiene control (including training).
6. Sanitary filtering of personnel arrangements, toilets and dressing facilities.
7. Facilities and equipment cleaning and sanitation plans (methods, chapters, chemicals used and approvals).
8. Raw materials acceptance criteria and controls (freshness, temperature, transport, consignment identification).
9. Cold chain assurance if needed.
10. Toxic materials handling and storing.
11. Protection of product from adulteration.
12. Specifications for other entrants as ingredients, additives or packaging.

13. Waste disposal system.
14. Labelling system and consignments codes, providing effective traceability.
15. Pests control plan. Insects, rodents, and other undesirable presences control.
16. Equipment and facilities preventive maintenance plan.
17. Storage and transport of finished products.

c) Approval will be granted and followed by numbering and listing.

Where the CA is satisfied that the establishments can meet the requirements respectively for production into domestic market, other countries or for export to the China, USA and Canada as per the positive outcomes of the regulatory visit performed by CA against standards laid down by the CA and the relevant specific requirements.

d) List sent to the China (only for China exporters)

The CA will list establishments or send applications to the GACC or as appropriate, once the recommendations have been accepted as complying with the requirements. It is acknowledged that the processing of the applications by the China can take within shortage possible time.

From the date of authorization, establishments can save edible aquatic animal products as being eligible for the China. For establishments exporting directly to the China, no exports can be made to the China until official written notification of gazetting by the China has been received.

No certification can be provided until the written notification of gazetting by the China has been received.

Note: It may take some time for notifications of new establishments to reach ports of entry in individual Member States. The CA accepts no responsibility for product held up as a result of this.

e) Relisting or renewal of approval

Consists of an annual full verification of approved establishments. Following an annual plan, the CA performs a general reassessment / audit of the system.

This should have the same content as a full verification / audit for approval.

Therefore annual renewal of approval will again include all of the previous steps to be taken in an annual basis, as programmed by the CA.

If the operator fails the full verification evaluation a letter will be issued requesting corrective actions within a time frame not exceeding 45 days.

f) Changes to listings (regarding China exports)

Any changes to the details about the listing for edible aquatic animal products establishments (e.g. establishment's name, official number, address) shall be notified to the China. This applies particularly to changes to the establishments name or official number.

Requests for changes to the listing for edible aquatic animal products establishments, identifying the details of the change, shall be notified to the CA in the first instance.

Notification of the changes will be forwarded to Animal and Plant Quarantine Department of the GACC Beijing as soon as verification provides official assurances.

Establishments will be notified in writing when the changes have been gazetted by the Animal and Plant Quarantine Department of the GACC Beijing. Until the establishments have received this written notification the old details shall continue to be used.

g) Delisting of fish establishments (all)

Suspension and reinstatement of certification by the RCA

If the level of compliance in a edible aquatic animal products processing establishment is unacceptable, certification of edible aquatic animal products may be suspended in the first instance until such time as the RCA considers a satisfactory level of compliance has been attained.

Notification of suspension, and reinstatement of certification, shall be given in writing.

If the level on non-compliance is not rectified under an agreed timeframe, the RCA could withdraw the premise from the official listing.

h) Communication of changes

Domestically

Any changes in the listing status or suspensions of either providers of exporter will be communicated to all parties involved under this scheme by an e-mail or fax notification from the CA.

Procedure to update the GACC List

All additions, amendments and deletions from the exporters listing will be forwarded to the GACC for approval.

6. Mechanism for Internal Listing

Initial listing procedure comprises the following steps:

a) Submission of application for approval

Operators operating a registered license or newly established, wishing to be included on the internal list for supply of raw materials and services to those establishments exporting directly for the China shall, in the first instance, complete the application form for China destined Value Chain Supplier / Service and forward as instructed to the local CA or authority delegated for auditing in this purpose by the CA. This is identified as the initial application for approval.

The Operator will receive information on the minimum hygiene requirements to comply with, in order to be accepted and listed as China destined Value Chain Supplier / Service.

b) Full Verification / Evaluation Audit of the Operator

A Full Regulatory visit - **Full Verification / Evaluation Audit** - will take place for approval of the operated. It includes an in depth full verification / audit of physical settings, operational conditions and control strategies, concerning the entire production process, following the Procedure of Regulatory Verification and specific application of the respective verification / audit forms.

c) Approval will be granted and followed by numbering and listing.

The CA will list the operators, as appropriate, once the CA is satisfied that the operator can meet the requirements for supplying or providing services for China export establishments as per the positive outcomes of the regulatory visit performed by CA (**or delegated authority**) against standards laid down by the CA and the relevant requirements.

d) List sent to the China approved export establishments

The CA will send the list of the approved operators to supply or provide services to the GACC approved edible aquatic animal products export establishments.

e) Relisting or renewal of approval

An annual, full verification audit of approval of the operators will be performed by the CA and/or **delegated authority**.

Regulatory Verification

1. Objectives

The objective of this chapter is to identify the different types of regulatory verification and how it is implemented.

2. Scope

Regulatory verification has the purpose to verify compliance of edible aquatic animal products business operations in respect to the regulatory requirements. The system of regulatory verification is a vital part of the obligations of control by part of the CA. It comprises:

- Documentary Verification (Desk Audits);
- Full Evaluation Audits,
- Routine inspections / audits
- Specific inspection activities (ex. Pre-shipment inspections).

The regulatory verification visits can be full, integral audits of all elements under checking for compliance or directed/specific to a particular aspect.

Depending on the type of process involved and whether a establishment, farm or a vessel, specific checklist can be used to focus the attention into the most relevant regulatory requirements. These checklists are presented in Chapter ---. Guidance for the compliance of regulatory criteria are shown in Chapter ---.

The regulatory verification is implemented following modern audit (inspection) procedures. These are presented in detailed in Chapter ---.

3. Types of regulatory verification

Under the Bangladesh context, the following different types of verification are carried out by the verification officers.

3.1. Documentary Check

A first documental verification is undertaken by the **Audit Team** after an establishment submits an initial request for official approval with the purpose of producing and/or exporting edible aquatic animal products.

The verification will comprise of a check on the documents submitted as part of the initial application for approval (as per Chapter ---), and will include:

2. General description of the company, facilities, products and process, packing and if needed storage capacity;
3. The description of operations followed (SOPs) and process parameters;
4. The documented prerequisite programmes (SSOPs), including waste water disposal system;

The HACCP plan (whenever necessary) and respective HACCP mandatory and preparatory requirements fully documented.
Control measures of Covid-19 & food safety guidance for food business operator.
The system to provide guarantees for the product traceability.
The documented and formalized withdrawal and recall procedures.

3.2. Full Verification / Evaluation Audit

Full verification by the Audit Team takes place when the establishment is in operation, including different shifts and activities in between shifts.

It includes an in-depth full verification of physical settings, operational conditions and control strategies, concerning the entire production process.

The verification team should evaluate the application of all pre-requisite programmes, including:

- The general hygiene conditions of building and surroundings.
- Water supply and water quality management system, detailing the internal distribution net, treatment if any, quality monitoring plan and related data filing.
- Ice storage of production (if needed), internal distribution and quality monitoring
- The absence of cross contamination / separation between dirty-clean (wet-dry) areas / air currents risks (lay-out considerations).
- Personnel health and hygiene control (including training).
- Sanitary filtering of personnel arrangements, toilets and dressing facilities.
- Facilities and equipment cleaning and sanitation plans (methods, chapters, chemicals used and approvals).
- Raw materials acceptance criteria and controls (freshness, temperature, transport, consignment identification) .
- Specifications for other entrants as ingredients, additives or packaging
- Waste disposal system.
- Labelling system and edible aquatic animal products codes, providing effective traceability.
- Pests control plan. Insects, rodents and other undesirable presences control.
- Equipment and facilities preventive maintenance plan.

3.3. Full Verification / Evaluation Audit for Approval / Renewal

The approval and renewal of operators (establishments) requires an annual full verification, following the conditions specified in Chapter 1.

Following an annual plan, the CA performs a general reassessment of the system, undertaking full verification audit for approval of establishments.

The date of the annual Verification audit for approval and renewal is set out with the company.

3.4. Routine verification / inspection

The CA performs a routine general reassessment of the system following a predetermined inspection frequency (set out in Chapter 4) based on the classification obtained from identified non compliances during the Full Verification for Approval and the Establishment Risk Category Classification (Chapter 4).

Routine verification is based on the same content as a full verification. However, it may consist of a full audit or just partial audit. This will be identified in the checklist and report and justified accordingly.

The routine verification / inspection may (or should) be undertaken without notice.

The results obtained after routine verification/ inspection may affect the routine inspection frequency initially defined on the annual approval. These results will be used for automatically updating the establishment grading status and consequently the inspection frequency.

3.5. Follow up verification / inspection

Such visits are specifically prepared for follow up of corrective actions requested during a previous verification / inspection activity.

Follow up verification are used to verify the correction of a previously noted defect / non conformity within an established deadline date.

Verification of the effective correction of defects / non conformities subject of the CAR, will be registered in the respective Follow up of corrective action request form, with the objective to close the CAR (which is kept open until verification of compliance).

3.6. Partial verification / inspection

The verification / inspection will consist on focusing the audit in only one or a group of the elements under assessment of compliance. Therefore the verification will be only object of a partial verification/assessment inspection.

Such visits are often used to follow up on items noted during a previous in depth verification. They can also be used to verify the condition of previously noted observations.

A section of a general checklist can be used for this purpose, or a specific worksheet may be created which is added to the original verification form on which the observations were noted.

Subsequently, the verifier should observe and record deviation or non-conformities as they are found and/or obtain product samples as required.

Partial verification/inspection should be undertaken without notice and may have the objective to assess/check that conditions during normal operations are equivalent to those during formal verification/audit.

3.7. Random Spot checks inspection

Consists of a partial verification and depending on the logistical capacity and utilization of precautionary principles, has the purpose of organizing additional non-programmed verifications. Therefore, it will serve as a parallel verification to check compliance of operators and give feedback on how the system is performing.

It is also a response of the system when a particular change in the risk environment may indicate the need for additional checks:

- at certain periods in
- certain areas types
- of process raw
- materials
- other reasons

Spot check verifications/inspections are always undertaken without notice.

4. Operational procedure for the Verification process

The verifiers/inspectors will observe and record all deficiencies and non conformities or deviations as they are found. Inspection forms / checklists will be used for this purpose.

Clearly identified deviations or non-conformities with the regulatory requirements or the declared procedures involving serious potential food safety problems will be immediately brought to the attention of the establishment management.

Corrective action should be immediately implemented or planned accordingly to the seriousness of the potential problem.

Corrective Action Requests (CAR) will be registered in a specific form (chapter 5.5 – for final report, in the end of the verification activity with a given deadline date for accomplishment of expected corrections.

For ease of use by the verifier, records are assessed and rated at the end of each item during the verification and are later compiled in the final report.

A Verification audit is only considered finished when the CAR are considered to be effectively applied.

5. Pre-shipment inspection (for all exports)

Such visits are specifically prepared for a go-ahead of consignments shipment. The CA, prior to establishments notification request, will inspect specifically the respective consignments file to be shipped (exported), against the required documentation, information and own-checks results.

Pre-shipment controls and testing will be carried out for all importing countries requirements. This may include sampling for testing.

Pre-shipment verification is used to detect and prevent the existence of any abnormality / hazard or lack of traceability and to evaluate the respective risk of any

possible food safety hazard. If this is the case the shipment of the consignment(s) will not be authorized.

6. "Checklists" for regulatory verification

The evaluation of compliance with the market access requirements will be established based on the outcomes in the use of "checklists".

These checklists have been designed based on relevant national, international and importing countries hygiene requirements and inspection guidelines.

The verification/audit and inspection checklists adopted by the CA are identified as follows:

- AP | Application Form for approval (Exporter registration and listing)
- F00 | Report Cover (to apply in all audit / inspection / verification activities).
- Forms for verification / evaluation of Processing Establishments:
  - F01a | Infra-structure Facilities
  - F01b | Hygiene and Good Manufacturing Practices
  - F02 | Pre-requisite Programs (SSOPs); documental and implementation
  - F03 | HACCP Documentary Verification
  - F04 | HACCP Verification Performance
  - F05 | Covid-19 & Food Safety Guidance Verification
  - F06 | Verification of Ice Plant
  - F07 | Verification of Cool Stores
  - F08 | Verification of off-shore vessels
  - F09 | Verification of coastal vessels
  - F10 | Verification of landing sites
  - F11 | Verification of Transports
  - F12 | Verification of Traceability
  - F13 | Corrective Actions Request
  - F14 | Follow up / closing of Corrective Actions
  - F15 | Organoleptic evaluation
  - F16 | Verification of Artisanal Farms and Aquaculture Systems
  - F17 | Verification of Hatcheries
  - F18 | Verification of Feed Mills

The checklists (forms) adopted by the CA are in general applied as follows:

- Desk audit: F00; F02 and F03.
- Approval / renewal of processing establishments: F00; F01a; F01b; F02; F03; F04; F11; may also include F05, F06, F07 F17.
- Routine inspection of processing establishments: F00; F01a; F01b; F02; F04; F12; F13; F14; may also include F05, F06, F07, F11.
- All the other checklists are quite specific to determined industry activities / suppliers of services to the processing establishments or verification / inspection procedures and therefore applied as specified in the title.

7. The result system

The basis of the evaluation system responds to two key decision factors applied during the evaluation of conformance using evaluation checklists:

The issue in consideration is clearly distinct in the checklists as per the requirements for compliance. The outcome will be Compliant

The issue in consideration is clearly distinct in the checklists as non-compliant as per the requirements for compliance. The outcome will be determined as a Non Compliance and evaluated as Low, Medium, or High Risk.

This means that the level of non-conformity will be decided on the basis of the severity and likelihood of the potential risk over the fitness for purpose as food, for the raw material or product under direct threat.

8. Evaluation of Compliance / Non-compliance by topic

For each item/issue inspected/verified the results are defined as:

Critical Non Compliance (CrNC)

The non-compliance is clearly unsatisfactory in terms of regulatory conformance and is subjecting the product to an immediate unacceptable level of exposure to any food safety hazard that jeopardizes the fitness for purpose as food.

The existence of 1 CrNC will be sufficient to compromise the approval, renewal or could affect the listing status of an establishment.

Non Compliance (NC) – Medium and Low Risk Levels

The issue under regulatory verification needs improvement and therefore is considered non-compliant. Although there is no immediate food safety compromise of the product.

These non-compliances are classified as medium or low risk potential and shall be corrected before next verification. If the issue under scrutiny is a usual recurrence, it may grant a CrNC result.

Observation (Obs) – registered in Comments section

The issue under regulatory verification is in general compliant, although may integrate defects or some level of deficiency or is considered just as an opportunity for improvement, however not having any impact of exposure of food safety hazard that could jeopardize the fitness for purpose of the product. The number of observations does not affect the overall outcome status of the establishments.

Compliance (C)

The issue under regulatory verification is under full compliance. Also used to note that the item/issue was in fact checked.

9. Establishment Rating

The establishments will be classified in accordance to the outcomes of the regulatory verification, based on the same logic that the evaluation by topic.

Rating and Classification procedure is fully described in Chapter 4.

10. Outcomes for Suppliers

The evaluation and result system for suppliers (farms, depots, transport vehicles, coastal vessels and landing sites) are evaluated similarly as above, although evaluation of compliance by topic is just defined simply as being in compliance or noncompliance (without identifying different levels of non-compliance). The overall outcome is defined in chapter 4.

For each item inspected/verified the compliance results are defined as:

Non Compliance (NC)

The non-compliance is clear in terms of regulatory conformance and is subjecting the product to an immediate unacceptable level of exposure to any food safety hazard that jeopardizes the fitness for purpose as food.

In case of identification of Critical Non Compliances, these will be noted on the comments column.

Compliance (C)

The issue under regulatory verification is under full compliance.

Observation (Obs)

The issue under regulatory verification is in general compliant, although may integrate defects or some level of deficiency or is considered just as an opportunity for improvement, however not having any impact of exposure of food safety hazard that could jeopardize the fitness for purpose of the product.

Based on the same logic that the evaluation by topic, the establishments would be classified in accordance to outcomes of the regulatory verification as per chapter 4:

Establishment Non Compliant

The overall level of non compliances in the establishment in terms of regulatory conformance, infrastructure or practices is exposing the raw materials and/or products to an unacceptable level of risk that jeopardizes the fitness for purpose as food.

Establishment Compliant

The establishment under regulatory verification is under substantial compliance in terms of regulatory conformance, infrastructure or practices.

Establishment Compliance Rating and Determination of Frequency of Verification

1. Objectives

The objective of this Chapter is to identify how to rate and categorize establishments and to determine the frequency of routine verification to be applied.

2. Scope

The chapter describes the process to be applied by the Competent Authority to rate establishments following to the outcomes of the regulatory verification using the respective verification forms / checklists identified in Chapter 3 and shown in Chapter 13. Complementary to that it is described the process to categorize the establishments as well as to determine the frequency of verification of each establishment to be followed in the official controls.

3. Overall Result of Verification

After evaluation of all verification items as per use of the necessary verification form(s) / checklist(s), in correspondence to the evaluation criteria defined in chapter 3, an overall result will be determined.

The calculation of the overall result integrates the total sum of each noncompliance level (LR, MR and CrNC), considering the sub-totals found in each checklist.

Consequently, the final result and grading of the establishment is obtained according to the limits defined for each noncompliance level, as follows:

Establishment Non-Compliant

The level of non-compliances in the establishment in terms of regulatory conformance, infrastructure (facilities) and/or practices (operational management) is exposing the raw materials and/or products to an unacceptable level of risk that jeopardizes the fitness for purpose as food.

The establishment is declared as Non-Compliant, due to a high risk evaluation outcome of the non-compliances, either from **existing critical non-compliances or a series of 8 or more non-compliances of medium risk**, which altogether could become sufficient for an exposure of the product to an unacceptable level of risk that jeopardizes the fitness for purpose as food.

A non-compliant establishment corresponds immediately to a failed establishment for exports to the China.

Establishment Compliant

The establishment under regulatory verification is under substantial compliance in terms of regulatory conformance of infrastructure or practices without existence of any Critical Non-compliance.

However, there are particulars that if not controlled could subject the product to a certain level of unacceptability of exposure to any food safety hazard that could jeopardize the fitness for purpose.

This certain level of unacceptability is defined according to the number of medium and low risk non compliances. If the non-compliance issues are a usual recurrence, it may than also grant a Non Compliance result for the establishment.

4. Categorization of Establishments

Categorization of establishments will be determined according to the risk profile presented by each establishment.

The Risk Profile of the approved establishments is obtained by quantifying 3 factors:

a) Activity & Dimension (risk size)

b) Risk priority regarding production type and process

c) Compliance degree

The Risk Profile is determined according to the following equation:

$$Rp = (S + Rc + C) / 3$$

Rp – Risk Profiler

S – Activity & Dimension (size and process level) risk

Rc – Production type (products associated) risk = Risk Category of Establishment

C – Compliance Degree

5. Frequency of Routine Verification

The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by edible aquatic animal products operators under food safety management programmes.

Routine Inspection Frequency (RIF) is determined using the Risk Profile of Establishments divided by the total number of months set out each year by the RCA.

RIF = Rp /3

Rp = (Size + Risk Category + Compliance) / 3

6. Frequency of inspection for suppliers to China exporters

The frequency of regulatory verification for establishments in compliance will be fixed according to the following scheme:

Operators	Approval grade	Approval Verification frequency	Routine inspection
Packing centres Auction centres Landing centres Depots Transports Ice plants	> 60% compliance 0 Critical NC	annual	1 inspection every each 3 months
Farms Hatcheries Feed	> 50%	> 80% = biannual 50-80% = annual	NRCP visits sampl
% of compliance is defined by the total number of compliant issues/items divided by total number of items checked.			

The RCA may however decide to adopt a stricter frequency, justified on a risk based judgment.

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

Reporting and Corrective Action Requests Protocol

1. Objectives

The objective of this chapter is to identify the reporting protocol and how to proceed for requesting corrective actions to business operators.

2. Scope

This chapter describes how inspectors/ auditors / verifiers of fish and fishery business operations shall report verification activities and how to proceed when a non-compliance is determined and a corrective action is necessary to be requested to the operator.

3. Verification Team Review

When the audit / inspection is finished the team of auditors/inspectors should meet in a private room to discuss the audit/inspection results. A suitable location is necessary to protect the confidentiality of the information.

The team should:

- review each issue according to compliance status and evaluate the risk degree
- identify in writing all deviations that require corrective action
- assign an overall rating
- decide on recommendations
- decide on a date for a follow up visit

4. Results and Reporting

It is important that operators understand the audit/inspection findings and the reason why certain items are unsatisfactory and require correction or improvement. The Team should prepare an Audit/Inspection report for presentation to the operator based on the forms (checklists and corrective action request form) available.

The Report should:
Provide an overall rating and evaluation
Describe the non-compliances found during the onsite audit/inspection.
Distinguish the deficiencies which are considered to be related to the physical settings (facilities), to the hygienic operation and process control, and to the follow up of HACCP plan application (operational management).
be signed and dated by the representative of the Competent Authority, and the manager of the establishment or the captain/owner of the vessel.

A copy of the finalized report form/notifications should be presented to the management of the establishment or captain of the vessel at the final management meeting.

Final Management Meeting

After the establishment verification, the audit/inspection team must meet with the appropriate member(s) of the establishment management team to:

- review the audit/inspection process;
- identify the main findings (positive and negative) present a draft report with results;
- highlight the unsatisfactory conditions;
- discuss and decide on a time period or a date for the correction of unsatisfactory conditions.

5. Corrective Action Required

Corrective Action Request, should always include planning with front-line management so that the problem will not recur. Urgency of corrective actions must always be measured by the degree of existing hazard and risk related to health and safety issues.

The auditor/ inspector should guide the operator in the development of an action plan which identifies each non-compliance and respective risk degree, and describes a corresponding course of action and target correction date.

A specific form will be used for this purpose.

6. Final Report and Covering Letter

As soon as possible, a printed copy of the finalized audit/inspection report, reviewed accordingly by the CA Heads should be forwarded to the company management.

The report must be accompanied by a covering letter. This should indicate:

- Main findings;
- Specific non compliances detected
- Corrective actions required
- Request for a written action plan by a certain date;
- Any formal changes as up-grading or down-grading export status of the establishment;
- Any other kind of sanctions to be applied

The copy of the report and letter should be registered and placed in the company file, along with a copy of any completed audit/inspection forms and other documents presented. The report will be the basis for further verification activities.

7. The Company's Written Action Plan

The written action plan submitted by the company must address all of the non-compliances reported in the inspection report.

An incomplete action plan is not acceptable and should be returned to the company for correction.

If the action plan is not submitted within the appropriate time frame, the CA should contact the company as a reminder.

Non-response may be grounds for the suspension of the products health certification by the Competent Authority. Further action, should be taken if the establishment management is uncooperative.

8. Specific actions in case of Critical Non-Compliance

A critical non-compliance is one which might result in imminent risk to the health of consumers.

In this case the inspector/auditor should refer to standing procedures and national legislation for guidance on emergency measures to be applied.

If potentially contaminated product has been distributed, the Competent Authority and the Company should consider whether withdrawal or recall is necessary.

If a product recall is to be initiated, the inspector/auditor should immediately contact the officer responsible for the rapid alert system in place at national level, with the relevant details.

China Certification Protocol

1. Objectives

To guide the CA Officers in the filling of the Chinese health certificate.

2. Scope

The chapter describes in detail how officers under CA shall fill in each of the sections of the China health certificate.

3. China Health Certificate

China Health certificates will only be issued for edible aquatic animal products processed in establishments that are listed on the General Administration of the Customs of P. R China (GACC) as approved establishment list.

A single, original, fully completed China Health certificate must accompany with each shipment.

The certificate provides the official guarantees from the Bangladesh CA to the China regarding the relevant provisions of Regulations …….. and certify that the edible aquatic animal products described were produced in accordance with those requirements, and in particular that they:

- Come from (an) establishment(s) implementing a food safety management programme in accordance with Regulation ……,
- 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 ……,
- Satisfy the health standards laid down in …… and the criteria laid down in …….. on microbiological & chemical criteria for foodstuffs,
- Have been packaged, stored and transported in compliance with ……,
- Have been marked in accordance with ……..,
- Have satisfactorily undergone the official controls laid down in ……...

4. Obtaining a China Health Certificate

It is the exporters' responsibility to request export certificates accordingly to the filling of a form destined for this purpose (same format as the ~~For~~**for Edible Aquatic Animal Products intended for export from the People's Republic of Bangladesh to the People's Republic of China**). This form will be signed and stamped by the CA after checking of the consignment, to include sensory analysis of sample. The signed and stamped export request, including agreed authorization of FIQC is then delivered to the FIQC Officer responsible for the signing of the export Health Certificate.

Issuing health certificates are subject to following main conditions:

- Only listed exporters may apply for official assurances regarding their products.
- Only export request certificates, produced officially by the FIQC, shall be used.
- Consignments pretended for exporting will be subject to a pre-shipment control of respective documentation, traceability and own-checks register, and sample testing
- The Health Certificate will be issued only after authorization of FIQC certification officers.

The certificate must provide an accurate description of the identity of the approved processor of the goods, the type of edible aquatic animal products being shipped, the quantity of product being shipped, and the final destination of the goods.

The name and number of the establishment where the edible aquatic animal products was packed or processed for export to the China must be recorded on the China Health Certificate. It must be recorded as on the List of Establishments Approved to Export edible aquatic animal products to the China (the China List).

Information published on the China List must match the information about the exporting establishment that is listed on the certificate and the product labels.

Bangladeshi exporters should ensure that their products are accompanied by the proper China documentation prior to being exported from Bangladesh, if transshipped via another country.

Certificates will be signed and stamped in ink that is a different colour than the remaining text on the certificate.

4.1 Preparation of the China Health Certificate

Exporters must ensure that the raised export certificate information is correct prior to it being submitted for issuing by a certifying officer.

The certificate will be completed in English & Chinese language for the country where the shipment will be subject to import controls. (Port of first entry).

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

General: Complete the certificate in capitals. To positively indicate any option, please tick or insert an X.

Where mentioned, the ISO codes use the two-letter country code in compliance with the international standard ISO 3166 alpha-2.

Completing the Health Certificate:

The Health Certificate comprises the following sections/boxes which should be completed as follows:

I. Information of competent authority	
Country of export :	
Country of Production:	
Competent authority:	
Department of certificate issuance:	
II. Identification of the fishery products	
Commodity name:	
Scientific name:	
Number of packages:	
Net Weight:	
III. Origin of the fishery products	
Production Place:	
Processing Type[1]:	
Production Mode:	
Aquacultured: Yes ☐ No ☐	Wild Caught: Yes ☐ No ☐
Aquaculture area:	Catch Area:
	Name & Number of Vessel for the catch:
Production and processing enterprise name and registration number:	
Production Date:	
IV. Information of Transport	
Name & address of Consignor:	
Name & address of Consignee:	

Place of dispatch production:	
Place of destination:	
Means of transport:	
Name of Vessel:	
Flight Number:	
Other transport means:	
Container Number:	
Seal Number:	
V. Health Attestaion	
This is to certify that - 1. The above fishery products were from the establishment approved by competent authority. 2. The products were produced, packed, stored and transported under sanitary condition which were under the supervision of competent authority. 3. The products & water, ice were inspected and quarantined by competent authority and not found any pathogenic bacteria, harmful subsataces and foreign substances regulated in the P.R.China. 4. The Edible Aquatic Animals were examined clinicaly by CA within 48 hours before export & not found any signs of infectious/contagious disease. 5. The products meet veterinary sanitary requirements and fit for human consumption.	
Done at place	Done at dates
Official Stamp	Official Veterinary Signature
Note:1. Refrigerated, Frozen, Dried, Smoked, Canned. 2. If any of the information required is not applicable, then the blank area must be filled with***.	

4.2 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.

5. Issue of export certificates

A certifying officer must not issue an export certificate unless:

a. The certificate is covered by the appropriate supporting documentation provided for in this Programme, and/or
b. Has current ~~first hand~~firsthand knowledge of the on-site operation to state that the information used in the export certificate set is complete and accurate.

The certifying officers issuing the export certificate must additionally check the contributing premises compliance status, product restrictions and other relevant information on the compliance database prior to issuing the export certificate.

An export certificate must not be issued by a certifying officer if the information provided by the exporter is known, to be incomplete, inaccurate, or otherwise, not in accordance with any requirement of the applicable legislation.

A certifying officer must not issue an export certificate that has been altered or modified in any way other than in accordance with an overseas market access requirement.

5.1 Multiple certification not permitted

Certifying officers may issue only one export certificate set per consignment.

5.2 Requirements for export certificates

Every export certificate must have:

- the certifying officer's name shown legibly below the signature.
- the certifying officer's signatory seal.
- the date of signature.

Only one original export certificate may be issued by a certifying officer as a single certificate.

Where declarations are entered on the reverse side of an export certificate, they must have the certifying officer's name and qualifications. It must also be signed, sealed and dated in the same manner as declarations entered on the front of the certificate.

Certifying officers must keep file copies of all paper export certificates they sign for 2 years.

The file copies must be exact replicas of the original completed certificate.

5.3 Numbering of export certificates

Certifying officers must ensure all export certificates are issued with a unique shoulder numbering sequence.

5.4 Date stamping of export certificates

Certifying officers, issuing export certificates, must enter the actual date the export certificate is issued in the designated box clearly.

6. Certification of Imported Products

China Health certificates for Edible Aquatic Animal Products exported from Bangladesh to the China and which are derived wholly or partly from raw materials products must:

- Have originated from a third country eligible to export the animal product to the China.

7. Certification Integrity standards

11.1 Conditions for certifying officers

Certifying officers delegated by the Competent Authority.

a. Have a status which ensures their impartiality and have no direct commercial interest in the products being certified or in the holdings or establishments in which they originate.
b. Are fully aware of the significance of the contents of each certificate which they sign.
c. Will keep strictly confidential the information obtained from a company

8. Recruitment and training of staff

The Competent Authority will appoint an adequate number of staff as may be necessary for the purpose of carrying out verification of establishments/ certification and will provide all necessary facilities for training.

9. Language considerations

Certificates should be bi-lingual, in English and in the official languages of the first port of entry into the China.

10. Traceability of certificates

The National Competent Authority would be able to link certificates with the relevant certifying officer and ensure that a copy of all certificates issued is retained.

11. Certifying Auditing

An external auditor or his/her representative would audit on an annual basis the competence and functions of certifying officers.
Without prejudice to any legal proceedings or penalties, the report of the audit would be furnished to the management for appropriate measures to penalize any instances of false or misleading certification which are brought to their attention.

12. Sanctions

If it is found in the course of the checks that:

- A certifying officer has knowingly issued a fraudulent certificate.
- An individual or other has made fraudulent use of their position or has altered an official certificate.

The CA management shall take all necessary measures to ensure, as far as is possible, that the individual or other cannot repeat the offence.
Such measures may include a refusal subsequently for the authorized nor certifying officer to sign an official certificate.

Sampling, sample collection, microbiological and chemical criteria

1. Objectives

The objective of this chapter is to identify the established procedure for sampling and sample collection for Edible Aquatic Animal Products.

2. Scope

This chapter describes how inspectors/ auditors / verifiers of fish and fishery business operators shall proceed for sampling and sample collection for edible aquatic animal products.

3. Inspection focus and sample size

The inspection will focus on the external quality of processed Edible Aquatic Animal Products, labelling and net weight inspection.

Samples are to be collected through random selection, for the purpose of examination (according to approved check list) of the external quality, labelling, net weight and other harmless qualities, using an acceptable quality level.

4. Sample collection process

The process of collection of samples for the purpose of microbiological testing in Edible Aquatic Animal Products.

While collecting samples for microbiological testing in edible aquatic animal products, utmost importance shall be given for correct reflection of the condition of bacteria and for that purpose sterile container and sterile poly bag shall be used for the purpose of collecting an aseptic sample. The collected sample shall be kept under safe condition so that it is not contaminated from outside.

In addition, the samples shall be stored in such a protected manner that the primary bacteria load present inside do not die or increase in number, the collected frozen samples shall be kept under temperature between -18ºC and -25ºC. The sample, which is not frozen, shall be kept inside refrigerator and up to the time of examination of the sample at 0º to 5ºC but not more than 36 hours.

Steps of sample collection are as follows:

4.1 Sample Container

For the purpose of collection of sample, a clean, dry, sterile and impervious container such as glass, plastic jar or bottle with large mouth, stainless steel pot or plastic bag whose shape may be sufficient to hold up to 200 g sample shall be used. The glass container shall have opening with screw cap.

4.2 Sampling devices and equipment

1. For the purpose of collecting of sample, sterile probe, drill, spoon, scope, stirrer, pipette, swab plate, knife, forcep, hammer, etc;
2. Scissor, knife, can opener for the purpose of opening carton;
3. Label or marker;
4. Insulated box or refrigerator to keep samples between 0º to - 5ºC;
5. Insulated container for transportation of frozen and chilled samples; and
6. Sterilizing equipment (small autoclave, oven) and sterilizing agent (70% alcohol).

4.3 Number of samples

For any consignment the number of samples is defined regarding to the type of testing to be performed. For microbiological testing will be applied table 2. For chemical testing applies section 7 and for water and ice applies section 5.

4.4 Quantity of the sample

Each sample may have minimum 200 g approximately.

4.5 Procedure for the collection of samples

The procedure for collection of sample of a fixed group of commodity is somewhat different. The general issues are mentioned here:

1. Wherever possible without opening the container (inner packet), intact container (inner packet) is to be procured;

2. When the container or carton is of big size, in that case through using sterile equipment, sample is to be collected and kept inside the container or poly bag by breaking in aseptic condition. In such case about 70% alcohol is to be used for washing or sponging the outer surface for the case of paper carton. The outer portion is to be separated through cutting the surface of the carton. Thereafter, with the help of sterile cutting equipment, the mouth of the container or poly bag shall be cut; and

   If the commodity inside the container is large and if it is not possible to mix the sample well, then samples shall be drawn from different portions.

4.6 Labelling

1. At the time of collecting of sample, if it is not possible to do so instantaneously, then marking and tags shall be attached; and

2. If refrigeration is required, that shall be mentioned on the label.

4.7 Transport of sample

1. The collected sample shall be sent to the laboratory as quick as possible;
2. Non-perishable and non-frozen substances shall be chilled between 0ºC to 5ºC, and shall be kept inside an insulated container with sufficient ice at temperature between 0ºC to 5ºC and until the substance reaches the laboratory, the same temperature shall be maintained. The sample can be chilled in refrigerator or by keeping in ice room to quickly lower the temperature and the product shall be transported in such a manner that water from the ice can flow outside;
3. Frozen samples may be kept in frozen condition until examination. Non-frozen samples soon after collection shall be kept inside the freeze and after the temperature comes down to 0ºC, the cargo shall be carried to the laboratory through insulated container; and
4. The sampling report shall be preserved and it shall be sent along with the sample.

4.8 Sampling report

The sampling report contains the following information:

a. The name of the sample collector and his designation;
b. The time, place and date of collection of samples;
c. The purpose or reason of sampling;
d. The nature of the commodity, characteristics and the name of importer/ exporter, etc;
e. The number of consignment, mark, number of inner packets and quality;
f. The name of the place or factory from where sample has been collected;
g. The process of sampling;
h. Number of sample and quantity;
i. The temperature of the product at the time of sampling;
j. Description in respect of what parameters are to be examined; and
k. Other necessary information.

5. Sample collection process for water and ice

Steps for the collection of samples of water and ice

5.1 The bottle or flask in which water is to be collected shall be of the size of 1(one) litter with autoclave worthy screw cap mouth and the bottles shall be sterilized at 180°C temperature. Opening and cleaning of the bottle shall be performed very carefully so that no sort of contamination occurs.

5.2 At the time of collecting of samples of water, the mouth of the tap shall be burnt well with spirit lamp and after the outflow of water from the tap up to 5(five) minutes, the water flowing through the tap shall be collected. If the activity relating to testing of the sample cannot be started within three hours, then the water bottle shall be kept in ice or at chilled temperature.

5.3 If chlorine is mixed with the sample of water (even in small quantity), it shall be neutralized. Solution prepared with one crystal of sodium thiosulphate or solution of 0.1 ml 2% thiosulphate shall be pushed inside the bottle to neuatralize the interior. Prior to examination of the sample of water, the water bottle shall be held upside down and jerked several times.

5.4 About one kilogram aseptical ice used in fish processing work is to be collected in a stainless steel/glass container. If testing cannot be started within a period of three hours then the bottle containing the sample shall be kept in ice. The water of melted ice shall be examined and in this respect, the ways of testing the water shall be followed.

6. Microbiological sampling plan and criteria

For the purpose of routine testing, five samples or the number of samples shall be collected through random sampling from each consignment.

Sample quantity:

1. Large fish; 200 g
2. IQF; one fish and in the case of small fish two or more fishes
3. Iced fillets; one whole fillet shall be collected as sample.
4. Large fish; representative portion shall be collected through cutting (e.g. three pieces from different parts of the fish).
5. Specimens of shrimp, lobster tail, cuttle fish and crab

7. Sample collection for the purpose of chemical testing

7.1 Chemical substance

From every consignment through random sampling, composite samples weighing about 1 (one) kg shall be collected from 12 (twelve) master cartons/boxs.

7.2 Food additives and proximate analysis

From each consignment 5 (five) samples each weighing 200 g shall be collected through random sampling.

7.3 Drugs (VMP) residues

From each consignment about 1 (one) kg composite sample is to be collected from 12(twelve) master carton through random sampling.

7.4 Chemical contaminants

About 1 (one) kg composite sample is to collected through random sampling from 12(twelve) master cartons.

7.5 Analysis of other chemical elements

For the purpose of other chemical or biochemical tests, 5 (five) samples of 200 g each are to be collected from each consignment.

8. Sample selection

Samples are to be collected through random selection based on product type, consignment number, product grade, palate, position of the palate (number of the row column & number of the perpendicular row).

Auditing and Inspection Procedures Protocol

1. Objectives

The objective of this chapter is to identify the proper procedures when auditing and inspection is carried out.

2. Scope

This chapter describes how inspectors/auditors/verifiers of Edible Aquatic Animal Products business operators shall proceed when carrying out the verification activities to the operators.

3. The Edible Aquatic Animal Products Auditor and Inspector

3.1 Objectives of the Audit / Inspection (Verification)

To ensure conformance with requirements.
To detect and request corrective actions of non-conformances
To determine the effectiveness of business operators controls
To apply a risk based approach
To focus on aiming the assurance of food safety by business operators

3.2 General Role of the Auditor / Inspector

The general role of the auditor / inspector is to assess the food safety conditions of the production, based on the legal requirements, and to take action to prevent damage to consumer health or death when conditions do not meet the required standards.

It should be noted that food can never be 100% safe. It is a biological material. In the case of most fishery products it is caught from a wild environment which is not subject to human controls. Sources of supply, processing technology and distribution systems are in a constant state of dynamic flux. Inspection, audit and control is a costly activity, and it is neither possible nor desirable to control everything all of the time.

The task of the inspector / auditor is therefore one of risk management that is, to ensure that the limited resources available are applied in an efficient and effective manner so that the risk of a food safety hazard causing harm to the consumer is minimized.

3.1 Tasks of the Auditor

Edible Aquatic Animal Products Auditors of FIQC tasks are as follows:

Undertake approval and/or regular annual audits for reapproval of establishments, farms, fishing vessels, depots, distribution centres, landing sites and markets, ice plants, chill and cold stores, and means of transport.

Undertake the first documental verification / audit when an establishment submits an initial request for official approval with the purpose of exporting Edible Aquatic Animal Products Includes:

- General description of the company, facilities, products and process.
- The description of operations followed.
- The documented prerequisite programmes.
- The HACCP plan (whenever necessary).
- Covid-19 & food safety guidance verification

The system to provide guarantees for the product traceability and withdrawal and recall procedures.
To prepare and submit reports to the Director regarding the approval or non-approval of sanitary conditions within the different entities controlled.
Monitor and control the implementation of the recommendations made as a result of the regular audits and routine inspection, including verifying that corrective measures demanded are realised in an efficient and effective manner.
Ensure the appropriate certification of edible aquatic animal products through the use of the different verification inspection / audit forms, checklists and health certification processes, and ensure the withdrawal or condemnation of non-compliant products.
Participate in the development of inspection / audit methods and the training of operators in the production chain.
Undertake the collection and synthesis of statistical data at each inspection point.

3.2 Tasks of the Inspector

Inspectors tasks are as follows:

a. Undertake regular routine and on-the-spot inspection of establishments, farms, fishing vessels, distribution centres, depots, landing sites, ice plants, chill and cold stores, and means of transport.
b. Undertake pre-shipment controls of consignment documentation, traceability records and respective own-checks controls and sample testing as demanded.
c. To prepare and submit reports to the Director regarding the status of sanitary conditions within the different entities controlled in accordance with the outcome result system applied through the regulatory verification procedure.
d. Monitor and control the implementation of the recommendations made as a result of the regular routine system, including verifying that corrective measures demanded are realized in an efficient and effective manner.
e. Ensure the appropriate certification of fishery products through the use of the different inspection forms and health certification processes, and ensure the withdrawal or condemnation of non-compliant products.
f. Participate in the development of inspection methods and the training of operators in the production chain.
g. To take samples and deliver them for analysis at an approved laboratory, to receive and interpret results and act accordingly.

h. Undertake the collection and synthesis of statistical data at each inspection point.

3.3 Duties of the Inspector / Auditor

Always remember that the inspector / auditor is an official representative of the Competent Authority and must exhibit a professional image when dealing with establishment officials. This includes:

a. respect for establishment policies when undertaking inspection / audits
b. maintaining a professional bearing
c. keeping strictly confidential information obtained from a company
d. maintaining a good level of personal cleanliness and tidiness
e. guarding against corrupt practices and conflicts of interest

4. Auditing / Inspection performance

A series of steps should be observed to perform a successful verification (inspection / audit), and communication of results, covering:

4.1 Preparation of the inspection / audit

The preparation of the inspection / audit should cover at least the following aspects:

1. Nomination of inspector / auditor or inspection / audit team
2. Definition of the objective
3. Familiarization
4. with the establishment's file, including description of company, the premises / vessel, the process, the product specifications, markets of destination. The outcomes of last verification activities. This documentation should be reviewed before the inspection / audit
5. Preparation of necessary checklists for verification of essential aspects
6. Arrangements for transport of inspection / audit team and transfer of any samples to testing laboratory
7. Arrange equipment material (such as thermometers, rapid tests, clip boards, worksheet, flash light, cameras, sampling equipment etc) and check that it is working
8. Confirmation with establishment (except for spot check inspection / audits or routine inspection)
9. Inform the laboratory to be ready to receive samples

4.1.1 Types of inspection / audit

The inspection / audits can be directed/specific to the verification of a particular aspect, or they can be general in character. The inspector/ auditor should always ensure that there is a clear objective for each inspection / audit exercise, and this is communicated to the team and to the establishment representative.

a) Full Verification

Full verification are taken as part of a formal approval, annual reapproval or regular assessment. They should take place when the factory/vessel/ establishment is in operation. Such an inspection / audit would include an in depth full verification of physical settings (facilities), operational conditions and control strategies (operational

management), concerning the entire production process. The team should evaluate the application of all generic good manufacturing practices and specific manufacturing and hygiene control criteria.

b) Interim Verification

Interim Verification may be planned for routine inspection activities. Their frequency and depth could be determined by:

application of a risk management strategy (risk categorization)

a change in the risk environment (e.g. type of process, raw material or other reasons) follow-up on items noted during a previous inspection / audit (correction of defects)

part of a general campaign by the Competent Authority to address specific aspects of food safety (for example, water safety controls, appropriate hand washing practices or appropriate use of cleaning chemicals).

Should be undertaken without prior notice to the establishment. At the establishment, entrance should granted immediately.

c) Spot check inspection

Spot check inspection are always undertaken without notice with entrance being immediately granted. They may not have a specific theme or rationale, but are intended to:

Check that conditions during normal operations are equivalent to those during formal inspection / audits

Ensure that there are no obvious contraventions occurring

4.1.2 Forms and Recording

The inspector / auditor should select from those available, the correct verification (inspection / audit) forms required for the type of verification and production activity concerned.

Model forms for different types of verification are defined, as follows:

- **AF** - **Application Form for approval** (Exporter registration and listing)
- **F00** - **Report Cover** (to apply in all audit / inspection / verification activities).
- **Forms for verification / evaluation of Processing Establishments:**
  - **F01a** **Infra-structure Facilities**
  - **F01b** - **Hygiene and Good Manufacturing Practices**
  - **F02** - **Pre-requisite Programs (SSOPs); documental and implementation**
  - **F03** - **HACCP Documentary Verification**
  - **F04** - **HACCP Verification Performance**
  - **F05** - **Covid-19 & Food Safety Guidance Verification**
  - **F06** - **Verification of Ice Plant**
  - **F07** - **Verification of Cool Stores**

- **F08 - Verification of off-shore vessels**
- **F09 - Verification of coastal vessels**
- **F10 - Verification of landing sites**
- **F11 - Verification of Transports**
- **F12 - Verification of Traceability**
- **F13 - Corrective Actions Request**
- **F14 - Follow up / closing of Corrective Actions**
- **F15 - Organoleptic evaluation**
- **F16 - Verification of Artisanal Farms and Aquaculture Systems**
- **F17 - Verification of Hatcheries**
- **F18 - Verification of Feed Mills**

4.2 Executing the inspection / audit

4.2.1 Arrival at Establishment

Prior to announcing their arrival at the establishment, it is recommended that the inspection / audit team verifies that they are ready for the job and well equipped.

The team leader, demonstrating courtesy and professionalism, should:

1. Ask for the establishment manager or person in charge
2. Present identification card or business card and introduce the team members
3. Explain what the team will do and agree on an inspection / audit time frame
4. Inform management that the results will be discussed once the inspection / audit has been completed and arrange for a tentative time to meet and discuss the results
5. Invite an establishment representative to accompany the inspection / audit team, preferably the Quality Assurance Manager.

The inspection / audit team must determine what the establishment working chapter will be during the course of inspection / audit (i.e. shift-work, hours of work, etc.).

To facilitate the best order of inspection / audit, the inspection / audit team and establishment management should formulate an inspection / audit chapter. All effort must be made to assess the items in an operational or working condition.

4.2.4 General Inspection / audit Considerations

The inspection / audit should be conducted as far as possible taking into account the following rules:

a. All team members should write up their own worksheet and findings and compare them after the inspection / audit.
b. Ask establishment management questions rather than the workers. An exception may be when you might want to determine if a worker understands what he/she is doing or what procedures he/she has been directed to follow during regular production or when there is a problem or deviation.
c. Do not make observations or give instructions to any staff other than the nominated representatives.
d. Set a good example to workers (e.g. when a wash basin is present in the inspection / audit area, wash your hands).

e. The inspection / audit team must observe a major clean-up before start-up (pre-operation) or after shut-down (post-operation).
f. If more than one shift is operating plan inspection / audit so that each shift is observed (even if necessary to go in different days).
g. If more than one shift is operating try to observe the changeover conditions between shifts. Changing shifts is usually object of application of different standard conditions, where non compliances can easily happen. Inspectors / Auditors should monitor the changeover routine between as many shifts as possible.
h. In the storage, mixing and blending areas, take note of all ingredients, additives, and processing aids, so that they can be verified for compliance with existing regulations.

i. In the labelling area(s), obtain a sample label of the product currently being processed and packed. Review the required label declarations while in the establishment. Attach the label to a worksheet so it can be reviewed more closely back at the office.
j. Remember to check special areas including: storage of cleaning chemicals, storage of pesticides, storage of ingredients, toilets and locker rooms.
k. During or after an in-depth or directed inspection / audit, samples may be obtained. Always notify establishment management of exactly what samples are required and the purpose of sampling. Draw the samples randomly, and according to the sampling plans. Wherever possible, the types of checks or analysis carried out on those samples should be a reflection of the infractions observed in the establishment.

4.3 Outcomes, reporting and follow up

4.3.1 Inspection / audit Team Review

When the inspection / audit are finished the team should meet in a private room to discuss the inspection / audit results. A suitable location is necessary to protect the confidentiality of the information.

The inspection / audit team should:

a. review each deficiency using a risk based assessment
b. identify in writing all deviations that require corrective action
c. assign an overall rating
d. decide on recommendations
e. decide on a date for a follow up visit

4.3.2 Results and Reporting

It is important that operators understand the inspection / audit findings and the reason why certain items are unsatisfactory and require correction or improvement. The Team should prepare an Inspection / audit report for presentation to the operator.

The Inspection / audit Report should:

a. Provide an overall rating resulting from the inspection / audit according to rating criteria and classification.
b. Describe the deficiencies found during the on site inspection / audit.

c. Distinguish the deficiencies which are considered to be related to the physical settings (facilities), to the hygienic operation and process control, and to the follow up of HACCP plan application (operational management).
d. Be signed and dated by the representative of the Competent Authority, and the manager of the establishment or the captain of the vessel.

A copy of the finalised report form/notifications should be presented to the management of the establishment or captain of the vessel at the final management meeting.

4.3.3 Final Management Meeting / Corrective Actions

After the inspection / audit, the team must meet with the appropriate member(s) of the establishment management to:

a. review the inspection / audit process
b. identify the main findings (positive and negative)
c. present a draft report with results
d. highlight the unsatisfactory conditions
e. discuss and decide on a time period or a date for the correction of unsatisfactory conditions; However a final decision on the timeframe will be subject to analysis of the Heads / Director of the CA.

Corrective action should always include planning with front-line management so that the problem will not recur. Urgency of corrective actions must always be measured by the degree of existing hazard related to health and safety issues.

The inspector/auditor should guide the operator in the development of an action plan which identifies each Critical and Medium / Low Risk Non-Compliances, and describes a corresponding course of action and target correction date.

4.3.4 Final Report and Covering Letter

A printed copy of the finalised inspection / audit report should be forwarded to the management as soon as possible.

The report must be accompanied by a covering letter. This should contain the following contents:

a. Main findings
b. Specific non compliances noted
c. Corrective actions required
d. Request for a written action plan by a certain date.
e. Any formal changes as up-grading or down-grading export status of the establishment
f. Any other kind of sanctions to be applied

The copy of the report and letter should be registered and placed in the company file, along with a copy of any completed inspection / audit forms and other documents presented. The report will be the basis for further verification activities.

The generic format for audit / inspection report for Full and Partial Verification (Audit /Inspection) activities should contain the following data and be structured as follows:

1. Establishment registration number and name
2. Date of audit/inspection

3. Scope
4. Auditor/inspectors
5. Establishment representatives
6. Reference document used
7. Audit findings
8. CARs reports attached
9. Conclusion

4.3.5 The Company's Written Action Plan

The written action plan submitted by the company must address all of the non-compliances reported in the inspection / audit report i.e. long term and short term.

An incomplete action plan is not acceptable and should be returned to the company for correction.

If the action plan is not submitted within the appropriate time frame, the CA inspector/ auditor should contact the company as a reminder.

Non-response may be grounds for the suspension of the products certification by the Competent Authority. Further action, should be taken if the establishment management is uncooperative.

4.3.6 Specific actions in case of Critical Non-Compliance

A critical non-compliance is one which might result in imminent risk to the health of consumers.

In this case the inspector / auditor should refer to standing procedures and national legislation for guidance on emergency measures to be applied.

If potentially contaminated product has been distributed, the Competent Authority and the Company should consider whether withdrawal or recall is necessary.

If a product recall is to be initiated, the inspector should immediately contact the officer responsible for the rapid alert system in place at national level, with the relevant details.

5. Inspection / audit of the Food Safety Management system

The inspection / audit should assess the Food Safety Management system plan development procedures, and evaluate how the plan is documented and implemented.
The inspection / audit should verify each of the steps required for the development of the HACCP plan, as set out. All should be documented and verified.

6. Covid-19 & food safety guidance verification

1. Food workers awareness of Covid-19 symptoms,
2. preventing the spread of Covid -19 in the work environment,
3. good stuff hygiene practice,
4. use of disposable gloves,
5. Physical distancing in the work environment

6. managing stuff sleekness in food premises
7. transport & delivery of ingredients and food products
8. regulating & placing signs at entry points for unwell or have Covid -19 symptoms for retail food premises
9. special monitoring on open food display in retail premises, stuff canteens to ensure the maintaining and hygiene situation, condition of the premises

6. Traceability inspection / audit

The inspector/ auditor should verify the efficiency of a traceability system adopted by a company. To make it possible, the system should be clearly documented and followed. The following, represent the key points to be observed.

Key points to be observe:

1. Name of supplier
2. Date and time of receipt
3. Divisions/additions to batch
4. Name of consignee
5. Date and time of despatch

7. Acting of the Inspector / Auditor

The Auditor / Inspector characteristics of effectiveness are defined according to their capacity for:

1. Observing (Seeing),
2. Hearing,
3. Communicating

7.1 Gathering information

The work of the auditor / inspector is based on the gathering of information. To this respect the auditor / inspector needs to know how to deal with people during an interview:

- Giving his undivided attention
- Keeping questions clear and concise
- Listening to the answers
- Persons questioned must answer for themselves
- Being polite and calm
- Using correct language and pronunciation

7.2 Questioning

The auditor / inspector should understand that the Questioning process is decisive. The following rules should be considered and trained.

1. RULE I: Having a well predefined purpose establishes a basis for sound judgment.

2. RULE II: The WRONG QUESTION won't provide the right answer.

3. RULE III: Avoid certain types of Questions to avoid loss of information or bad information.
4. RULE IV: Frame adequately the Question.
5. RULE V: Auditor / Inspector should be natural in the use of questions.

6. RULE VI: Questioning is complemented decisively by adequate listening (Active Listening).
7. RULE VII: Use of supportive behaviors to convey warmth and interest.
8. RULE VIII: Information received should guard against overgeneralizations.
9. RULE IX: Be objective and defend future position and relationship.

7.3 Objective and friendly approach

In respect to the information provided to, or gather by auditor / inspector, he should:

- Stick to the facts
- Do not interpret findings (should understand in an objective manner)
- Do not provide suggestions
- Finalize with Acknowledgement by the plant

Monitoring and Verification of Official Controls

1. Objective

This chapter has the objective to establish how monitoring and verification shall be applied in complement to the official controls. It also has the objective to describe how sampling shall be applied.

2. Scope

This chapter describes the procedure for monitoring and verification to be carried out by the Competent Authority personnel for the purpose of verifying the performance of the official controls. This chapter also comprises the procedure for undertaking sampling by CA staff.

3. Monitoring and Verification

Monitoring is defined as conducting "a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law .
The Competent Authority is required to have in place procedures to:

- Verify the effectiveness of official controls;
- Ensure that corrective action is taken when needed.

Monitoring is regarded as a sampling and testing exercise, undertaken with a view to assessing the status of the health conditions in relation to compliance with the legislation. It provides a means of checking on the effectiveness of the control systems in place.

Monitoring is intended to provide the CA with a clear understanding of the nature and extent of potential food safety problems, which might arise in the sector for which they are responsible. It is not intended to be an enforcement exercise.

Control and Evaluation within the Competent Authority

1. Objective

This chapter has the objective to establish how to undertake quality control, audit and performance evaluation of and within the official controls.

2. Scope

This chapter establishes the procedure for being developed by the Competent Authority itself of quality control and verification activities, internal audit and performance evaluation of the official controls performed by the CA.

3. Quality Control

The Head of each Regional Competent Authority or delegated Auditor controls the results of the routine inspection activities respecting the following quality control procedures:

a. Quality control of inspection reports in respect to verification of the following:

- All items have been covered;
- Technical coherence has been used when classifying non compliances and requesting corrective actions;
- Adequacy of CAR;
- Agreement on timeframe for CAR;
- Adequacy of writing;
- Analysis of comments given by the companies;

b). Control of the implementation timing of follow up inspections as planned;

c). Control of the fulfillment of the workplan defined for the inspection activities of the operators;

d) Control and verification of registering forms of checklists, certificates and related documents, in particular:

1. Reference number given and date for inspection activity.
2. Register in log book
3. Respective archive
4. Adequacy of references and respective filling cabinet;

e) Evidence of verification done

f). Control over the follow up of the results of the sampling;

g) Control over the timeframe of response to industries requests;

h) Organizing discussion panels with inspectors for refining uniform criteria for evaluation of non compliances and results of inspections.

The Director of FIQC will have a final overall control over the reports produced by the section of Inspection in respect to the inspections developed, in particular giving attention to:

- Technical coherence of classification of non-compliances and corrective actions requested;
- Adequacy of CAR;
- Agreement on timeframe for CAR;
- Adequacy of writing;
- Analysis of comments given by the companies;

4. Audit of the CA

Internal audit of the audit and inspection activities should be implemented to each Regional Competent Authority by the Central Competent Authority, in particular:

1. Audit during inspection to verify the performance of inspectors,
2. Audit of inspection and audit reports and cross-checks of previous inspections / audit reports and from the observations in loco at the company;
3. Comparison of different reports and different inspectors to evaluate the uniformity of criteria applied amongst the team of inspectors / auditors and amongst different times by the same inspector / auditor.
4. Verification of results of sampling.
5. Verification of organizational activities (archive, log book register, quality control verification, etc)

These verification and audit activities may also be executed by external contracted experts or by interaction programmes between the Regional CAs and CAs of other countries.

Audits should be documented, registered and archived accordingly. Audit reports shall be developed following the same rules established within the auditing procedures defined in particular for CA auditing of establishments.

5. Evaluation and performance indicators

Analysis and evaluation of the CA performance should be undertaken against the development and application of performance indicators to be selected from the following list:

a. Number of Alert notifications per year, product and hazard, with development of a ratio per number of inspections implemented and samples collected.

b. Number of border rejections per year, product and hazard, with development of a ratio per number of inspections implemented and samples collected.

c. Number of non compliances per category, type and risk grade; and non compliances per issue of checklist; resulting from the field audit and inspection activities. Maybe be analyzed against: type, grade of establishment; number of inspections; sample results; number of rejections; production quantities; etc.

d. Number of samples with analytical results non compliant (from monitoring program) in relation with number of inspections with positive or negative evaluation (from internal audit).

e. Number of non compliances per category, type and risk grade (from field audits and inspection) in relation with number of inspections with positive or negative evaluation (from internal audit).

f. Number of non compliances resulting from the control, verification and auditing activities over the inspection service; maybe applied with simple statistical treatment or with application of ratios according to different factors.

g. Total Number of inspections per quantity and value of production.

h. Number of establishments / vessels / other operators, in each rating classification category and historical evolution.

At the end of each year a report should be developed integrating the results obtained from the above indicators, with an evaluation analysis, followed by conclusions and recommendations.

Report and Organizational Protocol

1. Objective

This chapter has the objective to identify the reporting and organizational obligations of the official controls.

2. Scope

The chapter describes the procedure for the CA to report and publish the official controls and activities and results as well as the respective complementary monitoring and verification carried out by the CA. The chapter also describes the organizational system to be applied by the inspection.

3. Organizational System

The Competent Authority will produce an annual operational and action plan for undertaking the necessary activities of the official controls.

Monthly meetings will be held in each Regional Competent Authority for briefing of activities, results and for resuming action plan accordingly to present conditions.

An yearly or bi-annual national meeting will be held to present the annual reports findings, analysis and conclusions, including statistical analytical treatment of the performance data of the official controls performed by each Regional Competent Authority. These meetings will also be used for the purpose to held specific technical meetings for upgrading inspection performance and to harmonize inspection outcomes.

4. Report

The Competent Authority will prepare and publish electronically an annual report of its activities.

This will set out the degree to which the annual plan has been accomplished based on operational & technical.

5. Operational

The report will resume the activities of the CA and set out the conditions encountered. This will include:

a. Results of verifications audits and inspections (plant standard and ratings, number of non-compliances noted)

b. Outcome of non-compliance; actions undertaken and results of those actions, indicating how the food safety condition was affected
c. Numbers and types of certificates issued
d. Rejections, rapid alerts and problems encountered with products reaching export or domestic markets
e. Other information regarding the management of the competent authority (trainings, staff deployed, financial income and budgetary expenditure)
f. Performance indicators and evaluation of the CA
g. Statistical Analysis of data

Findings will be presented followed by conclusions and setup of recommendations for the following years plan. Variances from original assumptions will be explained.

6. Technical

The Microbiology and the Chemical Analysis Laboratory including externally sourced laboratory/ies as part of the monitoring programme will produce the technical component of the report.

This will include:

a. Type of species sampled

b. Numbers of samples
c. Parameters tested
d. Methodologies used
e. Results
f. Recommendations

Approval of official testing laboratories

1. Objective

This chapter has the objective to establish how official testing laboratories are approved for support of official controls.

2. Scope

This chapter establishes the procedure for the Competent Authority to approve official testing laboratories within the official control needs.

3. Approval Conditions

The Competent Authority bases its approval of laboratories carrying out tests, analysis and determinations of edible aquatic animal products, on the laboratory's compliance with the general criteria for testing laboratories laid down in the ISO 17025 standards.

If a laboratory has not yet gained accreditation for any specific parameter, the CA will provide an interim approval based on a verifiable accreditation plan with clearly defined time milestones to be followed.

Maintaining approval is based on maintaining the accreditation required and only approved laboratories doing the chemical and microbiology tests.

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Checklists for regulatory verification

1. Objectives

The objective of this chapter is to provide the different forms / checklists to undertake the regulatory verification.

2. Scope

Provision of checklist templates for the different units of regulatory verification.

3. Checklist

The verification/audit and inspection checklists adopted by the CA are identified as follows and are shown in annex:

- AF - **Application Form for approval** (Exporter registration and listing)
- F00 - **Report Cover** (to apply in all audit / inspection / verification activities).
- **Forms for verification / evaluation of Processing Establishments:**
  - F01a **Infra-structure Facilities**
  - F01b - **Hygiene and Good Manufacturing Practices**
  - F02 - **Pre-requisite Programs (SSOPs); documental and implementation**
  - F03 - **HACCP Documentary Verification**
  - F04 - **HACCP Verification Performance**
  - F05 - **Covid-19 & Food Safety Guidance Verification**
  - F06 - **Verification of Ice Plant**
  - F07 - **Verification of Cool Stores**
  - F08 - **Verification of off-shore vessels**
  - F09 - **Verification of coastal vessels**
  - F10 - **Verification of landing sites**

- ~~F11 - Verification of Transports~~
- ~~F12 - Verification of Traceability~~
- ~~F13 - Corrective Actions Request~~
- ~~F14 - Follow up / closing of Corrective Actions~~
- ~~F15 - Organoleptic evaluation~~
- ~~F16 - Verification of Artisanal Farms and Aquaculture Systems~~
- ~~F17 - Verification of Hatcheries~~
- ~~F18 - Verification of Feed Mills~~

Hygiene requirements for Edible Aquatic Animal products production

1. PART I – OBJECTIVE, INTRODUCTION AND SCOPE

2. Objective

This chapter has the objective to identify and guide on the interpretation of the hygiene requirements regulated for compliance of the industry.

3. Introduction

The present protocol constitutes the compliance manual to be applied by industry and to be followed by auditors and inspectors when performing their duties of auditing and inspection of fish business operators. The application of these requirements is directly related with audit and inspection checklists.

4. Scope

The hygiene requirements are divided in two sets depending on the activity of the operator in terms of production before or after fish processing:

4.1 Primary production (before processing) and associated operations

Includes:

a. Operators undertaking activities identified as primary production like farming, fishing and collection of live fishery products with a view for them being placed on the market.

   Fishing, the handling of fishery products (without changing their nature substantially) on board vessels (except freezer and factory vessels) and their transport to the first establishment (including auction halls) on land. This includes the fishing, handling and transport of fish caught in fresh water (rivers, lakes) and the production, rearing,

growing and harvesting of fish in aquaculture farms and their transport to an establishment.

b. Associated operators – those which undertake the following activities:

I. the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature, including live fishery products, within fish farms on land and from the place of production to establishments;
II. the transport of live animals;
III. any of the following activities, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping;

Hygiene requirements for operators undertaking activities identified as primary production.
are presented in Part I.
Specific requirements as applicable are presented in Part IV.

4.2 Activities after primary production

Operator carrying out any stage of production, processing and distribution of edible aquatic animal products after primary production and those associated operations listed in 2.1.
Hygiene requirements are presented in Parts II and III.
Specific requirements are presented in Part IV

5. PART II - PRIMARY PRODUCTION REQUIREMENTS

GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

I HYGIENE PROVISIONS

1. Primary fish products will be, as far as possible, protected against contamination, having also regard to any processing that primary products will subsequently undergo.

2. FBO will undertake control of hazards in primary production and associated operations, including the necessary measures:
   2.1 to control contamination arising from the air, soil, water, feed, veterinary medicinal products, and the storage, handling and disposal of waste;
   2.2 relating to animal health and welfare that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.

3. FBO rearing, harvesting or producing primary products of animal origin are to take adequate measures, as appropriate:
   3.1 to keep clean and, where necessary after cleaning, to disinfect in an appropriate manner:

3.1.1 any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed;
3.1.2 equipment, containers, crates, vehicles and vessels;

3.2 to ensure the cleanliness of aquaculture animals, as far as possible, during and post-harvest and slaughter;
3.3 to use potable water, or clean water, whenever necessary to prevent contamination;

3.4 to ensure that staff handling fish products are in good health and undergo training on health risks;
3.5 to prevent animals and pests from causing contamination, as far as possible;

3.6 to store and handle waste and hazardous substances so as to prevent contamination;

3.7 to prevent the introduction and spread of contagious diseases transmissible to humans through Edible aquatic animal products;
3.8 to take account of the results of any relevant analyses carried out on samples taken from aquatic animals or other samples that have importance to human health;

3.9 to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation and item instructions.

4. Fish business operators are to take appropriate remedial action when informed of problems identified during official controls.

II RECORD KEEPING

5. Fish business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the business.

6. Fish business operators are to make available to the Competent Authority relevant information contained in these records mentioned in 5, on request.
7. Fish business operators rearing aquatic animals are, in particular, to keep records on:

7.1 the nature and origin of feed fed to the aquatic animals, including batch number if applicable;
7.2 veterinary medicinal products or other treatments administered to the aquatic animals, dates of administration and withdrawal periods;
7.3 the occurrence of diseases that may affect the safety of products;

7.3 the results of any analyses carried out on samples taken from aquatic animals or other samples taken for diagnostic purposes, that have importance for human health;
7.4 any relevant reports on checks carried out on products.

8. Records should be kept within a traceability system.
9. The fish business operators may be assisted with the keeping of records by other persons, such as veterinarians, fisheries and aquaculture specialists/technicians.

PART III – Food Safety Management System

Applies only to FBO carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in section 2.1 (Part I)

Fish business operators (FBOs) shall put in place, implement and maintain a permanent procedure or procedures based on the Food Safety Management System principles and
Fish business operators shall:

1. provide the competent authority with evidence of their compliance with paragraph A) in the manner that the competent authority requires, taking account of the nature and size of the fish business;
2. ensure that any documents describing the procedures developed in accordance with this section are up-to-date at all times;
3. retain any other documents and records for an appropriate period.

PART IV - GENERAL HYGIENE REQUIREMENTS FOR POST-PRIMARY FBO

Applied only for FBOs carrying out post primary production activities.

Section I applies to all fish premises, except transportation
Section II applies to all rooms where fish is prepared, treated or processed
Section III applies to all transportation.
Sections V to XII apply to all stages of production, processing and distribution of fish products

SECTION I

General Requirements for All Fish Products Premises (other than those specified for transportation)

A. Infrastructure of Facilities

1. The layout, design, construction, site and size of fish premises shall permit:

a. minimization of cross-contamination,
b. separation of clean areas from dirty areas,
c. adequate maintenance,
d. cleaning and/or disinfection,
e. avoidance or minimization of air-borne contamination,
f. provision of adequate working space to allow for the hygienic performance of all operations,
g. protection against the accumulation of dirt,
h. avoidance of contact with toxic materials,
i. avoidance of shedding of particles into fish products,
j. avoidance of the formation of condensation or undesirable mould on surfaces,

k. good food hygiene practices,
l. protection against contamination, in particular, from pests;
m. infrastructure in the areas where fish is received, handled, processed and stored includes chill rooms, ice rooms and cold stores, when applicable.
n. provision, where necessary, of suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining fishery products at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.

B. Ventilation

2. There is to be suitable and sufficient means of natural or mechanical ventilation.
3. Mechanical airflow from a contaminated area to a clean area is to be avoided.
4. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

C. Lighting

5. Fish products premises are to have adequate and sufficient natural and/or artificial lighting.
6. Protected to prevent possible contamination of products by broken glass.
7. Easy to clean.
8. Maintained properly.

D. Drainage facilities

9. are to be adequate for the purpose intended.
10. are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.

E. Toilets

11. An adequate number of flush toilets are to be available and connected to an effective drainage system.
12. Toilets are not to open directly into rooms in which fish products is handled.
13. Sanitary conveniences are to have adequate natural or mechanical ventilation.

F. Wash-hand basins

14. Should be:

    a. available in adequate number, according to number of staff,
    b. suitably located,
    c. specifically designated for cleaning hands,
    d. provided with hot and cold running water,
    e. provided with materials for cleaning hands and for hygienic drying.

G. Changing facilities for staff

15. Where necessary, adequate changing facilities for personnel are to be provided.

H. Disinfectants room

16. Cleaning agents and disinfectants are not to be stored in areas where food is handled.

I. Waste storage

17. (See Section V)

J. Hygiene Condition

18. Fish premises are to be kept clean and maintained in good repair and condition.

SECTION II

Specific Requirements for Infrastructure of Facilities in Areas / Rooms where Fish Products are Prepared, Treated or Processed (including rooms contained in means of transport)

A.Design and Layout

1. Are to permit:
   a. good hygiene practices,
   b. protection against contamination between and during operations.

B.Floors

2. Surfaces are to be:
   a. easy to clean and, where necessary, to disinfect,
   b. maintained in a sound condition.
3. Surfaces are required to be:
   c. of impervious, non-absorbent, washable and non-toxic materials.
4. Floors, where appropriate, are to allow adequate surface drainage (constructed with sufficient slope);
5. Constructed with grooved junctions between floor and walls.

C.Walls

6. Surfaces are to be:
   a. easy to clean and, where necessary, to disinfect,
   b. maintained in a sound condition,
   c. Light coloured.
7. Surfaces are required to be:
   a. of impervious, non-absorbent, washable and non-toxic materials.
   b. of a smooth surface up to a height appropriate for the operations;

8. Ceilings and Overhead Fixtures
9. Are to be constructed and finished so as to:
10. prevent the accumulation of dirt,
11. reduce condensation,
12. reduce the growth of undesirable mould
13. reduce the shedding of particles;

E.Windows and other openings

9. Are to be constructed to prevent the accumulation of dirt, (ex. Windowsills made with a slope);
10. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning.
11. Where open windows would result in contamination, windows are to remain closed and fixed during production;

F.Doors

12. 12. Are to be:
    a. easy to clean and, where necessary, to disinfect,
    b. maintained in a sound condition,

c. Well closing.

13. Surfaces are required to be of smooth, non-absorbent and washable materials.
14. Door ribs constructed with a slope.

G.All Surfaces (including surfaces of equipment) in areas where products are handled, in particular those in contact with products

15. Are to be:
    a. easy to clean and, where necessary, to disinfect,
    b. maintained in a sound condition.
16. Surfaces are required to be of smooth, washable corrosion-resistant and non-toxic materials.
17. Structures and joints of smooth construction and tight for easy cleaning.

H.Specific facilities for working utensils

18. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment.
19. These facilities are to:
    a. be constructed of corrosion-resistant materials,
    b. be easy to clean
    c. have an adequate supply of hot and cold water.

I.Specific facilities for products washing

20. Adequate provision is to be made, where necessary, for washing fishery products.
    d. Every sink or other such facility provided for the washing of fishery products is to:
    a. have an adequate supply of hot and/or cold potable water,
    b. be kept clean and, where necessary, disinfected.

SECTION III

Transportation of Edible aquatic animal products

1. Conveyances and/or containers used for transporting fish products are to be:

    a. kept clean and maintained in good repair and condition to protect products from contamination,
    b. designed and constructed, where necessary, to permit adequate cleaning and/or disinfection.
    c. used in a way that fish products are placed and protected into those so as to minimise the risk of contamination.
    d. capable, where necessary, of maintaining fish products at appropriate temperatures and allow those temperatures to be monitored.
2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than fish products, where this may result in contamination.
3. Conveyances and/or containers used for transporting anything in addition to fish products or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.

4. Conveyances and/or containers used for transporting anything other than fish products or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.

SECTION IV

Equipment requirements

1. All articles, fittings and equipment with which fish products comes into contact are to be:

   a. effectively cleaned and, where necessary, disinfected at a frequency sufficient to avoid any risk of contamination;
   b. constructed, be made of such materials and be kept in such good order, repair and condition as to:
   c. minimise any risk of contamination;
   d. enable them to be kept clean and, where necessary, to be disinfected;
   e. installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.
2. Equipment is to be, where necessary, fitted with any appropriate control device to guarantee hygiene objectives.
3. Chemical additives, if used to prevent corrosion of equipment and containers, are to be used in accordance with good practice.

SECTION V

Fish waste

A. Fish products waste, non-edible by-products and other refuse

1. Are:
   a. to be removed as quickly as possible, from areas/rooms where fish products are present, so as to avoid their accumulation.
   b. to be deposited in closable containers, or evacuated using appropriate evacuation systems.
   c. to be eliminated in a hygienic and environmentally friendly way in accordance with national legislation applicable to that effect.
   d. not to constitute a direct or indirect source of contamination.

B. Waste containers

2. Are to be:
   a. kept in sound condition,
   b. easy to clean and to disinfect,
   c. of an appropriate construction.

C. Waste Storage and Disposal

3. Adequate provision is to be made.
4. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and free of animals and pests.

SECTION VI

Water supplies and Ice

A. Water

1. Water supply:
   a. There is to be an adequate supply of potable water, to ensure that fish products are not contaminated through the water;
   b. Clean water may be used with whole fishery products.
   c. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods;
   d. Clean water may also be used for external washing.
   e. When using clean water or clean seawater, adequate facilities are to be available for its supply.
2. Non-potable water use (for example for fire control, steam production, refrigeration and other similar purposes), is:
   a. to circulate in a separate duly identified system.
   b. not to connect with, or allow reflux into, potable water systems.
3. Recycled water used in processing or as an ingredient is:
   a. not to present a risk of contamination.
   b. 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 product in its finished form.

B. Ice

4. Ice which comes into contact with fish products or which may contaminate the products are to be:
   a. made from potable water,
   b. made from clean water when used to chill whole fishery products,
   c. made, handled and stored under conditions that protect it from contamination.

C. Steam

5. Steam used directly in contact with fish products s not to contain any substance that presents a hazard to health or is likely to contaminate the product.

D. Cooling water after heat treatment

6. Water used to cool hermetically sealed containers, of fish products, after heat treatment is to be ensured that is not a source of contamination for the product.

SECTION VII

Personal hygiene

1. Every person working in a fish products handling area is to:

   a. maintain a high degree of personal cleanliness
   b. wear suitable, clean and protective clothing
   c. observe adequate hygienical behavior.
2. Persons suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhea are:
   a. not to be permitted to handle edible aquatic animal products or enter any fish products handling area in any capacity if there is any likelihood of direct or indirect contamination.
   b. to report immediately the illness or symptoms, and if possible their causes, to the fish business operator.
3. Smoking, eating, drinking, spitting in work and storage premises of fish products must be prohibited.

SECTION VIII

Provisions applicable to fish products and operational practices

1. Raw materials or ingredients, other than live animals, or any other material used in processing products, are not to be accept, 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 FBOs operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.
2. Raw materials and all ingredients storage are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.
3. Fish products, at all stages of production, processing and distribution, are to be protected against any contamination likely to render the product unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.
4. Adequate procedures are to be in place to control pests.
5. Adequate procedures are also to be in place to prevent domestic animals from having access to places where products are prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).
6. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport and storage of fish products, provided that it does not result in a risk to health. FBO manufacturing,

handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage.

7. Fish products to be held at chilled temperatures, are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.

8. Thawing of fish products are to be undertaken in such a way as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins in the products. During thawing, products are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, fish products are to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.

9. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.

SECTION IX

Provisions applicable to the wrapping and packaging of fish products (including on board fishing vessels)

1. Wrapping and Packaging Materials are:
   not to be a source of contamination.
   to be stored in such a manner that they are not exposed to a risk of contamination.
2. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products.
3. The integrity of the container's construction and its cleanliness is to be assured, where appropriate, in particular in the case of cans and glass jars
4. Specific conditions to be applied:
   i. 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.
   ii. Frozen blocks prepared on board vessels must be adequately wrapped before landing.

SECTION X

Personnel Training

FBO are to ensure:

1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;
2. that those responsible for the development and maintenance of the HACCP procedure or for the operation of relevant guides have received adequate training in the application of the HACCP principles;
   and,
3. compliance with any requirements of national law concerning training programmes for persons working in food sectors.

9. PART V - SPECIFIC CONDITIONS

Part V presents the specific conditions which supplement the requirements in previous sections.

Part V does not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods when placed on the market live.

SECTION I

Requirements for vessels

I. STRUCTURAL AND EQUIPMENT REQUIREMENTS

A. All vessels

1. Design and construction does not cause contamination of the fish 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,
   smooth and easy to clean.
   durable and non-toxic.
3. Equipment and material used for working on fishery products must be made of corrosion-resistant material easy to clean and disinfect.
4. Water intake for using with fishery products, must be situated in a position that avoids contamination of the water supply.

B. Vessels preserving fresh fishery products for more than 24 hours

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 temperature approaching that of melting ice.
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.
3. 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.
4. 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.

C. Freezer vessels

1. Must have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18 °C;
2. Must have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18 °C.

3. Storage holds 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;
4. Must also meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours (previous subsection).

D. Factory vessels

1. Factory vessels must at least have:
   - receiving area:
     - reserved for taking fishery products on board, designed to allow each successive catch to be separated.
     - easy to clean.
     - designed so as to protect the products from the sun or the elements and from any source of contamination;
   - a hygienic system for conveying fishery products from the receiving area to the work area;
   - work areas:
     - that are large enough for the hygienic preparation and processing of fishery products,
     - easy to clean and disinfect,
     - designed and arranged in such a way as to prevent any contamination of the products;
   - storage areas for the finished products:
     - that are large enough,
     - designed so that they are easy to clean.
   - a place for storing packaging materials that is separate from the product preparation and processing areas;
   - waste storage hold, separate and designated for the storage of such waste, if a waste-processing unit operates on board;
   - 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;
   - a water intake situated in a position that avoids contamination of the water supply;
   - hand-washing equipment with taps designed to prevent the spread of contamination, for use by the staff engaged in handling exposed fishery products.
2. Factory vessels where crustaceans and molluscs are cooked, chilled and wrapped onboard, need not meet the requirements of previous point (1), if no other form of handling or processing takes place on board such vessels.
3. Factory vessels that freeze fishery products must also have equipment meeting the requirements for freezer vessels laid down in previous subsection.

HYGIENE REQUIREMENTS OF OPERATIONS CARRIED OUT ONBOARD VESSELS

1. Parts of vessels or containers set aside for the storage of fishery products, when in use, must:
   - be kept clean,
   - be maintained in good repair and condition.
   - not be contaminated by fuel or bilge water.
2. Fishery products after they are taken on board:
   - must, as soon as possible, 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.
   - 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.
3. 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.
4. Ice used to chill fishery products must be made from potable water or clean water.
5. Deheading and/or gutting on board, 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. 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.
6. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.
7. Whole fish intended for canning, frozen in brine:
   - 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.

SECTION II

Requirements during and after landing

1. Unloading and landing equipment that comes into contact with fishery products is constructed of material:
   - easy to clean and disinfect,
   - maintained in a good state of repair and cleanliness;

2. Unloading and landing operations will avoid contamination of fishery products, in particular by:
   - carrying out unloading and landing operations rapidly;
   - placing fishery products without delay in a protected environment at the temperature applicable, regarding if the product is fresh (will be the temperature approaching that of melting ice) or if frozen (not more than -18 °C);
   - not using equipment and practices that cause unnecessary damage to the edible parts of the fishery products.

3. Landing site buildings, auction and wholesale markets or parts thereof where fishery products are displayed for sale must ensure compliance with the following requirements:

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.

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.

At the time of display or storage of fishery products:

the premises must not be used for other purposes;

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

persons having access to the premises must not introduce other animals;

the premises must be well lit to facilitate official controls.

4. 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, when chilling was not possible on board the vessel.

SECTION III:

Product Requirements for Establishments, including Vessels, handling fishery products

1. Fresh Fishery Products
2. Chilled, unpackaged products, which are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, must be stored under ice in appropriate facilities. Re-icing must be carried out as often as necessary.
3. Packaged fresh fishery products must be chilled to a temperature approaching that of melting ice.
4. Heading and gutting operations 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.
5. Deheaded and gutted products must be washed thoroughly with potable water or, on board vessels, with clean water immediately after these operations.
6. Filleting and cutting operations must be carried out so as to avoid contamination or spoilage of fillets and slices.
7. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation.
8. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.
9. 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.
10. Whole and gutted fresh fishery products:

    may be transported and stored in cooled water on board vessels.

    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.

1. Frozen fishery products
1. Land establishments must have:

    freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18 °C;

    refrigeration equipment with sufficient capacity to maintain fishery products in cold storage at not more than -18 °C.

2. Cold storage facilities 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 room is the highest;
3. Date of production refers to the date of harvesting or catching; Until the stage at which a Edible aquatic animal products is labelled or used for further processing, FBO

must ensure that in the case of frozen fishery products intended for human consumption, the following information is made available to the food business operator to whom the Edible aquatic animal products is supplied and, upon request, to the competent authority:

~~6.~~2. the date of production;

~~7.~~3. the date of freezing, if different from the date of production.

1. Mechanical separated fishery products

1. Raw materials used must satisfy the following requirements:
   Only whole fish and bones after filleting may be used to produce mechanically separated fishery products;
   All raw materials must be free from guts.
2. The manufacturing process must satisfy the following requirements:
   Mechanical separation must take place without undue delay after filleting.
   If whole fish are used, they must be gutted and washed beforehand.
   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.

1. Fishery products contaminated or potentially contaminated with parasites

1. FBO placing on the market the following fishery products derived from finfish or cephalopod molluscs 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:
   fishery products intended to be consumed raw; or
   marinated, salted and any other treated fishery products, if the treatment is insufficient to kill the viable parasite;
2. For parasites other than trematodes the freezing treatment must consist of lowering the temperature in all parts of the product to at least:
   – 20 °C for not less than 24 hours; or
   – 35 °C for not less than 15 hours.
3. FBO need not carry out the freezing treatment set out in point 15 for fishery products:
   that have undergone, or are intended to undergo before consumption a heat treatment that kills the viable parasite. 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;
   that have been preserved as frozen fishery products for a sufficiently long period to kill the viable parasites;
   from wild catches, provided that:
      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;

the competent authority so authorises;

derived from fish farming, cultured from embryos and have been fed exclusively on a diet that cannot contain viable parasites that present a health hazard, and one of the following requirements is complied with:

have been exclusively reared in an environment that is free from viable parasites; or

the FBO verifies through procedures, approved by the competent authority, that the fishery products do not represent a health hazard with regard to the presence of viable parasites.

4. When placing on the market fishery products referred to in point 15 must be accompanied by a document issued by the FBO performing the freezing treatment, stating the type of freezing treatment that the products have undergone.
5. Before placing on the market fishery products referred to in points 17(c) and (d) which have not undergone the freezing treatment or which are not intended to undergo before consumption a treatment that kills viable parasites that present a health hazard, a FBO must ensure that the fishery products originate from a fishing ground or fish farming which complies with the specific conditions referred to in one of those points. This provision may be met by information in the commercial document or by any other information accompanying the fishery products.

SECTION IV

Processed fishery products: cooking crustaceans and molluscs

1. Rapid cooling must follow cooking.
   a. Cooling water 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.
   b. 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.
   c. After shelling or shucking, cooked products must be frozen immediately (at temperature not more than -18 °C), or be chilled as soon as possible to temperature approaching that of melting ice.

SECTION V

Heat treatment applied to hermetically sealed containers

1. Any heat treatment processing is to:
   raise every party of the product treated to a given temperature for a given period of time;
   prevent the product from becoming contaminated during the process;
2. FBO are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices, to ensure that the process employed achieves the desired objectives.
3. The process used should conform to an internationally recognized standard (e,g. Codex Alimentarius Code of Practice), for example, pasturization, ultra high temperature or sterilization).

SECTION VI

Storage of fishery products

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 -18°C 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 -9°C.
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.

SECTION VII

Transport of fishery products

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

   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;
   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 -18°C in all parts of the product, possibly with short upward fluctuations of not more than 3 °C.
2. FBO need not comply with point 1(b) when frozen fishery products are transported from a cold store to an 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.

SECTION VIII

General Health standards for fishery products

1. Microbiological criteria within the Competent Authority requirements must be met.
2. Organoleptic examination of fishery products must be carried out, in particular, this examination must ensure that fishery products comply with any freshness criteria.
3. FBO must ensure that the limits with regard to histamine are not exceeded, undertaking necessary controls.
4. Unprocessed fishery products must not be placed on the market if chemical tests reveal that the limits with regard to TVB-N or TMA-N have been exceeded.

5. Fishery products must 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. Subject to respective temperature treatment as indicated before.
6. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.
7. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market.
8. Fishery products subject to non-authorized veterinary drugs must not be placed on the market.
9. Fishery products containing residues of veterinary drugs above MRL must not be placed on the market.

Form: F00 Edition 01 Revision 00	Department of Fisheries Edible aquatic animal products Official Controls Protocol **F 00 – Cover page for verification report**	Page 1 of 1 Date of Issue: Date of Revision:

F00 – Verification Report Cover

Establishment:	**China Approval Number/DoF approval number:**
Address:	**Telephone/fax/e-mail**
Type of verification [ ] Documental [ ] Total [ ] Partial [ ] Random	
Verification Officers	**Representative of the establishment**

Situation of Dossier:

Attached forms

F01	**F02**	**F03**	**F04**	**F05**
F06	**F07**	**F08**	**F09**	**F10**
F11	**F12**	**F13**	**F14**	**F15**

F01.A – Full Verification Part A: Infrastructure condition

REF.:

Name of the establishment:	**China Approval Number:**
Verification Officers:	**Establishment representatives:**
References consulted:	**Verification type:** AA ☐ ARA ☐ FRV ☐ PI ☐ **Date and time of verification:**

Full Verification for: approval audit (AA), annual re-approval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

PART A: INFRASTRUCTURE AND LAYOUT

Cr= Critical Non Conformity **NC= No** Conformity (M= Medium risk / L=Low risk) **C=** Conformity

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
1. Layout					
1.1 Sufficient areas to carry out the work under sanitary and hygienic conditions?					
1.2 Does the layout preclude contamination?					
1.2.1 Clean (LowR) / Dirty (HighR) areas separated?					
2. Reception area					
2.1 Is the receiving area clean & in good state of repair?					
2.2 Are the floor, walls, ceiling made of nontoxic materials easy to clean and sanitize?					
2.3 Floors. Allows easy drainage of water or it has water removal equipment?					
2.4 Lighting (Natural/Artificial). Adequate and protected?					
2.5 Is there sufficient potable water supply?					
2.6 The isolation from outside, is it sufficient to avoid contamination? And the isolation to the inside (processing areas) does it preclude contamination?					
3. Processing areas (all rooms)					
3.1 Floors. Made of materials easy to clean and sanitize?					
3.2 Floors. Allows easy drainage of water or it has water removal equipment?					
3.3 Walls. Made of nontoxic impermeable materials easy to clean and sanitize?					
3.4 Windows. Easy to clean and sanitize and precludes external contamination?					
3.5 Ceiling. Made of impermeable materials easy to clean and sanitize?					
3.6 Doors. Made of impermeable materials easy to clean and sanitize and precludes external contamination?					
3.7 Ventilation. Adequate/sufficient? Allows a good extraction of moisture?					
3.7.1 Ventilation. Filters and parts easily accessible.					
3.7.2 Ventilation. Avoids contamination from contaminated areas. Ex: Dirty (HighR) to Clean (LowR)					
3.8 Drainage. Avoids contamination.					
3.9 Lighting (Natural/Artificial). Adequate and protected?					
4. Hand washing facilities (at respective areas)					
4.1 Are the facilities in entry areas in sufficient numbers?					
4.2 Are the taps non hand operated?					
4.3 Hand cleaning agents have technical specifications?					
4.4 Facilities provided with approved cleaning /sanitizer agents, disposable hand towels and trash bins?					

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
5. Chillers / Freezers / Ice rooms - structure					
5.1 Floors. Made of materials easy to clean and sanitize?					
5.2 Floors. Allow easy drainage of water or it has water removal equipment?					
5.3 Walls. Made of nontoxic impermeable materials easy to clean and sanitize?					
5.4 Ceiling. Made of nontoxic impermeable materials easy to clean and sanitize?					
5.6 Doors Made of impermeable materials easy to clean and sanitize?					
5.7 Lighting (Natural or Artificial) Is the lighting adequate and protected?					
6. Chillers and Freezers (capacity)					
6.1 Freezing capacity. Able to quick freeze product adequately?					
6.2 Capacity. Able to maintain raw materials/products at allowed Temperature? **Fresh:** near TºC melting ice (< 4ºC). **Frozen:** -18ºC. **Brine** -9ºC					
6.3 Monitoring storage Is there an efficient TºC control programme? TºC automatic-recording + TºC display + thermal sensor in warmest area?					
7. Protection against vermin and pests (all areas)					
7.1 Are there adequate vermin proofing and appropriate protection facilities?					
8. Instruments and working equipment (all areas)					
8.1 Are they made of non corrosive, easy to clean and sanitize?					
9. By-products / waste (all areas)					
9.1 Containers & Utensils: made of nontoxic non corrosive materials, easy to clean and sanitize? Distinctively different from product boxes and containers. Identified for the purpose.					
9.2 Adequate flow, evacuation and room for storage of by-products? Avoids cross contamination?					
9.3 Appropriate cleaning and washing area of waste bins/trays that avoids potential cross contamination?					
10. Potable Water supply (all areas)					
10.1 Sufficient pressure in all areas?					
10.2 Distinction between water pipes (potable and non)?					
10.3 Backflow control?					
10.4 Hoses are not in constant contact with the floor?					
11. Cleaning chemical and utensils					
11.1 Appropriate and identified storing area, that avoids potential cross contamination? Utensils and containers identified?					
12. Waste water (all areas)					
12.1 Is there an adequate and hygienic wastewater disposal system? with adequate drain lid?					
12.2 Drains and sumps are easy to clean and sanitize?					
~~8.1.~~ **Cleaning and Washing Area for trolleys, vehicles, trays, etc. And final drying storing area**					
13.1 In good conditions and easy to clean and sanitize?					
13.2 Appropriate cleaning, washing, storing area, that avoids potential cross contamination? Separate storing.					

		NC		C	
	Cr	M	L		Observations/Comments
14. Changing rooms and Toilets					
Toilets					
14.1. Placement. Not open directly onto the fish handling and processing areas?					
14.2 Usage. Are they equipped with working water-flushing systems?					
14.3 Floors. Made of materials easy to clean and sanitize?					
14.4 Floors. Allows easy drainage of water or it has water removal equipment?					
14.5 Walls. Made of impermeable materials easy to clean and sanitize?					
14.6 Ceiling. Made of impermeable materials easy to clean and sanitize?					
14.7 Wash hand basins. In exit areas and in sufficient numbers? Non-hand operated					
Changing rooms					
14.8 Placement. Control cross contamination from the exterior?					
14.9 Usage. Equipped with clothing storage facilities in good condition? Includes facilities for clean cloth supply.					
14.10 Floors. Made of materials easy to clean and sanitize?					
14.11 Floors. Allows easy drainage of water or it has water removal equipment?					
14.12 Walls. Made of impermeable materials easy to clean and sanitize?					
14.13 Ceiling. Made of impermeable materials easy to clean and sanitize?					
14.14 Wash hand basins. In exit areas and in sufficient number?					
15. Laundry Contracted or not					
15.1 Capacity in relationship to the number of workers?					
15.2 Internal. In good hygienic condition?					
15.3 Contracted. is the transportation done hygienically?					
16. External Environment (factory premises)					
16.1 Isolated, well maintained and clean?					
16.2 Cleaning and disinfections of transportation vehicles in a separate, adequate and equipped structure?					
17. Specific requirements – Value-added Products					
17.1 Specific area precluding contamination from general processing?					
17.2 Workers differentiated from general processing?					
Coming from specific changing rooms or entrance area?					
17.3 Equipment (containers, trays, etc) different and identified from used in general processing?					
18. Specific requirements - Ice Production					
18.1 Is ice produced from potable water, and in good hygienic condition?					
18.2 Ice storage and supply: precludes contamination?					
18.2.1 Containers / room designed for this purpose?					

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
19. Specific requirements – Cooking area					
19.1 Separated cooking area with adequate ventilation?					
17.2 Thermal process verification provided?					
21. Specific requirements - Laboratory					
21.1 Separated from processing areas and with controlled access?					
SUB-TOTAL PART A					

	General Comments
	Conformity evaluation

Verifiers name and signature	**Representative name and signature**[1]

DoF – Control	Date:	**Comments:**
Name: **Signature:**		

F01.B – Full Verification Part B: Hygiene and good manufacturing practices

REF:

Name of the establishment:	**China Approval Number:**
Verification Officers	**Establishment representatives**
References consulted:	**Verification type:** AA ☐ ARA ☐ FRV ☐ PI ☐ **Date and time of verification:**

Full Verification for: approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

PART B: Hygiene and good manufacturing practices

Cr= Critical Non Conformity **NC= No** Conformity (M= Medium risk / L=Low risk) **C=** Conformity

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
1. Facilities and equipment hygiene (all)					
1.1 Are they kept in a satisfactory state of cleanliness?					
1.2 Is vermin systematically exterminated?					
1.2.1 Are rodenticides, insecticides, disinfectants and any other toxic substance identified and stored where appropriate, which can be locked?					
1.2.2 Can these toxic products contaminate products?					
1.3 Are the working premises used only for products? If not, was the company authorized?					
1.4 Is potable water used for the designated purposes?					
1.5 Are the detergents and the disinfecting agents approved and adequately labelled?					
1.6 Are the facilities and equipment cleaned and disinfected at least once per day (end of the shift)?					
1.7 Are products/raw materials in direct contact with floor					
1.8 Are there instructions of not smoking, spitting, eating and drinking in working and storage premises?					
1.9 Do practices effectively control cross contamination?					
2. Personnel hygiene					
2.1 Has every worker undergone a medical examination?					
2.2 Is medical examination periodically carried out on workers handling products?					
2.3 Is any person that can contaminate the products excluded from handling them?					
2.4 Do all the workers wear suitable and clean working clothes? not exposed to the outdoors?					
2.5 Workers wear a headgear, covering completely the hair?					
2.6 Do they wash and disinfect their hands each time before commencing work?					
2.7 Are the wounds covered with waterproof bandages?					
2.8 Workers respect instructions of not smoking, spitting, eating and drinking in working and storage premises?					
2.9 Flow of workers effectively avoids cross contamination?					
2.10 First aid kit available? Contains impermeable dressings for cuts and sores?					

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
3. Cleaning / washing / sanitising of the facilities					
3.1 Is it done in appropriate frequency (including breaks and changing shifts)?					
3.2 Is it applied appropriate practices and equipment? Effectively avoids cross contamination of product?					
4. Ice utilization					
4.1 Is ice produced from potable water?					
4.2 Is ice stored and transported in containers designated only for this purpose?					
4.3 Are the ice containers clean and well maintained?					
5. Product Containers / trays (all)					
5.1 Clear differentiation / identification of use?					
5.2 Used only for the purpose identified.					
5.3 Are not on the floor?					
5.4 Do they lead to contamination?					
5.5 Cleaned, washed and sanitised after use?					
6. Containers for Fresh / Frozen shrimp / fish					
6.1 Do they protect shrimp/fish from contamination?					
6.2 Do they preserve shrimp/fish in a hygienic manner?					
6.3 Do they allow for easy drainage of water?					
7. Fresh products					
7.1 Are products that are not immediately processed, iced or refrigerated?					
7.2 Are iced products re-iced regularly?					
7.3 Are pre-packed products iced or refrigerated?					
8. Fresh and/or thawed **raw materials processing**					
8.1 Is handling, washing, sorting, and weighing done hygienically? Do these practices lead to contamination of product?					
8.2 Is Deveining, peeling, gutting, deheading, filleting, cutting done hygienically? Do they lead to contamination of product?					
8.3 Is Shrimp deveining, peeling, cutting carried in a place different from general processing?					
8.4 Are there delays in the processing activities?					
8.5 Are processed products rapidly refrigerated?					
8.6 Fish gutted or headed are immediately washed with potable water?					
8.7 Viscera and other undesirable parts of the fish quickly separated from the product?					
8.8 Fish filleting / cutting carried in a place different from the place where fish is gutted, deheaded or cleaned?					
9. Evacuation of waste					
9.1 Is waste adequately and frequently evacuated from processing premises?					
9.2 Are the waste containers and the waste storage premises cleaned and disinfected after each use?					
9.3 Can the stored waste be a source of contamination for the establishment?					
9.4 Are waste bins, boxes and trays different and differentiated of those used for products/raw materials and ice? (ex. by different colour)					

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
10. Thawing of raw material					
10.1 Is thawing carried out hygienically? And in adequate separate area?					
10.2 Is there a risk of contamination during thawing?					
10.3 Is melting water drained properly?					
10.4 Do practices effectively control cross contamination?					
11. Storage of frozen products					
11.1 Is the temperature of the frozen products appropriate?					
11.2 Is T ºC automatically recorded on the recorder?					
11.3 Is the recording kept for a duration equivalent to the shelf life of the product?					
11.4 There is independent storage of final product and raw materials?					
12. Separation of China products					
12.1 Includes control of authorised sources (under the control of the CA)?					
12.2 Includes physical separation of raw materials not fit to the China market ?					
12.3 Includes separation of processing from products not fit to the China market?					
12.4 Includes separation of storage from product not fit to the China market?					
13. Cooked Products					
13.1 Cooking followed by efficient cooling down to melting ice TºC.					
13.2 Only potable or clean sea cooling water used for cooling					
13.3 Pathogens control by authorized treatments (for cooked shrimps). Effective control of critical parameters.					
13.4 Approved Thermal treatments, documented/validated					
13.5 Records available for at least the product validity					
13.6 Cooked products to be frozen, quickly frozen (or chilled)					
13.7 Cooked products properly handled in clean controlled areas					
13.8 Microbiological verification tests done regularly					
	NC			**C**	
	Cr	**M**	**L**		**Observations/Comments**
SUB-TOTAL PART B					

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
TOTAL A + B					

General comments
Evaluation of Compliance

Verifiers name and signature	**Representative name and signature**[1]

DoF – Control	Date:	**Comments:**
Name: **Signature:**		

F 02 – Verification of pre-requisite and support programmes

REF.:

Name of the establishment:	**China Approval Number:**
Verification Officers	**Establishment representatives**
References consulted:	**Verification type:** AA ☐ ARA ☐ FRV ☐ PI ☐
	Date and time of verification:

Full Verification for: approval audit, annual reapproval, full routine verification, and partial inspection (according to selected sections)

Verification of Pre-requisite and Support Programmes (Documental and Implementation)

Cr= Critical Non Conformity **NC= No** Conformity (M= Medium risk / L=Low risk) **C=** Conformity

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
1. Facilities and equipment hygiene, cleaning and sanitation					
1.1 Documented system for **all** areas and equipment, [1]					
1.2 Properly designed & programmed: feasibility?					
1.2.1 Adequate hygiene control of toilets and other facilities for the personnel					
1.2.2 Adequate hygiene control of processing and storage areas.					
1.3 Satisfactory conditions? Cleaning effectiveness verified?					
1.4 Chemicals documented for specific purpose (have technical specifications)?					
2. Pest and vermin control					
2.1 Documented system for **all** areas and equipment, [1]					
2.2 Is effectiveness assessed against presence of pest and vermin?					
3. Staff training and Hygiene					
3.1 Documented system that covers training? records?					
3.2 System covers infectious and communicable diseases?					
3.3 System covers control over non hygienic [2] [1]					
3.4 Personnel hygiene control? Includes monitoring and [1]					
4. Water and Ice control					
4.1 Documented system that covers portability, has [1]					
4.2 Water distribution diagram?					
4.3 Are the ice containers clean and well maintained?					
4.4 Automatic treatment system used and operational?					
4.5 Monitoring of residual chlorine content if added?					
4.6 Surveillance of contamination indicators in place. Sampling plan adequate and systematically followed?					

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
5. Raw material reception					
5.1 Documented system for Organoleptic evaluation. Records?					
5.2 Includes refrigeration TºC control and C. Actions?					
5.3 Includes traceability control?					
6. Control during processing					
6.1 Documented system for control during general processing. Including traceability. Records for all?					
6.1.1 Includes refrigeration TºC control and C. Actions?					
6.1.2 Includes control over equipment and staff hygiene?					
6.1.3 Includes control over the condition and hygiene of product containers?					
6.2 Practices effectively control cross contamination?					
6.3 Documented system for Cooking control. Records?					
6.4 Regulatory Verification proves effectiveness of the systems?					
7. By product management					
7.1 Documented system for hygienic disposal. Records?					
7.2 Includes control over the condition and hygiene of containers?					
7.3 Practices effectively control cross contamination?					
8. Control during storage					
8.1 Documented system for temperature control during storage. Records?					
8.2 Regulatory Verification proves effectiveness of the [3]					
9. Control during thawing					
9.1 Documented system for thawing control. Records?					
9.2 Practices effectively control cross contamination from water used?					
10. Repairs and Maintenance (infrastructure & equipment)					
10.1 Documented system for maintenance?					
10.2 Includes responsible, records and timeframes?					
10.3 Regulatory Verification proves effectiveness of the control system?					
10.4 Does the system cover calibration of measuring devices?					
11. Goods reception[4]					
11.1 Documented system for controls of arriving goods. Records?					
11.2 Includes correct identification and backed by suppliers guarantees / certificates?					
12. Parasites control (if applicable)					
12.1 Documented system for parasite control. / Records?					
12.2 Includes visual inspection, removal and/or freezing to <-20ºC for 24hs?					

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
13. Traceability and Final Product recall					
13.1 Documented system for traceability and product recall. Records?					
13.2 Codification system capable to keep the traceability up and down?					
14. Separation of China products					
14.1 Documented system for separation control. Records?					
14.2 Includes control of authorised sources (under the control of the CA)?					
14.3 Includes physical separation of raw materials not fit to the China market ?					
14.4 Includes separation of processing from products not fit to the China market?					
14.5 Includes separation of storage from product not fit to the China market?					
14.6 Regulatory Verification confirms the effectiveness of the separation?					
TOTAL					

General comments
Evaluation of Compliance

Verifiers name and signature	**Representative name and signature**[5]

DoF – Control	Date:	**Comments:**
Name: **Signature:**		

F 03 – Documental verification of Food Safety Management System

REF.:

Name of the establishment:	**China Approval Number:**
Verification Officers	**Establishment representatives**
References consulted:	**Verification type:** AA ☐ ARA ☐ FRV ☐ PI ☐ **Date and time of verification:**

Full Verification for: approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

Documental Verification of Food Safety Management System

Cr= Critical Non Conformity **NC= No** Conformity (M= Medium risk / L=Low risk) **C=** Conformity

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
DOCUMENTATION					
1. Facilities and process description					
1.1 Company/section general description providing sufficient information?					
1.2 Compromise. Commitment for HACCP (food safety) clearly expressed?					
1.3 HACCP team: Responsibilities documented and updated?					
1.4 HACCP team: Adequate qualification and experience available? (CV) (training)					
1.5 HACCP team: Documented references and resources utilized?					
1.6 Personnel. Informed about the objectives of HACCP?					
2. Product Description					
2.1 Products description clear and complete?					
2.2 Include origin and specifications of raw material?					
2.3 Include composition, packaging, distribution, validity, storage condition? Processing technology applied.					
2.4 Include additives and/or ingredients in the final product.?					
3. Users or consumers					
3.1 Sensitive consumers identified?					
3.2 Instructions given for the distribution, storage & use?					
4. Processing specification:					
4.1 Flow diagram includes each stage of processing chain? (at least)					
4.2 Flow diagram confirmed?					
5. Hazard ID and Analysis [1]					
5.1 Includes Ph, Ch and Bi hazards associated to raw					
5.2 Includes Ph, Ch and Bi hazards associated to each step of processing?					
5.3 Hazards evaluated in terms of likelihood and severity (risk assessment)? (evaluation of significance)					

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
5.4 Includes references, bibliography or external advice used on the analysis?					
5.5 Identifies potential process and staff variations?					
5.6 Preventive measures identified to control each relevant risks (significant hazard)?					
6. Determination of CCP					
6 1 The Identification is consistent with the identified hazards?					
6.2 It includes references to methodologies and resources used?					
6.3 Control measures were identified for each CCP?					
7. Adoption of Critical Limits					
7.1 Established for each CCP determined before?					
7.2 Are the CLs able to be checked / monitored, simple and routinely, during production?					
7.3 Limits validated taking into account published/experimental evidence?					
8. Monitoring of CCP					
8.1 Responsibilities and activities documented for each CCP.					
8.2 Includes what, who, when and how each CCP is monitored?					
8.3 Includes verifiable records and identification of the responsibilities?					
9. Corrective Actions					
9.1 Responsibilities and activities documented for each CCP?					
9.2 Includes what, who, when and how corrective actions are taken?					
9.3 Are CA realistic and cover destination of non suitable products ?					
9.4 Includes measures or action to avoid re-occurrence?					
10. Verification Procedures					
10.1 Responsibilities and activities documented for each CCP?					
10.2 Includes what, who, when and how verification activities take place?					
10.3 Includes final product testing and calibration of equipment?					
10.4 Includes action in case that verification shows non compliances?					
11. Documentation and Records					
11.1 Records are documented for each component of the HACCP plan?					
11.2 Includes what, who, when and how records are taken and stored?					
11.3 Procedure for the annual plan review adopted and documented?					
TOTAL					

General comments
Evaluation of Compliance

Verifiers name and signature	**Representative name and signature**[2]

FIQC/DoF – Control	Date:	**Comments:**
Name: **Signature:**		

F 04 – Verification of Food Safety Management System plan performance

REF.:

Precondition: this verification can only be performed if the establishment is in Conformance with the requirements of **F02 – Verification of pre requisites and support programmes; This form is for use only during industry operations**

Name of the establishment:	**China Approval Number:**
Verification Officers	**Establishment representatives**
References consulted:	**Verification type:** **AA** ☐ **ARA** ☐ **FRV** ☐ **PI** ☐ **Date and time of verification:**

Full Verification for: approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

Verification of Food Safety Management System plan performance

Cr= Critical Non Conformity **NC= No** Conformity (M= Medium risk / L=Low risk) **C=** Conformity

	NC			C	
	Cr	**M**	**L**		**Observations/Comments**
OBSERVATIONS					
1. Changes and Modifications					
1.1 Changes or modification in process -raw materials included in the plan?					
1.2 Changes or modification in process -raw materials have been subject to the necessary plan revision?					
1.3 Modifications non communicated or approved if affecting product.?					
1.4 The responsible (as documented) is in control of operations?					
2. Documentation and Records (all areas)					
2.1 Records are available in their respective areas and updated?					
2.2 Records can be traced and reviewed as far as the last regulatory verification?					
3. Management of the Plan					
3.1 Preventive measures followed and verifiable?					
3.2 Monitoring procedures followed and verifiable?					
3.3 Corrective actions followed and verifiable?					
3.4 Verifications activities followed and verifiable?					
TOTAL					

General comments
Evaluation of Compliance

Verifiers name and signature	**Representative name and signature**[1]

FIQC/DoF – Control	Date:	**Comments:**
Name: **Signature:**		

F05.A Verification of Covid-19 & Food Safety Guidance for ~~FVO~~FBO

Precondition: this verification can only be performed if the establishment is in Conformance with the requirements of **F02 – Verification of pre requisites and support programmes; This form is for use only during industry operations**

Name of the establishment:	**China Approval Number:**
Verification Officers	**Establishment representatives**
References consulted:	**Verification type:** **AA** ☐ **ARA** ☐ **FRV** ☐ **PI** ☐
	Date and time of verification:

Full Verification for: approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

Verification of Covid-19 & Food Safety Guidance for FVO

Cr= Critical Non Conformity **NC= No** Conformity (M= Medium risk / L=Low risk) **C=** Conformity

	NC	**C**	
Elements to verify			**Observations/Comments**
1. Food Workers (Awareness of Covid-19 symptoms)			
1.1 are the worker suffering by a fever (high temperature -37.5 degrees Celsius or above)?			
1.2 are the worker suffering by a cough-this can be any kind of cough, not just dry ?			
1.3 are the worker suffering by shortness of breath?			
1.4 are the worker suffering by breathing difficulties?			
1.5 does the worker feels fatigue?			
2. Food Workers: preventing the spread of Covid-19 in the work environment			
2.1 are the worker maintaining proper hand hygiene-washing with soap and water for at least 20 seconds (follow WHO advice)?			
2.2 does the worker use of of alcohol-based hand sanitizers frequently?			
2.3 are the worker maintaining good respiratory hygiene (cover mouth and nose when coughing or sneezing, dispose of tissues and wash hands)?			
2.4 are the worker frequent cleaning/disinfection of work surfaces and touch points such as door handles?			
2.5 have there any scope avoiding close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.			
3. Food workers: use of disposable gloves & storing status			
3.1 does the worker use of hand gloves?			
3.2 does the worker dispose of gloves properly?			
3.3 does the worker changing the gloves from time to time?			
3.4 are there any bins for storing used gloves?			
5.1 Are the facilities in entry areas and in sufficient numbers?			
5.2 Are the taps non hand operated?			
5.3 Have detergent and sanitizing agents available technical specs?			
5.4 Are the facilities provided with disposable hand towels and bins?			

6. Food Workers: Physical distancing in the work environment			
6.1 Stagger work station on either side of processing line			
6.2 Status of PPE (face mask, air nets, disposable gloves, clean overalls)			
6.3 slip reduction work shoes			
6.4 Number of working staff with reduced interactions facility			
6. Changing room and toilets			
6.1 Toilets not opening directly to production, working area? Adequate number?			
6.2 Changing rooms sufficient in number/size?			
6.3 Changing rooms easy to clean and sanitise?			
7. Hygiene conditions			
7.1 Good general condition of cleanliness in work areas?			
7.2 Forklifts, trolleys, containers, boxes, pipes, easy to clean?			
7.3 Cleaning chemicals and utensils store separated and labelled?			
7.4 Cleaning and Pest control chemicals have supplier's guarantees?			
7.5 Offal and debris managed to preclude cross contamination?			
8. Staff training and Personnel hygiene			
8.1 Has every worker undergone a medical examination?			
8.2 Do all the workers wear suitable and clean working clothes?			
8.3 Flow of workers effectively avoids cross contamination?			
8.4 Documented system that covers training, with records?			
8.5 System covers infectious and communicable diseases?			
8.6 System covers control over non hygienic behaviours?[2]			
8.7 First aid kit contains impermeable dressings for cuts and sores?			

General comments
Evaluation of Compliance

Verifiers name and signature	Representative name and signature[1]

FIQC/DoF – Control	Date:	Comments:
Name: Signature:		

F 05.B –Verification of conditions on Ice Plants

REG.:

Name of the establishment:	China Approval Number:
Verification Officers	Establishment representatives

References consulted:	Verification type:	AA		ARA		FRV		PI	
	Date and time of verification:								

Full Verification for: approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

Verification of conditions on Ice plants

NC= No Conformity **C=** Conformity

Elements to verify	NC	C	Observations/Comments
1. Production			
1.1 Good general conditions of cleanliness, hygiene and maintenance?			
2. Storage areas			
2.1 Floors. Made of materials easy to clean and sanitize?			
2.2 Floors. Allows easy drainage of water or it has water removal equipment?			
2.3 Walls. Made of impermeable materials easy to clean and sanitize?			
2.4 Ceiling. Made of impermeable materials easy to clean and sanitize?			
2.5 Doors Made of impermeable materials easy to clean and sanitize?			
2.6 Lighting (Natural or Artificial) Is the lighting adequate and protected?			
2.7 Delivery area. Good general conditions of hygiene and maintenance? Precludes contamination?			
3. Pest and vermin control			
3.1 Effectiveness assessed against presence of pest and vermin? Records?			
4. Safe Water monitoring (potable / clean sea water)			
4.1 Is the fresh water used from a verifiable safe source? Records?			
4.2 Is the sea water used from a verifiable safe source? Records?			
5. Hand washing basins			
5.1 Are the facilities in entry areas and in sufficient numbers?			
5.2 Are the taps non hand operated?			
5.3 Have detergent and sanitizing agents available technical specs?			
5.4 Are the facilities provided with disposable hand towels and bins?			
6. Changing room and toilets			
6.1 Toilets not opening directly to production, working area? Adequate number?			
6.2 Changing rooms sufficient in number/size?			
6.3 Changing rooms easy to clean and sanitise?			

	NC	C	Observations/Comments
7. Hygiene conditions			
7.1 Good general condition of cleanliness in working areas?			
7.2 Trolleys, containers, boxes, pipes, easy to clean?			
7.3 Cleaning chemicals and utensils store separated and labelled?			
7.4 Cleaning and Pest control chemicals have supplier's guarantees?			
7.5 Offal and debris managed to preclude cross contamination?			
8. Staff training and Hygiene			
8.1 Documented system that covers training, with records?			
8.2 System covers infectious and communicable diseases?			
8.3 System covers control over non hygienic behaviours?[1]			
8.4 First aid kit contains impermeable dressings for cuts and sores?			
8.5 Adequate and complete protective gear, not expose to the outdoors?			
9. Practices			
9.1 Utensils, tools, equipment (ice crusher if applicable) adequate & in good condition, precluding contamination?			
9.2 Trolleys, containers, boxes, exclusive for ice?			
9.3 Practices (ice crushing, storing, packing, delivery) preclude contamination?			
TOTAL			
General Comments:			
Evaluation of Compliance			

Verifiers name and signature	**Representative name and signature**[2]

DoF – Control	Date:	**Comments:**
Name: **Signature:**		

F-06 - Verification of conditions on Cool Stores (Chill or Cold store)

REF.:

Name of the establishment:	China Approval Number:
Verification Officers	Establishment representatives
References consulted:	Verification type: AA [ ] ARA [ ] FRV [ ] PI [ ] Date and time of verification:
Type of storage: [ ] Chill [ ] Cold	

Full Verification for: approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

Verification of conditions on cool stores - To be applied to cold and chill storage

Cr= Critical Non Conformity NC= No Conformity (M= Medium risk / L=Low risk) C= Conformity

If chill storage: just applies NC/C

Elements to verify	NC			C	
	Cr	M	L		Observations/Comments
1. Production					
1.1 Good general conditions of cleanliness, hygiene and maintenance?					
1.2 Sanitation Program documented and implemented accordingly? includes, monitoring and verification (what, who, when and how methodology)? Records?					
2. Storage facility and areas (include packing room)					
2.1 Floors. Made of materials easy to clean and sanitize?					
2.2 Floors. Allows easy drainage of water or it has water removal equipment?					
2.3 Walls. Made of impermeable materials easy to clean and sanitize?					
2.4 Ceiling. Made of impermeable materials easy to clean and sanitize?					
2.5 Doors Made of impermeable materials easy to clean and sanitize?					
2.6 Lighting (Natural or Artificial) Is the lighting adequate and protected?					
2.7 Delivery area. Good general conditions of hygiene and maintenance? Precludes contamination?					
2.8 Capacity. Able to maintain raw materials/products at allowed T? [1]					
2.9 Monitoring Temperature recording + Temperature display + thermal sensor in warmest area?					
2.9.1 Cold Store monitoring – Automatic temperature recording system?					
2.10 Cold room Is there good insulation from external temperature? Layout adequate?					
2.11 Exterior environment – Clean and in good condition? Precludes contamination?					
3. Pest and vermin control					
3.1 Have program? Effectiveness assessed against presence of pest and vermin? Records?					
4. Safe Water monitoring					
4.1 Is the fresh water used from a verifiable safe source? Records					

Elements to verify	NC			C	
	Cr	M	L		Observations/Comments
5. Hand wash basins					
5.1 Are the facilities in entry areas and in sufficient number?					
5.2 Are the taps non hand operated?					
5.3 Are detergent and sanitizing agents available, listed and approved?					
5.4 Are the facilities provided with disposable hand towels and bins?					
6. Changing room and toilets					
6.1 Toilets not opening directly to production, working area? Adequate number?					
6.2 Changing rooms sufficient in number/size?					
6.3 Changing rooms easy to clean and sanitise?					
7. Hygiene conditions					
7.1 Good general condition of cleanliness in work areas?					
7.2 Forklifts, trolleys, containers, boxes, pipes, easy to clean?					
7.3 Cleaning chemicals and utensils store separated and labelled?					
7.4 Cleaning and Pest control chemicals have supplier's guarantees?					
7.5 Offal and debris managed to preclude cross contamination?					
8. Staff training and Personnel hygiene					
8.1 Has every worker undergone a medical examination?					
8.2 Do all the workers wear suitable and clean working clothes?					
8.3 Flow of workers effectively avoids cross contamination?					
8.4 Documented system that covers training, with records?					
8.5 System covers infectious and communicable diseases?					
8.6 System covers control over non hygienic behaviours?[2]					
8.7 First aid kit contains impermeable dressings for cuts and sores?					
9. Storage of frozen fishery products Practices					
9.1 Is the temperature of the frozen products appropriate?					
9.2 Is temperature recorded on the recorder?					
9.3 Is the recording kept for a duration equivalent to the shelf life of the product?					
9.4 There is independent storage of final product and raw materials?					
9.5 Includes appropriate separation of storage from product not fit to the China market?					

	NC			C	
	Cr	M	L		Observations/Comments
9.6 Loading/unloading practices carried out without affecting critically temperature of the product and of the inside temperature of the cold room?					
9.7 Adequate and effective traceability system in place?					
TOTAL					

General comments

Evaluation of Compliance

Verifiers name and signature	Representative name and signature[3]

DoF – Control	Date:	Comments:
Name: Signature:		

F-07 – Verification of conditions and systems on off shore vessels

REF::

Applies to vessels holding fish for more than 24 hrs

Name of the vessel: License number:	China Approval Number:
Verification Officers	Vessel owner / representative:
References consulted:	Verification type: AA [ ] ARA [ ] FRV [ ] PI [ ] Date and time of verification:
Type of vessel: [ ] Freezer [ ]RSW [ ] Ice	

Full Verification for: approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

Verification of conditions and systems on offshore vessels

Cr= Critical Non Conformity NC= No Conformity (M= Medium risk / L=Low risk) C= Conformity

If vessels are non freezer vessels and not directly exporting, applies only: NC/C

	NC			C	
Construction and material	**Cr**	**M**	**L**		**Observations/Comments**
1. Contact surfaces and utensils					
1.1 Designed, constructed and maintained to facilitate hygiene?[1] Precluding contamination of catch?					
1.2 Minimize the potential for cross contamination from crew activities?					
1.3 Bilge water do not allow for contamination of product from engine?					
1.4 Fish hold in good general condition of cleanliness, hygiene and maintenance?					
2. Hygiene conditions					
2.1 Good general condition of cleanliness in work areas?					
2.2 Fish holds, containers, boxes, pipes, easy to clean?					
2.3 Cleaning chemicals and utensils store separated and labelled?					
2.4 Cleaning and pest control chemicals store separated and labelled??					
2.5 Offal and debris managed to preclude cross contamination?					
3. Pest and vermin control					
3.1 Program in place? Effectiveness assessed against presence of pest and vermin?					
4. Safe Water monitoring					
4.1 Is the fresh water used from a verifiable safe source?					
4.2 Is the seawater intake away from engine and toilets outlet?					
4.3 Ice originated from a controlled provider or made from clean seawater?					
5. Processing Area					
5.1 Area has the minimal standards of maintenance and hygiene?					
5.2 Offal / debris managed to preclude cross contamination?					

	NC			C	
Construction and material	**Cr**	**M**	**L**		**Observations/Comments**
6. Fish Holds and Temperature Control					
6.1 Ice vessels. Hold in good condition and sufficient space for ice?					
6.2 RSW Vessels. Records of temperature monitoring and control?					
6.3 Freezers Records of temperature monitoring and control?					
6.4 Cooling capacity. Able to maintain fish at required temperature?[2]					
6.5 Automatic Temperature recording + Temperature display + thermal sensor in warmest area?					
6.6 Thermometer and temperature control equipment calibrated?					
7. Crew training and Hygiene					
7.1 Crew understand the minimal requirements of personal hygiene?					
7.2 Control over infectious and communicable diseases?					
7.3 Control over non hygienic behaviours?[3]					
7.4 First aid kit contains impermeable dressings for cuts and sores?					
8 Additives					
8.1 Salt used for brine has suppliers guarantees for its purpose?					
9 Common crew areas[4]					
9.1 Good general conditions of cleanliness, hygiene and maintenance?					
Specific requirements for Vessels listed for direct export					
10. Hygiene control system					
10.1 Documented system for **all** areas and equipment, with records?					
10.2 Satisfactory conditions? Is cleaning effectiveness verified?					
11. Maintenance					
11.1 Documented system for establishment maintenance?					
11.2 Includes responsible, records and timeframes?					
11.3 Verification proves effectiveness of the control system?					
12. Goods reception[5]					
12.1 Documented system for controls of arriving goods. Records?					
12.2 Includes correct identification and backed by suppliers guarantees?					
13. Fish Parasites control					

13.1 Documented system for parasite control? Records?					
13.2 Includes visual inspection, removal and/or freezing to < 20C° for 24hs?					
14. Traceability and Product recall					
14.1 Documented system for traceability and product recall? Records?					
TOTAL					

General comments

Evaluation of Compliance

Verifiers name and signature	**Representative name and signature**[6]

DoF – Control	Date:	**Comments:**
Name: **Signature:**		

Form: F-08 Edition 01 Revision 00	Department of Fisheries Edible aquatic animal products Official Controls Protocol F-08 – Verification of Coastal vessels	Page 1 of 1 Date of Issue: Date of Revision:

F-08 – Verification of conditions for coastal vessels

REF.:

Applies to vessels holding fish for less than 24 hrs									
Name of the vessel: License number:	Approval Number:								
Verification Officers	Vessel owner / representative								
References consulted:	Verification type:	AA		ARA		FRV		PI	
	Date and time of verification:								

Full Verification for: approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

NC= No Conformity C= Conformity

Construction and material	NC	C	Observations/Comments
1. Structure, Contact surfaces and utensils			
1.1 Designed, constructed and maintained to facilitate hygiene? Precludes contamination?			
1.2 Good maintenance condition of fish boxes and holds?			
1.3 Designed, constructed and maintained to protect fish from environment (hot T°C, sun, wind)?			
2. Unload			
2.1 Managed in a way to avoid cross contamination?			
3. Ice usage			
3.1 Ice originated from a controlled provider?			
3.2 Handling of ice minimizes potential for cross contamination?			
4. Fuel storage			
4.1 Separated from catch and ice?			
5 Training and Hygiene			
5.1 Crew understand the minimal requirements of personal hygiene?			
5.2 Practices avoid cross contamination?			
TOTAL			

Corrective Actions Request

Non Conformity	Timeframe	Action Required	CA verified

Comments

Evaluation of Compliance:

Verifiers name and signature	Fisherman name and signature[1]	Verification by DoF or delegated authority Date:

F ~~10~~ 06 – Verification of conditions for transports

REF.:

Type: [ ] Freezer [ ] Chiller [ ] truck with non insulated cargo box

Name of transport company:	**Approval Number:**
Identification of the vehicle:	**Company representatives:**
	Verification type: AA [ ] ARA [ ] FRV [ ] PI [ ] **Date and time of verification:**
Verification Officers:	**References consulted:**

Full Verification for: **approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)**

NC= No Conformity **C**= Conformity

	NC	C	Observations / Comments
Construction and material			
1. Contact surfaces and utensils			
1.1 Adapted to fit purpose?			
1.2 Designed, constructed and maintained to facilitate hygiene? Non-absorbent surfaces? Precludes contamination?			
1.3 Good maintenance condition of cargo area?			
1.4 Containers, boxes, baskets of proper material? (smooth, non-absorbent, non-toxic, corrosion resistant) With adequate drainage?			
2. Transport, Load and Unload			
2.1 Managed to avoid cross contamination?			
2.1.1 Effective separation from different foods or from non-food items?			
2.1.2 Stacked avoiding drainage from upper boxes?			
2.1.3 Protection of product from sun and rain, dust and fumes?			
2.1.4 People not walk or sit over the containers or baskets of fish / shrimp?			
2.1.5 Product not stacked directly on ground?			
3. Ice usage and Temperature control			
3.1 Ice originated from a controlled provider?			
3.2 Handling and storage of ice minimizes potential for cross contamination?			
3.3 Temperature monitoring on freezer trucks?			
4. Fuel storage			
4.1 Separated from product and ice?			
5 Training and Hygiene			
5.1 Drivers understand the minimal requirements of personal hygiene?			
6. Traceability			
6.1 Product identified guarantees traceability? Records?			
TOTAL			

Corrective Actions Request

Non Conformity	Timeframe	CA Required	CA Verified

General Comments

Evaluation of Compliance

Verifiers name and signature	Transporter name and signature[1]	Verification by DoF or delegated authority Date:

Form: F 11 Edition 01 Revision 00	Department of Fisheries Edible aquatic animal products Official Controls Protocol F 11 – Verification of Traceability	Page 1 of 1 Date of Issue: Date of Revision:

F 011 – Verification of traceability

REF.:

Name of the establishment:	Approval Number
Verification Officers:	Representative of the establishment:
References consulted:	Verification type: AA ☐ ARA ☐ FRV ☐ PI ☐ Date and time of verification:
Type of operator:	Identification/marks/codes:
Type of product:	

Full Verification for: approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

NC= No Conformity C= Conformity

	NC	C	Comments
1. Criteria			
1.1 Provider and/or origin clearly identified and verified?			
1.2 Integrity of the lot maintained during the transport to the establishment?			
1.3 Integrity of the lot maintained during the process in the establishment?			
1.4 Separation or addition of lots is registered?			
1.5 Identification/marks/codes allow tracking of the products?			
1. 6 Product recall plan is formalized and operational?			
2. Records review			
2.1 Destination of products identified and data is verifiable?			
2.2 Suppliers are listed under the control of the CA for the China?			
2.3 In case of product recall, records are updated and complete?			
TOTAL			

Corrective Actions Request

Non Conformity	Timeframe	Action Required	CA verified

Comments back page

Evaluation of Compliance

Verifiers name and signature	Operator name and signature[1]	Verification by DoF or delegated authority Date:

F 12 – Corrective Actions Request **REF.:**

Name of the establishment:	**Approval Number:**
Verification Officers:	**Representatives of the establishment:**
Checklists in Reference:	

Non conformity	**Required action**	**Proposed Timeframe**[1]
Infrastructure		
Hygiene & Practices		

Non conformity	Required action	Proposed Timeframe[2]
HACCP & Pre-RP		
Comments		

Verifiers name and signature	Representative name and signature[3]

DoF – Control	Date:	Comments:
Name: Signature:		

Form: F13 Edition 01 Revision 00	Department of Fisheries Edible aquatic animal products Official Controls Protocol **F 13 – Corrective Action Request (CAR) Follow-up and closing**	Page 1 of 1 Date of Issue: Date of Revision:

F 013 – Follow up / closing of Corrective Actions REF.:

Name of the establishment:	**Approval Number**
Verification Officers:	**Representatives of the establishment:**
Date:	**Date of last verification:**
Checklists in Reference:	

Non conformity	**Closing**			
	Y	**N**	**Extension**	**Comments**
Observations				

Verifiers name and signature	**Representative name and signature**[1]

DoF	Date:	**Comments:**
Name: **Signature:**		

F ~~14~~ 07 – Organoleptic evaluation

	REF.:
Name of the establishment:	**Approval number:**
Verification Officers:	**Representatives of the establishment:**
Type of product:	**Identification/marks/codes:**
Production stage:	**Temperature of product:**

WILL HAVE TO BE DEVELOPED

Verifiers name and signature **Date and time of verification**

F ~~15~~ 08 – Verification of aquaculture farms

REF::

Name of the Farmer / farm: **License number:**							**Approval Number:** **GAP Certification:**			
Farm type: Artisanal		**Advanced farming systems**					**Company representative:**			
Verification Officers										
References consulted:		**Verification type:**	**AA**		**ARA**		**FRV**		**PI**	
		Date and time of verification:								

Full Verification for: approval audit (AA), annual reapproval (ARA), full routine verification (FRV), and partial inspection according to selected sections (PI)

Verification of aquaculture farms

NC= No Conformity **C**= Conformity

ALL TYPES OF FARMS	**NC**	**C**	Obs.
1. Site Location and selection			
1.1 Is the site sensitive to environment interferences (pollution, flooding, dangerous activities around, faecal contamination, etc)?			
1.2 Are dangerous chemicals used in the vicinity?			
1.3 Are dangerous pollutants present around?			
2. Ponds conditioning, fertilizers and feed			
2.1 Were the ponds properly conditioned?			
2.2 Only safe fertilizers used?			
2.3 Feed stock properly rotated?			
2.4 Feed ingredients approved by the CA?			
2.5 Feeds clearly labelled & composition declared?			
2.6 Feeds not containing prohibited substances?			
3. Veterinary medicines and withdrawal periods			
3.1 No use or Only authorized drugs applied?			
3.2 Indications, doses and administration records, Vet signed?			
3.3 Shrimp/Fish treated kept separated? Records?			
3.4 Withdrawal periods respected? Records?			
4. General hygienic conditions			
4.1 Harvesting materials, containers, boxes, pipes, surfaces easy to clean?			
4.2 Are they kept in a satisfactory state of cleanliness?			
4.3 Domestic animals excluded?			
4.5 Are rodenticides, insecticides, disinfectants and any other toxic substance kept stored where they can be locked?			
4.6 Can these toxic products contaminate the fish products or the ponds water?			
6. Containers for shrimp /fish			
6.1 Do they protect fish from contamination?			
6.2 Do they preserve fish in a hygienic manner?			
6.3 Do they allow for easy drainage of water?			

5. Personnel			
5.1 Have farmer(s)/workers undergone GAP training?			
5.2 Is any person that can contaminate the products excluded from handling them?			
5.3 Do all the workers wear suitable and clean working clothes?			
5.4 If they have wounds are they covered with waterproof bandages?			
5.5 Does the staff respect and understand minimal hygiene instructions of not smoking, spitting, eating and drinking during work?			
6. Ice			
5.1 Does ice come from suitable source, produced from potable water?			
5.2 Is ice stored in containers designated for this purpose?			
5.3 Are the ice containers clean and well maintained?			
8. Traceability			
8.1 Register and records maintained respecting the buying of post-larvae and selling of shrimp/fish?			
8.2 Feeds (types, name, provenience and batch number) provided to each batch production are registered and identifiable?			
8.3 It is possible to identify from where post-larvae came from and to where/whom shrimp/fish was sold to?			
TOTAL			

In case of advanced farming systems

Minimum prerequisite plans to be in place, monitored and properly registered (*)			
Prerequisite plan	**Y**	**N**	**Comments**
~~9.~~5. Veterinary drug withdrawal periods control			
~~10.~~6. Monitoring of residues for vet drugs and pesticides			
~~11.~~7. Personnel Hygiene and health control			
~~12.~~8. Quality of water and ice management			
~~13.~~9. Pest control			
~~14.~~10. Cleaning and disinfection			
~~15.~~11. Quality of feeds supplies control			
~~16.~~12. Waste and debris management/elimination			
~~17.~~13. Identification of the lots and withdrawal plans			

All the plans are required. No file can be considered in their absence

General comments

Evaluation of Compliance

Verifiers name and signature	**Representative name and signature**[1]

Form: F16 Edition 01 Revision 00	Department of Fisheries Edible aquatic animal products Official Controls Protocol **F 16 – Verification of a hatcheries**	Page 1 of 2 Date of Issue: Date of Revision:

F16 – Full Verification of Hatchery:

REF:

Name of the establishment:	Approval Number:
Verification Officers	Establishment representatives
References consulted:	Verification type: AA ☐ ARA ☐ FRV ☐ PI ☐ Date and time of verification:

Full Verification for: approval audit, annual re-approval, full routine verification, and partial inspection (according to selected sections)

NC= No Conformity C= Conformity

Infrastructure condition, good manufacturing practices and Hygiene	NC	C	Observations/Comments
1. Water collection, storage and management unit			
1.1 Sufficient structures (breeding and quarantine requirements)			
1.3 Ponds and tanks are drainable and capable of being dried.			
2. Water treatment, purification and settling			
2.1 Incoming water from non-polluting sources, of appropriate quality and able to be treated: Sources of brine / of brackish water / of fresh water			
2.3 Treatment facility is isolated from other water supply system			
2.4 There is settlement tank(s)			
2.5 Incoming water is disinfected			
3. Maturation unit (e.g. shrimp)			
3.1 Physically isolated			
4. Nauplii/Larva production unit			
4.1 Spawning and hatching techniques are used which promote production of high quality, disease free eggs and nauplii			
4.2 Tanks are physically isolated.			
5. Artemia hatching facilities			
5.1 Physically isolated and adequate			
5.2 Disinfection of the Artemia nauplii from viral, bacterial, fungal, and parasitic diseases and removal of unhatched cysts from the nauplii.			
6. Larval rearing facilities			
6.1 Tank water of Larval rearing facilities is as good as the level of treatment applied to it			
6.2 Nauplii are stocked at a proper density			
7. Mechanical unit (power supply, blower, boiler, thermostat etc.)			
7.1 A 3 phase electrical connection to ensure un-interrupted power supply.			
7.2 Standby generator(s) to meet the emergency requirements.			
7.3 Standby generator not located adjacent to maturation area			
8. Laboratory and required equipment			
8.1 Broodstock to be used is checked for disease at least MBV and WSSV			
8.1 The sample of larvae is taken quickly to the laboratory to provide information on the stage, condition, feeding and digestion and presence of any disease or physical deformity.			
8.2 Samples are sent to a PCR laboratory once (2-3 days before harvest) or twice (at nauplius or PL5 also) during the cycle for viral diseases			
9. Effluent Management			
9.1 System that nChinatralizes or dilutes chemical levels before discharge into natural bodies of water.			
9.2 Records on effluent monitoring maintained and available			
10. Storage and Disposal of Hatchery Supplies			

~~10.1 Fuel, lubricants and disinfection, cleaning and medicinal chemicals stored and disposed in safe and responsible manner.~~

Form: F16	Department of Fisheries	Page 2 of 2
Edition 01	Edible aquatic animal products Official Controls Protocol	Date of Issue:
Revision 00	**F 16 – Verification of a hatcheries**	Date of Revision:

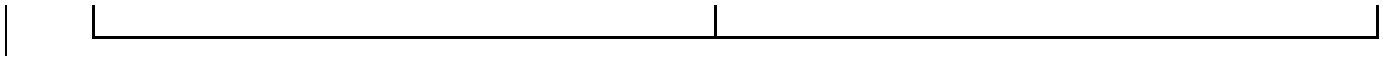
	NC	C	Observations/Comments
11. Drug and Chemical Management			
11.1 Hatchery maintains inventory records for all veterinary drugs and chemicals used.			
11.2 Antibiotics banned or unapproved not present or used			
11.3 Utilisation of authorised drugs, are registered and traceable by lot / tank; Quarantine and withdrawal periods are respected.			
11.4 Documented SOPs			
12. Sanitation			
12.1 Foot bath properly located and maintained			
12.2 Hand washing station properly located and maintained			
13. Requirement of land			
13.1 Land area is more than 0.75 acre			
13.2 Facility's production areas built to adequately contain hatchery stocks and minimize the risk of disease contamination of native species through drainage or accidental release			
14. Technical manpower			
14.1 Adequate supervisory, technical and supporting staff for all stages of operation.			
15. Annual fish seed production information			
15.1 Annual fish seed production information is available			
16. Bagda brood collection and rearing			
16.1 Bagda broods collected from more than 40m depth in sea			
16.2 Only large, productive, healthy, disease free shrimp are selected			
17. Production capacity			
17.1 Production capacity of hatchery: minimum 5 (five) lakh PL (0.5 milion)			
			Observations/Comments
TOTAL			

General Comments

Evaluation of Compliance

Verifiers name and signature	**Representative name and signature**

DoF – Control	Date:	**Comments:**
Name:		
Signature:		



Form: F17 Edition 01 Revision 00	Department of Fisheries Edible aquatic animal products Official Controls Protocol **F 17 Verification of a Feed Mills**	Page 1 of 3 Date of Issue: Date of Revision:

F17 Full Verification of Feed Mill:

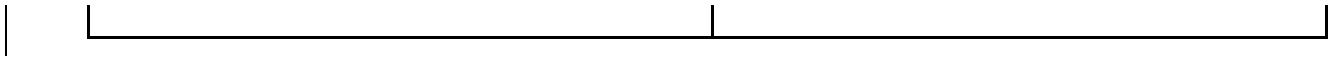
REF:

Name of the establishment:	**Approval Number:**
Verification Officers	**Establishment representatives**
References consulted:	**Verification type:** AA ☐ ARA ☐ FRV ☐ PI ☐ **Date and time of verification:**

Full Verification for: approval audit, annual reapproval, full routine verification, and partial inspection (according to selected sections)

NC= No Conformity C= Conformity

Infrastructure condition, good manufacturing practices and Hygiene	NC	C	Observations/Comments
1. Factory building			
1.1 Buildings, and facilities in good repair.			
1.2 Adequate layout and space for equipment, processing, receiving, shipping and storage of feed and ingredients.			
1.3 Work areas are reasonably clean, orderly and well lit			
1.4 Chemicals or toxic substances are physically separated from feed and feed ingredients.			
1.5 Infrastructure minimizes access to birds and pests			
2 Fish feed manufacturing machineries			
2.1 Equipment allows inspection and use of clean-out procedures.			
2.2 All equipment is reasonably clean and properly maintained.			
2.3 All equipment is of suitable size, design, construction, and precision for the intended purpose.			
2.4 Magnets and screens are routinely checked for proper operation and cleaning.			
2.5 Machinery have appropriate dust extraction / protection			
3. Fish feed weighing and packing house			
3.1 Packaging done in a clean, contaminant free environment.			
3.2 Feed / ingredients packaged in a manner to maintain identity.			
3.3 Labels comply with applicable laws and regulations.			
4. Quality fish feed storage or godown			
4.1 Sacks are stored on pallets in a clean environment free of contaminants and are not in contact with walls or the floor.			
4.2 Ingredients are stored in a separate location from finished feeds and are clearly identified.			
4.3 Damaged, moldy or adulterated products are not present.			
4.4 Pest infestation is not apparent.			
4.5 Storage promotes "first in/first out" usage.			
4.6 Open or torn bags are not present ????.			
5. Water supply			
5.1 Water used as an ingredient is suitable for animals			
6. Laboratory and required technical manpower			
6.1 Feeds analyzed to propensity for variation and potential risk.			
6.2 Corrective actions are documented.			
6.3 Trained personnel review test results.			
7. Quality control management and hygienic environment			
7.1 Lot number of ingredients are recorded, visually inspected and sampled before use.			



	NC	C	Observations/Comments
7.2 All finished feed products are sampled and visually inspected by trained personnel.			
8. Waste management unit and sewerage facilities			
8.1 Garbage containers are sufficient and clean			
8.2 Sewerage facilities are clean and good repair.			
8.3 Waste ingredients and unwanted finished product is recovered as feed only after confirmation that are not hazardous			
9. Boundary wall			
9.1 Boundary wall is sufficient to prevent unwanted pests/ animal			
10. Feed ingredient receiving unit			
10.1 All ingredients are approved for use in commercial feed			
10.2 At receiving all raw materials assessed by authorized person			
10.3 Ingredients are stored in a separate location from finished feeds and are clearly identified.			
10.4 Ingredients storage promotes "first in/first out" usage.			
11. Processing unit			
11.1 The establishment describes the manufacturing operation for the feed (e.g., formulation, mixing and production practices).			
11.2 A trained employee is designated as the person responsible for the production process.			
11.3 Different production stages are carried out according to pre-established written procedures and instructions.			
11.4 All equipment are under a routine maintenance and cleaning chapter, including monitoring allowable tolerances for moving parts.			
11. Mixing unit			
11.1 Mixers are used according to manufacturer's specifications.			
11.2 The accuracy and efficiency of the mixing process is regularly checked at intervals.			
11.3 Mixers and conveyers do not contain excessive buildup of old material.			
12. Boiler, air compressor, control panel			
12.1 Where the temperatures of the finished feed, process and/or environment are critical to the product's safety and legality, this is adequately controlled, monitored and the control measures are recorded			
13. Pelleting unit conditions			
13.1 Adapted to the stability of the incorporated feed additives.			
14 Fish feed weighing equipment			
14.1 Fit for the purpose and easily cleanable.			
15 Packing and leveling, traceability documentation unit			
15.1 The packaging is designed to protect finished feed.			
15.2 Labels meet regulatory requirements			
15.3 Records kept for each delivery of incoming feed: Date/time of intake / Name of incoming feed / Quantity / Name of supplier / Delivery order or reference / Analytical results relevant for the feed safety management / Country of origin			
15.4 Purchased Premixtures and Additives, additional records kept: Approval or registration number / Manufacturers' batch number(s) / number of containers for each batch			

	NC	C	Observations/Comments
15.5 Additives, additional records kept: Generic name of the feed additives / Average quantities of active substances guaranteed by the supplier / Instructions of use / Shelf life time			
15.6 Records kept for each batch of manufactured products: Nature of the feed (product number, species of destination) Batch number / Manufacturing date/time, Nature and proportion of feed materials, premixtures and feed additives used in accordance with the actual formula; Procedures followed to ensure safety requirements and avoidance of carry over			
15.7 Records kept on recipient of the final product: Nature of the feed (product number, species of destination) Batch number / Name and address / Date/time of delivery / Delivery order or reference / Delivery vehicle identification.			
16. Recall Procedure			
16.1 All feeds are identified by a code that links the product to a traceable history of production.			
17. Staff Training			
17.1 Personnel working in direct contact with feed and/or feed ingredients undergone training to minimize the risk of adulteration of feed and/or feed ingredients.			
17.2 Records are available that demonstrate personnel competence and training			
18. Personnel Hygiene			
18.1 All personnel in direct contact with feed and feed ingredients conform to good hygienic practices.			
19. Supervision			
19.1 Supervisors are knowledgeable of all aspects of the quality assurance program.			
TOTAL			

General Comments
Evaluation of Compliance

Verifiers name and signature	**Representative name and signature**

DoF	Date:	**Comments:**
Name: **Signature:**		

Application Form: Producer / Exporter registration and listing

Registration to be included in the listing of producers authorised for:	**CA Verification**
[ ] Production of fish products [ ] export to the China [ ]exports to other countries [ ] supplier of processing establishments	
1. Exporter Identification	
A unique identification will be assigned to each exporter.	
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	[ ] Farm
[ ] Fishing Vessel	[ ] Fishing Vessel [ ] Coastal [ ] Off Shore [ ] Reefer
[ ] Cool Store	[ ] Cool Store
	[ ] Ice Factory
	[ ] Transporters
	[ ] Depot

Type of Product	
[ ] Wild Caught [ ] Fresh/Frozen [ ] Aquaculture [ ] Smoked [ ] Conserved [ ] Others:	Species:

1. Applicant Declaration: To be completed by applicant. I declare that:

~~18.~~14. I am authorised to make this application as the producer/exporter/supplier or person with legal authority to act on behalf; and

~~19.~~15. the information supplied in this application is truthful and accurate to the best of my knowledge; and

~~20.~~16. the applicant is a Bangladeshi, and in within the meaning of applicable sections of company registrations and tax purposes legislation, and

~~21.~~17. 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 Bangladeshi, and

~~22.~~18. I accept that verifications and control of Fish &Fishery Products establishments, will be performed by the Ministry of Fisheries and Livestock – Department of Fisheries as the Competent Authority (CA), and

~~23.~~19. I accept that the obtaining of this registration is conditional to a positive outcome of a Verification visit performed by Competent Authority against standards laid down under the relevant requirements and the contents of the CA procedures issued and managed by the CA, and

~~24.~~20. I accept that maintaining this registration as part of the listing of companies allowed to produce/export/supply/export to the China, is dependent on continuous regulatory compliance and ongoing performance against standards laid down under the relevant requirements and the contents of the CA procedures issued and managed by the CA, and

~~25.~~21. I accept that receiving health certificates that this registration entitles me, is dependent on regulatory compliance and ongoing performance against standards laid down under the relevant requirements and the contents of the CA procedures issued and managed by the CA.

Name:	**Date:**
Designation:	**Signature:**

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 China under prior verification regimes, this ID would be maintained.

Official Use Only: