Kingdom of Saudi Arabia

Saudi Food and Drug Authority

Operations Sector

Manual of Procedures: Export of Cultured Shrimp and Finfish products to European Union

(Export Legislation)

8th Edition

25th October 2023

Date: 08 Oct 2023
Saudi Food and Drug Authority,
Kingdom of Saudi Arabia

The official regulation and procedures concerned with export of Aquaculture Products to the European Union shall abide with the following stipulations:

- Saudi Food & Drug Authority (SFDA) has been assigned as the Competent Authority in dealing with all matters related to the export of food products and food by-products from Saudi Arabia (Feed Law issued by Council of Ministers (Decree No. 377 dated 17/9/1435H)
- Formation of Saudi Food and Drug Authority to manage food and drug sectors of Saudi Arabia – Council of Ministers resolution No:1 dated 07/01/1424 H, 4693/R dated 26/01/1428H
- On behalf of SFDA, the Import and Export of Food & Pesticides Permission Section (IEFPPS), which functions under Executive Department of Registration and Licenses of Saudi Food & Drug Authority (SFDA), shall supervise the system of export of aquaculture products to European Union.
- The Vice-president of Operations Sector, SFDA shall be responsible for all final decisions, approvals and endorsements concerning export of feed and food products from Saudi Arabia.
- The official regulation and procedures concerned with the export of Aquaculture Products to the European Union as approved by the Saudi Food Drug and Authority – SFDA, shall be applicable for all Establishment exporting to European Union as follows:

    - The Import and Export of Food & Pesticides Permission Section (IEFPPS) shall, on behalf of SFDA supervise and coordinate the system of export of Aquaculture Products European Union.

- The Food Factory Inspections Section (FFIS) shall coordinate all audits and inspections in the Establishments with the help of SFDA Branches. The auditors from the SFDA Branches shall carryout audits and inspections.
- All stipulations and controls shall be in line with the applicable EU regulations and guidelines, which shall be implemented, monitored and verified by Import and Export of Food & Pesticides Permission Section (IFFPPS)
- Any changes or amendments in the EU Regulations, communicated to the Competent Authority shall be endorsed and incorporated in the "Manual of Procedures - Export of Aquaculture Products to European Union".
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- Interim decisions shall be taken by Technical Committee (TC) in accordance with national regulation, other applicable standards etc. shall be incorporated in subsequent revisions of this manual
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- The revisions and changes shall be approved by the Vice President Operations Sector, SFDA.

SFDA hereby approves the export legislations and content of "Manual of Procedures: Export of Aquaculture Products to European Union" to be followed in all matters related to the said export.

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Sami Al Sager

Vice-president, Operations Sector

Saudi Food and Drug Authority

Contact details of major Government Departments that are involved in the Export of Aquaculture Products to European Union:

1. The Competent Authority:

A. **The Office of Executive Department of Support inspection Executive** Department of Support inspection– Operations Sector

Saudi Food and Drug Authority

P.O. Box SFDA – 3292

Northern Ring Road, Hitteen Area unit (1)

Riyadh – 13513 – 7148, KINGDOM of SAUDI ARBIA

Tel: 00966 11 2038222 Ext.5368, Fax: 00966 11 2751367

B. **Department of Imports and Exports**

Import and Export of Food & Pesticides Permission Section (IFFPPS)

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2. The Ministry of Environment, Water and Agriculture – MEWA

The General Director

General Directorate of Fisheries

Ministry of Environment, Water and Agriculture

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Part I
Working Procedures & Structure

1. Subject Matter, Scope and Definitions

1.1. Subject Matter

1.1.1. These stipulations lay down the general working procedure and administrative structure of the Saudi Arabian government system for the export of Aquaculture Products to European Union.

1.1.2. The administrative framework and unified procedures are adopted to ensure a harmonized system to implement and monitor the export of Aquaculture Products to EU.

1.2. Scope

1.2.1. This administrative structure and procedures shall apply to the export of Aquaculture Products.

1.2.2. The administrative structure, procedures and stipulations shall cover all the requirements of producing a safe product complying with applicable EU regulations.

1.3. **Definitions -** The definitions shall be applicable for Export system for Aquaculture Products to European Union.

1.3.1. **GDF- MEWA** General Directorate of Fisheries, Ministry of Environment, Water and Agriculture.

1.3.2. '**Animal**' - Any invertebrate or vertebrate animal.

1.3.3. **'Animal By-Products** - Entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption.

1.3.4. '**Associating Department'** – a government department associated with the Competent Authority in the management of export of Aquaculture Products to European Union.

1.3.5. '**Aquaculture'** - Aquaculture is the farming of aquatic organisms, including fish, mollusks, crustaceans and aquatic plants. Farming implies some form of intervention in the rearing process to enhance production, such as regular stocking, feeding, protection from predators, etc. Farming also implies individual or corporate ownership of the stock being cultivated.

1.3.6. '**Batch'** – A unit of production produced in a single plant using uniform production parameters, such as the origin of the materials, or a number of such units, when produced in continuous order in a single plant and stored together as a shipping unit.

1.3.7. '**Branches'** – The local stations of Competent Authority / Government agency at different locations primarily responsible for audits, inspections and sample collection

1.3.8. **CA** – The Competent Authority.

1.3.9. '**Carcasses'**– The dead body of the animal as defined in point 1.9 of Annex I to Regulation (EC) No 853/2004.

1.3.10. '**Clean Seawater'** means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food;

1.3.11. '**Competent Authority'** – The central authority of Saudi Arabia competent to ensure compliance with the requirements of this Regulation or any authority

to which that competence has been delegated. Saudi Food and Drug Authority – SFDA shall be the Competent Authority of Saudi Arabia which is the corresponding office to European Union for all matters concerning export of Aquaculture Products.

1.3.12. '**Derived Products**'– Products obtained from one or more treatments, transformations or steps of processing of animal by-products.

1.3.13. '**DAF**' – Department of Animal Feed, SFDA.

1.3.14. '**IEFPPS**'– Import and Export Food &Pesticide Permission Section, SFDA

1.3.15. **'FFIS'** – Food Factory Inspections Section, SFDA

1.3.16. **'EDIS'** – Executive Department of Inspection Support & Branches, SFDA.

1.3.17. **'EDRL'** – Executive Department of Research and Laboratories, SFDA.

1.3.18. **'EDSPA'** – Executive Department for Standards and Product Assessments.

1.3.19. '**Establishment**' – Any place where any operation involving the handling of Aquaculture Products. The term 'Establishment' also implies the Establishment or management of the Establishment. But if a specific process is carried out in the primary production of Aquaculture (in hatcheries and farms) specific terminologies shall be used.

1.3.20. **Executive Body/Agency** – government agency involved in the program of export of Aquaculture Products to European Union.

1.3.21. '**Export'** – Product movement from Saudi Arabia to European Community (or to other countries if specified).

1.3.22. '**Farmed Animal'** – Any animal that is kept, reared, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins or any other product obtained from animals or for other farming purposes.

1.3.23. '**Feed'** or 'Feeding Stuff' – Feed or feeding stuff as defined in Article 3(4) of Regulation (EC) No 178/2002.

1.3.24. '**Food'** or 'Foodstuff' – Food or foodstuff as defined in Article 2 of Regulation (EC) No 178/2002.

1.3.25. '**Fresh fishery products'** - means unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling.

1.3.26. '**Hatchery'** - an Establishment which produces the seedlings and supply to farms.

1.3.27. '**Incineration'**- The disposal of Aquaculture by-products/derived products as waste, in an incineration plant, as defined in point 4 of Article 3 of Directive 2000/76/EC.

1.3.28. '**MEWA'** - Ministry of Environment, Water and Agriculture, Saudi Arabia (Competent Authority for export of Fish and Fishery products to Non-EU countries)

1.3.29. '**Mechanically separated fishery product'** - means any product obtained by removing flesh from fishery products using mechanical means resulting in the loss or modification of the flesh structure.

1.3.30. '**Notifiable Diseases'** - the diseases that are to be notified (informed) to the National Animal Health Authority, OIE and other International agencies on an urgent basis.

1.3.31. '**Outbreak'** – The spreading of a notifiable animal disease (here, Aquaculture diseases) within the local community;

1.3.32. '**Pet Animal**' – Any animal belonging to species normally nourished and kept but not consumed, by humans for purposes other than farming.

1.3.33. '**Placing on the Market'** – Any operation with a purpose of products or derived products to a third party in the European Community or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party.

1.3.34. **'Potable water'** - means water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

1.3.35. '**Prepared fishery products**' - means unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting, and chopping.

1.3.36. '**Primary Production Or Primary Production units/sector'** – The primary production of Aquaculture includes Aquaculture Hatcheries, Aquaculture Farms, Other rearing units, its environment and all the related operations before processing. This also includes harvested animals (from farm) dispatched for processing.

1.3.37. '**Processing Plant (Aquaculture Processing Plant)**' – is the place where the Aquaculture Products are processed for human consumption. The activity of the processing plant commences with the receipt of raw material from the primary production units.

1.3.38. '**Products of animal origin'** – Products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004.

1.3.39. '**Quarantine Station'** - A facility where the Aquaculture is kept in complete isolation and away from direct or indirect contact with other Aquaculture, so as to permit long-term observation and testing for diseases

1.3.40. **SFDA** – Saudi Food and Drug Authority

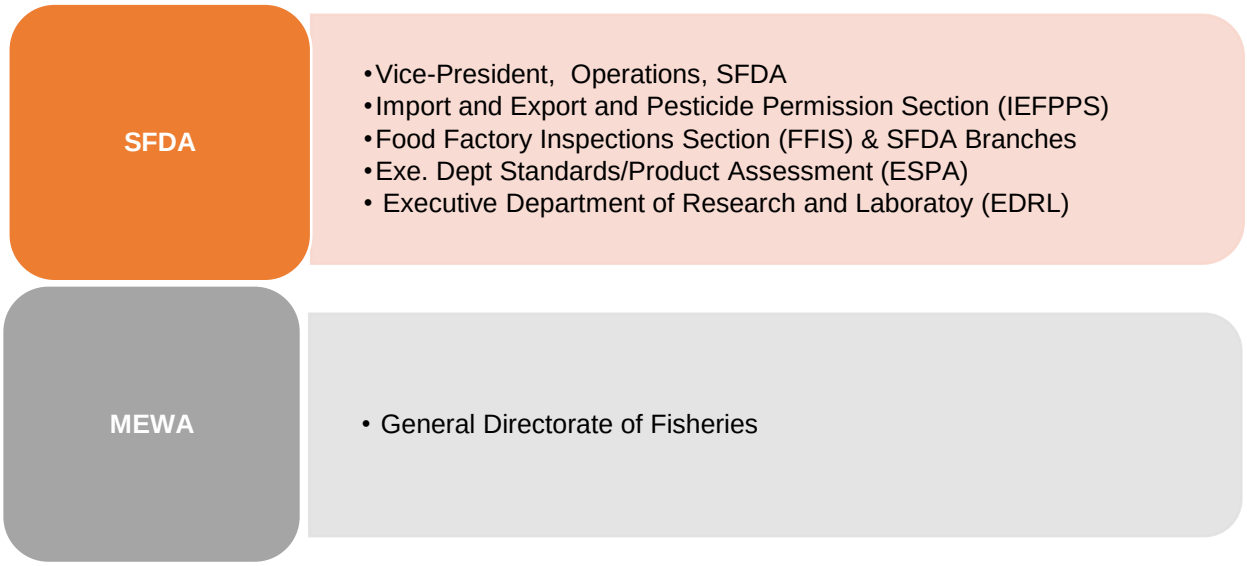
1.3.41. '**Transit'** – The movement through the European Community from the territory of a third country to another third country, other than by sea or by air.

1.3.42. '**Waste'** – It is the waste as defined in point 1 of Article 3 of Directive 2008/98/EC.

1.3.43. **Wild Animal'** - Any animal not kept by humans.

Chart 1

Government Departments Involved in the Export of Aquaculture Products



2. Government Agencies Involved in Export of Aquaculture Products

2.1. **Saudi Food and Drug Authority-SFDA** shall be the Competent Authority of Saudi Arabia in the export of Food Products, headed by the office of Vice-President, Operations Sector.

2.1.1. The SFDA consists of four main sectors including Operations, Food, Drug and Medical Devices.

2.1.2. The Operations sector of SFDA handles all matters connected with import and exports of food, feed, drugs and medical devises (except live animals, export of fish and fishery products to non-EU countries).

2.1.3. Refer Appendix- 1 for the organizational structure – Export System for Food Products including Aquaculture Products

2.1.4. Among the SFDA departments the following departments are involved in export control of Aquaculture Products as follows:

2.1.4.1. Import and Export of Food & Pesticides Permission Section (IEFPPS)

2.1.4.2. Food Factory Inspections Section (FFIS) and SFDA Branches.

2.1.4.3. Executive Department of Standards/Product Assessment (ESPA).

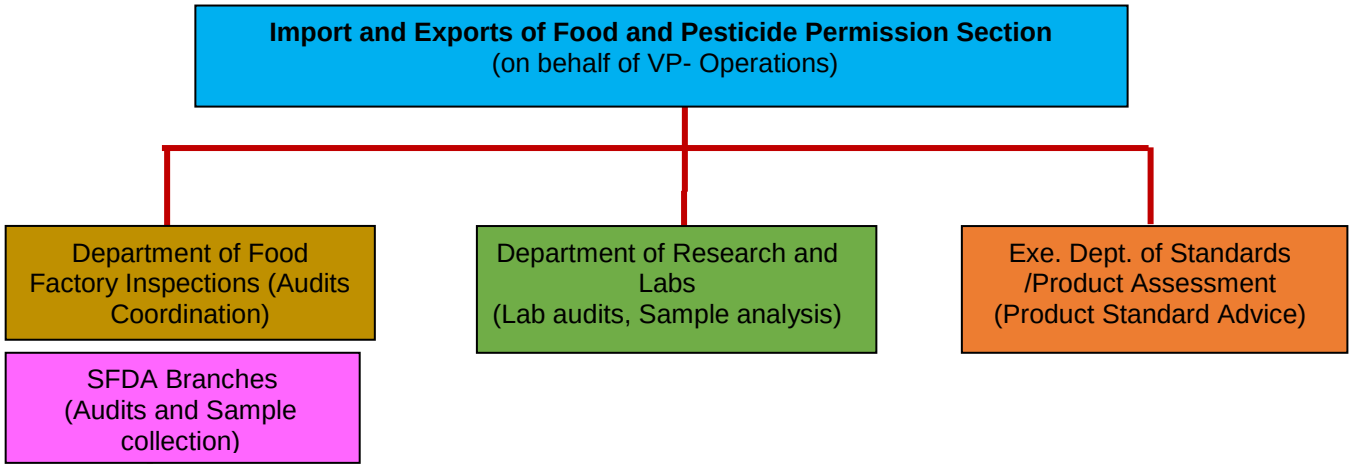
2.1.4.4. Executive Department of Research and Laboratory (EDRL).

2.1.5. IEFPPS shall be, on behalf of SFDA, coordinating and supervising all activities related to Aquaculture Products Export

Other Departments shall function as other '**Associating Departments'** from SFDA

Chart-2

Interactions of SFDA Departments



Ministry of Environment, Water and Agriculture (MEWA) shall be the other important government agency that participates in the export of Aquaculture Products from Saudi Arabia.

2.1.6. In MEWA, the General Directorate of Fisheries (GDF-MEWA) shall be responsible for all aquaculture related matters of the country concerning animal resources, animal production, animal health, animal welfare, animal biosecurity in aquaculture and related lab analyses.

2.1.7. The General Directorate of Fisheries shall supervise all the matters related to export of Aquaculture Products.

3. Roles and Responsibilities of the Competent Authority and its Departments

3.1. **The Office of Vice-President, Operations Sector –** This office shall be responsible for matters such as:

3.1.1. Final approval of all matters related to export of food, feed products, by-products and derived products.

3.1.2. Standing as the communication link point between the Kingdom of Saudi Arabia and the importing countries.

3.1.3. Providing guarantees to importing countries and its official bodies that food products, by-products, derived products and feed exported from the Kingdom of Saudi Arabia has undergone strict official controls to meet the consumer safety, animal health and quality stipulations.

3.1.4. Sending list of Approved Establishments to the importing countries.

3.2. **Import and Export of Food & Pesticides Permission Section (IEFPPS).**

3.2.1. The IEFPPS shall be responsible for coordination and supervision of all activities and assignments related to exports of Aquaculture Products, on behalf of the office of the Vice-president, Operations Sector.

3.2.2. Responsibilities of IEFPPS in the Export of Aquaculture Products

3.2.2.1. The overall supervision of activities related to the said export.

3.2.2.2. Receiving reports and recommendation from the Technical Committee for further action.

3.2.2.3. Communication with other committees and Establishments about different matters related to food export as well as for the product standards.

3.2.2.4. Coordination between different committees, Competent Authority (CA) and Establishment.

3.2.2.5. Proper distribution of documents, directives, communications and other relevant information among the committees.

3.2.2.6. List the tests/analyses to be conducted by Government agencies and Establishment laboratory through the Manual.

3.2.2.7. Ensure that the Technical Committee meetings and other meetings are held as per schedule.

3.2.2.8. Making necessary arrangements to convene deferent committee meetings.

3.2.2.9. Regular monitoring of overall activities of the Establishment to ensure that the Establishments meet the government stipulations

3.2.2.10. Ensuring “Manual of Procedures - Export of Aquaculture Products” meets applicable national and international stipulations.

3.2.2.11. Coordinating for the final approval of Establishments for exports to various countries. Refer Appendix-2 for Establishment Approval.

3.2.2.12. Allocation of 'Approval Number' to Approved Establishments that exports food products, (in consultation with the office of Vice President and other departments involved in other food exports).

3.2.2.13. Identifying external (national/international) laboratories, to conduct tests and analysis, as the need arises to meet the analysis requirements for food and feed exports.

3.3. The Food Factory Inspections Section (FFIS) and SFDA Branches

3.3.1. The FFIS is responsible for coordination of Establishment inspection and audits (including GLP audits) and sample collection for analysis

3.3.2. The FFIS shall coordinate with the SFDA Branch offices to assign auditors for Establishment audits.

3.3.3. The FFIS shall Participate in the Approval, Renewal audits

3.3.4. The FFIS shall issue formats/checklists to be used during Establishment inspections.

3.3.5. Auditors/inspectors of the SFDA Branches shall visit Establishments to ensure that the all the assigned tasks are carried out as per schedule through regular inspections and audits.

3.3.6. The Branches shall collect samples for analysis as per test requirements

3.4. Executive Department for Research and Laboratories - EDRL

3.4.1. The EDRL and its laboratories shall be responsible for all the lab tests and analyses of Aquaculture Products intended for export.

3.4.2. Divisions under EDRL

3.4.2.1. Food Control Laboratories

3.4.2.2. Monitoring Laboratory

3.4.2.3. Central Laboratory and Research Centre

3.4.2.4. Reference Laboratory

3.4.2.5. Packaging and Packaging Material Control laboratory

3.4.3. The General Functions of the EDRL in SFDA

3.4.3.1. Development of integrated system of accredited Food Laboratories.

3.4.3.2. Conduct tests and analysis of food items (both produced in the local market and also imported food).

3.4.3.3. Coordinate among different SFDA Food Laboratories.

3.4.3.4. Supervision and follow-up of all laboratories.

3.4.3.5. Ensure food safety through lab tests and analyses.

3.4.3.6. Implement surveillance programs in applicable departments.

3.4.3.7. Provide scientific, technical recommendation in case of dispute on test results between SFDA labs and declare the final decision.

3.4.3.8. Coordinate with other SFDA departments for laboratory supplies.

3.4.3.9. Meet the technical and administrative requirements of ISO 17025.

3.4.3.10. Capacity building for needed equipment and trained manpower.

3.4.4. The specific functions of EDRL as the National Reference Laboratory Department in the export of Aquaculture Products is explained in Article # 7 - 'Details of Laboratory System' of this manual.

3.5. Executive Department for Standards and Product Assessment - EDSPA

3.5.1. EDSPA shall be responsible for setting up product specifications, standards and technical regulations

3.5.2. General Functions of EDSPA

3.5.2.1. Setup standards and technical regulations of food, agricultural goods/products, feed, pesticides, and food packaging materials.

3.5.2.2. Represent Saudi Arabia in international events related to food standards and regulations (Codex).

4. Authority and Central/regional organization of the Competent Authority

4.1. Competencies, prerogatives and powers of SFDA as the Competent Authority.

4.1.1. SFDA shall have the overall responsibility of all matters pertaining to food and feed exports.

4.1.2. SFDA shall frame the legal, procedural, analytical requirements of export of Aquaculture Products from Saudi Arabia.

4.1.3. SFDA shall maintain well equipped, technically qualified, adequately trained manpower to handle audits, tests, legal formalities etc.

4.1.4. SFDA as CA, shall be the ultimate authority for approval, dismissal, suspension, and withdrawal of approval of export.

4.1.5. The CA shall have full authority to levy penalties / disciplinary steps, other action on Establishments that export Food Products from Saudi Arabia.

4.2. Organization of the Competent Authority at Central, Regional and Local Level

4.2.1. Saudi Food and Drug Authority represented by the office of the Vice President, Operations Sector, SFDA, has its head office in Riyadh.

4.2.2. The Riyadh Office shall head the Competent Authority Functions and responsibilities.

4.2.3. The Import and Export of Food & Pesticides Permission Section (IEFPPS) shall carry out the coordination of all food exports from its head office in Riyadh.

4.2.4. The office of IEFPPS in Riyadh shall monitor and manage the work activities of associating SFDA departments in the regional/local offices in different locations in Saudi Arabia.

4.2.5. IEFPPS shall be headed by the Head of Section /Manager.

4.2.6. All directions for control and instruction for system procedures and changes shall originate from the Riyadh office of IEFPPS to ensure and guarantee harmonized system in the whole country through its regional offices.

4.2.7. The FFIS that supervises the audits and inspection for all food exports which has its head office in Riyadh shall coordinate with SFDA Branches for effective audits and inspections.

4.2.8. The EDRL that carries out the analyses for food exports has its head office in Riyadh headed by the Executive Director of EDRL.

4.2.9. EDRL has regional laboratories to meet the national analyses requirements.

4.2.10. The Executive Department for Standards and Product Assessment (EDSPA) headed by the Executive Director has its head office in Riyadh.

CHART – 3

Regional Structure of Competent Authority

Competent Authority	Offices	Responsibilities
Office of V.P, Operations	Riyadh	The overall responsibility of export of food products.
Import and Export of Food & Pesticides Permission Section (IEFPPS)	Riyadh	Coordination of Food Exports
Food Factory Inspections Section (FFIS) and Branches	Riyadh (H.O)	1. Routine Establishment inspection
	All Branches	2. Issuing Health Certificate
		3. Collecting samples for analysis
Exe. Dept. for Research & Laboratories - EDRL	Riyadh (H.O)	1. Supervision of lab tests and Controls
	Dammam	2. GLP control in CA Labs
	Jeddah	3. GLP control in Establishment Labs
Exe. Department of Standards & Product assessment-EDSPA	Riyadh Office	Responsible for Standards and Regulations

5. Responsibilities of GDF-MEWA

5.1. GDF -MEWA, the General Directorate of Fisheries of Ministry of Environment, Water and Agriculture (MEWA) shall be the other important government agency working together with SFDA to ensure Aquaculture Products exported meet applicable requirements.

5.2. The General Directorate of Fisheries shall be responsible to provide all information about the general health status of the Aquaculture animals.

5.3. Concerned departments of MEWA shall provide all information about the prevalence status of infectious animal diseases in Saudi Arabia, which is listed in the Aquatic Animal Health Code of the World Organization for Animal Health.

5.4. In addition, responsible departments in MEWA shall provide other regulations on the prevention and control of infectious aquatic animal diseases in Saudi Arabia, including rules for imports of live animals.

5.5. The main focus of General Directorate of Fisheries shall be on the primary sector (environment, Aquaculture farms, till the raw material reaches processing establishment).

5.6. General Directorate of Fisheries shall be responsible for the National Residue Monitoring Program, Animal Health Monitoring, Disease/pathogen Control etc. and shall conduct all related inspections, audits, sample collection, lab tests etc.

5.7. General Directorate of Fisheries shall conduct audits (through MEWA's branch offices) in Establishments verifying the health requirements of Aquaculture production, and in particular the health status of the animals, use of veterinary medical products and it compliance, Animal welfare status etc.

5.8. General Directorate of Fisheries also shall take necessary corrective/legal actions in the primary sector to combat noncompliant results.

5.9. Keeping the fact that SFDA shall be responsible for overall supervision and final decisions of Drug and Residue Control in Saudi Arabia, General Directorate of Fisheries shall assist in controls in the primary sector as explained in the following clauses.

5.10. The specific functions and responsibilities of the General Directorate of Fisheries in MEWA in context of official controls on export of Aquaculture products are as follows:

5.10.1. Regulate Aquaculture Farming

5.10.2. Regulate Aquaculture drug residue program

5.10.3. Regulate general Aquaculture farming operation

5.10.4. Monitor and manage Aquaculture diseases

5.10.5. Regulate usage of veterinary drugs/chemicals

5.10.6. Regulate veterinary drug/chemical supply

5.10.7. Set National veterinary drug residue tolerance limit

5.10.8. Ensure that the Establishment laboratory meets requirements

5.10.9. List prohibited Vet. drugs/chemicals/pharmacologically active substances

5.10.10. Set national tolerance limit for veterinary drugs

5.10.11. Set national tolerance limits for other chemical contaminants, dyes etc.

5.10.12. Collect samples for “National Residue Monitoring Program- NRMP”

5.10.13. Fix frequency of sample collection

5.10.14. Fix types of samples, sampling methods and securing procedures

5.10.15. Collect and send samples for NRMP to Laboratories

5.10.16. Receive and review residue test results

5.10.17. Take necessary action when residues are detected above admissible limits

5.10.18. Collect background information and details of production and exports.

5.10.19. Define the scope of “National Residue Monitoring” plan

5.10.20. Set sample collection / testing frequencies and levels of controls

5.10.21. Set targeting criteria (if any)

5.10.22. Send copy of all reports of routine audits conducted (in farm) to the Competent Authority before last day of every calendar year

5.10.23. Provide all information about the general health status of farmed Aquaculture.

5.10.24. Provide all information about the existence status of infections aquatic animal diseases (OIE listed) in Saudi Arabia

5.10.25. Manage regulations on the prevention and control of infectious animal diseases in Saudi Arabia

5.10.26. Manage, control and monitor rules of Aquaculture imports (live animals, larvae, eggs etc.)

5.10.27. Establish strategies and regulations on animal disease control

5.11. Organization of the GDF- MEWA at Central, regional and local level

5.11.1. The office of the General Directorate of Fisheries with its head office in Riyadh carries out functions under the MEWA. The head office is responsible for managing all the activities related to aquaculture resources, aquaculture production, animal welfare, animal health and related test and analysis.

5.11.2. This office coordinates the work activities of its regional/local offices in different locations in Saudi Arabia. All such offices shall be under the direct control of the Head Office in Riyadh.

5.11.3. The head of General Directorate of Fisheries, shall supervise all the assigned responsibilities related to the Export of Aquaculture Products.

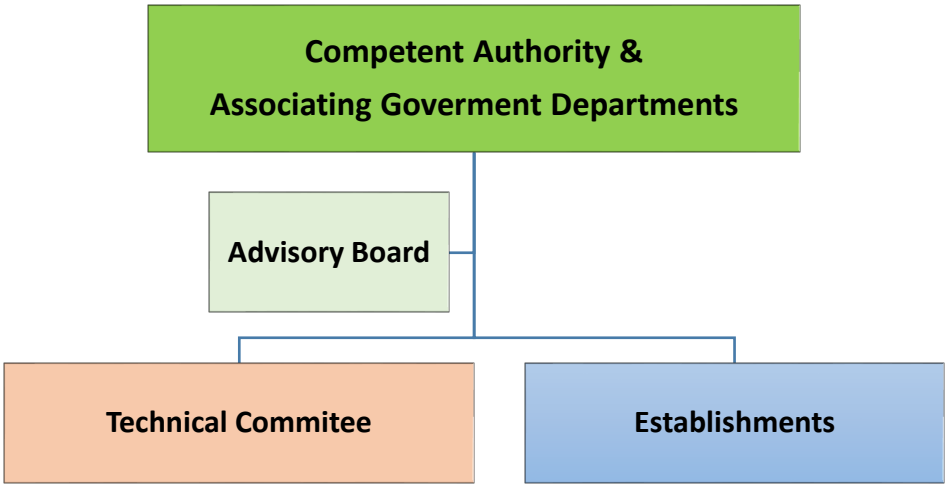
5.11.4. All directions for control, system procedures and changes shall originate from the head of General Directorate of Fisheries, Riyadh and ensure and guarantee harmonized system in the whole country through its regional offices.

6. Basic Administrative Structure of EU Export Control System

The agencies that form part of the Administrative structure for Export of Aquaculture Products are Competent Authority (along with the Associating Departments), Advisory Board, Technical Committee and Establishments.

CHART – 4

Organizational Structure – Exports Control System



6.1. Competent Authority and Associating Departments

6.1.1. Structure of the Competent Authority – The structure of CA shall be as follows:

6.1.1.1. The office of the Vice President, Operations Sector shall head the Competent Authority

6.1.1.2. The Import and Export of Food & Pesticides Permission Section (IEFPPS). shall be the executing body who act on behalf of the Vice-President of Operations Sector in all matters of Export of Aquaculture Products

6.1.1.3. Other associating departments shall support IEFPPS in the said assignments

6.1.2. The functional head of Competent Authority

6.1.2.1. The functional Head of Competent Authority shall be the Vice – President of Operations.

6.1.2.2. The Section head of IEFPPS shall assist the VP Operations to perform the duties and act on his behalf, in the context of export of all food and feed products.

6.1.3. The Functions of the Functional Head

6.1.3.1. Evaluation and approval of suggestions/ recommendations/ observation of the 'Technical Committee'.

6.1.3.2. Endorsement of approved amendments in the Manual of Procedures – Export of Aquaculture Products suggested by the Technical Committee.

6.2. **Advisory Board –** The Advisory Board shall be the body, which provide proactive advice to the export system. This body shall also help in solving problems and shall handle issues that require special attention.

6.2.1. **Structure of the Advisory Board** – The advisory board shall include the following members:

6.2.1.1. One member (minimum) from Import and Export of Food & Pesticides Permission Section (IEFPPS).

6.2.1.2. One member from Food Factory Inspection Section (FFIS)

6.2.1.3. One member (minimum) from The General Directorate of Fisheries of MEWA

6.2.1.4. Members from other departments as required.

6.2.1.5. One representative from the Establishment

6.2.1.6. Consultants / advisors if needed (as nominated)

6.2.2. **Functions of the Advisory Board :**

6.2.2.1. Give advice on specific issues related to export of Aquaculture products.

6.2.2.2. Give specific suggestion/review/update for the export system of Aquaculture products.

6.2.2.3. Evaluate proposals for changes in food export system and give advice.

6.2.2.4. Other advisory tasks as assigned by Technical committee.

6.3. **Technical Committee**

6.3.1. Technical Committee (TC) shall comprised the following:

6.3.1.1. Representatives from SFDA (two members from the Import and Export of Food & Pesticides Permission Section (IEFPPS).; one representative

from Food Factory Inspections Section (FFIS), one representative from Laboratory Dept. (EDRL) and one representative from each Branch (as required).

6.3.1.2. Two representatives from General Directorate of Fisheries of MEWA

6.3.1.3. Establishment Representative (One technical representative from each Establishment that export food. But the Establishment shall not involve in any Governmental decision making.

CHART – 5

Technical Committee

SFDA	•Two representatives from IEFPPS •One representqtave from FFIS • Branch Representatives (as required) •One representative from EDRL
GDF- MEWA	•Two representatives from MEWA
ESTABLISHMENT	•One technical representative from each EU approved Establishment

6.3.2. Functions of the Technical Committee - The Functions shall include:

6.3.2.1. Conducting detailed analysis and discussion on procedural, scientific and Technical matters connected with food exports.

6.3.2.2. This committee through Establishment audits, shall ensure that the Establishment follows procedures and meet stipulated standards.

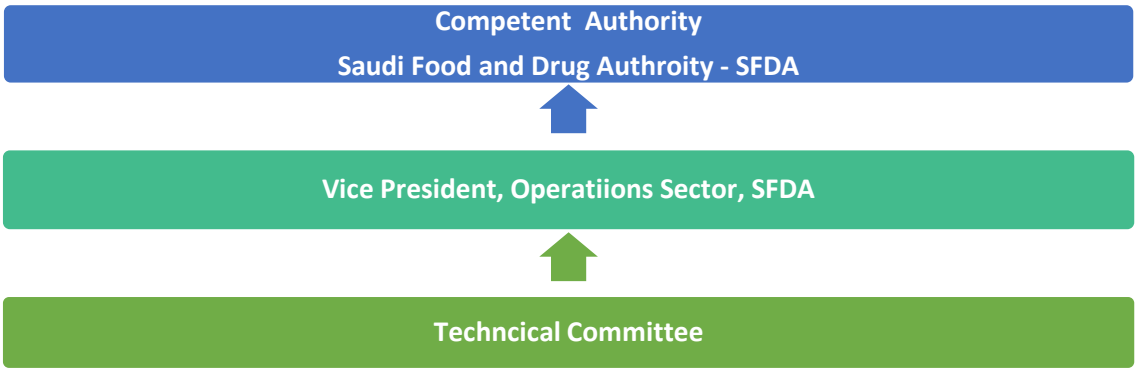
6.3.2.3. This committee shall review Aquaculture Product exports carried out by approved Establishments, their issues related to primary production, processing, storage, export, inspections, laboratory analysis etc.

6.3.2.4. This committee also shall be responsible for suggesting amendments in the Manual of Procedures: Export of Aquaculture Products" and update the manual as needed.

6.3.2.5. This committee shall convene meeting at least once in three months.

CHART – 6

Reporting line of Committees



6.4. **Establishments** - The Establishment shall be responsible to:

6.4.1. Accept and implement directions and advice officially issued by the CA.

6.4.2. Follow all conditions and procedures specified in the 'Manual of Procedures: Export of Aquaculture Products'.

6.4.3. The direct implementation of the standards and procedures prescribed by the Competent Authority.

6.4.4. Receive the assigned Government auditors and assist with them for conducting inspections/audits.

6.4.5. Give access to the auditors and inspectors of the Competent Authority to all buildings, premises, installations and/or other infrastructure.

6.4.6. Make available any documents and records required for audit as considered necessary by the Competent Authority for review/evaluation.

6.4.7. Abide by the national rules and regulations.

6.4.8. Develop and maintain required infrastructure facilities as stipulated and required for production of safe food/food products/by-products.

6.4.9. Maintain adequate qualified manpower for the export procedures.

6.4.10. Keep all necessary documents and records to a required period as stipulated by the CA.

6.4.11. Maintain hygiene and sanitation requirements in the Establishment.

6.4.12. Get all audits registered in 'Establishment Audit Register' after each audit

6.4.13. Give a Guarantee Letter (Appendix-3) at the time of Approval Audit and during every Annual Renewal Audit stating that "There is no possibility of any type of contamination to the products produced in the Establishment resulting in any public health or animal health risks. And there is a scientifically designed full traceability system for all products and processes." signed by the person in charge of the Establishment.

6.4.14. The Establishment shall not involve in making legislative procedures or in 'law making' in any way, unless suggestions are invited by the CA.

6.4.15. To send samples (self-monitoring) to CA approved labs for analysis.

6.4.16. The national standard/regulation or the International standard/regulation whichever stricter shall be followed in the export.

6.4.17. Relevant codes of practice of the Codex Alimentarius also shall be followed in operations as required.

6.4.18. Provide the Competent Authority with evidence of their compliance to the laws, regulations and stipulations of this manual

6.4.19. Establishments that export Aquaculture Products shall, as appropriate, adopt the following specific measures:

6.4.19.1. Compliance with microbiological criteria for foodstuffs;

6.4.19.2. Compliance with temperature control requirements for food;

6.4.19.3. Maintenance of the cold chain;

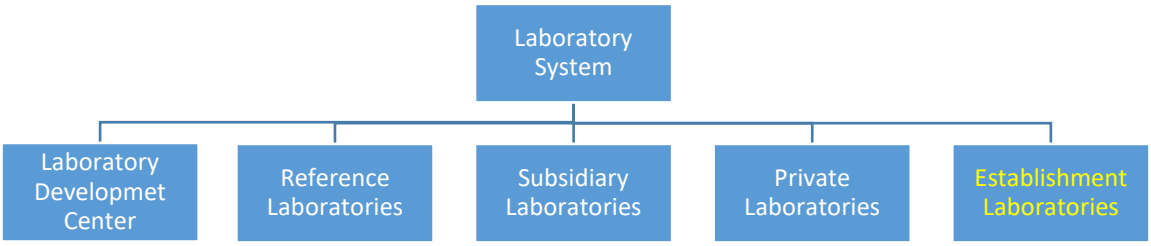
6.4.19.4. Sampling and analysis, using appropriate methods laid as per national /international requirements/ national legislation that offer scientifically valid results.

7. Details of the 'Laboratory System

The EDRL Laboratory of SFDA in Riyadh shall be the National Reference Laboratory for all analyses concerned with the export of Aquaculture Products. Subsidiary Reference Laboratories (Government owned) and Approved External Reference Laboratories shall function under the National Reference Laboratory to meet the analysis requirements of the said exports.

CHART – 7

Laboratory System



7.1. The Working Structure of Laboratories: As shown in the above figure, the Laboratory Working Structure shall comprise a National Reference Laboratory, Subsidiary Reference labs, External Reference Labs and Establishment Labs.

7.1.1. National Reference Laboratory – SFDA Laboratory in Riyadh (under EDRL) shall function as the National Reference Laboratory.

7.1.2. Subsidiary Reference Laboratories – The Subsidiary Reference Laboratories that conduct analyses for Aquaculture Products shall include the following laboratories:

7.1.2.1. EDRL Laboratory in Dammam

7.1.2.2. EDRL Laboratory in Jeddah

7.1.2.3. Central Laboratory of MEWA (Ministry of Environment, Water and Agriculture) in Riyadh

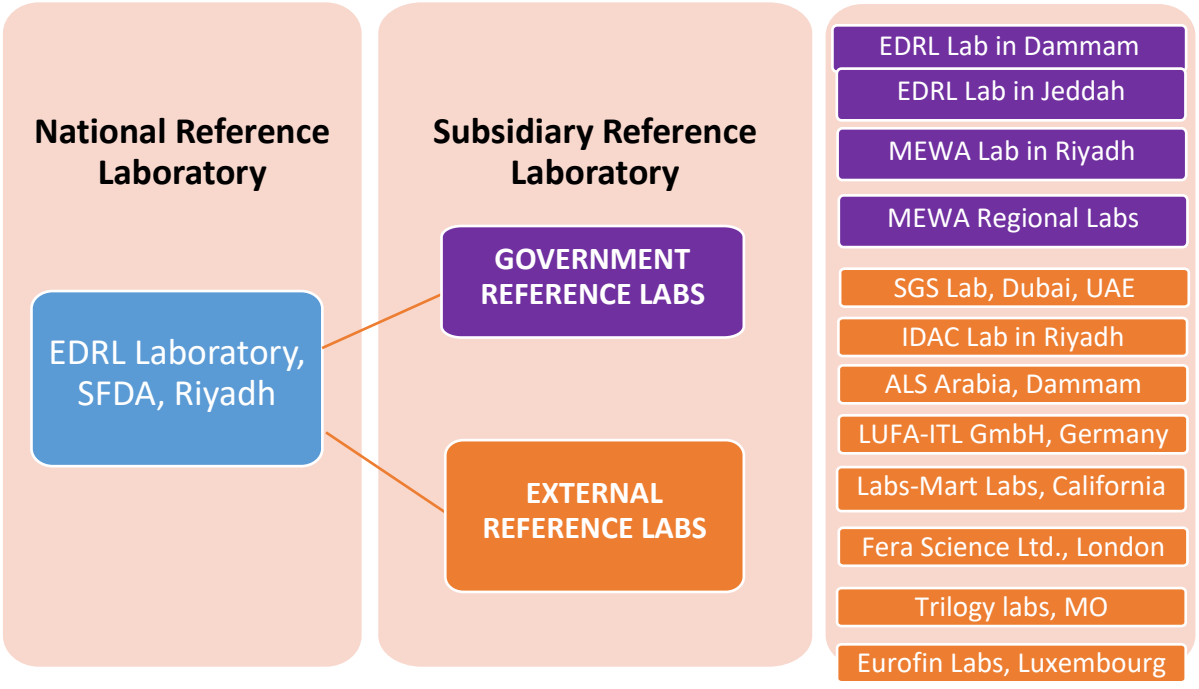
7.1.2.4. Regional Laboratories of MEWA in Jeddah, Medina, Al Hassa, Abha, Hail, Jezan and Al Qassim

7.1.3. **External Reference Laboratory** – External Reference Laboratories are one kind of Subsidiary Reference Laboratory of this system, but not owned by the Government of Saudi Arabia. The External Reference Laboratories shall be

approved by the Competent Authority to meet the analysis requirements of food export. External Reference Laboratories include both national and international labs.

CHART – 8

Laboratory Working Structure



7.2. Responsibilities of Reference Laboratories

7.2.1. **National Reference Laboratory -** The SFDA Central Laboratory (of EDRL) in Riyadh shall be the National Reference Laboratory. This Laboratory shall be responsible for the coordination of all matters related to Laboratory tests and analyses. The other responsibilities of this laboratory shall be as follows:

7.2.1.1. Receive the list of analyses and tests to be conducted in connection with export from the Competent Authority.

7.2.1.2. Assigning of tests and analyses to different National/International Reference Laboratories with the assistance of IEFPPS as required. .

7.2.1.3. Ensure that the analytical methods used in different laboratories for tests/analyses are valid and scientifically accepted.

7.2.1.4. Ensuring the analytical methods used for test and analysis of samples are validated.

7.2.1.5. Conducting analysis for samples received in the SFDA Laboratory, Riyadh.

7.2.1.6. Receiving lab reports of tests from all Reference Laboratories.

7.2.1.7. Compilation of reports received from Reference Laboratories.

7.2.1.8. Dispatch of compiled test results to the Establishment with copy to other associating government bodies.

7.2.1.9. Record keeping of lab results for all tests/analyses conducted in all reference Laboratories.

7.2.1.10. Keep GLP in the National Reference Laboratory.

7.2.1.11. Maintenance of GLP Compliance Program for all laboratories as per the 'Good Laboratory Practice Manual'.

7.2.1.12. Audit of Establishment Laboratories once in every six months to check the adherence to GLP.

7.2.1.13. Keep a separate file for every Establishment and keep all tests/analyses reports concerned with that Establishment.

7.2.2. **Subsidiary Reference Laboratories** – The EDRL Laboratories in Dammam and Jeddah, MEWA Laboratories owned by Ministry of Environment, Water and Agriculture in Riyadh are assigned as Subsidiary Reference Laboratories. The responsibility of these laboratories shall be as follows:

7.2.2.1. Receive samples dispatched by the government auditors from Establishment.

7.2.2.2. Conduct the tests and analyses as per the assignment given by the National Reference Laboratory.

7.2.2.3. Send the test results to the National Reference Laboratory.

7.2.2.4. Keep confidentiality of all lab tests and results,

7.2.2.5. Keep a file for each Establishment and keep all tests/analyses reports concerned with that Establishment.

7.2.2.6. Keep GLP in the Subsidiary Reference Laboratory.

7.2.3. **External Reference Laboratories –** The External Reference Laboratory shall be approved by the Competent Authority from time to time based on the analysis requirement. The Competent Authority shall identify, evaluate and engage such reliable laboratories located in Saudi Arabia or abroad for analysis.

The responsibilities of the External Reference Laboratories shall be as follows:

7.2.3.1. Receive samples for analysis as advised by the Executive Bodies that functions under the supervision of SFDA.

7.2.3.2. Conduct test/analysis as per the analysis requirement communicated by the Executive Bodies.

7.2.3.3. Send test/analysis reports to the concerned executive body from where the analyses request was received.

7.2.3.4. Keep confidentiality of all lab tests and results.

7.2.3.5. Keep GLP in the External Reference Laboratory.

7.2.4. **Establishment Laboratory** – There shall be an own laboratory for the Establishment to carry out regular analyses and tests. The responsibilities of this Laboratory shall be as follows:

7.2.4.1. Conduct regular tests/analyses as per the list issued by CA.

7.2.4.2. Keep record of all tests/analyses conducted.

7.2.4.3. Send tests/analyses reports to the Competent Authority along with other documents to get health certificate (from Competent Authority) for each consignment to be exported.

7.2.4.4. Keep GLP in the Establishment Laboratory.

7.3. GLP Monitoring System

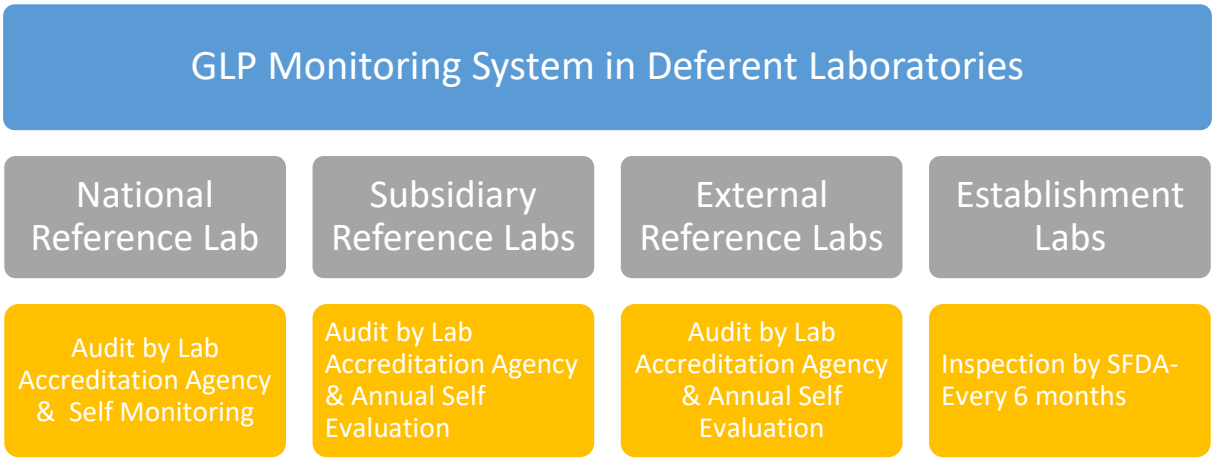
7.3.1. The Good Laboratory Practices of all laboratories shall be monitored.

7.3.2. The Government Laboratories where there are hurdles for an external agency to conduct GLP monitoring shall be carried out though the accreditation agency. Such labs shall also conduct internal audits (self-assessment).

7.3.3. The government auditors (from SFDA and MEWA) shall carry out GLP audits in the Establishment laboratory along with the other audits or separately as convenient.

CHART – 9

Good Laboratory Practice Monitoring



7.4. **Type of samples collected and tested –** Various samples collected for analysis to ensure compliance to export requirements are of the following groups:

7.4.1. Samples drawn during routine /surveillance programs by FFIS.

7.4.2. Drinking water sample drawn by FFIS once a year from each Establishment.

7.4.3. Samples collected for chemical contaminants (veterinary drug & heavy metals residues) and for biological contaminants, etc. for National Residue Monitoring Program.

7.4.4. Self-monitoring samples collected and analyzed by the Establishment.

7.4.5. Other relevant samples as required (need based).

7.5. **Sample Collection and Dispatch**

7.5.1. Collection of samples shall be done by auditors/inspectors of the Competent Authority and MEWA based on the type of samples.

7.5.2. Approved scientific sample collection methods (Sample number, Sample Collection, Sample Preparation, Sample Dispatch) shall be adopted.

7.5.3. The sample shall be directly dispatched to the assigned Reference Laboratories (National Reference Laboratory and/or Subsidiary reference laboratories).

7.5.4. The Dispatch of test results to Establishments – The lab test results shall not be sent to Establishment unless there is a nonconforming results in the report.

7.6. **Verification of the Appropriateness of Methods of Sampling, Methods of Analysis and Detection Tests**

7.6.1. The appropriateness of the methods of sampling, analysis etc. shall be verified initially by the Competent Authority.

7.6.2. The review of the methods of sampling, analysis, etc. shall be again carried out during the time of revision of manual.

7.6.3. Verification shall be carried out also when a new sampling/analysis method is adopted.

7.7. **Actions Taken Following Unsatisfactory Results of Analyses** (of samples drawn during official audits and visits)

7.7.1. Step 1 – The information shall be immediately communicated to the following agencies as given below.

7.7.1.1. Competent Authority

7.7.1.2. Farm/Establishment

7.7.1.3. Other associating government bodies

7.7.2. Step 2 – The lot from which the final product samples were collected and kept aside from sales/export shall be re-sampled. In any case, if any such product found already released, communication shall be sent to hold the product pending retest results.

7.7.3. Step 3 – If the second sampling (retained samples) also reveals the unsatisfactory results, the lot from which the sample was collected, decision shall be taken to reprocess or discard the lot based on the type, nature and level of the residue detected. However, if the second sample reveals the results are normal then the product shall be released.

7.7.4. Step 4 – The CA shall investigate the reason for such incidents and necessary corrective and preventive measures shall be taken and the Farm/Establishment shall be advised accordingly.

7.7.5. Step 5 – All information regarding potential incidents (with history, action taken and future plans etc.) shall be communicated to concerned agencies.

7.7.6. The action taken on high residue levels reported higher than the admissible limits as per the “National Residue Monitoring” shall be as per the procedure described in the “National Residue Monitoring Program”.

7.8. **Allocation of Tests to Laboratories –** Procedure by which laboratories are designated by the CA to carry out the analysis of samples taken during official audits, inspection etc. shall be as follows:

7.8.1. As much as possible the tests shall be conducted by the National Reference Laboratory and Subsidiary Reference Labs owned by the government.

7.8.2. CA shall be responsible for identifying and approving external competent laboratories (national and international) to meet the analysis/test requirements as needed.

7.8.3. Tests shall be allocated to labs based on its capability, efficiency, time taken for completion of analysis, professional/scientific credentials etc.

7.9. Criteria for Ensuring Lab Competency, Reliability and Accuracy

7.9.1. The selection of laboratory is carried out only if they comply with standard reference methods. This is ensured by the following:

7.9.1.1. Selecting labs with organized systems/certifications to conduct test and analysis (ISO/IEC17025 or equivalent) to comply with the requirements.

7.9.1.2. Site visit to the laboratories and inspection as needed.

7.9.1.3. Writing down the test methods in the test result report as a proof of methods adopted in the analyses and tests

7.10. List of Approved External reference Laboratories

#	Name of Reference Laboratory	Accreditation status
1	**IDAC Laboratory**, Riyadh, Saudi Arabia	ISO 17025:2005
2	**LUFA-ITL GmbH**, Germany	DIN EN ISO/IEC 17025:2005
3	**Labs-Mart Laboratories,** 24469 Indoplex Circle Farmington Hills, MI 48335-2527, California	ISO 17025:2005
4	**Fera Science Limited,** 30 Berners Street, London, W1T 3AB	ISO 17025:2005
5	**Trilogy lab,** 870 Vossbrink Dr.Washington, MO 63090	ISO 17025:2005
6	**Eurofin Laborarories,** Eurofins GSC Lux Sarl Val Fleuri 23 L - 1526 Luxembourg	ISO 17025:2005
7	**ALS Arabia,** Dammam, Saudi Arabia	ISO 17025:2005
8	**SGS Lab, Dubai, UAE**	ISO 17025:2005 and DAC accredited

Part II
Specific Stipulations for Aquaculture Products

1. Subject Matter, Scope and Definitions

1.1. Subject Matter

1.1.1. These stipulations lay down public health and animal health rules for the production of Aquaculture Products and exported from Saudi Arabia to European Union.

1.1.2. The rules and regulation also aims to prevent and minimize risks to public and animal health arising from those products, and, in particular, to protect the safety of the food and feed chain.

1.2. Scope

1.2.1. These stipulations shall apply to production 'Aquaculture Products' for human consumption, and has the intention of manufacturing of safe food and also to control public health risks and applicable animal diseases.

2. Obligations – Starting Point in the Manufacturing Chain and Obligations

2.1. As soon as the Establishments generate Aquaculture products falling within the scope of this manual, they shall identify them and ensure that they are dealt with in accordance with the stipulations of this manual

2.2. Establishments shall ensure at all stages of collection, the transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use and disposal within the businesses under their control that Aquaculture products satisfy the requirements of this Manual which are relevant to their activities.

2.3. The Competent Authority shall monitor and verify that the relevant requirements of all EU regulation are fulfilled by the Establishments /Establishments along the entire chain of Aquaculture production.

2.4. The Competent Authority shall maintain a system of official controls in accordance with relevant EU regulations and national legislations.

2.5. The Competent Authority shall ensure that the Aquaculture production operations from hatchery to the export are carried out with an aim to produce Aquaculture products ensuring consumer safety, product quality and control of Aquaculture diseases.

2.6. The Competent Authority shall ensure that adequate systems are in place ensuring:

2.6.1. The primary production measures are adequate to ensure aquatic animal heath, animal welfare and safe raw material for manufacturing of safe Aquaculture products

2.6.2. The products are collected, identified and transported without undue delay;

2.6.3. Treated, used or disposed of in accordance with the applicable EU Regulations.

2.6.4. Tests are carried out to ensure product safety and quality

3. Special Conditions for Handling Aquaculture Products

3.1. Animal Health Restrictions

3.1.1. Infected (or suspected for infections with transmittable diseases to animals or humans) animals shall not be received from farms/areas or processed in Establishments which are subject to restrictions and products shall not be stored in the Establishments.

3.2. Conditions of pre-processing

3.2.1. Heading, gutting, peeling, deveining, filleting etc shall be carried out under hygienic conditions avoiding the contamination of the product.

3.2.2. Where the pre-processing operations are done by hand, workers must pay particular attention to the washing of their hands and all working surfaces shall be cleaned thoroughly.

3.2.3. If machines are used, they shall be cleaned at frequent intervals and disinfected after each working day.

3.2.4. If the gutting, heading, peeling, deveining, filleting etc are carried out after cooking, the product shall be immediately frozen or kept chilled at a temperature which will preclude the growth of pathogens and be stored in appropriate premises.

3.3. Conditions for fresh, chilled products

3.3.1. Where chilled, unpackaged products are not dispatched, prepared or processed immediately after reaching the Establishment, they shall be stored in ice in the Establishment‘s cold room.

3.3.2. Re-icing shall be carried out as often as necessary; the ice used, with or without salt, shall be made from drinking water or clean sea water and be stored under hygiene conditions in receptacles provided for the purpose; such receptacles shall be kept clean in a good state of repair.

3.3.3. Prepared fresh products shall be chilled with ice or mechanical refrigeration plant creating similar temperature conditions.

3.3.4. Product preparation such as heading, peeling, deveining, etc shall be carried out hygienically and proper washing shall be carried out subsequently.

3.3.5. Containers used for the dispatch or storage of fresh fishery products shall be designed in such a way as to ensure both their protection from contamination and their preservation under sufficiently hygienic conditions.

3.3.6. There shall be proper control of temperate while the product is handled in the Establishment.

3.3.7. The product temperature should not go above 40C for more than 20 minutes.

3.3.8. The product temperature during temporary storage shall be at the temperature of melting ice.

3.4. Waste Management

3.4.1. Process waste materials shall be separated from the area and removed frequently from the vicinity of products intended for human consumption.

3.4.2. Unless special facilities are provided for the continuous disposal of waste, the latter shall be placed in leak proof, covered containers which are easy to clean and disinfect.

3.4.3. Waste must not be allowed to accumulate in working areas. It shall be removed in containers either continuously or as soon as the containers are full and at least at the end of each working day.

3.4.4. The containers, receptacles and/or the premises set aside for waste must always be thoroughly cleaned and if appropriate, disinfected after use.

3.4.5. All waste bins shall be non-hand operable

3.4.6. Waste stored shall not constitute a source of contamination for the Establishment or of pollution of its surroundings

3.4.7. There shall be proper procedures for solid waste disposal.

3.4.8. There shall be proper system to ensure that the wastewater going out from the processing plant is properly disposed to avoid environmental degradation.

3.5. Conditions for frozen products

3.5.1. Freezers equipment shall be sufficiently powerful to achieve a rapid reduction in the temperature so that the temperatures laid down to in this directive can be obtained in the products

3.5.2. Cold store (Freezer store) refrigeration system shall be sufficiently powerful to keep products in storage rooms at a temperature not exceeding –180C irrespective of the ambient temperature.

3.5.3. Fresh products used as raw material for frozen products must comply with the conditions mentioned in the 'conditions of fresh, chilled products as mentioned in the clause given above.

3.6. Conditions for cooked products

3.6.1. When the cooking is carried out to inhibit the development of pathogenic microorganisms, or if it is a significant factor in the preservation of the product, the treatment shall be scientifically recognized.

3.6.2. The time and temperature of cooking shall be monitored and recorded by the concerned staff.

3.6.3. A rapid cooling must follow cooking. Water used for this purpose shall be drinking water or clean seawater. If no other method of preservation is used, cooling must continue until the temperature approaching that of melted ice is reached.

3.6.4. Fresh/frozen products to be cooked must comply with the conditions mentioned in the 'conditions of fresh/chilled/frozen products' as mentioned in previous clauses.

3.7. Conditions for other type of Prepared/ Processed Products

3.7.1. If the Establishment plan to produce any other type of prepared/processed product of cultured shrimp / finfish, appropriate standards shall be enforced by the Competent Authority to meet the product quality and safely.

3.8. Conditions for mechanically separated fishery products

3.8.1. Establishments manufacturing mechanically separated fishery products must ensure compliance with the following requirements.

3.8.2. The raw materials – Only whole fish and bones after filleting may be used to produce mechanically separated fishery products;

3.8.3. All raw materials shall be free from guts.

3.8.4. The Mechanical separation must take place without undue delay after filleting.

3.8.5. If whole fish are used, they shall be gutted and washed beforehand.

3.8.6. After production, mechanically separated fishery products shall be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilizing treatment.

4. Health Standards for Aquaculture Products

The Establishment shall check public health parameters to ensure customer safety

4.1. Microbiological and Parasitological Standards of Aquaculture Products – the establishment shall carry out regular Microbial tests as given in the Appendix-16 and The Establishment shall ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market. They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.

4.1.1. **Chemical Standards of the Aquaculture Products** – the establishment shall carry out regular chemical tests as given in the Appendix-17. In addition to that residues of relevant chemical contaminants including prohibited substances, hormones antibiotics, pestices etc. shall be monitored by the National Residue Monitoring Program.

5. **Organoleptic Inspection for Aquaculture Products**

5.1. Organoleptic Inspection – The Establishment shall carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.

5.1.1. Histamine – Food business operators shall ensure that the limits with regard to histamine are not exceeded.

5.1.2. Total Volatile Base Nitrogen- 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.

5.2. Toxic substances from fishes toxic to human health

5.2.1. Products derived from poisonous fish of the following families shall not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.

5.2.2. Products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market.

5.3. The Establishment shall carry out regular Samples of the final products taken during or on withdrawal from storage at the processing plant shall comply with the following standards:

6. **Packaging**

6.1. Packaging shall be carried out under satisfactory conditions of hygiene, to preclude contamination of the Aquaculture products.

6.2. Packaging materials used shall comply with all the EU stipulations of hygiene.

6.3. The material shall be strong enough to protect the products adequately.

6.4. Packaging materials shall not be re-used.

6.5. Unused packaging material shall be stored in premises away from the production area and be protected from dust and contamination.

6.6. The transportation of packaging material shall be carried out in such a way to avoid possibility of contamination.

7. Labelling

7.1. The product label shall include Product name, Product Type, List of ingredients (if applicable), Net weight, Date of production/Batch number, Date of Expiry (period of expiry), Special storage conditions, Name and address of the processor, Special declaration or buyers specifications (if any).

7.2. The minimum durability of the product shall be mentioned in the label of individual pack and the expiry date/month shall be preceded by “Use By …” as applicable.

7.3. The specific labelling requirements of fish eggs shall follow applicable EU stipulations

7.4. The labelling details shall be printed clearly so that information is legible.

7.5. The requirements details and particulars shall meet all applicable EU labelling requirements.

8. Storage

8.1. In storage fresh aquaculture products, thawed unprocessed products, and cooked and chilled products from crustaceans and mollusks, shall be maintained at a temperature approaching that of melting ice.

8.2. Frozen products shall be kept at a temperature of not more than –18 °C in all parts of the product; however, whole frozen products in brine intended for the manufacture of canned food may be kept at a temperature of not more than –9 °C.

8.3. Aquaculture products kept alive shall be stored at a temperature and in a manner that does not adversely affect food safety or their viability.

8.4. Aquaculture Products shall be packed and stored properly in appropriate places.

8.5. The storage temperature of any specific aquaculture product shall be maintained as per the national regulation and shall complying to the EU stipulations to safeguard product safety and quality.

8.6. Products in storage conveyors, elevators etc. (if any) shall be protected from casual contamination.

8.7. All storage facilities shall be emptied and cleaned on regular basis, to the extent necessary to prevent contamination.

8.8. Leakages and condensation in the storage area shall be prevented.

8.9. The Product shall be stored properly, under appropriate temperature conditions, until dispatched.

8.10. The permitted duration of storage / 'product expiry period' shall be as per the EU standards as applicable.

8.11. The frozen products in the store as well as in transportation container shall be arranged with proper space around cartons to allow air flow.

8.12. The products from the store shall be handled in the FIFO manner.

8.13. The product store shall be provided with adequate lights

8.14. The store shall be provided with a temperature monitoring devise and the display is located at a place where it is easily readable with a provision to obtain continuous temperature Chart.

8.15. The sensor of the temperature monitoring devise shall be located at the furthest point from the blower.

8.16. Products shall not be stored with other products, which may contaminate them or affect their hygiene, unless they are packaged in such as to provide satisfactory protection.

9. Transportation

9.1. During transport, fishery products shall be maintained at the required temperature.

9.2. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and mollusks, shall be maintained at a temperature approaching that of melting ice;

9.3. Frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned food, shall 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.

9.4. If fishery products are kept under ice, melt water must not remain in contact with the products.

9.5. Fishery products to be placed on the market live shall be transported in such a way as not adversely to affect food safety or their viability.

9.6. Products shall not be transported with other products, which may contaminate them or affect their hygiene, unless they are packaged in such as to provide satisfactory protection.

9.7. Vehicles used for the transport of fishery products shall be suitable for maintenance of temperature maintenance throughout the transport period.

9.8. The inside surfaces of the means of transport shall be finished in such a way that they do not adversely affect the fishery products. They shall be smooth and easy to clean and disinfect.

9.9. Means of transport used for fishery products may not be used for transporting other products likely to impair or contaminate fishery products, except where the fishery products can be guaranteed uncontaminated as a result of such transport being thoroughly cleaned and disinfected.

9.10. Products may not be transported in a vehicle or container which is not clean or which should have been disinfected.

9.10.1. Conditions for Chemical Storage and Transport connected with Aquaculture Products.

9.10.1.1. The Chemicals & Food Additives shall be kept in separate rooms.

9.10.1.2. The chemical storage rooms shall be under lock and key system

9.10.1.3. Food additives must not be kept along with sanitizing agents

9.10.1.4. There shall be identification labels for different chemicals

9.10.1.5. The chemicals shall be transported in such a way that they cross contaminate the product or other ingredients

9.10.2. Packaging material storage and transport:

9.10.2.1. Packaging materials shall be protected from dust and contaminants.

9.10.2.2. They shall be properly arranged in the store with walking space around the bundles

9.10.2.3. The packaging materials are handled in the FIFO manner.

9.10.2.4. The transportation of packaging material shall be so programmed to preclude possibility of contamination.

10. Traceability

10.1. Establishments producing, storing, and transporting Aquaculture Products shall keep all details and records of the raw material, other incoming materials, certificates, commercial documents, health certificates etc.

10.2. There shall be a system to trace the final product back to the hatcheries and ensure a strong traceability system.

10.3. The raw material arrived, material on line, final product in the store and product in the market shall be covered under the traceability system.

10.4. Establishment shall ensure that Aquaculture products are traceable at all stages of the chain of manufacturing, use and disposal. Refer Appendix-4 for the detailed procedure of “Traceability”.

10.5. Establishment shall keep all production details and documents pertaining to the daily production of Aquaculture Products.

10.6. All details and information shall be made available to the Competent Authority on request.

10.7. There shall be a documented Product Recall Program to recall products in case of an emergency situation. Refer to Appendix-5 for the detailed Product Recall Program.

10.8. The Establishment shall keep all information and documents for a period equivalent to the expiry period of the product.

11. Registration of Establishment

11.1. All Establishments intending to export Aquaculture Products shall be registered in the office of the Competent Authority.

11.2. On registration the Establishment shall provide full details about its operation.

11.3. The Competent Authority shall inspect the premises and grant/deny approval based on the inspection outcome.

11.4. The Establishment, before commencing processing of Aquaculture products operations, shall notify the Competent Authority about the details of activity such as

production, transport, handling, processing, storage, placing on the market, distribution etc.

11.5. The registered Establishment shall provide the Competent Authority with up-to-date information including any significant change in activities such as any closure of an existing Establishment or plant.

11.6. There is an on-line registration in SFDA for establishments that produce food and food products in Saudi Arabia as well as establishments in the third country that export food products to Saudi Arabia.

12. Approval of Establishments or Plants

12.1. Establishment intended to export Aquaculture Products to European Union shall get their processing facility approved by the Competent Authority.

12.2. Only those Establishments which own Aquaculture farm and hatchery (fully integrated) shall be approved for exports Aquaculture Products to EU.

12.3. If any aquaculture products accepted in the Establishment for processing other than from own Aquaculture farms, such farms shall comply all the EU requirements and stipulations. Such suppliers shall be regularly inspected by the Competent Authority for regulatory as well as hygiene and sanitation compliances.

12.4. The Establishments shall carry out processing of Aquaculture products, employing manufacturing processes stipulated in applicable European Union regulations.

12.5. Approved Establishment shall produce Aquaculture Products only from safe and quality raw material.

12.6. Refer to Appendix-2 for detailed Establishment Approval procedures.

13. General Requirements of Aquaculture Processing

13.1. Transport of live animals to processing plant (in live animal export)

13.1.1. Food business operators transporting live animals to processing plant shall ensure compliance with the following requirements.

13.1.1.1. During collection and transport, animals shall be handled carefully without causing unnecessary distress.

13.1.1.2. Animals showing symptoms of disease or originating from a source known to be contaminated with agents of public-health/animal health importance may only be transported to the processing plant when permitted by the Competent Authority.

13.1.1.3. Containers for delivering harvested animals to the processing plant, where used, shall be made of non-corrodible material and be easy to clean and disinfect.

13.1.1.4. Immediately after emptying and, if necessary, before re-use, all equipment used for collecting and delivering live animals shall be cleaned, washed and disinfected.

13.2. Requirements of Processing plant

13.2.1. Food business operators shall ensure that the construction, layout and equipment of processing plants that produces Aquaculture Products meet the following requirements.

13.2.2. The construction of the facility shall be a permanent structure.

13.2.3. The premises shall be constructed in a way permitting their effective cleaning and disinfection and where appropriate the construction of floors is impermeable to water facilitates the draining of liquids.

13.2.4. The floors shall be without crevices and water stagnation. Proper system shall be provided for water drainage.

13.2.5. The ceiling of the product handling area shall be made of easy to clean material and kept in good condition facilitating hygienic production.

13.2.6. There shall be adequate natural/artificial lights (with proper protection), ventilation facility with proper air filtration system and temperature control system in the production area.

13.2.7. The production premises shall have access to adequate facilities for personal hygiene such as number of lavatories, rest rooms, changing rooms and washbasins for staff.

13.2.8. The lavatories shall be flush lavatories.

13.2.9. The toilets/lavatories should not open directly to the processing area

13.2.10. The doors shall be self-closing type and foot dips with sanitizing agents at doors.

13.2.11. Water taps in all wash basins shall be no-hand operating type.

13.2.12. All washbasins shall be provided with Soap dispensers and single-use towels/ Paper tissue and waste bins

13.2.13. There shall be hand washing and sanitizing facility provided at different product handling sections.

13.2.14. The premises, production and connected areas shall have appropriate arrangements for protection against pests, such as insects, rodents and birds and there shall be a documented pest control program – implemented regularly monitored and records kept.

13.2.15. The Establishment shall keep all installations and equipment in good condition with documented maintenance plans and schedules and records kept.

13.2.16. There shall be adequate separation for dirty and clean areas (Raw material handling area, processing area, finished product handling areas) inside the Establishment.

13.2.17. The instruments, tables, containers, conveyor belts and other accessories shall be made of corrosion resistant materials

13.2.18. There shall be adequate number of containers and utensils used inside the processing plant.

13.2.19. There shall be appropriate arrangements for the cleaning and the disinfection of containers and vehicles in place to avoid risks of contamination.

13.2.20. There shall be appropriate documented cleaning procedures established, practiced and documented for all parts of the Establishment and/or plant.

13.2.21. The Establishment shall use sanitizing agents & detergents (chemical agents, soap solutions etc.) approved by the Competent Authority for effective cleaning and sanitation.

13.2.22. The plant surrounding shall be concreted, asphalted or compressed, in order to prevent windblown dust contamination.

13.2.23. There shall be a specific space for the reception of harvested animals and for their inspection before processing.

13.2.24. To avoid product contamination, there shall be sufficient number of rooms, appropriate to the operations being carried out

13.2.25. They shall be facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

13.2.26. The equipment for washing hands used by the staff engaged in handling exposed product waste shall have taps designed to prevent the spread of contamination.

13.2.27. There shall be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.

13.2.28. There shall be separate places with appropriate facilities for the cleaning, washing and disinfection of transport equipment such as crates; and means of transport.

13.2.29. They shall have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary services.

13.2.30. There shall be chill rooms to store products on-line in case of intermediate holding/storage. The chill rooms shall be equipped with suitable chilling units to keep the product temperature well below 4o C.

13.2.31. The Establishment shall follow the instructions of the Competent Authority to ensure that the post-harvest inspection is carried out under suitable conditions for required parameters.

13.3. Special conditions for Water Management and Ice Production System.

13.3.1. The water used at any point of processing or coming in contact with the product, need to be safe and suitable for human consumption. The water management system must so developed that the product safety is not affected by the water.

13.3.2. The water used for the processing operation shall be either Potable Fresh water or Clean Sea Water. The water shall be obtained from a hygienic source, which precludes all chances of contamination.

13.3.3. If the water source is from public water supply system, all precautionary measures needed to be taken in order to avoid chances of sabotage

13.3.4. The water transportation system shall be clean and hygienic. If trucks transport the water a documented routine cleaning/sanitation program should be followed.

13.3.5. All the water distribution pipes and connected systems shall be rust proof. Regular maintenance shall be done for the plumbing system to ensure the safety of the water.

13.3.6. There should be proper water filtration system for the effective removal of dust and undesirable particle from the water.

13.3.7. There shall be proper method for water sanitizing using Chlorination, UV lights, Ozone or similar methods.

13.3.8. If the sanitizing is done with chlorination, the chlorine levels shall be followed as per the details given in the Appendix- 13 for different usages.

13.3.9. Proper records shall be kept for the water sanitizing programs and it's monitoring.

13.3.10. The water production capacity and water storage capacity should match with the quality of product processed in the Establishment.

13.3.11. The 'portability' of the drinking water need to be tested as given in the schedule given by the Competent Authority.

13.3.12. Water parameters shall be tested as per Appendix- 14, every week by the Establishment and once in three months by FFIS as a routine practice

13.3.13. The Potable Water shall be collected by FFIS and tested for different parameters mentioned in Appendix- 15, initially and then once in every Year in an official laboratory.

13.3.14. The water portability certificates needs to be available in the respective departments for verification.

13.3.15. If any raw water (non-drinking water/unclean seawater) is used in the processing plant for cleaning or other purposes, taps of such water taps shall be identified from process water with identification marks.

13.3.16. The ice used for processing activities shall be prepared from either from Potable Fresh water or from Clean Sea Water

13.3.17. If ice is not produced from same the potable water used in the Processing plant for which the annual testing (by an official laboratory) and routine testing (by FFIS and establishment), these tests shall be carried out for the water with which the ice is produced as mentioned in the Article.1 .J of this same chapter and records shall be kept.

13.3.18. Block ice, flake ice, cube ice, Ice slurry, Tube or similar forms can be used for processing operation

13.3.19. The ice machinery which is used for producing ice shall be kept clean and without rust.

13.3.20. The ice machines shall be kept under good state of repair.

13.3.21. There shall be proper method adopted for sanitation of water used for ice production.

13.3.22. The ice production capacity should match with the quantity of product handled.

13.4. Hygiene during processing

13.4.1. The Establishment shall ensure that the processing of Aquaculture takes place in accordance with the following requirements:

13.4.1.1. The processing operation shall be organized in such a way as to prevent or minimize contamination.

13.4.1.2. To this end, the Establishment shall ensure in particular that the temperature of the product on-line is maintained at not more than 4ºC.

13.4.1.3. and where the premises are approved for the processing of aquaculture products, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.

13.4.2. Exposed aquaculture products shall be stored and transported separately from packaged products, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

13.4.3. The premises have sufficient size for work to be carried out under adequate hygiene conditions. Their design and layout shall be such as to preclude contamination of the product and keep quite separate the clean and contaminated parts of the building.

14. Hygiene Requirements

14.1. Any person working in the Establishment shall wear suitable, clean and, where necessary, protective clothing.

14.2. Persons working in the unclean sector shall not enter the clean sector without first changing their work clothes and shoes or without having disinfected them.

14.3. Equipment and machinery shall not be moved from the unclean to the clean sector without first being cleaned and disinfected.

14.4. The Establishment shall establish a procedure relating to the movements of persons in order to monitor their movements and describe the correct use of foot-baths and wheel baths.

14.5. Training shall be given to employees on Hygiene and Sanitation procedures.

14.6. Smoking/spitting/eating/drinking in work/storage premises shall be prohibited.

14.7. All the employees who work in the product handling area shall obtain Health Certificates from a Government agency, as proof of fitness to work in the Establishment.

14.8. Hand swab tests shall be conducted as factor of verification of staff hygiene.

15. General Precautions and Conditions

15.1. In the Establishment, Aquaculture products shall be handled in such a way as to avoid risks of contamination.

15.2. After processing, derived products shall be handled and stored in such a way as to avoid risks of contamination

15.3. Establishment shall check regularly the applicable parameters, particularly temperature, time, pressure, time, size etc.

15.4. The raw material, on-line product samples, final products etc. shall be inspected manually or using automatic devices as required by the process.

15.5. That measuring equipment shall be calibrated regularly and calibration records shall be kept.

15.6. Calibration of equipment - Calibration shall be carried out for essential equipment at regular intervals and necessary documents kept.

15.7. Metal detection of final product - There shall be provision for metal detection in the final product before it leaves the Establishment premises.

15.8. Plant maintenance program – There shall be a documented plant maintenance program which covers all area of operation connected with the processing of cultured shrimp and finfish products.

15.9. Food additives- Establishments are permitted to use only those food additives, which are approved by the Competent Authority. The Competent Authority approves the usage of following food additives

#	Name of the additive	Permissible level	Product
1	Sodium Metabisulfite (E 223)	Max. limit 150mg/kg –SO2 in edible portion of raw product, 50mg/kg for cooked crustaceans	Shrimps
2	Sodium Polyphosphates (E452)	Application level 5g/kg	Shrimps
3	Boric Acid (E 284) / Sodium Tetrabotare (Borax) (E 285)	Max Limit 4g / kg, in edible portion (expressed as boric acid)	Caviar
4	Sorbic acid (E 200)		
5	Potassium sorbate (E 202)		
6	Iso ascorbic acid (Erythorobic acid) (E 315)		
7	Sodium Chloride	As needed. (No limits defined as it is common 'Table Salt'.)	Any product

15.10. Pest Control – The Establishment must carry out an effective pest control program in order to ensure the product safety and quality. Necessary insect/pest protection measures such as insect screens on windows, self-closing types of doors, concealed or properly protected (with gratings) drains etc. shall be in place. There shall be regular monitoring and record keeping for the pest control program including bait maps and pest control stations.

16. Handling of Product during Processing

16.1. The treatment, processing or storage of products in Establishments approved by Competent Authority for export shall be carried out under conditions which prevent cross-contamination in a dedicated part of the Establishment or plant.

16.2. The Establishment shall abide by all the specific requirements laid down in national as well as EU Community veterinary legislation.

16.3. The Establishment shall ensure that the processing of Aquaculture Products takes place in accordance with food safety and quality requirements

17. Implementing measures

For the implementation of all applicable stipulations of the EU regulation, necessary measures shall be laid down relating to the following:

17.1.1. Infrastructure and equipment requirements applicable within the Establishment.

17.1.2. Hygiene requirements applicable to handling of all types of Aquaculture Products including “General Hygiene Requirements” stated in previous clauses.

17.1.3. Conditions and technical requirements for the handling, treatment, transformation, processing and storage of Aquaculture Products.

17.1.4. Conditions for treatment of waste water.

17.1.5. Evidence (from the Establishment) of validation of the treatment, transformation and processing of Aquaculture Products, on their ability to prevent public and animal health risks.

17.1.6. Conditions for the prevention of cross-contamination when animal products that are intended for human consumption are stored treated or processed in a dedicated part of an Establishment.

17.1.7. Conditions for the disposal (including 'Incineration') of raw material or final product, if suspected/discovered causing animal health or public health implications.

17.1.8. Other measures, stipulations and conditions required for the implementation of applicable EU regulation.

18. Own Checks and HACCP System

18.1. Own Checks

18.1.1. The Establishment shall have a quality and safety controlling department to ensure quality, safety and regulatory compliance of the product, process and the facility.

18.1.2. The Establishment shall put in place, implement and maintain own checks in the production of Aquaculture Products in order to monitor compliance with all applicable EU Regulations.

18.1.3. The Establishment shall ensure that no Aquaculture products suspected or discovered not complying with EU Regulations leave the Establishment, unless destined for disposal.

18.1.4. The Quality Control department shall not report to the Manager who is responsible for production. The QC department shall report to the higher-level management. This is to ensure unbiased and uninfluenced QC inspection.

18.1.5. The employees of Quality Control department must have adequate academic qualification as well as experience to handle the QC assignments.

18.2. Hazard Analysis and Critical Control Point System

18.2.1. Establishments that carry out processing, handling and storage of Aquaculture Products shall put in place, implement and maintain a permanent written procedure or procedures based on the hazard analysis and critical control points (HACCP) system principles.

18.2.2. To comply with the "7 Principle" requirements of HACCP system, the Establishment shall:

18.2.3. Identify any possible hazards that are likely to occur shall be prevented, eliminated or reduced to acceptable levels **(Principle # 1).**

18.2.4. Identify the critical control points (CCPs) at every step at which control is essential to prevent or eliminate hazards or reduce it to acceptable levels **(Principle # 2).**

18.2.5. Establish Critical Limits (CLs) at critical control points which separate acceptability from unacceptability, for the prevention, elimination or reduction (to the acceptable level) of identified hazards **(Principle # 3).**

18.2.6. Establish and implement effective monitoring procedures at every critical control point **(Principle # 4).**

18.2.7. Establish corrective action when monitoring indicates deviation of critical limit (CL) and the critical control point is not under control **(Principle # 5).**

18.2.8. Establish specific procedures to verify that the measures outlined are complete and working effectively in controlling hazards **(Principle # 6).**

18.2.9. Carryout verification procedures regularly.

18.2.10. Prepare required documents and maintain adequate records commensurate with the nature and size of the businesses to demonstrate

the effective application of the measures set out in above said points **(Principle # 7).**

18.2.11. To ensure that the HACCP system is effectively established, the Establishment shall:

18.2.11.1. Form a HACCP team with members from different departments of the Establishment who are directly involved in food safety.

18.2.11.2. Describe the product in order to have detailed information to facilitate the implementation of HACCP system.

18.2.11.3. Specifically identify and record the intended use of the product.

18.2.11.4. Construct a flow-diagram of the step-by-step process involved in the production of Aquaculture Products.

18.2.11.5. Verify every step of the process inside the processing area of the Establishment to ensure that every process step of the production is listed in the flow-diagram.

18.2.12. To ensure that the HACCP performs efficiently, the Establishment shall design and adopt prerequisite/foundation programs as follows:

18.2.12.1. Good Manufacturing (Production) Practices/Standard Operating Procedures for every operation.

18.2.12.2. Good Hygiene Practices/Sanitation Standard Operating Procedures to ensure product/personnel hygiene.

18.2.13. When any modification is made to a product, process or any stage of production, processing, storage or distribution, the Establishment shall review their procedures and make the necessary changes.

18.2.14. Implementation of HACCP in Establishment that exports Aquaculture Products shall be in accordance with all applicable EU regulations

19. National Guides to Good Practices

19.1. The Competent Authority and associating Government agencies shall prepare national guides for Good Practices for the Establishment that produce Aquaculture Products to follow in relevant areas including HACCP, biosecurity, Good Laboratory Practices, hygiene procedures etc. as needed.

19.2. The Competent Authority shall ensure that such National Guidelines are relevant and to the best interest of the country as well as of the Establishments. The Competent Authority shall also make sure that the suggestions and guidance given are relevant and pragmatic.

20. Placing on the Market

Aquaculture Products shall be proposed for placing in EU Markets relating to the following:

20.1. Safe Sourcing – Safe sourcing shall include the use of material from which no unacceptable risks to public and animal health arise. Aquaculture Products produced in the Establishment destined for European Union Markets shall be produced only from safe and quality raw material.

20.2. Safe Treatment – Safe treatment shall include application of a manufacturing process to the material used which reduces to an acceptable level risks to public/animal health arising from the material used or from other substances resulting from the manufacturing process. The Aquaculture Products destined for EU markets shall be processed under safe process methods to prevent risks arising to public and animal health in accordance with applicable EU laws.

20.3. Safe End Use – Safe end uses shall include the use of Aquaculture Products under conditions which pose no unacceptable risks to public and animal health.

21. Import of Aquaculture and Aquaculture Product

21.1. The Competent Authority shall impose strict measures on the import of Aquaculture products to Saudi Arabia in view of prevention of possible introduction of infectious animal disease through imports.

21.2. The countries importing Processed Aquaculture Product shall be screened by a designated office of the Competent Authority – Import and Export of Food & Pesticides Permission Section (IEFPPS).

21.3. The import control of Aquaculture products shall be ensured through a questionnaire, country visit and inspection.

21.4. Import of live Aquaculture animals is prohibited in to the kingdom unless with special approval from Ministry of Environment, Water and Agriculture.

21.5. The Competent Authority has documented guide line published for inspectors who inspect third country Competent Authorities and Establishments and the process of approval. Refer to Appendix- 6 and 7.

22. Saudi Arabia, Meeting Requirements as Third Country

22.1. Saudi Arabia as third country intending export of Aquaculture Products to European Community:

22.1.1. Shall develop, adopt, maintain and monitor adequate legislation for the production, handling, storage and export of Aquaculture Products meeting the EU requirements.

22.1.2. Shall ensure a strong organization for the Competent Authority, with:

22.1.2.1. Effective inspection services in the country

22.1.2.2. Well-defined powers/responsibilities

22.1.2.3. Adequate supervision to which they are subject to

22.1.2.4. Delegated authority to monitor effectively the application of legislation

22.1.3. Shall ensure effective measures for safe production, manufacture, handling, storage and dispatch of Aquaculture Products intended for the export to EU warranting no risk for public or animal health.

22.1.4. Shall provide assurance that Saudi Arabia abides by applicable requirements of EU in compliance with relevant health conditions. Refer to Appendix-3.

22.1.5. Ensure that Saudi Arabia shall not pose any risk to public or animal health in the European Community through the managing the health status of aquaculture animals in the country, having particular as regards to exotic animal diseases and general health situations in the country.

22.1.6. Has system in place for quick transmission of information about the existence of Aquaculture diseases in its territory, in particular the diseases listed in the Aquatic Animal Health Code of OIE - the World Organization for Animal Health.

22.1.7. Has strict regulations implemented for the prevention and control of infectious Aquaculture diseases in force in Saudi Arabia including rules on imports from other third countries.

23. Export

23.1. The Aquaculture Products exported to EU shall be complying with the requirements of applicable EU regulations in order to make sure that the stipulations are at least as strict as the production and marketing of such Aquaculture Products within the European Community.

23.2. All necessary documentation shall be done for every export taking place to EU countries. Every consignment shall be accompanied by Health Certificate, other

commercial documents, declarations etc. as required to the fulfilment of import requirements of Aquaculture Products in the European Community.

23.3. The process of issuing the Health Certificate shall follow the steps as given in Appendix-8.

23.4. Please see the model health certificate – Appendix-8.

23.5. In case of transit of Aquaculture Products of Saudi origin in European Community, shall meet all requirements stipulated in the applicable EU regulations.

24. Procedure for Approval

24.1. The Competent Authority shall approve Establishments only where an on-site visit, prior to start-up of any activity, has demonstrated that they meet the relevant requirements laid down in accordance with applicable EU regulations including:

24.1.1. Good Manufacturing (Operating) Practices in the Establishment

24.1.2. Hygiene and Sanitation procedures and practices (Good Hygiene Practice)

24.1.3. Own check (HACCP) system

24.1.4. Laboratory and Analytical system

24.1.5. Animal Health Monitoring System

24.1.6. Disease Control and Prevention System

24.2. The Competent Authority may grant conditional approval if it appears, from the on-site visit, that the Establishment or plant meets all the infrastructure and equipment requirements with a view to ensuring the application of the operational procedures in compliance with applicable EU Regulations.

24.3. The Competent Authority shall grant full approval only if it appears, from another on site visit carried out within three months of granting conditional approval, that the Establishment or plant meets all the stipulated requirements.

24.4. The Competent Authority shall test/ evaluate the competency/ adequacy of Lab technicians, HACCP system, Laboratory facility etc. and approve if found qualified.

24.5. If the Establishment plant still does not meet all these requirements, the Competent Authority shall terminate the conditional approval.

24.6. The step by step procedure to approve Establishments shall follow Appendix-2

25. Official Controls

25.1. The Competent Authority shall at regular intervals carry out official controls and supervision of the handling of Aquaculture Products for the export to European Union.

25.2. The Competent Authority shall apply stipulations of relevant EU regulations to verify compliance.

25.3. The Competent Authority may take into account adherence to guides to good practice, when carrying out its official controls.

25.4. The Competent Authority shall ensure the right reference methods are employed in microbiological, chemical and other analyses.

25.5. The audits, inspections and monitoring carried out as part of official control shall follow the details given in Appendix-9.

26. Impositions, Suspensions, Withdrawals and Prohibitions on Operations

If the official controls and supervision carried out by the Competent Authority and other associating government agencies reveal that one or more of the requirements of this Regulation are not met; the Competent Authority shall take appropriate action.

26.1. Impositions – The Competent Authority, based on the inspection and audits as part of official controls shall impose specific conditions on Establishments or plants in order to rectify existing deficiencies

26.2. Suspensions – The Competent Authority shall in particular, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health suspend approvals of Establishments or plants approved pursuant to this Regulation, in following situations:

26.2.1. The conditions for approving or operating the Establishment or plant are no longer fulfilled.

26.2.2. The Establishment can be expected to remedy the deficiencies within a reasonable period of time.

26.2.3. The potential risks to public and animal health do not require withdrawal of approval.

26.3. Withdrawals – The Competent Authority shall in particular, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health withdraw approvals of Establishments approved pursuant to this Regulation, in the following situations:

26.3.1. The conditions for approving or operating the Establishment are no longer fulfilled.

26.3.2. The Establishment cannot be expected to remedy the deficiencies within a reasonable period of time.

26.3.2.1. For reasons relating to the infrastructure of the Establishment or plant;

26.3.2.2. For reasons relating to the personal capacity of the Establishment or the staff under his supervision; or

26.3.2.3. Because of serious risks to public and animal health requiring major adjustments to the operation of the Establishment before the Establishment may apply for re-approval.

26.4. Prohibitions – The Competent Authority shall, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health, temporarily or permanently prohibits Establishments from carrying out operations, as appropriate, following receipt of information indicating:

26.4.1. Unacceptable and unjustifiable noncompliance demonstrating that the requirements of EU regulations/legislation are not met; and

26.4.2. Potential risks to public or animal health arising from such operations to a dangerous level.

27. Re-Approval of Establishments

27.1. If the approval of the Establishment is suspended/withdrawn/terminated due to a reason, the Establishment could export products again to European Union only once the Establishment is reapproved by the Competent Authority.

27.2. The re-approval of the Establishment shall depend on the suspension/withdrawal/ termination of the approval; adequacy of the corrective action taken; confidence of the Competent Authority to re-approve the Establishment etc.

27.3. The decision for re-approval shall be under the sole discretion of the Competent Authority.

27.4. The procedure of re-approval shall follow the details provided in Appendix- 10.

28. Listing of Approved Establishments

28.1. The Competent Authority shall draw up a list of Establishments which have been approved in accordance with the relevant EU Regulations in the country.

28.2. The Competent Authority shall assign an official number to each approved Establishment, which identifies the Establishment with respect to the nature of its activities.

28.3. The Competent Authority shall make details of the Establishment(s) along with the relevant details to DG- SANTE for the approval from the European Union and listing for official purposes.

29. Keeping Establishments in the Approved List

29.1. The establishments shall be given approval to export to EU for one year.

29.2. After one year and thereafter every year the Establishment shall be audited for renewal of the approval status by the audit team comprised of auditors/inspectors of SFDA and MEWA as assigned by the Competent Authority.

29.3. Those Establishments that are qualified in the renewal audit shall be retained in the Approved List of Establishment qualified for export of Aquaculture Products to European Union.

30. Removal of Establishment(s) from the Approved List of Establishments:

30.1. If an Establishment fails to comply with EU regulation, posing major risk to public/animal health/consumer safety/casing critical system damage/report of fraud/legal violations; name of such Establishment shall be removed from the

Approved List of Establishments exporting Aquaculture Products to EU by the CA after a thorough investigation.

30.2. Removal from the Approval List shall be communicated to concerned offices of the European Union.

30.3. The decision of the Competent Authority on the removal of the Establishment from the list of approved Establishment shall be final in this matter.

31. Infringements and Penalties

31.1. The Competent Authority shall lay down the rules on penalties applicable to infringements of the stipulation of this legislation – Manual of Procedures: Export of Aquaculture Products to European Union.

31.2. The penalties provided for shall be effective, proportionate and dissuasive.

31.3. The Competent Authority without prejudice shall ensure that the penalties are imposed as appropriate.

31.4. Details of action taken by the Competent Authority on infringements and violations of this legislation are given in Appendix-11

32. General Clauses

32.1. Measures to eliminate conflict of interest and biased decision – In order to ensure that that staff or members of the official control system are devoid of any conflict of interest or biased decision the following precautionary measures are taken.

32.1.1. Distribution of Responsibilities - Specific responsibilities allotted to the each inspection agency such as the Competent Authority (Saudi Food and Drug Authority – SFDA), office of the Vice-President, Import and Export of Food & Pesticides Permission Section (IEFPPS)., Food Factory Inspections Section

(FFIS) and Branches, Dept of Animal Feeds (DAF), Exe. Dept Standards/Product Assessment (ESPA), Executive Department of Research and Laboratory (EDRL), General Directorate of Fisheries of Ministry of Environment, Water and Agriculture etc., as explained in this Manual.

32.1.2. Mosaic Audit Pattern – The government agencies such as IEFPPS, FFIS, EDRL, SFDA Branches and General Directorate of Fisheries of MEWA shall conduct separate routine audits. SFDA Branches shall carry out audits under the supervisor of FFIS, once every six months which is a general supervisory audit which cover elements of EU export system and cross verifies other audit details, whereas General Directorate of Fisheries of MEWA shall carry out their audit once every four months.

32.1.3. Audit Interlink – As an inter-link between these three audits, the Competent Authority shall convene a Technical Committee meeting every three months to discuss all matters concerned with Official Control.

32.1.4. Combination of Officials for Common Consensus – The approval audit of an Establishment and renewal audit of an already approved establishments shall be carried out by a combined audit team comprise of auditors of different government bodies.

32.1.5. The comprehensive network of audits and pattern of inspections designed for monitoring shall ensure elimination of conflict of interest and biased decisions of staff performing Official Controls.

32.2. Provisions to Guarantee a Harmonized System in the Whole Country

32.2.1. The Competent Authority (SFDA) operates all activities from head office in Riyadh, Saudi Arabia and responsibilities as described in this Manual.

32.2.2. The head office of CA shall directly monitor and coordinate the EU export system activities.

32.2.3. The relevant clauses and stipulations of the 'Manual of Procedures' are communicated to all concerned executive bodies and staff who carry out Official Control procedures.

32.2.4. Changes, amendments etc., in procedures/documentation shall be discussed in the Technical Committee meeting where all associating government agencies participate.

32.2.5. The Vice-President of Operations Sector, SFDA shall verify and ensure the implementation of systems and procedures of export of Aquaculture Products to EU across Saudi Arabia through the supervision by IEFPPS.

32.2.6. Training shall be given to auditors and inspectors on procedures to ensure unified and harmonized methods are adopted across the country.

32.3. 'Internal Control' Provisions in the CA and EU Export Monitoring System

32.3.1. The head office of the Competent Authority shall responsible for ensuring legal compliance and adherence to the written procedures.

32.3.2. During 'Renewal Audit' of the Establishment, CA auditor shall verify the process of audit carried out by the auditors (from all government agencies) to ensure compliance to legalization and written procedures.

32.3.3. Representatives of the Competent Authority shall visit offices of the associating government agencies as well as local/regional offices of the CA for reviews and evaluation as needed to ensure internal control practices, system compliance and adherence to specifications and stipulations.

32.3.4. The CA, during its direct Establishment audit through SFDA Braches, shall inspect the records of audits carried out by different inspectors of different associating government agencies to ensure that the audit schedule is met and

a harmonized approach is demonstrated in different audits and compliance to legalization and written procedures are in place.

32.4. Training program for the EU export system maintenance.

32.4.1. The Competent Authority and associating governing departments shall conduct training programs for the EU system Auditors/ Inspectors/ Technicians and Establishment as required.

32.4.2. Each government agency that is associated with EU export of Aquaculture Products shall conduct trainings for their inspectors as needed.

32.4.3. The Establishments shall conduct training for their technicians and quality control personnel on EU export system procedures and controls at a defined frequency.

32.4.4. The Establishment shall conduct GMP/SOP Training, Hygiene/Sanitation training, HACCP training etc. on a regular basis.

32.4.5. There shall be a documented training program. Refer to Appendix-12.

33. National Provisions

33.1. The Competent Authority shall develop, review and adopt regulations on a national level in Saudi Arabia to comply with the Commission requirements for the export of Aquaculture Products to European Union.

33.2. The Competent Authority shall communicate to the European Commission (DG – SANTE) of the national regulations Saudi Arabia adopts in areas under their competence which directly concerns the proper implementation of applicable EU Regulations.

34. National Residue Monitoring Program

34.1. The Competent Authority shall make sure that the National Residue Control and Monitoring is implemented in the country.

34.2. General Directorate of Fisheries of MEWA shall be responsible for National Residue Monitoring Program of Aquaculture Products.

34.3. The National Residue Monitoring Program is described in the Animal Health and Residue Control Program manual.

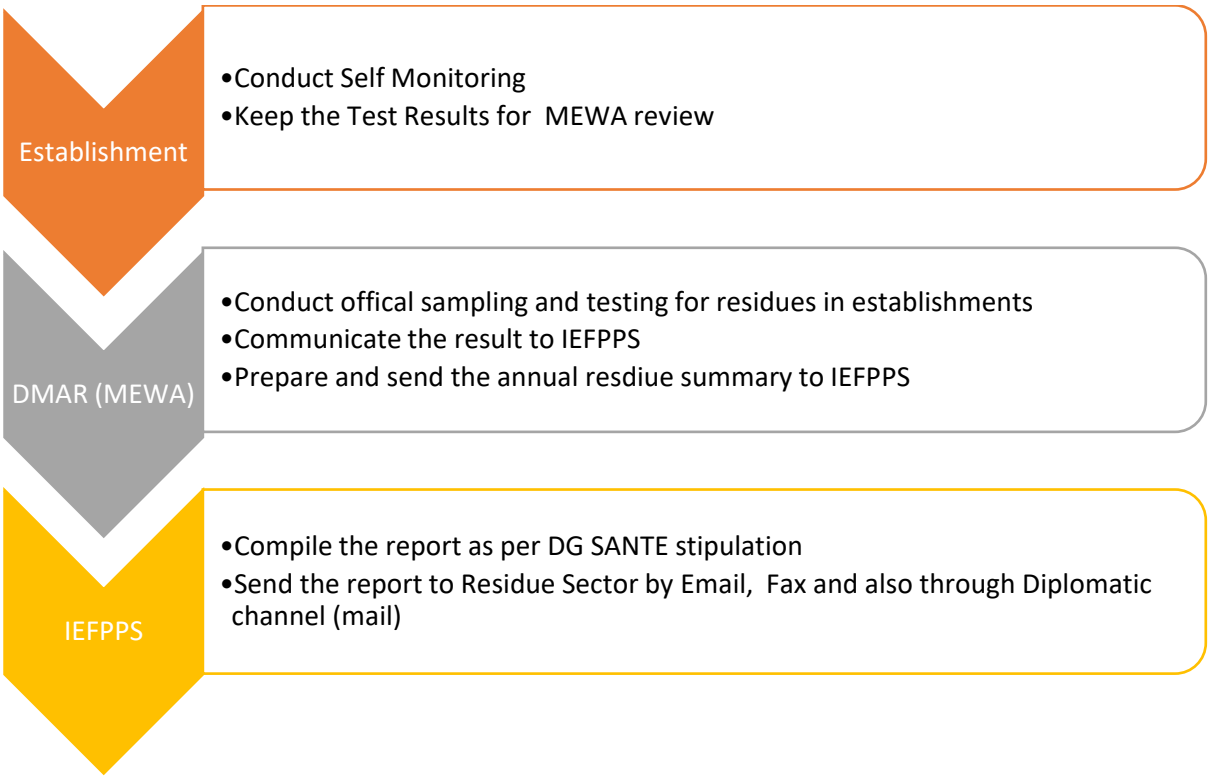
34.4. The Residue Monitoring Program shall be applicable to all Aquaculture products that are intended for human consumption.

35. Annual Reporting to EU (DG SANTE)

The Competent Authority shall communicate the status of residues (veterinary drug residues, contaminants, heavy metals, dyes etc.) as stipulated by the EU regulation to DG SANTE as given below:

CHART – 10

The Annual Residue Reporting System



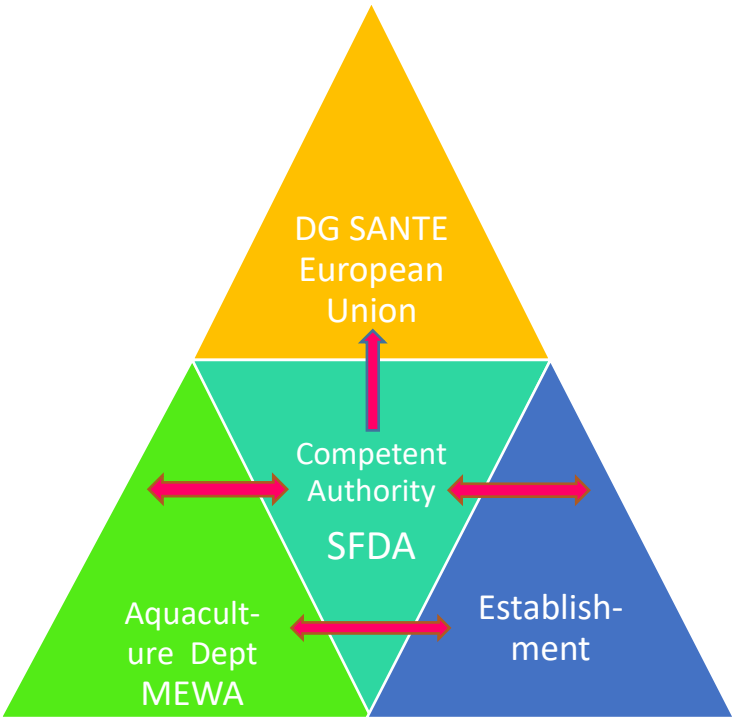
36. Communication

The office of the Vice-president of Operations Sector, SFDA shall be the only contact point to DG SANTE and EU from Saudi Arabia for exports of Aquaculture Products. Other associating government agencies shall be authorized to communicate with the establishments and CA (and vice-versa). The general pattern of communication is given in the figure below:

Chart-11

The Communication Pattern

(Between Government Agencies and DG Sante)



37. Record Keeping

37.1. The Competent Authority, Executive Bodies and Establishments shall keep relevant records concerning with export of Aquaculture Products to European Union.

37.2. The records shall be available for inspections and verification by concerned official bodies and European Union representatives.

37.3. The checklists for Official Controls shall be prepared and use in audits and inspections.

37.4. The Official Control inspections shall include Hatchery, Farms, Processing Plant, and allied departments and all necessary records and documents shall be kept.

37.5. The Date shall be stored properly with high level of confidentiality and safety. Only authorized persons shall access the records, files and documents. If the data is

stored electronically, all security provision such as pass-word, access control, fire-wall, back-ups etc. shall be ensured for the data control protection.

37.6. The 'own-check system' based on the HACCP principles shall be compulsorily approved by CA and all the documents and records shall be maintained.

37.7. The records shall be maintained at least for two years.

37.8. Major Audit Forms used are the following:

37.8.1. Combined Audit Form for Establishment Approval and Renewal

37.8.2. Routine audit forms of the CA

37.8.3. Routine Audit Form General Directorate of Fisheries – MEWA

37.8.4. GLP Audit Check-list

37.9. Other Forms

37.9.1. Application form for permission to export

37.9.2. Non-conformity Report

37.9.3. Establishment Audit register

37.9.4. Inspection Summary Report

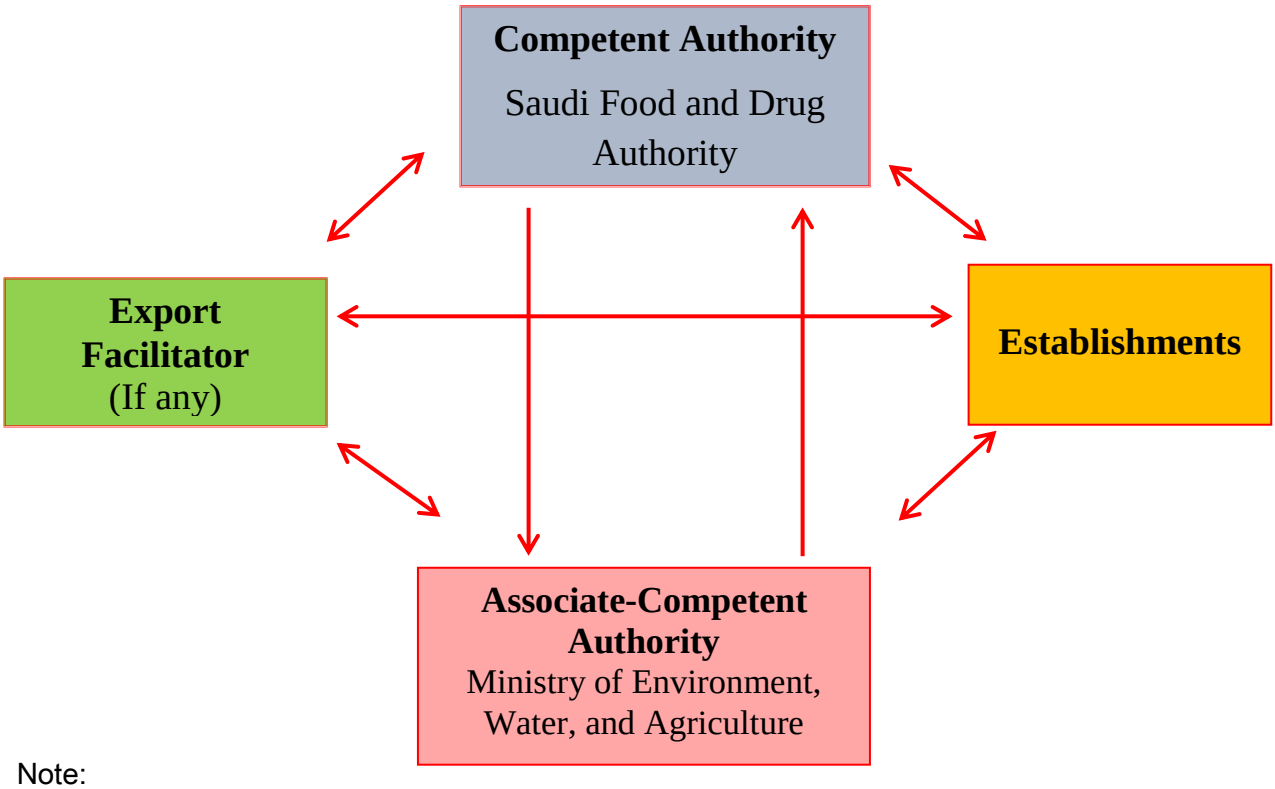
37.9.5. Sample Dispatch Form

Appendix – 1

Organizational Structure – EU Export System

Food Export from Saudi Arabia

General Organizational Connection



Note:

1. Ministry of Municipality shall be consulted / linked in case of local Public Sanitation, staff Health, Hygiene and other related aspects.
2. Ministry of Health shall be connected to the export system, if any specific need arises for public health, epidemic situations.
3. As required Saudi Wild Life Authority shall be incorporated for such requirements.
4. Other government agencies shall be linked to the system as need arises.

Appendix-2

Establishment Approval Procedures

The following steps shall be observed in the approval of Establishments in Saudi Arabia for the export of food products:

1. **Step-1.** Request for application form - The Establishment shall request the CA (in writing) for the Application Form to apply for the approval for Export of food products.
2. **Step-2.** Issue of application form - Up on receipt of written request from the Establishment, the CA shall issue application form along with a copies of all relevant manuals, documents, formats etc. concerning the export of respective food products within 5 days from the date of receipt of request. The CA shall open a new file for the Establishment.
3. **Step-3.** Submission of application- The Establishment shall read the manual carefully and fill the application form. The signed application shall be submitted to the CA with a covering letter, along with following documents:
   3.1. HACCP manual for review and approval.
   3.2. Application for the approval of Laboratory.
   3.3. Application for approval of technicians (along with bio-data).
   3.4. Application for approval of applicable sanitizing agents.
   3.5. Application for approval of applicable feed additives etc.
4. **Step-4.** Evaluation of application- The CA shall evaluate the application form and the attached documents within 15 days and decide whether to select the establishment for primary audit.
5. **Step-5.** Communication with Executive Bodies - Once the establishment is selected for primary audit, the Competent Authority shall intimate other Executive bodies, Namely General Directorate of Fisheries – MEWA and Saudi Standards, within 5 days about the primary audit of the Establishment.

6. **Step-6.** Fixing of date for primary audit - Based on the mutual discussion a date shall be fixed within 5 days for the primary Audit of the Establishment and this shall be intimated

to the Establishment at least one week in advance. There shall be a gap of minimum 10 days between the intimation and the date of audit.

7. **Step- 7.** Primary audit of the Establishment - The audit team comprises of three approved auditors (two from SFDA and one from General Directorate of Fisheries – MEWA) shall visit the Establishment together and shall conduct the primary audit using prescribed audit form. Among the auditors, one shall be assigned as the lead auditor. The audit team shall evaluate the competency of Laboratory Technicians (who are applied for approval as 'approved technician), adequacy of HACCP system, capacity of Laboratory System and approve only if qualified. The team also shall approve the sanitation chemicals / compounds, additives for their use in the establishment.
8. **Step-8.** Submission of audit report - The audit team shall submit a combined audit report to the Competent Authority within three days from the Audit date.
9. **Step-9.** Evaluation of audit report - The CA shall evaluate the audit report. The reported non-conformities (if any) shall be communicated to the Establishment within 5 days in writing with a specific deadline from one to 3 month based on the nature of the nonconformity. If there are no non-conformities, this audit shall be considered as the final audit and steps # 10, 11, 12 and 13 shall not applicable for such cases. The Competent Authority may grant a conditional approval to the Establishment.
10. **Step- 10.** Corrective actions by the Establishment - The Establishment shall take necessary corrective actions against the non-conformities reported in the primary audit report. If the establishment requires more time than what is stipulated by the CA, the establishment shall request the same to the CA within 5 days. The extension of time shall be the discretion of the CA.
11. **Step- 11.** Submission of completion report of corrective action - The Establishment shall submit the completion report to CA about the corrective actions taken as per the time stipulated in the Step # 9 & 10.

12. **Step- 12.** Communication with the Executive Bodies - Based on the completion report of Corrective Actions submitted by the Establishment, the CA shall assess the case. If the nonconformance were minor and if the establishment gives assurance of corrective action taken, CA may decide to approve the establishment without a further audit. In such case 'Steps 13 to 15' shall be skipped. If the nonconformance was/were major type(s), the CA shall communicate to other executive bodies within 5 days to fix a date for the Final Audit.
13. **Step-13.** Fixing of date for final audit- Based on the mutual discussion a date shall be fixed within 5 days for the Final Audit of the Establishment and this shall be intimated to the Establishment at least one week in advance. There shall be a gap of minimum 10 days between the intimation and the date of audit.
14. **Step- 14**. Final audit of the Establishment - The audit team comprises of three approved auditors (two from SFDA, and General Directorate of Fisheries – MEWA) shall conduct the Final Audit in the Establishment based on the Corrective action report submitted by the Establishment.
15. **Step-15.** Submission of audit report - Within three days from the final audit, the audit team leader shall submit a combined audit report of the final audit o CA along with the recommendation to approve or not to approve the establishment for export of food products.
16. **Step-16** Certification of approval status and allocation of approval number - If the final audit report recommend for approval of the Establishment, the CA shall study the audit report and announce its decision within 5 days from the date of receipt of audit report. If the establishment is approved for export, a certificate shall be sent to the establishment with copies to other executive body (ARS – MEWA). The approval certificate shall be essentially specify the Name and address of the Establishment, Date of Approval, Approval number of the Establishment, Validity (till next renewal audit) of verification. The establishment must print the health mark prescribed by the CA and the approval number on all the packages/ labels of products exported.

17. N.B. Rejected establishment can’t apply again before three months from rejection date, after that they proceed with the normal process for application mentioned above in clause No. (11).

Appendix- 3

Guarantee Letter (Model)

Letter of Guarantee

The Saudi Food and Drug Authority - Competent Authority of Saudi Arabia hereby guarantee that all exports of Aquaculture Products from Saudi Arabia to European Union shall undergo official controls to ensure that the use of additives shall be carried out in line with import requirements of …….. (name of the importing country). The whole processes and the product shall meet all the applicable food safety stipulations

……

Vice-president, Operations

Saudi Food and Drug Authority

Appendix-4

Traceability Procedures

Traceability is defined as the ability to trace the application, location, and/or history of an activity or item by means of recorded data.

The purpose of Traceability procedures are to ensure incoming materials (including primary and other relevant packaging materials and processing aids) and products are:

- Appropriately identified during receipt, processing, storage and marketing; and
- Traceable both forward (to the immediate customer) and backward (to the immediate suppliers)

Ultimately this shall provide standard guide lines to have a traceability of the final product up to the egg source in the parent farms.

The procedure shall include identification of raw materials including primary and any other relevant packaging and processing aids, intermediate / semi-processed products, part-used materials, finished products and materials pending investigation.

A. RESPONSIBILITY

1. The responsibility in maintaining proper records on final products, products, farm animals and incoming materials shall be upon assigned officers/ mangers of the Establishment.
2. The responsibility of record keeping, data management and control shall be upon the Establishment.
3. The responsibility of animal/ product / by-product test and analysis carrying shall be up on the Laboratory of the Establishment.
4. The responsibility of inspection and monitoring of the Traceability system shall be the Competent Authority-SFDA and MEWA

B. PROCEDURE

1. All raw materials, ingredients, packaging materials, procured shall be from approved suppliers, where it is not possible to procure from approved supplier, the establishment shall provide the justification for the same and ensure identity.
2. The Establishment shall keep required food chain information to prove the traceability.
3. There shall be specific coding / numbering system to trace the products and by-products to its origin. Such system shall give link to parent stock, egg source, farm animal, products, by-products, ingredients, packaging materials etc
4. There shall be traceable animal health program including sensitivity tests, medicines, medication, vaccines/vaccination details (if any).
5. There shall be records and links to details of animal diseases, treatments, mortality, stock termination etc.
6. The traceability information shall include
    a. Reference of origin of animals
    b. Farm identification details
    c. The drugs and medicines uses
    d. Animal details and health status
    e. production details (of primary production and final product)
    j. Relevant dates and location information
    k. Feed ingredient (raw material) information including source and composition.
    l. Feed and feeding information including feed tracing
    m. Feed safety information
7. The traceability shall be ensured during production storage and transportation through relevant documentation which shall be checked and approved by responsible officers of the Establishment, cross verified by the Competent Authority.
8. Any reworking, reprocessing, redirection of products or by-products shall be addressed through relevant food safety plans such as HACCP, ISO 22000 and relevant products are traceable and records shall be maintained.

Appendix-5
Product Recall Program

'Recall' is defined as - the action to be taken to remove from sale, distribution and consumption, a product which may pose public health / animal health hazards. This program explains what shall be done when food products of animal origin has to be removed from supply or use by consumers for public health animal health (biosecurity) and food safety reasons.

The scope of this procedure shall include identification, isolation and action on food of animal products that is to be taken back from the market or distributed area.

A. INTRODUCTION

This procedure is to enables and facilitate the complete and timely withdrawal of 'lots' of unsafe end products. It explains what shall be done when identified unsafe food products have to be removed from supply or use by consumers for public health and safety reasons.

The product Recall procedure shall be applied only for major public health animal health (biosecurity) and food safety issues. This procedure shall not be applicable for products withdrawal for minor reasons not associated public health animal health (biosecurity) and food safety, such as product expiry, use-by date or any such trade reasons.

B. CLASSIFICATION

The product removal from the market are classified in to three Classes. The Class-1 and Class-2 are 'Recalls" and the Class-3 is classified as product withdrawal, as shown below.

CLASS-1 RECALL- Most Critical Situation

This arises when there is a reasonable probability that the use or consumption of the product would cause adverse major public health consequences, death, animal health consequences,

Biosecurity etc. For example; presence of pathogenic organisms, toxic chemicals or harmful foreign bodies shall be classified as “CLASS-1 RECALL”

CLASS-2 RECALL- Emergency Situation

This arises when the product may have serious defects, which represent some level of potential animal/ public health risk.

CLASS-3 – PRODUCT WITHDRAWAL - (Non-hazardous Situations)

The product may have non-hazardous defect that is deemed to be misleading into the public, illegal or do not perform to customer expectations

In all classes of Recall (Class 1 & 2) there shall be an immediate remedial action as follows:

- Permanent removal of unsafe products from the market or from use
- Temporary removal of unsafe goods from market followed by correction and return to the market.

Class 3 (Product withdrawal) is a low impact situation where the consequences to life and biosecurity are very rare.

C. STAGES OF RECALL PROCEDURES

The prime objectives of product Recall plan are

i. To stop distribution and sales of affected item as soon as possible

ii. Notify the public, agencies, appropriate authorities of the problem

iii. Retrieve effectively and efficiently any product, which is potentially unsafe from the market place.

The ‘Product Recall Plan’ shall facilitate urgent action by detailing an established procedure to follow, clearly nominating the roles of the key personnel and acting as a reference document for key information for the effective execution of the program.

The steps involved in the ‘Product Recall Plan’ shall be as follows:

1. Receipt of complaint/issue - Potential Recall situations can arise from consumers, commercial customers, retail and wholesale trade, health authorities, government agencies, media or internal sources.

Class 1or 2 complaints, Class 3 withdrawal or any other potential issue that may result in a Recall situation shall be forwarded immediately to the Vice-president, Food Sector, SFDA - Competent Authority. The Competent Authority shall immediately communicate the matter to the concerned agencies as appropriate.

2. Risk assessment of complaint/issue

On behalf of Vice-president Food Sector, the head of EDAF in conjunction with other concerned government agencies as appropriate, shall assess the situation:

- Seeking technical advice from external agencies as appropriate.
- Consider potential consequences, including impact on sensitive age groups
- Consider stock, products, extent of distribution and likelihood of occurrence.

Following an assessment, if the Head of EDAF decides to initialize the Recall protocol, all the concerned agencies shall be notified and Recall Protocol activated

3. Institute Log of events - The first stage of Recall protocol is to initiate Log of events, the Log of events is initially completed by the Competent Authority though the role may later be delegated as a Recall process progresses.

The Head of EDAF shall gather all relevant information on the “Potential Hazardous Food Notification” form including the details of the product, including product type, product identification, quantity, batch/ lot identification details, distribution details etc

4. Initial Decision on Recall Classification Following the initial Risk Assessment, the Competent Authority in conjunction with the MEWA shall make the Primary Classification of Recall as follows

5. Notify to concerned agencies (only to those agencies which are to be primarily involved in the Recall)- The Recall notification shall be communicated to the those concerned national agencies as Primary Notification (This is not the final conclusive communication)

6. Notifying international agencies - The Recall notification shall be communicated to the concerned international agencies, authorities and individuals by the Competent Authority if required, based on the criticality and expected impact of the situation. (The final conclusive communication shall be send later)

7. Stop Production and Quarantine Stock (for Class 1 & 2 Recall) In Class 1 & 2 Situations, stocks of the product concerned are to be identified, isolated and quarantined. If the situation covers product that is currently under production, the production of the offending product is to be stopped.

The Competent Authority in conjunction with other agencies, as appropriate is to initiate the actions above and start proceedings to trace any stock that may be in the distribution network. If not already notified, The Competent Authority shall notify all relevant agencies, establishments and/or individuals as applicable.

Notifications are to be conducted by phone followed by email/fax

8. Convene Recall Committee – A recall committee shall be formed based on the product and nature of recall. The meeting of the Recall committee is convened by the Competent Authority in association with MEWA. The committee shall decide on the extent of Recall, responsibilities for actions from the initial meeting, account codes to capture costs, arrange responsibilities for notification.

9. Review and Classify Recall - The Recall committee shall review the situation and review the Primary Recall Classification and confirm/ or amend the classification.

10. Make ‘Plan of Action’ – based on the decision of the re-call committee a ‘Plan of action’ shall be prepared and responsibilities shall assigned

11. Notify Customers, Trade agencies, Government agencies etc - The final Recall communication shall be sent to all relevant agencies in the prescribed formats.

12. Initiate Physical Action – the physical action shall include the following:

a. Send Recall letters
b. Isolate stock in warehouse (Store House)
c. Isolate stock in trade
d. Collect stock
e. Secure disposal / conversion as per 'Plan of Action'

13. Monitoring the effectiveness of Recall Action

To be effective, Recall notification shall reach as far as the product has been distributed. The effectiveness of the Recall is assessed upon the amount of product received as a percentage of the amount of product, which left the producer while taking in account the retail turnover of the product.

D. FOLLOW-UP ACTION

The follow-up action consists of;

- a check on the effectiveness of the Recall
- an investigation of the reason for the Recall
- and remedial action to prevent a recurrence of the problem

On completion of the Recall, investigation will be initiated in order to take remedial action to prevent the recurrence of the problem, which gave rise to Recall.

Appendix-6

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
(255)
Food Sector

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
(٢٥٥)
قطاع الغذاء

Guidelines for Inspectors Auditing competent authorities and foreign establishments

Drawing upon its control and regulatory missions and its concern for compliance with the relevant bylaws, SFDA requires authorized inspectors auditing competent authorities and their respective food establishments (abattoirs and food plants) to abide by the following guidelines:

1. Any treats of meals, feasts, parties or otherwise provided (in-house or elsewhere) by the establishments subject to the audit shall not be accepted. However, a light lunch during the audit is acceptable inside the facility.

2. Any offers for domestic or non-domestic tours or visits apart from the diplomatically coordinated and agreed upon schedule shall not be accepted.

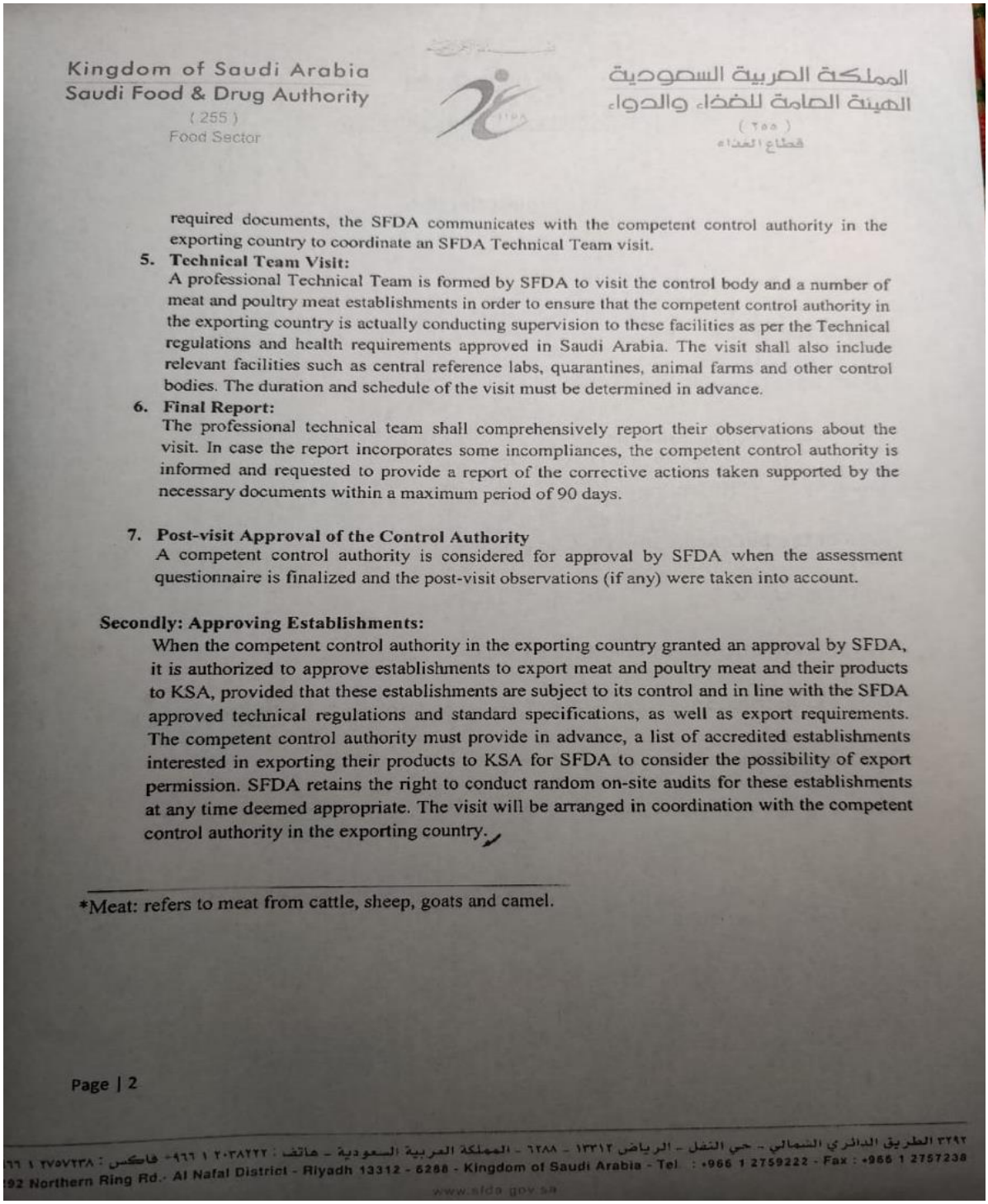
3. Presents and gifts, except for souvenirs or gifts commonly acceptable within SFDA's official norms, shall be rejected.

4. The transport of the technical team from their place of stay to the designated sites subject to inspection (e.g. abattoirs, and plants) shall be facilitated by the official competent authority in the exporting country. In case of long distances where air travel is required, the flight ticket shall be incurred by the technical team.

5. A list of recommended accommodations can be suggested in coordination with the competent authority, provided that bookings and accommodation charges are to be taken care of by the technical team.

6. In case the competent authority's representative failed to accompany the technical team during the on-site audit of the designated establishments, the inspection process shall be

Appendex-7



required documents, the SFDA communicates with the competent control authority in the exporting country to coordinate an SFDA Technical Team visit.

5. **Technical Team Visit:**
   A professional Technical Team is formed by SFDA to visit the control body and a number of meat and poultry meat establishments in order to ensure that the competent control authority in the exporting country is actually conducting supervision to these facilities as per the Technical regulations and health requirements approved in Saudi Arabia. The visit shall also include relevant facilities such as central reference labs, quarantines, animal farms and other control bodies. The duration and schedule of the visit must be determined in advance.
6. **Final Report:**
   The professional technical team shall comprehensively report their observations about the visit. In case the report incorporates some incompliances, the competent control authority is informed and requested to provide a report of the corrective actions taken supported by the necessary documents within a maximum period of 90 days.

7. **Post-visit Approval of the Control Authority**
   A competent control authority is considered for approval by SFDA when the assessment questionnaire is finalized and the post-visit observations (if any) were taken into account.

Secondly: Approving Establishments:

When the competent control authority in the exporting country granted an approval by SFDA, it is authorized to approve establishments to export meat and poultry meat and their products to KSA, provided that these establishments are subject to its control and in line with the SFDA approved technical regulations and standard specifications, as well as export requirements. The competent control authority must provide in advance, a list of accredited establishments interested in exporting their products to KSA for SFDA to consider the possibility of export permission. SFDA retains the right to conduct random on-site audits for these establishments at any time deemed appropriate. The visit will be arranged in coordination with the competent control authority in the exporting country.

*Meat: refers to meat from cattle, sheep, goats and camel.

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Appendix-8

Model of the Health Certificate

Each Health Certificate that accompany a consignment of Aquaculture Products to European Union shall meet the following conditions:

1. The Health Certificate shall be produced thorough the TRACES NT system meeting requirement of EU countries.
   https://webgate.ec.europa.eu/tracesnt/login
2. Each establishment shall have official login ID of TRACES NT for export Health certification process. All information as required shall be provided in HC application.
3. Responsibilities of Issuing officer:
   a. The health certificate shall be approved or rejected online through TRACES NT system by SFDA head office / branch offices by certifying officer.
   b. The TRACES NT approved health certificate shall be printed, signed and stamped by certifying officer. Use only specific stamp approved by the competent authority.
   c. It shall be drawn up in official language of EU member state / importing country.
   d. cross out the statements that are not relevant/applicable to the consignment being certified.
   e. The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.
   f. The health certificate is issued before the products are landed into the EU.
   g. The original Certificate shall accompany the consignment to the importing country.
4. All certifying officers shall officially complete the training on issuing Health certificate.

Appendix-9

Official Control exercised by the Competent Authority

This stipulation shall be laid down by the Competent Authority to meet the requirements of importing country to define and implement official controls in Establishments that intend export of food products. Saudi Food and Drug Authority, as Competent Authority shall be responsible for this.

1. **Details of official controls exercised by the Competent Authority and other associating Government agencies:**

1.1. Types of 'Audits' - The official controls are exercised mainly through audits. The audits shall be carried out by the auditors from Saudi Food and Drug Authority (SFDA) and Ministry of Environment, water and Agriculture (MEWA).

1.2. Each audit will be minimum one man-day (with minimum 6- 8 hours on site) this include drawing of samples for tests and analysis.

1.3. The types of audit shall be as follows:

1.3.1. Approval Audit

1.3.1.1. Approval audit shall be conducted by a team of auditors from Competent Authority and MEWA.

1.3.1.2. The team shall inspect the Establishment to check the level of compliance to the requirements for export.

1.3.1.3. The Approval / Renewal Audit team shall approve technologists in the Establishment Laboratory for conducting tests/analyses in the Establishment Laboratory.

1.3.2. Renewal Audit

1.3.2.1. There shall be an annual renewal audit conducted jointly by the auditors from Competent Authority and MEWA to renew the approval of the Establishment for food export.

1.3.3. Routine Audit

1.3.3.1. There shall be routine audits conducted by The Competent Authority and MEWA independently

1.3.3.2. Routine audit is the back bone of the official control which ensures the system strength and compliance.

1.3.3.3. There shall be a defined frequency for the routing audits.

1.3.3.4. The audits shall be unannounced,

1.3.4. Special Audit – This type of audit shall be conducted in case of a special need to ensure compliance.

2. Responsibilities of Government agencies in different type of 'Audits'

2.1. Food Factory Inspection Section (FFIS) and SFDA Branches

2.1.1. Approval Audit –Under the supervision of FFIS the inspectors from SFDA Branches shall take part in the Establishment's approval audits (primary as well as final audit) for the export of food products.

2.1.2. Routine Audit -The FFIS the SFDA branches shall conduct regular over all monitoring once every three months to ensure the establishment's compliance to stipulations and standards set up for food export. The inspectors of SFDA Branches shall collect routine samples and send to Reference Laboratories for analysis

2.1.3. Renewal Audit – The FFIS the SFDA branches shall take part in the annual renewal audit of the establishment along with MEWA.

2.2. Animal Resources Sector General Directorate of Fisheries – MEWA.

2.2.1. Approval Audit -The General Directorate of Fisheries -MEWA shall take part in the approval audits (primary as well as final audit) of the Establishment for the export of food products from Saudi Arabia.

2.2.2. Routine Audit -The General Directorate of Fisheries -MEWA shall conduct regular monitoring at least once every two weeks to ensure that the hatcheries and farms are operating in coordination with the Establishment and no hazardous drugs/chemicals are used during the operations in hatcheries and farms. General Directorate of Fisheries of MEWA shall collect special samples as part of National Residue Monitoring program and send to Reference Laboratories for analysis.

2.2.3. Renewal Audit – The General Directorate of Fisheries -MEWA shall take part in the annual Establishment renewal audit along with EDAF of SFDA

3. Audit Reporting

3.1.1. Audit report as the feedback of inspections/audits shall be submitted to Competent Authority and also to the management of Establishments.

3.1.2. The findings of the inspections and audits shall be entered in the respective Audit Forms.

3.1.3. In case of any major nonconformities or violations reported, that shall be communicated to all concerned parties for necessary action.

3.1.4. Competent Authority during their audit in the Establishments shall review all inspections carried out by MEWA to ensure the frequency of the Official Control inspection is met.

3.1.5. Corrective Action: Necessary actions shall be taken as required following the inspections and audits. Each agency is responsible for the follow-up of their audit findings.

3.1.6. The Competent Authority shall make sure that necessary follow-up is made by respective agencies.

4. **Non-conformities and Corrective Action –** If a Non-conformance is reported in the audit, it shall follow the steps as given below:

4.1. Reporting of Non- conformance

4.1.1. Analysis of Non- conformance

4.2. Classification of Non- conformance

4.3. Enforcement Action with Target Date

4.4. Communication to Establishment

4.5. Establishment response and action

4.6. Review / inspection of Corrective action taken

4.7. Closing of 'Non-conformance Report'

Appendix-10

Procedure of re-approval of the Establishments

This stipulation lay down the procedure of re-approval of Establishments if their approval for food export is suspended/withdrawn/ terminated. Saudi Food and Drug Authority, as Competent Authority shall be responsible for this procedure.

1. In case of critical violations, major nonconformities reported during official control audits; or due to 'no-operation' in the Establishment, the approval of the Establishment shall be suspended or withdrawn by the CA.
2. In case of an operational nonconformance reported, if the operation is suspended till the nonconformity is rectified, CA shall visit and verify the adequacy of the corrective action taken and give permission to restart the operation and export.
3. During the suspension period, no food products shall be produced for exports and no Health Certificate shall be issued for such periods.
4. In case, due to a major violation which may result in major food safety, system damages (as decided by CA), and the approval shall be withdrawn and the establishment shall not be permitted to export food any longer.
5. If an Establishment communicate to CA that they are not producing, processing or exporting food products for a period longer than 6 months, then their approval shall be suspended for the said period.
6. In cases of withdrawal of approval by CA due to any of the reasons mentioned above, the permission to sanction re-approval of the establishment shall be as per the decision and specific instructions of CA.
7. If CA decides to sanction re-approval to the Establishment, the procedures shall follow the same steps of a fresh approval of an Establishment.

8. The Establishment that wishes to reinstate their approval for food export from the country after the ‘non-operation’ period more than 6 months; same steps of a new approval shall be followed.
9. Other actions to be taken on non-conformities observed or/and reported during the official inspection / audits / tests varies from case to case, CA shall suggest measures for corrective action / legal action as necessary.

Appendix- 11

Penalties and official control actions on infringements and violations

This stipulation describes official action which shall be taken by the Competent Authority on infringements and violations if reported from approved Establishments.

Saudi Food and Drug Authority, as Competent Authority shall be responsible for all legal actions in consultation with other associating government bodies. Ministry of Environment, Water and Agriculture shall be responsible for the imposing legal action including penalties on area of animal health, animal welfare and biosecurity.

1. Authorities and powers

1.1. The authority and powers vested on the Competent Authority and associating government bodies for sanctions for non-compliance (infringement procedures), product seizure and disposal of products shall be binding for all Establishment approved for export to European Union.

1.2. The Competent Authority and its executive bodies shall carry out inspections on establishments on a predetermined frequency. The non-compliance(s) identified during the audit shall be notified to establishment to take corrective measures.

1.3. Non-conformities noticed (if any) during the inspection with regard public health / animal health immediate measures will take to quarantine the product and as necessary.

1.4. The Competent Authority shall have full power to take any decision to impose the restriction(s) on the establishment(s). The steps involved are as follows:

1.4.1. Reporting of nonconforming products with identification.

1.4.2. Analysis of the severity of the nonconformity by the Competent Authority and/or Associating government agencies

1.4.3. Grading the Nonconformity based on the gravity and criticality as follows:

1.4.3.1. Minor Nonconformity

1.4.3.2. Critical Nonconformity

1.4.4. Action on Minor Nonconformity

1.4.4.1. Discussion with the CEO or person in charge of the Establishment and give necessary advice /instruction to the establishment (no seizure of product).

1.4.4.2. A time scale also shall be given to the Establishment to rectify the Nonconformity and to respond back to Competent Authority and/or associating government agencies.

1.4.5. Action on Critical Nonconformity

1.4.5.1. Discussion with the CEO of the Establishment and provide details about the situation followed by product seizure, reconfirmation of the Nonconformity, Isolation of products as decided by the Competent Authority and/or Associating government agencies.

1.4.6. Repeated occurrence of a 'Minor' non-conformity in the next audit, unless with special permission from the Competent Authority and/or Associating government agencies shall be considered as a 'Critical' non-conformity.

1.4.7. Product Disposal – Competent Authority and/or Associating government agencies shall take decision on the isolated product based on the criticality of the observation as follows:

1.4.7.1 Rework,

1.4.7.2. Diversion or

1.4.7.3. Destroy

1.4.8. The Competent Authority and/or Associating government agencies shall advise the CEO/or his deputy of the Establishment on the decision to be implemented.

1.4.9. Monitoring – The Competent Authority and/or Associating government agencies shall supervise the action taken by the Establishment.

1.4.10. Documentation – all relevant documents shall be kept.

1.5. Legal powers of Competent Authority related to infringement procedures, product seizure and disposal:

1.5.1. The Competent Authority has full power to take any decision to impose the restriction(s) on the establishment(s) associating government agencies shall involve in this process as defined in the governmental system.

1.5.2. The specific legal powers of the Competent Authority related to infringement procedures, product seizure and disposal are as follows:

1.5.2.1. The decision of CA on infringement procedures, product seizure/disposal will be the 'final'.

1.5.2.2. Exporting the disposed products (instructed by CA to reprocess/ redirect/ dispose) shall result in cancellation of export approval of the Establishment.

1.5.2.3. The CA has the power and authority to impose Penalties, take legal action on observation of nonconformities.

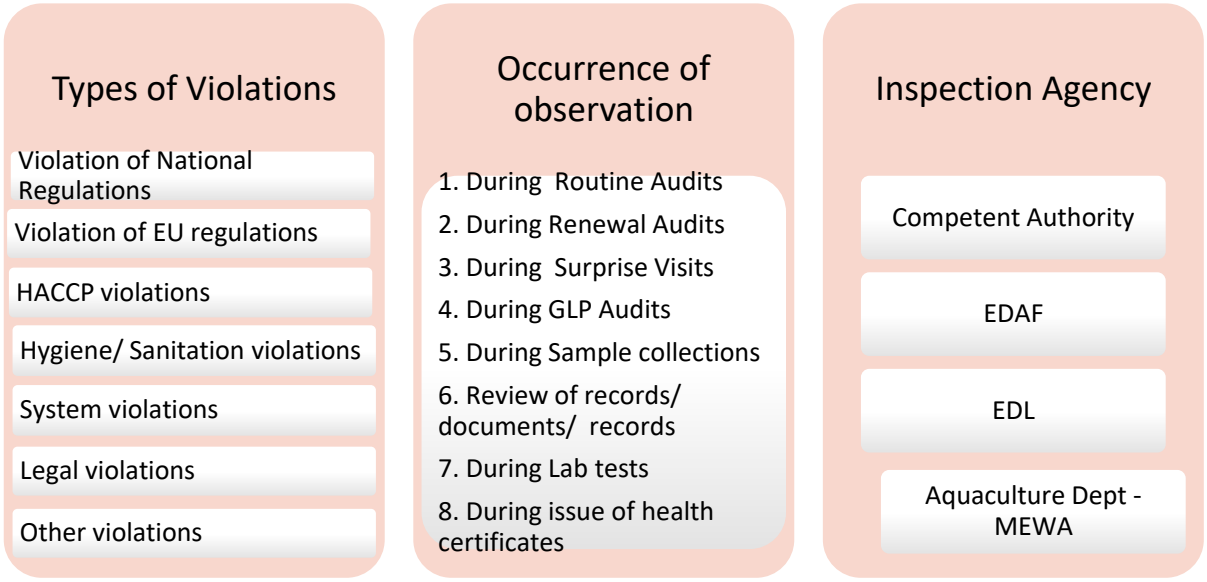
1.5.2.4. Any dispute on the action taken on violation, product seizure/detention or product disposal shall be handled only by the Head of CA.

1.5.2.5. The details of action shall be communicated/discussed with the CEO/or his deputy of the Establishment before implementation.

1.6. Typing (grouping) of various violations

The violations in the system shall be generally grouped as follows:

Grouping and details of violations



Appendix-12

Training Procedures

SFDA – The Competent Authority, Animal Resource Department – MEWA, and the Establishments shall identify /assess their respective training needs, develop, training, plan and shall maintain training records.

The trainings of each of these three agencies shall include:

- Induction Training
- Specific Training programs
- Review of Training Needs
- Annual Training Plan
- Records and Documentation

A. RESPONSIBILITY

1. The Competent Authority - SFDA

The Competent Authority Shall be responsible for the advising the overall training program of the export system. The CA also shall be specifically responsible for the staff training of departments as required.

The Competent Authority is responsible for the review of the training needs in light of export requirements, short and long-term export plans, technological advances and changes in national and international legislations etc.

2. General Directorate of Fisheries – MEWA

AD-MEWA shall be responsible for the overall training related to Residue Monitoring, Animal Health, Disease Monitoring and Management in the country. AD-MEWA shall be also responsible for their staff training.

The General Directorate of Fisheries -MEWA shall be responsible for reviewing the training schedules/ plans, training subjects as needed based on the changes and updates and changed in Residue monitoring, Animal Health, Animal Welfare and Related Areas.

3. The Establishment

The Establishment shall be responsible for the establishment level training for different staff groups such as workers, supervisors, laboratory, quality control and other staff in Hatcheries, Farms, Processing Plant and the Establishment (Rendering Plant)

The Establishment shall be responsible for the identification of the training needs of personnel within their areas of responsibility, and for ensuring that all personnel are suitably trained in the different aspects of export of food to the degree necessary to perform the tasks required.

All agencies shall be responsible for the maintenance of Training records and associated documents.

B. PROCEDURE

1. Induction Training

Each agency shall establish an Induction Training Program for all new employees to introduce the concepts of export requirements. The training shall include

- System out line
- Individual / and combined responsibilities for the implementation and maintenance of the system
- Statutory regulations and stipulations.
- Specifications and standards of product and processes
- Specific aspects associated to the job.

The responsible officer in each agency shall ensure that the Induction training is performed within the individual's probationary period and records are maintained.

2. Specific Training Program

Each agency shall plan and conduct Specific Training Program in the relevant areas applicable in the specific food that is proposed for Export. On Job training, Refresher training and Specific training shall be carried out for specific staff group as applicable.

3. Review of Training needs

Each agency shall, convene a 6 monthly or annual system review and ensure the review:

- Considers all process activities in order to identify areas or activities that are affected by lack of training or specialist personnel
- Considers training needs to meet existing requirements and future requirements in line with long term plans, new technology or changes of legislation
- Reviews any External Training courses relevant to the process that will support the betterment of the system in terms of quality, safety and legal compliance.
- Reviews the effectiveness of the training already provided.

- Reviews the benefits derived from training already provided

The reported “Training need” shall be reported to the Head of each agency for approval and necessary action.

4. Annual Training Plans

The concerned officer shall prepare Training Plans to ensure that individuals at each relevant function or level are aware of:

- The requirements of the food export and other applicable stipulations, the importance of conformance to policies and procedures and their roles and responsibilities in implementation.
- The potential consequences of deviation from procedures
- The actual or potential significant environmental impacts of their work and the benefits of improved personal performance

5. Records and Documentation

All the training details of the employee and the department shall be recorded in suitable files / computer system with all necessary details.

Each agency shall maintain all records associated to ‘training provided’ during the employment term of the individual employee, and for 3 years after cessation of employment.

Appendix- 13 Chlorination Chart

Sl. No	Location/Type	Chlorine Level (ppm)
1	Line water (processing water)	< 0.5 ppm
2	Wash water (for utensils & processing line, machineries)	50 ppm (followed by a wash with ,5 ppm water)
3	Floor wash water	100 ppm
3	Foot Dip Water	50 ppm
4	Hand bowl (Hand dip) Water	20 ppm
5	Water used for ice production	<0.5 ppm

Appendix- 14
Water parameters to be tested weekly by the Establishment

Sl. No	Parameter	Admissible limit
1	Ammonia	0. 5 mg/l
2	Color	Acceptable to consumer & no abnormality
3	Conductivity	2500 $\mu S\ cm^{-1}$ at 20 ^{0} C
4	Ph	6.5-9.5
5	Odour (Smell)	Acceptable to consumer & no abnormality
6	Taste	Acceptable to consumer & no abnormality
7	Turbidity	Acceptable to consumer & no abnormality
8	Total Plate Count-Colonies (at 220C)	100 cfu/ml
9	Total Plate Count-Colonies (at 370C)	20 cfu/ml
10	Escherichia coli (E. coli)	0 cfu/ml
11	Total Coliform Bacteria	0 cfu/ml

Appendix-15 Water parameters to be tested initially and then once every year

S.no	Parameter	Parametric value
Part - A – Bacteriological Parameters		
1	Escherichia coli	0 cfu/100ml
2	Enterococci	0 cfu/100ml
Part - B - Chemical Parameters		
3	Acryl amide	0.1 µg/l
4	Antimony	5.0 µg/l
5	Arsenic	10.0 µg/l
6	Benzene	1.0 µg/l
7	Benzo(a)pyrene	0.01 µg/l
8	Boron	1.0 mg/l
9	Bromate	10.0 µg/l
10	Cadmium	5.0 µg/l
11	Chromium	50.0 µg/l
12	Copper	2.0 mg/l
13	Cyanide	50.0 µg/l
14	1,2 – Dichlorethane	3.0 µg/l
15	Epichlorhydrin	0.10 µg/l
16	Fluoride	1.5 mg/l
17	Lead	10.0 µg/l
18	Mercury	1.0 µg/l
19	Nickel	20.0 µg/l
20	Nitrate	50.0 mg/l
21	Nitrite	0.50 mg/l
22	Pesticides	0.1 µg/l
23	Pesticides –Total	0.50 µg/l
24	Polycyclic aromatic hydrocarbon	0.1 µg/l
25	Selenium	10.0 µg/l
26	Tetrachlorethane & Trichloroethane	10.0µg/l
27	Trihalomethanes –Total	100.0 µg/l
28	Vinyl Chloride	0.50 µg/l
Part –C - Indicator Parameters		
29	Aluminium	200.0 µg/l
30	Ammonium	0.50 mg/l
31	Chloride	250.0 mg/l
32	*Clostridium perfringenes*(including spores)	0 number/100 ml
33	Colour	Acceptable to consumers and to abnormal change
34	Conductivity	2500 µs cm^{-1} at 20 ° C
35	Hydrogen ion concentration	>6.5 and < 9.5 pH Units
36	Iron	200 µg/l
37	Manganese	50 µg/l
38	Odour	Acceptable to consumers and to abnormal change
39	Oxidisability	5.0 mg/l O_2
40	Sulphate	250 mg/l
41	Sodium	200 mg/l

42	Taste	Acceptable to consumers and to abnormal change
43	Colony count 22	No Abnormal Change
44	Coliform bacteria	0 number/100 ml
45	Total Organ Carbon(TOC)	No Abnormal Change
46	Turbidity	Acceptable to consumers and to abnormal change µg/l
47	Tritium	100 Bq/l
48	Total Indicative Dose	0.10 mSv/year

Appendix- 16 Microbiological and Parasitical Standards of shrimp and finfish
(Frequency CA – Every visit, Establishment - Every Day code batch)

A. Microbiological Standard

1. Raw Material

Microbiological Criteria for Fresh Shrimp/ Finfish (cfu/ g)				
Microorganism	N	c	m	M
Total bacterial count (TPC)	5	2	500,000	1,000,0000
Escherichia coli	5	2	10	500
Staphylococcus aureaus (coagulase + ve)	5	1	1000	10000
Salmonella sp. *(in 25 g)*	5	0	0	0

2. Final Product

a. Microbiological Criteria for Fresh, Chilled Shrimp/ Finfish (cfu/ g)				
Microorganism	N	c	m	M
Total bacterial (Plate) count – TPC	5	2	500,000	1,000,0000
Escherichia coli	5	2	10	500
Staphylococcus aureaus (coagulase + ve)	5	1	1000	10000
Salmonella sp. *(in 25 g)*	5	0	0	0
b. Microbiological Criteria for Frozen Shrimp/ Finfish (cfu/ g)				
Microorganism	N	c	m	M
Total bacterial (Plate) count – TPC	5	0	1,000,000	-
Escherichia coli	5	3	10	500
Staphylococcus aureaus (coagulase + ve)	5	1	100	1000
Salmonella sp. *(in 25 g)*	5	0	0	0
c. Microbiological Criteria for Cooked Shrimp/ Finfish (cfu/ g)				
Microorganism	N	c	m	M
Total bacterial (Plate) count - TPC (Whole product)	5	2	10,000	100,000
Total bacterial (Plate) count – TPC (Shelled product)	5	2	50,000	500,000
Escherichia coli	5	2	1	10
Staphylococcus aureaus (coagulase + ve)	5	2	100	1000
Salmonella sp. *(in 25 g)*	5	0	0	0

n - number of units comprising the sample.
m - limit below which all results are considered satisfactory
M - acceptability limit beyond which the results are considered unsatisfactory
c - number of sampling units giving bacterial count of between m and M

B. Parasitical Standard

Parasites - The visual inspection for parasites shall be conducted for raw material
(Admissible limit – 0)

Appendix- 17
Chemical Standards of shrimp and finfish (previously appendix 19)
(Frequency CA – Every visit, Establishment - Every 6 months)

Chemical Parameters for Shrimp/ Finfish products		
No.	**Parameters**	**Admissible limit**
1	Sodium Metabisulfite***1**	150mg/kg –SO_2 in edible portion of raw product, 50mg/kg for cooked crustaceans
2	Boric Acid / Sodium tetra borate (Borax)	4g / kg, in edible portion -expressed as boric acid (Caviar)
3	TVB-N	< 30 mg/100 g
4	Mercury	0.5 ppm (Shrimp), 0.5 ppm (Finfish)***2**
5	Cadmium	0.5 ppm (Shrimp), 0.05 ppm (Finfish)***3**
6	Lead	0.5 ppm (Shrimp), 0.3 ppm (Finfish)
7	Melamine	2.5 mg/kg
8	**Dioxins and PCBs*4**	
	Sum of Dioxins	3.5 pg/g wet weight
	Sum of Dioxin and Dioxin like PCBs	6.5 pg/g wet weight
	Sum of of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180	75 ng/g wet weight
9	**Benzo (a) Pyrene**	
	Smoked Fishery products	2.0 µg/kg wet weight
	Unsmoked Fish Muscle	2.0 µg/kg wet weight
	Unsmoked Crustaccean	5.0 µg/kg wet weight

***1** Sodium Metabisulfite residue shall be tested for every day production batch by establishment*

***2** This Mercury level is applicable for fishes mentioned in 3.3.1.1 of Appendix- 1, (EC) no 1881/2006 including Acipenser spp. . For other species the limit is 0.5 ppm*

***3** For specific species, Cadmium levels mentioned in EU Regulation No. 488/2014 shall be followed as applicable.*

***4** For specific species, Dioxin/PCBs levels mentioned in EU Regulation No.1259/2011 shall be followed as applicable .*
- General Reference to this Appendix- EC No. 1881/2006