Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Food Sector
The Executive Dep. for Local Markets Control
Registration & Licensing Department

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
قطاع الغذاء
الإدارة التنفيذية للرقابة على الأسواق المحلية
إدارة التسجيل والتراخيص

Kingdom of Saudi Arabia

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

(Export Legislation)

Fourth Edition
1st July 2014

Date: 1 July 2014

Executive Department for Local Markets Control-EDLMC, SFDA

Kingdom of Saudi Arabia.

The official regulation and procedures concerned with export of cultured shrimp and finfish products to the European Union shall abide with the following stipulations:

- The General Directorate of Quality Control and Laboratories (GDQCL)was initially assigned as the Competent Authority of Kingdom of Saudi Arabia in dealing with all matters related to the export of Saudi fishery products to European Union (Ministry of Commerce and Industry Decision No.1479 dated 10.6.1422 (H).

- The High Level Coordination Committee which comprises of Director Generals of three executive bodies, namely Executive Director for Local Markets Control Department (EDLMC), Aquaculture Department of Ministry of Agriculture AD-MA) and Saudi Arabian Standards Organization (SASO) shall facilitate the effective implementation procedures for export of Saudi fishery product to EU (Communication number 3355/5/18/c) dated 29/10/1424 (H).

- The above said decision is amended by a new decision No.1597 dated 17.10.1431 (H) to assign Executive Department for Local Market Control-EDLMC, SFDA as the Competent Authority (which originally was the GDQCL).

- Formation of Saudi Food and Drug Authority – SFDA from Council of Ministers resolution No: 4693/R dated 26/01/1428H

- The official approval of Saudi Arabia for the export of aquaculture products to EU, published in the Official Journal of European Union dated 11th March 2005 (2005/218/EC, 2005/219/EC & 2005/233/EC).

The Executive Department for Local Markets Control hereby approve the stated content of "Manual of Procedures - Export of Cultured Shrimp and Finfish Products to European Union" as the export legislation and to be followed in all matters related to the export of cultured shrimp and finfish products to EU.

Interim decisions shall be taken by Technical Committee (TC) / High Level Coordination Committee (HLCC) in accordance with European Council stipulations, which shall be incorporated in the manual during subsequent revisions.

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Dr. Mohammad Ali Al Nasser
Executive Director, Executive Department for Local Markets Control - EDLMC,
Saudi Food and Drug Authority.

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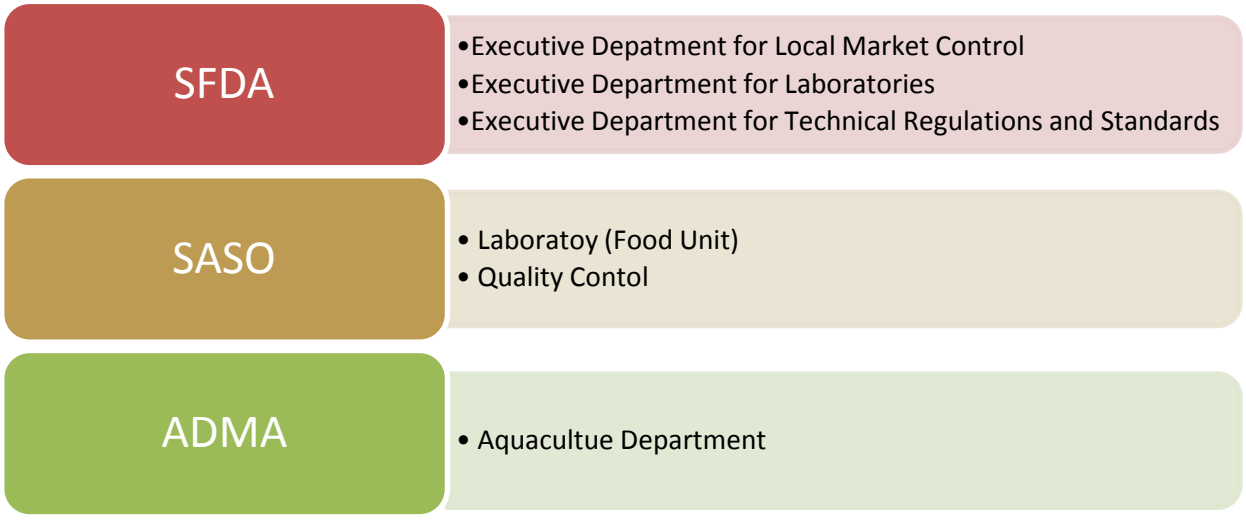
Part # 1

Working Procedures & Structure

1. **Details of Government Agencies involved**- There are three government agencies involved in the matters related to the export of cultured shrimp and finfish products from Saudi Arabia to European Union.

1.1. Saudi Food and Drug Authority
1.2. Saudi Standards, Metrology and Quality Organization
1.3. Aquaculture Department – Ministry of Agriculture

CHART- 1



2. **The basic responsibilities of Government departments**

2.1. **The Executive Department for Local Markets Control (EDLMC) of Saudi Food And Drug Authority (SFDA)**- The ELDMC shall be the 'Competent Authority

(CA)' of Saudi Arabia to coordinate and supervise all matters related to export of cultured shrimp and finfish products from Saudi Arabia to European Union.

EDLMC shall be the communication link between the Kingdom of Saudi Arabia and the European Union in all matters related to the above said exports.

2.2. **Saudi Standards, Metrology and Quality Organization-SASO (Previously known as Saudi Arabian Standards Organization)** - Saudi Standards, Metrology and Quality Organization (SASO) shall be one of the three executive bodies of the High Level Coordination Committee (HLCC).

SASO also shall work with the CA to ensure that the products export to EU meet the specific requirements. The main focus of SASO shall be on 'Processing Operation', 'Final Product Quality' and 'Laboratory Control'.

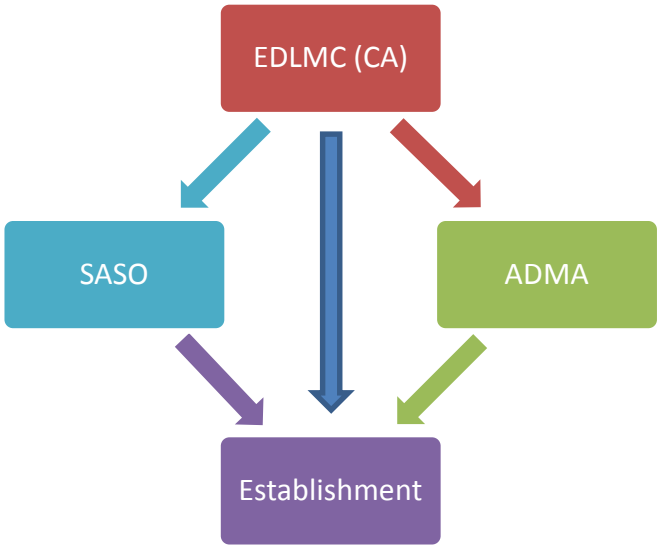
2.3. **Aquaculture Department** of **Ministry of Agriculture (AD-MA**) - Aquaculture Department - Ministry of Agriculture (AD-MA) shall be one of the three executive bodies of the High Level Coordination Committee (HLCC). AD-MA shall work along which CA to ensure that the products export to EU meet the specific requirements.

The main focus of AD-MA shall be on the primary sector (Environmental water body, hatcheries, farms, and harvested shrimp and finfish from farms). AD-MA shall be responsible for the National Residue Monitoring Program, Aquatic Animal Disease and authorized to conduct all related inspections, Lab tests, audits, sample collection.

AD-MA also shall take necessary corrective/ legal actions in the primary sector to combat noncompliant results as required.

3. Organizational Structure/ Line of authority and Functions of different Government agencies in EU export control

CHART- 2



3.1. Saudi Food and Drug Authority (SFDA)

The SFDA is comprised of five sectors such as Food, Drug, Medical Devises, Joint Services and Information Technology. The Food sector handles all matters connected with food.

The Executive Department for Local Market Control (EDLMC) which is one of the departments in SFDA shall be the Competent Authority in Saudi Arabia coordinating all matter to related to export of Shrimp and Finfish exports to European Union

3.1.1. Address and Contact Details of EDLMC

The Executive Department for Local Markets Control (EDLMC),
Saudi Food and Drug Authority (SFDA)
P.O.Box SFDA – 3292, Northern Ring Toad, Al Nafal District
Riyadh – 13312 – 6288, KINGDOM of SAUDI ARBIA
Tel: 00966 11 2038222 Ext 3133, 3130, 3351
Fax: 00966 11 2750356
Email: MNAsser@sfda.gov.sa: MSFaifi@sfda.gov.sa:
bfoqiel@sfda.gov.sa

3.1.2. There are ten departments function under the food sector of SFDA, out of which three departments are involved in EU export control of Shrimp and Finfish products such as:

3.1.2.1. Executive Department for *Local* Market Control (Competent Authority)

3.1.2.2. Executive Department for Laboratories (EDL)

3.1.2.3. Executive Department for Technical Regulations Standards (EDTRS)

3.2. Saudi Standards, Metrology and Quality Organization (SASO)

3.2.1. Address and contact details of SASO

SASO - Saudi Standards, Metrology and Quality Organization
PO Box 3437, Riyadh- 11471,
Kingdom of Saudi Arabia
Tel: +966 11 4520000 Fax: +966 11 4520086
Email: info@saso.org.sa

3.2.2. Departments of SASO involved in EU Export system

3.2.2.1. Department of laboratory (Food Unit)

3.2.2.2. Department of Quality Control

3.2.3. Functions and responsibilities of SASO

Saudi Standards, Metrology and Quality Organization (SASO) works with the CA to ensure that the products export to EU meet the specific requirements. The main focus of SASO is on 'Processing Operation', 'Final Product Quality' and 'Laboratory Control'. SASO shall be responsible also for setting up standards for products to be exported to European Union. The specific functions and responsibilities of SASO in Laboratory Controls are as follows:

3.2.3.1. Receive the list of analysis and tests to be conducted in connection with export of cultured shrimp and finfish products from the Competent Authority.

3.2.3.2. Assigning of tests and analysis to Different National and International Reference Laboratories.

3.2.3.3. Conducting analysis for samples received in the SASO Laboratory, Riyadh.

3.2.3.4. Receiving tests/analyses result reports from all Reference Laboratories.

3.2.3.5. Compilation of reports received from reference laboratories

3.2.3.6. Dispatch of compiled test results to the establishment with copy to other executive bodies (GDQCL and AD-MA).

3.2.3.7. Record keeping of analysis results for all tests/analyses conducted in all reference Laboratories.

3.2.3.8. Keep Good Laboratory Practices (GLP) in the National Reference Laboratory

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

3.2.3.10. Audit of Establishment Laboratories to check the adherence to GLP

3.2.3.11. Keep a separate file for every establishment and keep all test/analyses reports concerned with that establishment.

3.2.3.12. Send copy of reports of all routine audits conducted by SASO to the CA before the last day of every calendar year

3.3. Aquaculture Department – Ministry of Agriculture AD-MA

3.3.1. Address and contact details of AD-MA

Aquaculture Department,
Ministry of Agriculture
King Abdulaziz Street, Riyadh,
Zip code 11195, Saudi Arabia
Tel: +966-114172000, +966-114016666 Ext: 3100,
Fax: +966-114055851

3.3.2. Departments of AD-MA involved in EU Export System- (No other departments involved)

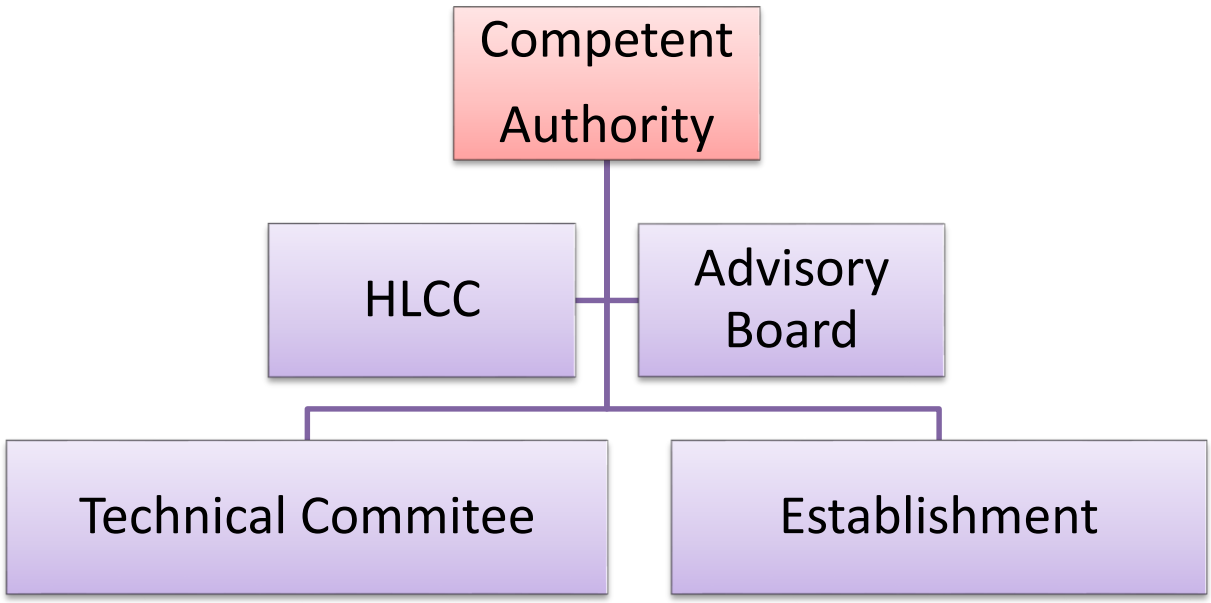
3.3.3. Function and Responsibilities of AD-MA - The main focus of AD-MA shall be on the primary sector (Environmental water body, hatcheries, farms, and harvested shrimp and finfish from farms). AD-MA shall be responsible for the National Residue Monitoring Program and authorized to conduct all related inspections, audits, sample collection. AD-MA also shall take necessary corrective/legal actions in the primary sector to combat noncompliant results as required. The specific functions and responsibilities of the AD-MA in establishing official controls as follows:

3.3.3.1. Regulation on shrimp / finfish culture
3.3.3.2. Regulation on residue program
3.3.3.3. Regulation on general aquaculture operation
3.3.3.4. Regulations and requirements of aquatic animal diseases
3.3.3.5. Regulation on usage of aquaculture drugs/chemicals
3.3.3.6. Regulation on aquaculture drug/chemical supply
3.3.3.7. Setting National residue tolerance limit
3.3.3.8. Ensure that the Establishment Lab meets requirements
3.3.3.9. Listing Prohibited aquaculture drugs/chemicals/ pharmacologically active substances
3.3.3.10. Setting National tolerance limit for aquaculture drugs
3.3.3.11. Setting National tolerance limits for other substances
3.3.3.12. Sampling for “National Residue Monitoring”
3.3.3.13. Fixing frequency of sample collection
3.3.3.14. Fixing types of samples, sampling methods and securing procedures
3.3.3.15. Collecting and sending samples for NRMP to Laboratories
3.3.3.16. Receiving test results
3.3.3.17. Set measures when residues are detected above admissible limits.
3.3.3.18. Collect background information and details of production and products exported to Europe
3.3.3.19. Define the scope of “National Residue Monitoring” plan.
3.3.3.20. Set frequencies and levels of controls
3.3.3.21. Set targeting criteria (if any)
3.3.3.22. Send copy of all reports of routine audits conducted by ADMA to the CA before last day of every calendar year

4. Basic Administrative Structure of EU Export Control System

4.1. Competent Authority
4.2. High Level Coordination Committee
4.3. Advisory Board
4.4. Technical Committee
4.5. Establishments

CHART - 3



5. The Competent Authority - Structure and Functions.

5.1. The Name of the Competent Authority

The Executive Department for Local Markets Control (EDLMC),
Saudi Food and Drug Authority (SFDA)

5.2. EDLMC - General Defined Functions in SFDA

5.2.1. Process and Issue Licenses to food processing establishments and also classifying them according to the risk

5.2.2. Conduct field inspections to ensure compliance (for new licenses, and renewal of licenses)

5.2.3. Conduct on-the-ground (surveillance) inspections in the licensed food processing establishments to ensure technical, food safety and consumer health compliances

5.2.4. Provide support for monitoring centers and crisis management

5.2.5. Impose penalties on noncompliant establishments in coordination with Executive Department for standards /regulations/ legal departments

5.2.6. Other relevant related tasks as needed

5.3. EDLMC as Competent Authority of EU Export Control: EDLMC, the Competent Authority of the Kingdom of Saudi Arabia, which carries out the overall supervision of activities related to the export of cultured shrimp and finfish products to the European Union. CA shall be the communication link between the Kingdom of Saudi Arabia and the European Union in all matters related to the above said exports. This apex body shall receive reports and recommendation from the High Level Coordination Committee for further action. The CA shall communicate to EU, other committees and Establishments about different matters related to the fishery product export as well as for the product standards. The Competent Authority shall be responsible for the following

5.3.1. Over all supervision of all matters related to export of cultured shrimp and finfish products to the European Union

5.3.2. Perform as the communication link between the Kingdom of Saudi Arabia and European Union

5.3.3. Provide guarantees to the official body of EU (DG SANCO) that fishery products for export to the EU have undergone official controls as required by the EU stipulations

5.3.4. Final approval of all matters related to export of cultured shrimp and finfish products to the European Union

5.3.5. Coordination between the High Level Coordination Committee, Technical Committee and Establishment

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

5.3.7. Issue list of tests/analyses to be conducted by Reference Laboratory and Establishment laboratory.

5.3.8. Issuing formats/checklists to be used during establishment inspections.

5.3.9. Ensure that the High Level Coordination Committee and Technical Committee meet as per schedule.

5.3.10. Making necessary arrangements to convene deferent committee meetings.

5.3.11. Regular monitoring overall activities of the Establishment to ensure that the Establishments meet the stipulations in the “Manual of Procedures: Export of Cultured Shrimp and Finfish products to EU”.

5.3.12. Ensuring “Manual of Procedures - Export of Cultured Shrimp and Finfish products to European Union” meets the requirements of relevant EU directives.

5.3.13. The CA should ensure that analytical methods used for test and analysis of samples are validated

5.3.14. Approval of Government Auditors for Establishment audits based on the recommendation of executive bodies.

5.3.15. Visiting the Executive bodies (EDLMC, AD-MA & SASO) to ensure that the all the assigned tasks are carried out as per schedule.

5.3.16. Final approval of Establishments for export to EU countries.

5.3.17. Allocation of 'Health mark' & 'Approval Number' to Approved Establishments.

5.3.18. Sending list of Approved Establishments to the European Union.

5.3.19. Identifying external (national/international) laboratories to conduct tests if need arises.

5.3.20. Competent Authority (EDLMC) - Structure

5.3.20.1. Registration and Licensing

5.3.20.1.1. Licensing and follow-up

5.3.20.1.2. Electronic data updating

5.3.20.1.3. Issue export (health) certificates for export

5.3.20.2. Food Control

5.3.20.2.1. Annual audit and inspection planning

5.3.20.2.2. Inspection of Regional Offices

5.3.20.2.3. Training of auditors / inspectors

5.3.20.2.4. Performance evaluation of auditors

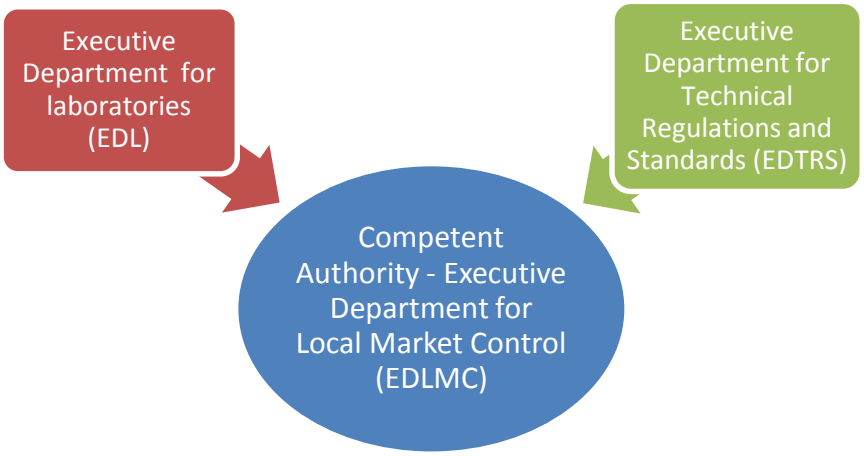
5.3.20.3. Enforcement

5.3.20.3.1. Enforce food laws and applicable regulations

5.3.20.3.2. Resolve all issues related to the inspection in coordination with legal and other concerned departments.

5.4. Functions and Structure of Associating Departments of the Competent Authority

CHART - 4



5.4.1. Structure and functions of Executive Department for Laboratories – EDL (Associating Department No.1).

The EDL has the following division under the department such as

a. Food Control labs
b. Monitoring laboratory
c. Central lab and Research Centre
d. Reference Laboratory
e. Packaging and packaging Material Control laboratory

The functions of the Department include:

5.4.1.1. Development of integrated system of accredited food Laboratories
5.4.1.2. Conduct tests and analysis of food items (both produced in the local market and also imported items)
5.4.1.3. Coordinate among different SFDA food laboratories
5.4.1.4. Supervision and follow-up of all laboratories

5.4.1.5. Ensure food safety through lab tests and analysis

5.4.1.6. Implement surveillance programs in applicable departments

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

5.4.1.8. Coordinate with other SFDA departments for laboratory supplies

5.4.1.9. Meet the technical and administrative requirements of ISO 17025

5.4.1.10. Capacity building for needed equipment's and trained manpower

5.4.2. Structure and function of Executive Department for Technical Regulations and Standards EDTRS (Associating Department No.2).

The EDTRS has the following division under the department such as

a. Technical Regulations and Standards Setting

b. Technical Committees

c. Regional and International Department

d. Conformity

General Functions of EDTRS include

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

5.4.2.2. Represent Saudi Arabia in international events related to food standards and regulations

5.5. Competencies, prerogatives and powers of the Competent Authority

5.5.1. The CA shall have overall responsibility for Export to EU.

5.5.2. The Competent Authority shall frame the legal, procedural, analytical requirements of export to fisheries products to EU. From Saudi Arabia.

5.5.3. The CA shall maintain well equipped, technically qualified, adequately trained manpower to handle audits, tests, legal formalities etc.

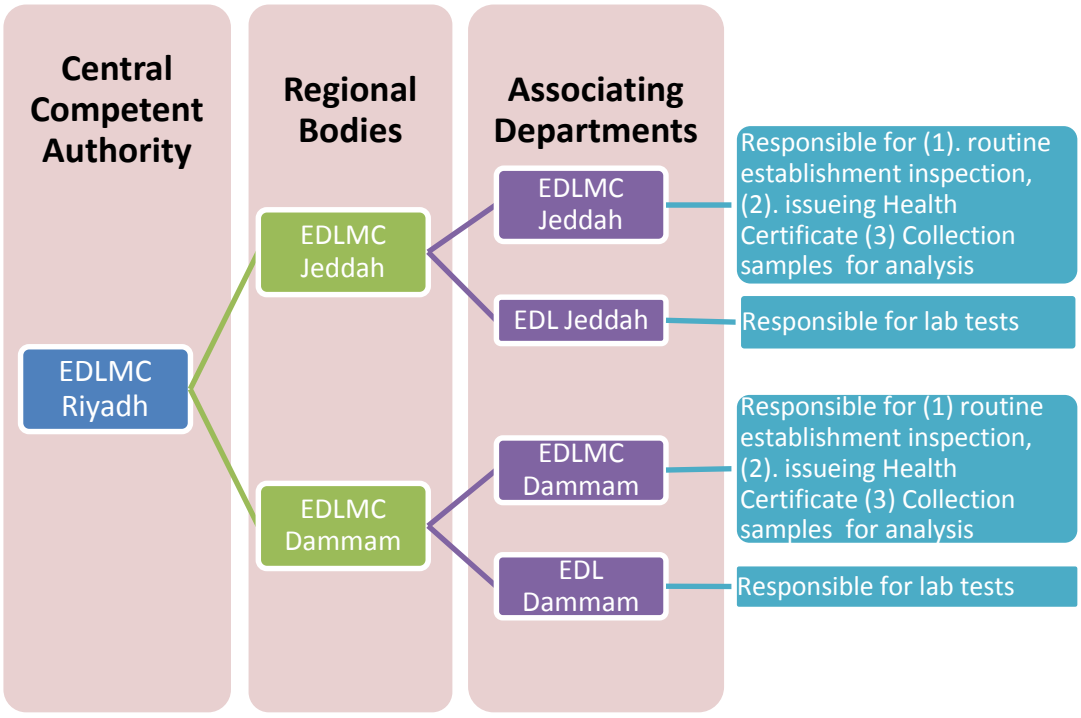
5.5.4. The ultimate authority for approval, dismissal, suspension, withdrawal of export sanctions to European Union shall be the CA

5.5.5. The CA shall have full authority to levy penalties / disciplinary steps, other action on establishments that export fisheries products to EU.

5.6. Organization of the CA at central, regional and local level

The Executive Department for Local Market Control (EDLMC) is under SFDA, with its Head Office in Riyadh. The CA has regional/local offices in different locations function under the direct control of the Head Office

CHART - 5



The EDLMC (CA) is headed by the Executive Director of the Department, whose office also is stationed in Riyadh. Under the Executive Director of the CA, there is a Coordinator to supervise the whole activities of related to

fisheries export to European Union. In every regional/local office, there is an officer in-charge for EU export affairs who is under the advice and supervision of the EU affairs coordinator.

All directions for control and instruction for system procedures and changes shall originate from the Riyadh office of the Competent Authority to ensure and guarantee harmonized system in the whole country.

6. High Level Coordination Committee (HLCC)

6.1. Structure of HLCC - The HLCC shall have the following members:

6.1.1. EDLMC – Represented by Executive Director EDLMC

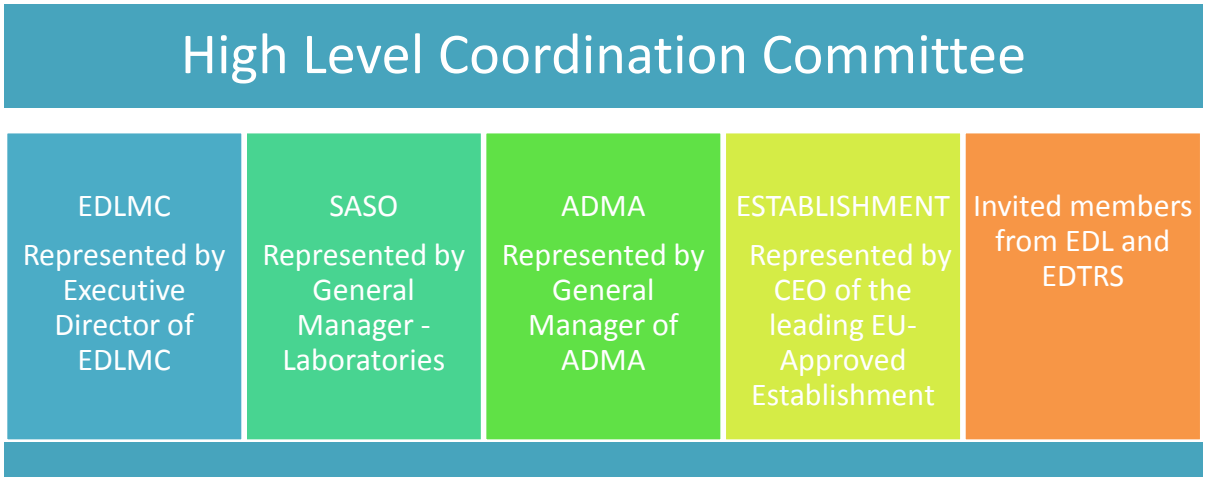
6.1.2. SASO – Represented by General Manager-Laboratories

6.1.3. AD-MA – General Manager Aquaculture Department

6.1.4. Establishment Representative – CEO from the leading Establishment that exports to EU. (He will be the 'Ex officio' member to represent Establishments. So if the CEO of the Leading Establishment is unable to participate, then the CEO of the next Establishment will be invited)

6.1.5. Invited Members: HLCC may invite representatives from Departments such as EDL, EDTR, other agencies/establishments as required.

CHART - 6



6.2. General Functions of HLCC

This Committee shall be the second level committee reporting to CA, which helps CA for the proper implementation and evaluation of systems and procedures of export of cultured shrimps and cultured shrimp products to EU.

The High Level Coordination Committee (HLCC) shall be responsible for:

6.2.1. Evaluation and approval of suggestions/observation /recommendations of the 'Technical Committee' before it is forwarded to the Competent Authority for final approval.

6.2.2. Recommending amendments in the "Manual of Procedures - Export of Cultured Shrimp and Finfish Products to European Union" suggested by the Technical committee.

6.2.3. This committee shall convene meeting at least once in a year. But CA can invite needed members for special meetings as required.

7. Advisory Board

The Advisory Board shall be the body which provide proactive advises to the EU export system. This body shall also help in solving problems and shall handle issues that require special attention.

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

7.1.1. One member (minimum) from EDLMC (Competent Authority)

7.1.2. One member (minimum) from EDL

7.1.3. One member (minimum) from EDTRS

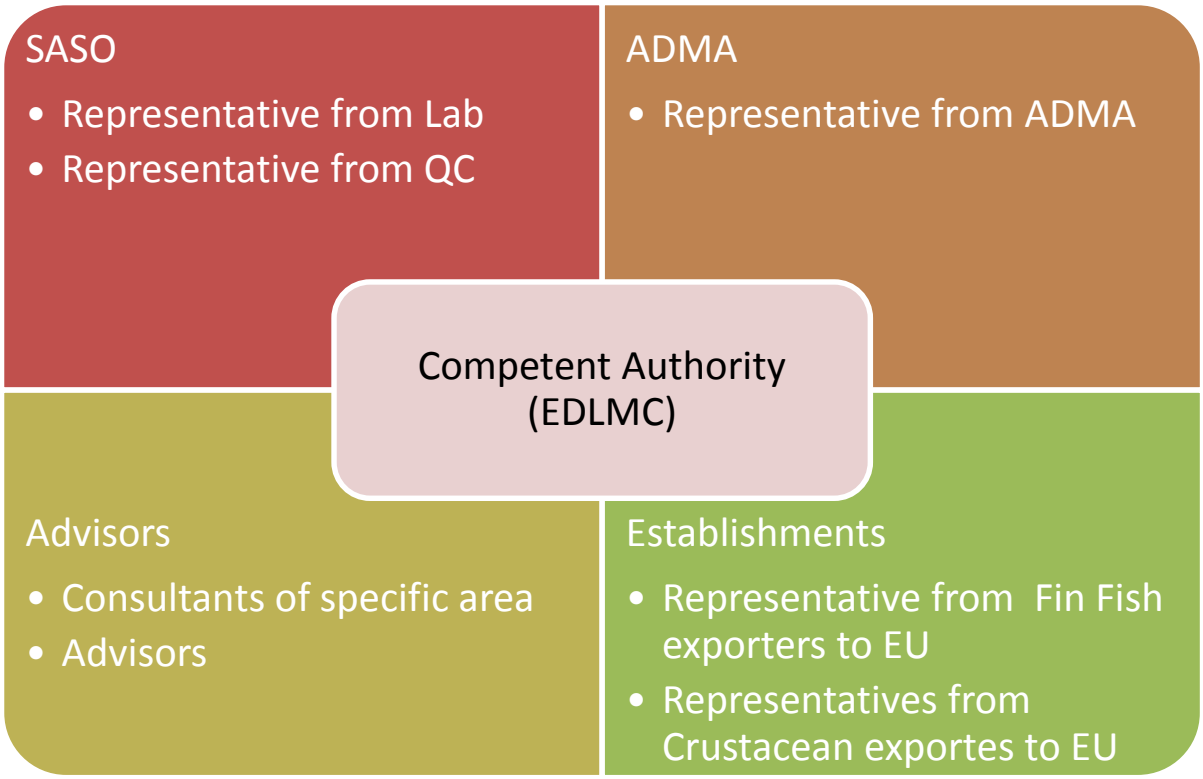
7.1.4. One member (minimum) from SASO

7.1.5. One member (minimum) from AD-MA

7.1.6. One representative from Shrimp/ Fish producing Establishment

7.1.7. Consultants / advisors

CHART - 7



7.2. Functions of the Advisory Board shall be as follows:

7.2.1. Give advice on specific issues related to EU export

7.2.2. Give suggestion for revision of EU system review and revision

7.2.3. Evaluate proposals for changes in EU export system and give advice

7.2.4. Other assignments as given by Technical committee and HLCC

8. Technical Committee

Technical Committee (TC) shall be comprised of Technical Representatives from The Executive Department for Local Markets Control (EDLMC), Aquaculture Department - Ministry of Agriculture (AD-MA), Saudi Standards, Metrology and Quality Organization (SASO) and the Establishments.

CHART - 8

SFDA	•Representatives from EDLMC •One representative from EDL •One Representative from EDTRS
SASO	•One representative from SASO FOOD Lab Unit •One representative from Quality Control Department
AD-MA	•One representative from ADMA
ESTABLISHMENT	•One technical representative from each EU Approved establishment

8.1. Functions of the Technical Committee

The Technical Committee (TC) shall be responsible for the following:

8.1.1. Conducting detailed analysis and discussion on procedural, scientific and Technical matters connected with exports to European Union.

8.1.2. This committee shall ensure that the Establishment follows procedures and meet stipulated standards through the assigned auditors.

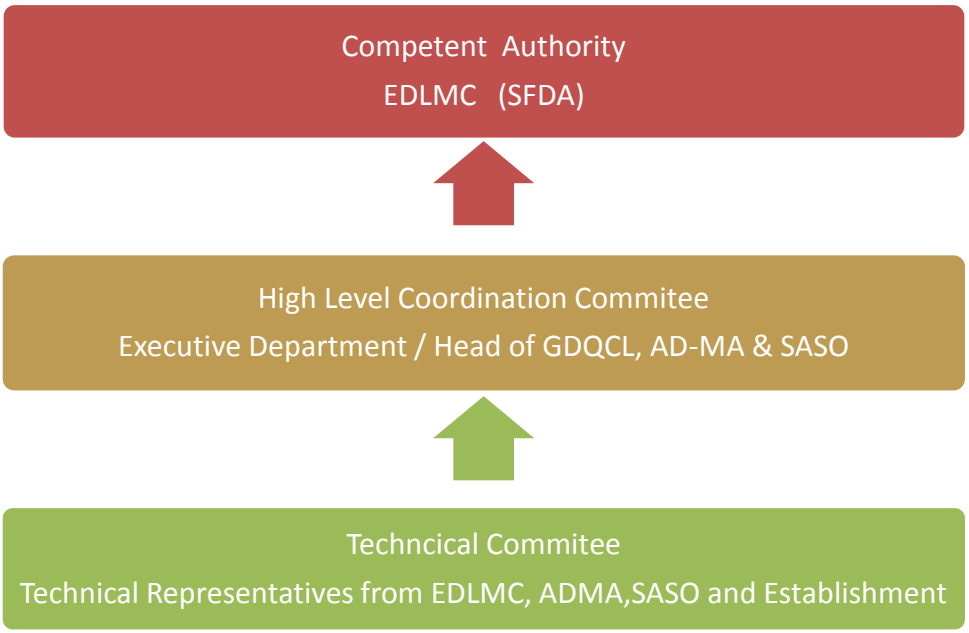
8.1.3. This committee shall review the EU exports carried out by different EU approved establishments, their issues related to primary production, processing, storage, export, inspections, laboratory analysis etc.

8.1.4. This committee also shall be responsible for suggesting amendments in the "Manual of Procedures: Export of Cultured Shrimp and Finfish Products to EU" and update the manual as needed.

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

9. Reporting line of Committees

CHART - 9



10. Establishments

Establishment is the premise where cultured shrimp and finfish products are prepared, processed and stored.

10.1. General Functions of the Establishment

The Establishment shall be responsible to:

10.1.1. Accept and implement directions and advices officially communicated by the Competent Authority.

10.1.2. Follow all conditions and procedures specified in the 'Manual of Procedures: Export of cultured shrimp and finfish products to European Union'.

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

10.1.4. Receive the assigned Government auditors and coordinate with them for conducting inspections/audits.

10.1.5. Abide with the national rules and regulations

10.1.6. Adopt and practice the stipulations and directives and specific advices officially communicated by the Competent Authority.

10.1.7. Adhere to the specified and procedures as defined in the manual

10.1.8. Implement applicable national/international standards advised by CA

10.1.9. Develop and maintain required infrastructure facilities as stipulated

10.1.10. Maintain adequate qualified manpower for the export procedures

10.1.11. Bear the cost of tests, analyses, inspection, Audits, Certification etc. of the EU Export procedures as applicable.

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

10.1.13. Maintain hygiene and sanitation requirements in the establishment

10.1.14. Provide necessary assistance and provisions for Government inspectors, auditors for the conduct of audit, inspections etc.

10.1.15. Get all audits registered in the 'Establishment Audit Register' after every audit.

10.1.16. Give a Guarantee Letter 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 food products produced in the Establishment and there is a scientifically designed full traceability system for all products" signed by the CEO of the Establishment.

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

10.1.18. To send samples (self-monitoring) to only CA approved laboratories for analysis

11. Procedure for approval of Establishments for export of cultured shrimp and finfish products to European Union by the Competent Authority

11.1. **Step-1. Request for application form** - The Establishment shall request to the competent authority (in writing) for the application form to apply for approval to export cultured shrimp and finfish products to European Union.

11.2. **Step-2. Issue of application form** - Up on receipt of written request from the Establishment, the Competent Authority shall issue application form to the Establishment along with a copy of "Manual of Procedures - Export of Cultured Shrimp and Finfish products to European Union" within 7 days from the date of receipt of request. The Competent Authority shall open a new file for the Establishment.

11.3. **Step-3. Submission of application**- The Establishment shall read the manual carefully and fill the application. The signed application shall be submitted to the Competent Authority with a covering letter, along with following documents

a. HACCP manual for review and approval
b. Application for the approval of Laboratory
c. Application for approval of technicians (along with biodatas)
d. Application for approval of applicable sanitizing agents
e. Application for approval of applicable food additives etc.
f. The original test report of water in respect of water complying requirements of Council Directive 98/83/EC dated 3.11.1998 used for processing and ice manufacture

11.4. **Step-4. Evaluation of application**- The Competent Authority shall evaluate the application form and the attached documents within 7 days and decide whether to select the establishment for primary audit.

11.5. **Step-5. Communication with Executive Bodies** - Once the establishment is selected for primary audit, the Competent Authority shall intimate other Executive bodies (Namely Aquaculture Department – Ministry of Agriculture (AD-MA) and Saudi Standards, Metrology and Quality Organization (SASO) within 3 days about the primary audit of the Establishment.

11.6. **Step-6. Fixing of date for primary audit** - Based on the mutual discussion a date shall be fixed within 7 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.

11.7. **Step- 7. Primary audit of the Establishment** - The audit team comprises of three approved auditors (one each from EDLMC, AD-MA and SASO) 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.

11.8. **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.

11.9. **Step-9. Evaluation of audit report** - The Competent Authority shall evaluate the audit report. The reported non-conformities (if any) shall be communicated to the Establishment within 7 days in writing with a specific deadline from 1 to 3 month based on the nature of the nonconformity. If there are no nonconformities, this audit shall be considered as the final audit and steps # 10, 11, 12 and 13 shall not applicable for such cases.

11.10. **Step- 10. Corrective actions by the Establishment** - The Establishment shall take necessary corrective actions against the non-conformities reported in the primary audit. If the establishment requires more time than what is stipulated by the Competent Authority, the Establishment shall request the same to the Competent Authority within 7 days. The extension of time shall be the discretion of the Competent Authority.

11.11. **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.

11.12. **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 7 days to fix a date for the Final Audit.

11.13. **Step-13. Fixing of date for final audit**- Based on the mutual discussion a date shall be fixed within 7 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.

11.14. **Step- 14. Final audit of the Establishment** - The audit team comprises of three approved auditors (one each from EDLMC, AD-MA and SASO) shall conduct the Final Audit in the Establishment based on the Corrective action report submitted by the Establishment.

11.15. **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 to CA along with the recommendation to approve or not to approve the establishment for export of cultured shrimp and finfish products to the European Union.

11.16. **Step-16 Certification of approval status and allocation of approval number** - If the final audit report recommend for approval of the Establishment, the Competent Authority shall study the audit report and announce its decision within 7 days from the date of receipt of audit report. If the Establishment is approved for export to the European Union, a certificate shall be sent to the Establishment with copies to other executive bodies (AD-MA and SASO). 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 competent authority and the approval number on all the packages/ labels of products exported to European Union.

(If an Establishment is not given approval to export to EU, it can apply again for approval only after three months. Such establishment must follow all steps once again while applying for next time and a freshly filled Application Form specifying corrective action taken on the previous Audit Report remarks).

12. **Procedure for re-approval of an Establishment once the approval is suspended or withdrawn.**

12.1. In case of critical violations, nonconformities reported in the Establishment; or due to 'no-operation' in the Establishment, the approval of the Establishment shall be suspended or withdrawn by the CA.

12.2. In case of an operational nonconformance reported, if the operation is suspended until 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.

12.3. During the suspension period, no product should be produced for EU exports and no Health Certificate shall be issued for such periods.

12.4. 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 to European Union any longer.

12.5. If an Establishment communicate to CA that they are not producing, processing or exporting products for EU for a period longer than 6 months, then their approval shall be suspended for the said period.

12.6. 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.

12.7. If CA decides to sanction re-approval to the Establishment, the procedures shall follow the same steps of a new approval as given in Clause No. 11

12.8. For those Establishment to reinstate their approval to export to EU after the 'non-operation' period; same steps of a new approval as given in Clause No. 11 will be followed.

12.9. 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.

13. Listing of establishments for Export to EU

13.1. The establishment (and its included facilities such as Shrimp/ fish farm, Processing Plant, Cold store etc.) approved by the CA based on the procedures specified in this manual, shall be serially numbered and listed by the CA as KSA-01, KSA-02, KSA-03 etc.

'KSA' stands for Kingdom of Saudi Arabia; 01, 02, 03 etc. stands for individual establishments approved for export of fisheries products to European Union.

13.2. The CA shall communicate to concerned EU office for including the establishment in the 'Third country establishments' list' giving guarantee that the establishment shall meet all the EU requirements for the export of fisheries products.

13.3. CA shall keep an updated list of "Approved Establishments"

14. **Keeping the establishment in the Approved List**

The establishments shall be given approval to export to EU for one year. Thereafter every year the establishment shall be audited for renewal of the approval status by the audit team comprised of auditors/inspectors of EDLMC, AD-MA and SASO under the supervision of the CA.

Those Establishments that are qualified in the renewal audit shall be retained in the Approved List

15. **Removal of Establishment from the Approved List of Establishments:**

15.1. If an establishment fails to comply with EU regulation, pausing major risk to consumer safety / casing critical system damage / report of fraud / legal violations; name of such Establishments shall be removed from the Approved List of Establishments exporting fisheries products to EU by the CA after a thorough investigation.

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

15.3. The decision of CA shall be final in this matter.

16. **Details of monitoring by Government agencies**

16.1. Types of 'Audits'

The official controls are exercised mainly through audits. The audits shall be carried out by the auditors from the CA – The Executive Department for Local Market Control (EDLMC), Aquaculture Department of Ministry of Agriculture (AD-MA) and Saudi Standards, Metrology and Quality Organization (SASO). Each audit will be minimum one man-day (with

minimum 6- 8 hours on site) this includes drawing of samples for tests and analysis.

The types of audit shall be as follows:

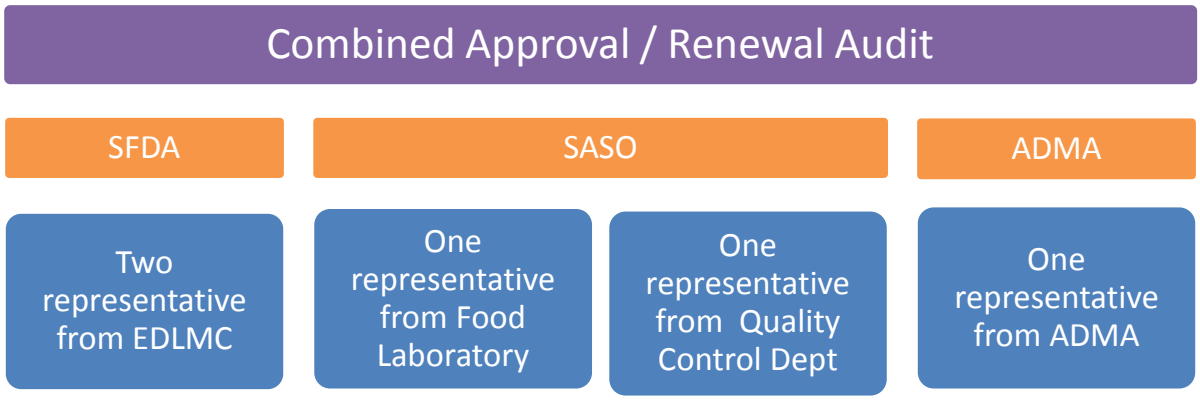
16.1.1. Approval Audit – Approval audit shall be conducted by a team of auditors from Competent Authority and other Executive bodies (AD-MA and SASO). The team shall inspect the establishment to check the level of compliance to the requirements to export to European Union and to approve Laboratory Technologists of the Establishment for conducting tests/analyses in the Establishment Laboratory.

16.1.2. Renewal Audit – There shall be an annual renewal audit conducted jointly by the auditors from Competent Authority and other Executive bodies (AD-MA and SASO), to renew the approval of the Establishment to export to European Union.

16.1.3. Routine Audit – There shall be routine audits conducted by competent authority as well as Executives bodies as per a defined schedule based on which necessary action shall be taken.

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

CHART - 10



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

16.2.1. Competent Authority – EDLMC

16.2.1.1. Approval Audit -The Competent Authority shall take part in the Establishment's approval audits (primary as well as final audit) for the export of cultured shrimp and finfish products to EU.

16.2.1.2. Routine Audit -The Competent Authority shall conduct regular over all monitoring once every three months to ensure the establishment's compliance to stipulations and standards set up for export to European Union. The Competent Authority shall collect routine samples and send to Reference Laboratories for analysis (This samples include Product, Water and Ice)

16.2.1.3. Renewal Audit – The Competent Authority shall take part in the annual renewal audit of the establishment along with other Executive bodies (AD-MA and SASO).

16.2.2. Aquaculture Department, Ministry of Agriculture (AD-MA)

16.2.2.1. Approval Audit -The AD-MA shall take part in the approval audits (primary as well as final audit) of the establishment for the export of cultured shrimp and finfish products to European Union.

16.2.2.2. Routine Audit -The AD-MA shall conduct regular monitoring once in three months to ensure that the hatcheries and farms are operating in coordination with the processing activity and no hazardous chemicals are used during the operations in hatcheries and farms. AD-MA shall collect special samples as part of National Residue Monitoring program and send to Reference Laboratories for analysis at least twice a year.

16.2.2.3. Renewal Audit – The AD-MA shall take part in the annual Establishment renewal audit along with CA and SASO.

16.2.3. Saudi Standards, Metrology and Quality Organization (SASO)

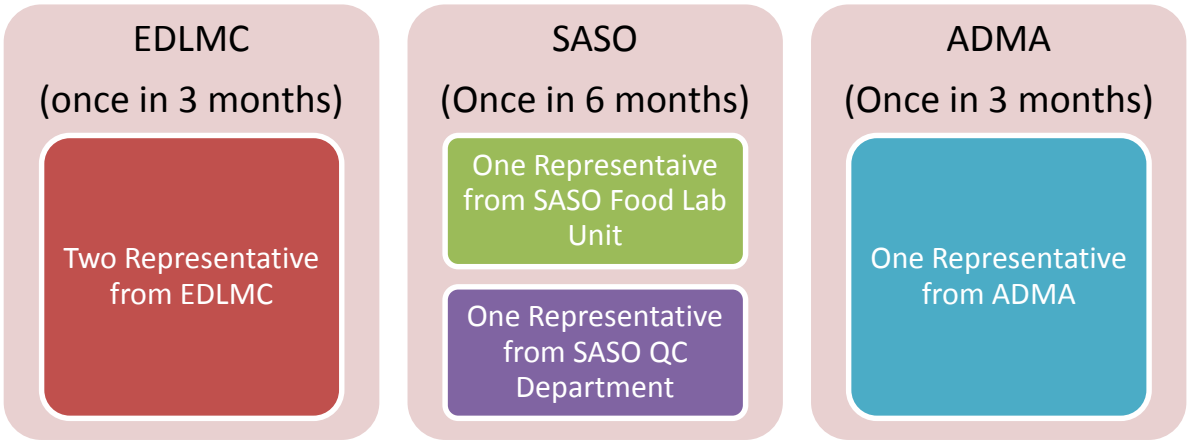
16.2.3.1. Approval Audit - The SASO shall take part in the approval audits (primary audit as well as in the final audit) of the establishment for the export of cultured shrimp and finfish products to EU.

16.2.3.2. Routine Audit - The SASO shall conduct regular monitoring once in six months to ensure that the processing operations carried out in the Establishment meet the required sanitation and production standards. The SASO shall inspect the final product for its conformity to the specification including labeling. The SASO shall take final product sample for inspection and send to Reference Laboratories for analyses.

16.2.3.3. Renewal Audit - The SASO shall take part in the annual renewal audit of the establishment along with CA and AD-MA

16.3. Routine audit frequency

CHART - 11



16.4. Feedback of inspections/audits to the CA hierarchy, and to the management of establishments, etc. - The findings of the inspections and audits shall be entered in the respective Audit Forms. In case of any major nonconformities or violations reported, that shall be communicated to all concerned parties for necessary action. CA during their audit in the establishments shall review all inspections carried out by other executive bodies involved in Official Controls.

16.5. Action to be taken following official controls - Actions shall be taken as required following the inspections and audits. Each agency is responsible for the follow-up. The Competent Authority shall make sure that necessary follow-up is made by respective agencies.

16.6. Actions taken following non-conformities observed or/and reported during official inspections/audits are as follows:

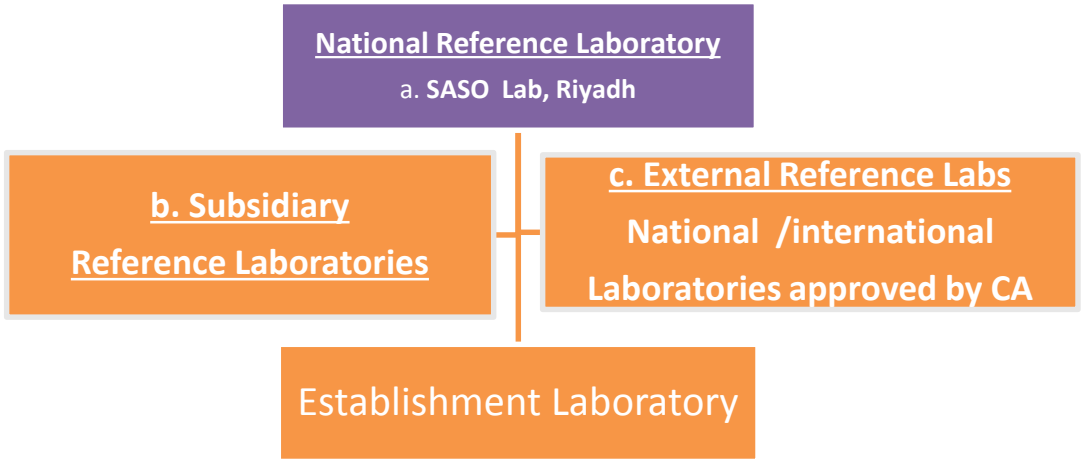
16.6.1. Reporting of Non- conformance
16.6.2. Analysis of Non- conformance
16.6.3. Classification of Non- conformance
16.6.4. Enforcement Action with Target Date
16.6.5. Communication to Establishment
16.6.6. Establishment response and action
16.6.7. Review / inspection of Corrective action taken
16.6.8. Closing of 'Non-conformance Report'

17. **Details of the 'Laboratory System'**

The SASO Laboratory, in Riyadh is the National Reference Laboratory for all analysis concerned with the export of cultured shrimp and finfish products to European Union. Two other laboratories of EDL (EDL Lab in Dammam and

Jeddah) shall work together with the Reference Laboratory to carry out the analysis requirements along with other approved External Reference Labs

CHART - 12

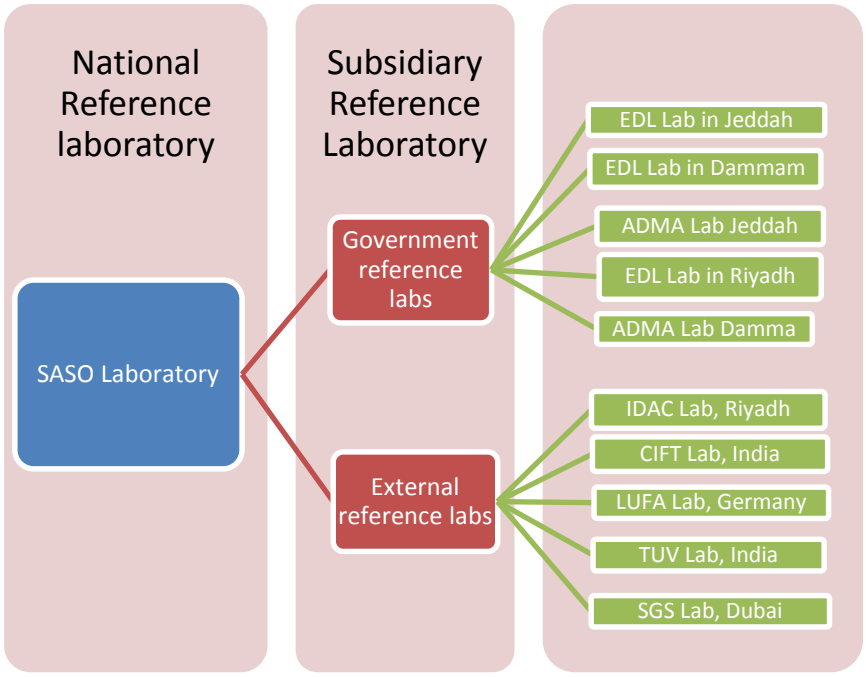


17.1. The Working Structure of Laboratories

As given in the above figure, the Laboratory Working Structure shall comprise a National Reference Laboratory, Subsidiary reference labs, External Reference Labs and Establishment Labs.

17.2. The details (list and location) of the laboratory system

CHART - 13



17.3. Responsibilities of Reference Laboratories

17.3.1. National Reference Laboratory - The SASO Central Laboratory 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 responsibility of this laboratory shall be as follows:

17.3.1.1. Receive the list of analysis and tests to be conducted in connection with export of cultured shrimp and finfish products from the Competent Authority.

17.3.1.2. Assigning of tests and analysis to Different National and International Reference Laboratories.

17.3.1.3. Ensure that the analytical methods used in different laboratories for analysis are validated

17.3.1.4. Conducting analysis for samples received in the SASO Laboratory, Riyadh.

17.3.1.5. Receiving tests/analyses result reports from all Reference Laboratories.

17.3.1.6. Compilation of reports received from reference laboratories

17.3.1.7. Dispatch of compiled test results to the establishment with copy to other executive bodies (EDLMC and AD-MA).

17.3.1.8. Record keeping of analysis results for all tests/analyses conducted in all reference Laboratories.

17.3.1.9. Keep GLP in the National Reference Laboratory

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

17.3.1.11. Audit of Establishment Laboratories to check the adherence to GLP

17.3.1.12. Keep a separate file for every establishment and keep all test/analyses reports concerned with that establishment.

17.3.2. Subsidiary Reference Laboratories

The GDQCL laboratories in Dammam and Jeddah are assigned as Subsidiary Reference Laboratories. The responsibility of these laboratories shall be as follows:

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

17.3.2.2. Conduct the test and analyses as per the assignment given by the National Reference Laboratory.

17.3.2.3. Send the test results to the National Reference Laboratory

17.3.2.4. Keep a file for each establishment and keep all test/analyses reports concerned with that Establishment.

17.3.2.5. Keep GLP in the Subsidiary Reference Laboratory.

17.3.3. External Reference Laboratories

The External Reference Laboratory shall be approved by the Competent Authority from time to time based on the analysis requirement. The responsibilities of the reference laboratories shall be as follows:

17.3.3.1. Receive samples for analysis as advised by the Executive Bodies (CA, AD-MA & SASO)

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

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

17.3.3.4. Keep GLP in the External Reference Laboratory.

17.3.4. Establishment Laboratory

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

17.3.4.1. Conduct regular tests/analyses as per the list issued by the Competent Authority.

17.3.4.2. Keep record of all tests/analyses conducted.

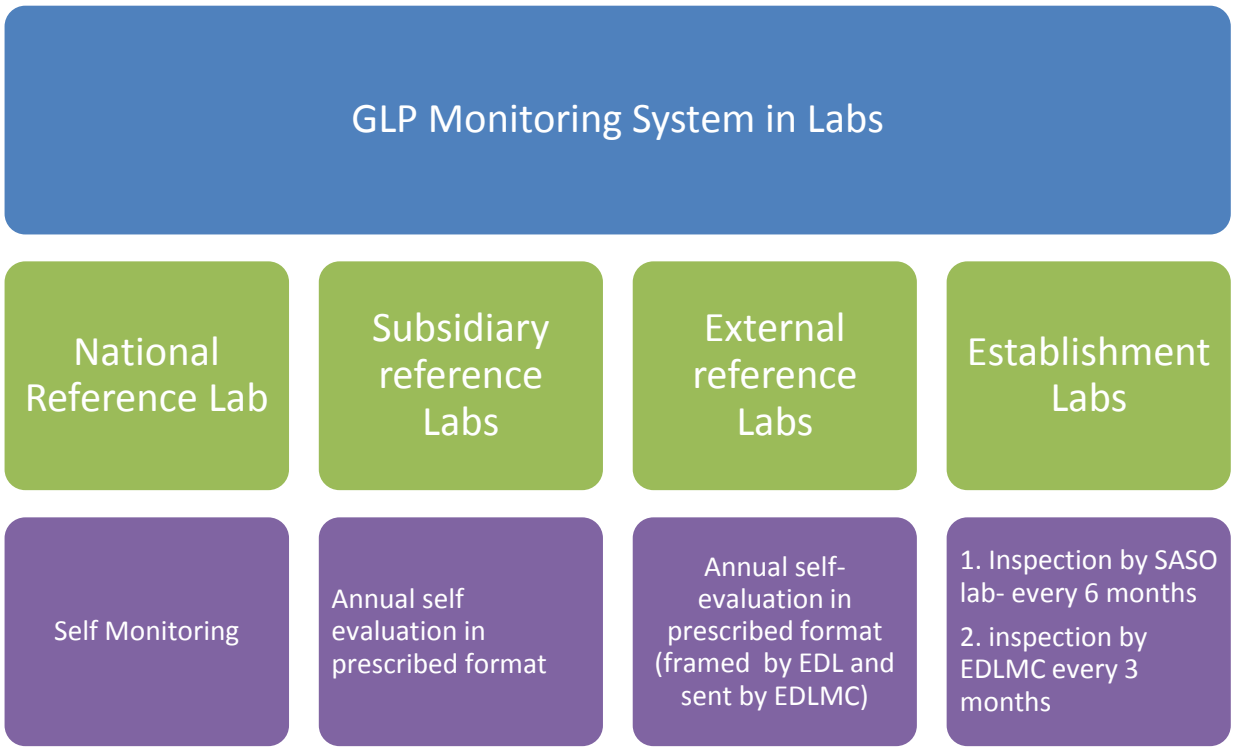
17.3.4.3. Send test/analyses reports to the Competent Authority along with other documents to get health certificate (from Competent

Authority) for each consignment to be exported to European Union.

17.3.4.4. Keep GLP in the Establishment Laboratory.

17.4. GLP monitoring system

CHART - 14



17.5. Type of samples collected and tested

Various samples collected for analysis to ensure compliance to EU export requirements are of the following groups:

17.5.1. Samples drawn during routine /surveillance audit by EDLMC, AD-MA and SASO

17.5.2. Drinking water sample drawn by CA once every year from each establishment

17.5.3. Samples collected by AD-MA for aquaculture residues, contaminants, heavy metals, dyes etc. for National Residue Monitoring Program

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

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

17.6. Sample collection and dispatch - Collection of samples for analysis in the Reference Laboratory shall be done by auditors / inspectors of different government agencies as mentioned in the previous articles. Approved scientific sample collection methods (Sample number, Sample Collection, Sample Preparation, Sample Dispatch) shall be adopted. The sample shall be directly dispatched to the assigned Reference Laboratories (National Reference Laboratory or/and Subsidiary reference laboratories) as mentioned.

17.7. 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.

17.8. Verification of the appropriateness of methods of sampling, methods of analysis and detection tests - The appropriateness of the methods of sampling, analysis etc. shall be verified initially. The review of the methods of sampling, analysis, etc. shall be again carried out during the time of revision of manual. Verification is also carried out when a new sampling/ analysis method is adopted.

17.9. Actions taken following unsatisfactory results of analyses (of samples drawn during official audits and visits)

17.9.1. Step #1 - The information shall be immediately communicated to (1) Competent Authority (2) Farm/Establishment (3) Other Executive bodies

17.9.2. 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, those products shall be recalled.

17.9.3. Step # 3 - If the second sampling (double number of 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 will be released.

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

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

17.10. Procedure by which laboratories are designated by the CA to carry out the analysis of samples taken during official audits, inspection etc.

17.10.1. CA shall assign the responsibility of laboratory system to SASO. As far as possible the tests shall be conducted by the National Reference Laboratory and subsidiary reference labs owned by the government.

17.10.2. CA shall approve other competent laboratories (national and international) to meet the analysis / test requirements as needed.

17.10.3. The CA shall be responsible for identifying external (national/ international) laboratories to conduct tests if need arises.

17.11. Criteria to ensure competency, reliability, accuracy (reference methods) and requirement compliance of designated laboratories

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

17.11.1. Selecting labs with organized systems/ certifications to conduct test and analysis (like ISO 17025) to comply the requirements.

17.11.2. Site visit of the laboratories and inspection as needed.

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

17.12. List of approved external reference laboratories

SN	Name of Reference Laboratory	Accreditation status	Accreditation body
1.	Central Institute of Fisheries Technology, India	ISO 17025:2005	National Accreditation Board for Laboratories (NABL), India
2.	IDAC Laboratory, Riyadh, Saudi Arabia	ISO 17025:2005	International Accreditation Service IAS, USA.
3.	LUFA-ITL GmbH, Germany	DIN EN ISO/IEC 17025:2005	DAkkS Deutsche Akkreditierungsstelle GmbH
4.	TUV SUD South Asia, Bangalore, India	ISO 17025:2005	National Accreditation Board for Laboratories (NABL), India
5.	SGS Gulf Limited, Dubai	ISO 17025:2005	Dubai Accreditation Agency (DAC)

18. **Procedure to issue 'Health Certificate' for fishery products exported to EU:**

Once the Establishment is approved for export to European Union, the establishment shall start production for export to Europe following the stipulations in the 'Manual of Procedures: Export of Cultured Shrimp and Finfish Products to European Union'. There shall be proper documents kept for such productions. Procedure to issue Health Certificate for each consignment as follows:

18.1. Approved establishment laboratory collects routine samples and the approved Lab technicians shall conduct tests/analyses as per the list of analysis stipulated by the Competent Authority. Proper records shall be kept for the analysis conducted.

18.2. When one consignment is ready for export to European Union, the establishment submits a request to the Competent Authority to issue 'Health Certificate'.

18.3. The request application shall include the following documents

18.3.1. Product Details (Type of product, Species of the shrimp / fish, Product break-up with packing details, Day code, Type of packing, Total gross weight, Total net weight)

18.3.2. Microbiological, Parasitological test certificate confirming quality

18.3.3. The Lab Certificate that confirms Product Quality and Safety

18.4. The Competent Authority shall verify the above said documents

18.5. The 'Health Certificate' shall be issued for that specific consignment.

(The efficiency, accuracy and frequency of the tests/analyses conducted by the Establishment Laboratory shall be verified and ensured during the routine audits by the Competent Authority and

other Executive Bodies by verifying Lab records of the Establishment and Sample Analysis in Reference Laboratories)

18.6. Procedures to ensure reliable certification (of Health Certificate)

18.6.1. The certificate is signed by the approved staff of the CA.

18.6.2. The ink color of the signature of the officer who sign the Health Certificate shall be different from the print color of the Health Certificate.

18.6.3. The official seal of the certificate is separately placed by the office of the Regional / local Competent Authority.

18.6.4. The issued certificates are serially numbered

18.6.5. The copy of the issued certificates are kept in files and verified by CA

19. General Clauses

19.1. The authority of CA for sanctions for non-compliance (infringement procedures), product seizure and disposal of products to be imposed over food business operators:

The Competent Authority and its executive bodies shall carry out inspections of establishments on a predetermined frequency. The non-compliance(s) identified during the audit shall be notified to establishment to take corrective measures. Any non-conformity noticed (if any) during the inspection with regard food safety, immediate measures will take to quarantine the product and as necessary.

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:

19.1.1. Reporting of nonconforming products with identification.

19.1.2. Analysis of the severity of the nonconformity by CA

19.1.3. Grading the Nonconformity in to i. Minor Nonconformity or Critical Nonconformity

19.1.4. Action on Minor Nonconformity – Discussion with the CEO or person in charge of the Establishment and give necessary advice /instruction to the establishment (no seizure of product). A time scale also shall be given to the Establishment to rectify the Nonconformity and to respond back to CA.

19.1.5. Action on Critical Nonconformity – 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 CA.

19.1.6. Repeated occurrence of a 'Minor' non-conformity in the next audit, unless with special permission from the CA shall be considered as a 'Critical' non-conformity.

19.1.7. Disposal – CA shall take decision on the isolated product for i. Rework, ii. Diversion or to Destroy and advise the CEO/or his deputy of the Establishment

19.1.8. Documentation – all relevant documents shall be kept.

19.2. CA Legal powers related to infringement procedures, product seizure and disposal:

19.2.1. The Competent Authority has full power to take any decision to impose the restriction(s) on the establishment(s).

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

19.2.3. The decision of CA on infringement procedures, product seizure and disposal will be 'the final' one.

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

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

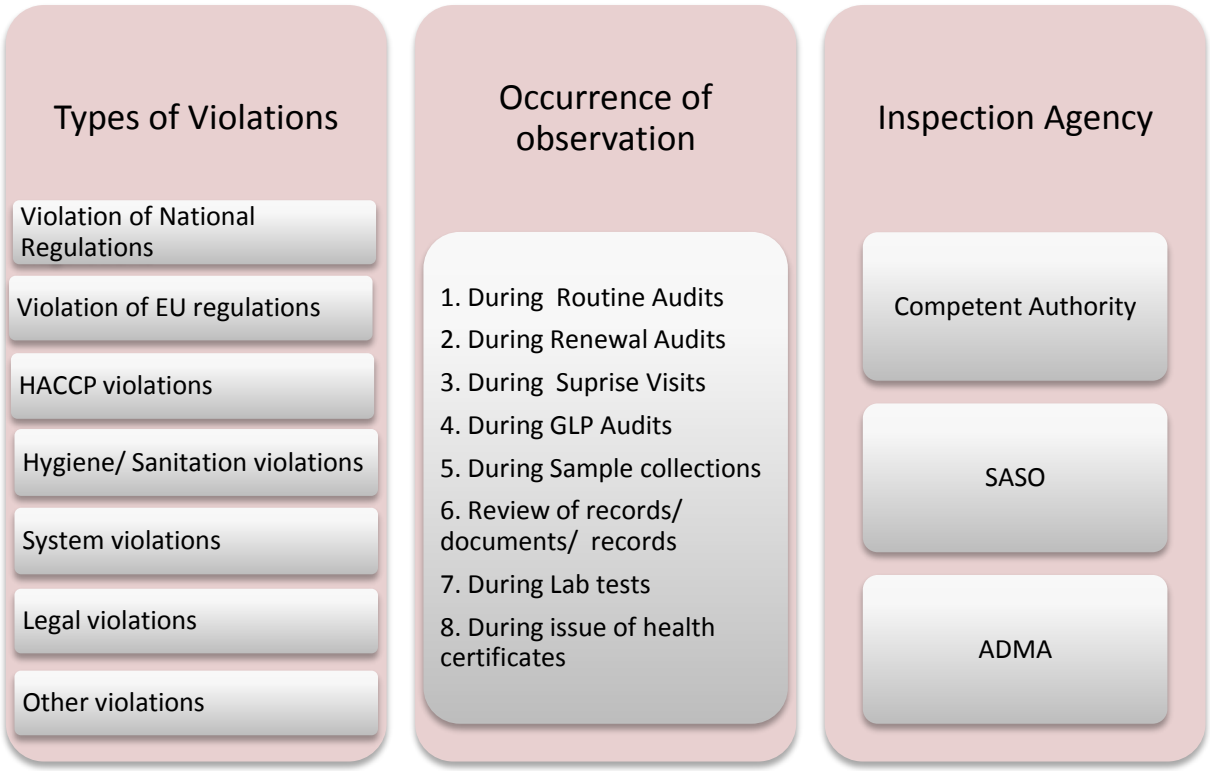
19.2.6. Any dispute on the action taken on violation, product seizure/detention or product disposal shall be handled only by the Head of CA.

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

19.3. Typing (grouping) of various violations

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

CHART - 15



19.4. Measures put in place to ensure that staff is free from any conflict of interest and biased decision

19.4.1. Specific responsibilities allotted to the each inspection agency (CA, AD-MA and SASO) explained in this Manual of Procedures – Export of Cultured Shrimp and Finfish Products to European Union.

19.4.2. Three government agencies such as EDLMC (CA), AD-MA and SASO conduct separate routine audits. CA audit shall be carried out every three months which is a general supervisory audit which cover elements of EU export system and cross verifies other audit details.

19.4.3. As an inter-link between these three audits, the CA shall convene a Technical Committee meeting every three months to discuss all matters concerned with Official Control.

19.4.4. 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 these three executive bodies. The comprehensive network of audit thus designed for monitoring shall ensure avoiding conflict of interest and biased decisions of staff perform Official Controls.

19.5. Provisions to guarantee a harmonized system in the whole country

19.5.1. The CA operates all activities from Head Office in Riyadh, Saudi Arabia and responsibilities as described in Manual of Procedures – Export of Cultured Shrimp and Finfish Products to European Union

19.5.2. The Central CA shall directly monitor and coordinate the EU export system activities. The relevant clauses and stipulations of the 'Manual of Procedures' is communicated to all concerned executive bodies and staffs who carry out Official Control procedures.

19.5.3. Changes, amendments etc. shall be discussed in the technical committee meeting where members from all the three (EDLMC, AD-MA and SASO) executives body members.

19.5.4. The High Level Coordination Committee (HLCC) comprise of Directors / Heads of EDLMC, AD-MA and SASO also shall help the Competent Authority for proper implementation and evaluation of systems and procedures of export of cultured shrimps and finfish products to EU across the country.

19.6. Internal Control provisions in the CA and EU Export Monitoring System

19.6.1. The Central CA shall responsible for ensuring legal compliance and adherence to the written procedures.

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

19.6.3. Representatives of Central CA visit the offices of executive bodies as well as local/ regional offices of the CA for reviews and evaluation as needed to ensure unified practices in audits, system compliance and adherence to specifications and stipulations.

19.6.4. The CA, during its direct audit in establishments shall inspect the records of audits carried out by different inspectors of different executive bodies 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.

19.7. Training program for the EU export system maintenance

19.7.1. CA shall conduct training programs for the EU system Auditors / Inspectors / Technicians and Establishment as required.

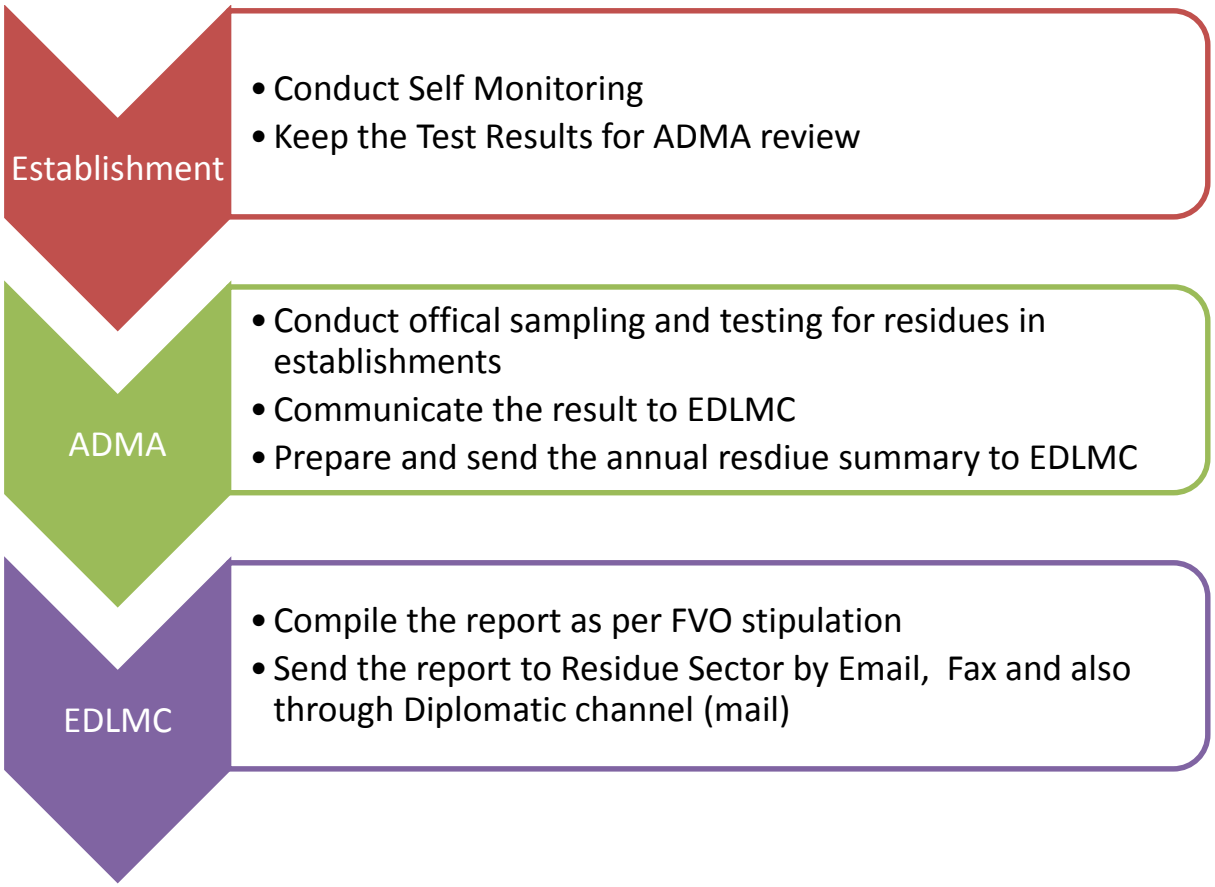
19.7.2. Each government agency who are associated with EU export of fisheries products shall conduct trainings for their inspectors as needed.

19.7.3. The Establishments shall conduct training for their technicians and quality control personnel at a defined frequency.

20. Annual Reporting to EU (FVO)

CA shall communicate the status of residues (aquaculture residues, contaminants, heavy metals, dyes etc.) to DG SANCO (FVO) a given below:

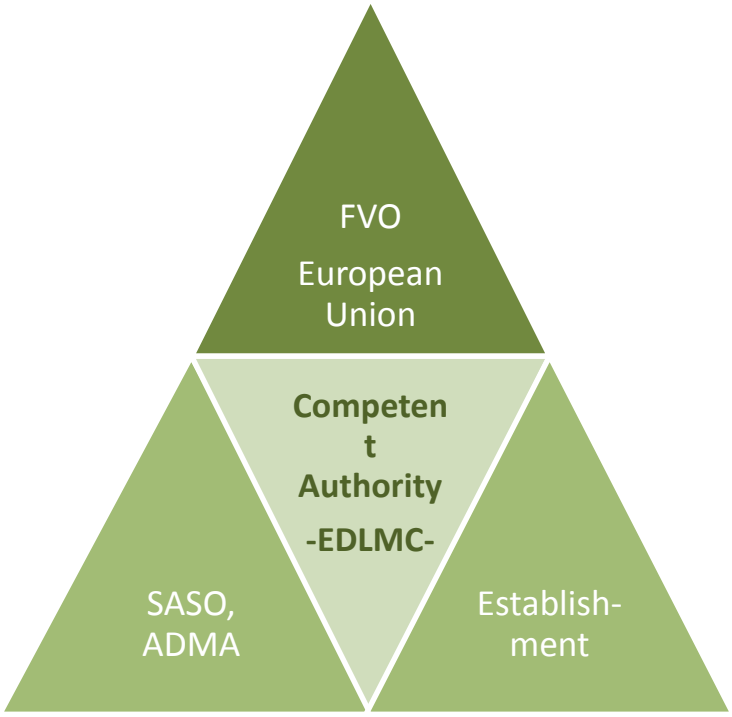
CHART - 16



21. Communication

CA shall be the only contact point to FVO and EU from Saudi Arabia for exports of Shrimp and Finfish products. Other executive bodies are authorized to communicate with the establishments, CA (and vice-versa). The general pattern of communication is given in the figure below:

CHART - 17



22. Record keeping

The Competent Authority, Executive Bodies and Establishments shall keep relevant records concerning with export of cultured shrimp and finfish products to European Union. The records shall be available for inspections and verification by concerned official bodies and European Union representatives.

The checklists for Official Controls are prepared and in use in audits and inspections. The Official Control inspections include Hatchery, Farms, Processing Plant, Cold store etc. of the establishments. The 'own-check system based on the HACCP system is compulsorily approved by CA.

Major Audit Forms used are as follows

22.1. Audit forms of the EDLMC (CA)

- 22.1.1. Approval Audit form
- 22.1.2. Renewal Audit
- 22.1.3. Routine Audit (Surveillance)

22.2. Audit Forms of AD-MA

- 22.2.1. Routine audit (Surveillance)
- 22.2.2. Approval/ Renewal audit -The findings of approval audit and renewal audit are reported in the CA's form

22.3. Audit Forms of SASO

- 22.3.1. Routine audit (Surveillance)
- 22.3.2. GLP audit check list (Laboratory Check)
- 22.3.3. Approval /Renewal audits - The findings of approval audit and renewal audit are reported in the CA's form

22.4. Other Forms

- 22.4.1. Nonconformity Report
- 22.4.2. Establishment Audit register
- 22.4.3. Inspection Summary Report
- 22.4.4. Sample Dispatch Form

Part # 2

Conditions and Procedures for Export

Note: All new amendments notified in the European Union Journal from time to time must be complied by the Establishment.

Chapter - 1

General Conditions for Establishments on Land

Article -1: General conditions relating to premises & equipment's

A. Working areas must 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.

B. The construction of the facility must be a permanent structure

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

D. There must be adequate separation for dirty and clean areas (Raw material handling area, processing area, finished product handling areas) inside the processing plant

E. The floors of the product handling area must be water proof and easy to clean and disinfect. The floor must be kept in good condition and suitable for hygienic production of fisheries products

F. The floors must be without crevices and water stagnation. Proper system must be provided for water drainage.

G. The walls of the product handling area must be smooth, easy to clean, durable and with impermeable surface. The walls must be kept clean and suitable for hygienic production.

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

I. Adequate number of doors must be provided in the Establishment. The doors inside the Establishment must be self-closing type. Doors must be made of durable material, which is easy to clean.

J. There must be adequate natural or artificial lights (with proper protection) provided in the Establishment.

K. There must be adequate ventilation facility with proper air filtration system.

L. There must be proper temperature control system inside the Establishment in order to prevent rise in temperature, which affect the product quality.

M. There must be hand washing and sanitizing facility provided at different product handling sections.

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

O. There must be adequate number of containers and utensils used inside the processing plant.

Article - 2: General conditions of 'Plant Hygiene and Sanitation'

A. There must be provision for washing / sanitizing of plant, equipment's and utensils.

B. There must be a written schedule for the washing of floors, equipment's, machineries, utensils etc.

C. There must be adequate numbers of Rest rooms, change rooms, Hand washing facilities, Foot dips, Hand sanitizing points available in the Establishment in order to ensure food hygiene in the Establishment.

D. The containers and utensils used inside the processing plant must be clean and suitable for hygienic product handling

E. There must be enough number of toilets for the staff facilities.

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

G. Water taps in all wash basins must be no-hand operating type

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

I. All doors inside the processing plant must be self-closing type

J. All entrance to processing hall must have foot dips with sanitizer

K. All hand dip bowls must have required level of sanitizer

L. All waste bins must be non-hand operable

M. All toilets must be flush lavatories

N. Level of chlorine in water for different purpose must follow the stipulations specified in Annexure #1

O. When the sanitizing agent (disinfectant) is added to the water for disinfection, enough contact time need to be given for the disinfectant to act.

P. The Establishment must use only those Sanitizing agents & Detergents (chlorinating agents, soap solutions etc.) approved by the Competent Authority

Q. If any hyper-chlorinated water is used for disinfection of utensils or product contact surfaces, such items/surfaces must be washed with potable water before used for product handling.

R. Swab tests need to be conducted for product contact surfaces as factor of verification to ensure plant sanitation.

Article.3 - General conditions of hygiene applicable to staff.

A. All the employees who work in the product handling area must obtain Health Certificates from a Government agency, as proof of fitness to work in the processing plant.

B. The employees who are working with the product must be provided with adequate uniforms including head cover, mouth mask, hand gloves, Boots etc.

C. Training must be given to employees on Hygiene and Sanitation procedures.

D. Staff assigned to the handling and preparation of fishery products must be required to wash their hand at least each timework is resumed; wounds on the hands must be covered with waterproof dressing.

E. Smoking, spitting, eating and drinking in work and storage premises of fishery products must be prohibited

F. Hand swab tests need to be conducted as factor of verification of staff hygiene.

Chapter – 2

Special conditions for
Water Management and Ice Production System

Article.1 - Water management system

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.

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

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

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

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

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

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

G. If the sanitizing is done with chlorination, the chlorine levels must be followed as per the details given in the Annexure # 1 for different usages.

H. Proper records must be kept for the water sanitizing programs and it's monitoring.

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

J. The 'potability' of the drinking water need to be tested as given in the schedule below

a) Water parameters must be tested as per Annexure # 2, every week by the Establishment and once in three months by EDLMC as a routine practice
b) Parameters to be collected by EDLMC and tested initially and then once in every Year in an official laboratory as per Annexure # 3

K. The water potability certificates needs to be available in the respective departments for verification.

L. 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 must be identified from process water with identification marks.

Article.2 - Ice production & management

A. The ice must be prepared from either from Potable Fresh water or from Clean Sea Water
B. 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 EDLMC and establishment), these tests must 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 must be kept.
C. Block ice, flake ice, cube ice, Ice slurry, Tube or similar forms can be used for processing operation

D. The ice machinery which is used for producing ice must be kept clean and without rust.

E. The ice machines must be kept under good state of repair.

F. There must be proper method adopted for sanitation of water used for ice production.

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

Chapter – 3

Special Conditions for Handling Fishery Products on Shore

Article.1 - Conditions for fresh, chilled products

A. Where chilled, unpackaged products are not dispatched, prepared or processed immediately after reaching the Establishment, they must be stored in ice in the Establishment's cold room. Re-icing must be carried out as often as necessary; the ice used, with or without salt, must be made from drinking water or clean sea water and be stored under hygiene conditions in receptacles provided for the purpose; such receptacles must be kept clean in a good state of repair. Prepared fresh products must be chilled with ice or mechanical refrigeration plant creating similar temperature conditions.

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

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

D. There must be proper control of temperate while the product is handled in the Establishment.

E. The product temperature should not go above 4^0 C for more than 20 minutes.

F. The product temperature during temporary storage must be at the temperature of melting ice.

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

H. Unless special facilities are provided for the continuous disposal of waste, the latter must be placed in leak proof, covered containers which are easy to clean and disinfect. Waste must not be allowed to accumulate in working areas. It must be removed in containers either continuously or as soon as the containers are full and at least at the end of each working day. The containers, receptacles and/or the premises set aside for waste must always be thoroughly cleaned and if appropriate, disinfected after use. Waste stored there must not constitute a source of contamination for the Establishment or of pollution of its surroundings

Article.2 - Conditions for frozen products

A. Freezers equipment's must 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

B. Cold store (Freezer store) refrigeration system must be sufficiently powerful to keep products in storage rooms at a temperature not exceeding -18^0C irrespective of the ambient temperature.

C. Fresh products used as raw material for frozen products must comply with the conditions mentioned in the 'conditions of fresh, chilled products (Article # 1)

Article.3 - Conditions for cooked products

A. 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 must be scientifically recognized.

B. The time and temperature of cooking must be monitored and recorded by the concerned staff.

C. A rapid cooling must follow cooking. Water used for this purpose must 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.

D. Fresh/frozen products to be cooked must comply with the conditions mentioned in the 'conditions of fresh, chilled products (Article # 1) 'conditions of frozen products (Article # 1)

E. Heading, gutting, peeling, deveining, filleting etc. must be carried out under hygienic conditions avoiding the contamination of the product. Where such operations are done by hand, workers must pay particular attention to the washing of their hands and all working surfaces must be cleaned thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected after each working day. If the gutting, heading, peeling, deveining, filleting etc. are carried out after cooking, the product must be immediately frozen or kept chilled at a temperature which will preclude the growth of pathogens and be stored in appropriate premises

F. Every manufacturer must carry out microbiological checks on his production at regular intervals ,complying with the standards to be fixed as per Annexure # 4

Article.4 - Conditions for other type of Prepared/ Processed Products

A. 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.

Chapter – 4
Packaging

Article.1 – General conditions of packaging

A. Packaging must be carried out under satisfactory conditions of hygiene, to preclude contamination of the fishery products.

B. Packaging materials and products liable to enter into contact with fishery products must comply with all the rules of hygiene

C. The packaging material must not be such as to impair the organoleptic characteristics of the fishery products

D. The packaging material must not cause transmission of such substances to the fishery products which are harmful to human health.

E. They must be strong enough to protect the fishery products adequately

F. Packaging materials may not be re used.

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

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

Chapter – 5
Labeling

Article.1 – General conditions of labeling

A. The product label must include Product name, Product Type, List of ingredients (if applicable), Net weight, Date of production/production code, Date of Expiry (period of expiry), Special storage conditions, Name and address of the processor, Special declaration or buyers specifications (if any). Gross weight need to be mentioned in the glazed products as required

B. If the product is packed in consumer pack, each individual pack must have the above said labeling details.

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

D. The Labeling details must be printed clearly so that information is legible.

Chapter – 6

Storage & Transport

Article.1 - General conditions for product storage & transport

A. Products must be kept at optimum temperature during storage and transport

B. The fresh or thawed fishery products and cooked and chilled cultured shrimp / finfish products must be kept at the temperature of melting ice.

C. Frozen fishery products, must be kept at a temperature of -18^0C or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than 3 ^{0}C, during transport

D. Other type of processed products must be kept at the specific temperatures required for that specific condition of storage.

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

F. The products from the store must be handled in the FIFO manner

G. The product store must be provided with adequate lights

H. The store must 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.

I. The sensor of the temperature monitoring devise must be located at the furthest point from the blower

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

K. Vehicles used for the transport of fishery products must be suitable for maintenance of temperature maintenance throughout the transport period.

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

M. 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.

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

Article.2 - Conditions for storage & transport of items other than cultured shrimp/finfish products

A. Chemical Storage and Transport

a) The Chemicals & Food Additives must be kept in separate rooms
b) The chemical storage rooms must be under lock and key system
c) Food additives must not be kept along with sanitizing agents
d) There must be identification labels for different chemicals
e) The chemicals must be transported in such a way that they cross contaminate the product or other ingredients

B. Packaging material storage and transport:

a) Packaging materials must be protected from dust and contaminants
b) They must be properly arranged in the store with walking space around the bundles
c) The packaging materials are handled in the FIFO manner
d) The transportation of packaging material must be so programmed to preclude possibility of contamination.

Chapter 7

Conditions for General Matters

Article.1 – Conditions on general matters concerning to processing

A. Calibration of equipment's/instruments – Calibration must be carried out for essential equipment's at regular intervals and necessary documents kept.

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

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

D. 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

1. Sodium Metabisulfite (E 223) - Max. limit 150mg/kg –SO_2 in edible portion of raw product, 50mg/kg for cooked crustaceans
2. Sodium Polyphosphates (E452) - Application level 5g/kg
3. Boric Acid E 284 / Sodium tetrabotare (Borax) (E 285) – Max Limit 4g / kg, in edible portion (expressed as boric acid)
4. Sorbic acid (E 200)
5. Potassium sorbate (E 202)
6. Iso ascorbic acid (Erythorobic acid) (E 315)
7. Sodium Chloride

E. Solid waste management - There must be proper procedures for solid waste disposal.

F. Wastewater management - There must be proper system to ensure that the wastewater going out from the processing plant is properly disposed to avoid environmental degradation.

G. 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. must be in place. There must be regular monitoring and record keeping for the pest control program including bait maps and pest control stations.

Chapter -8

Quality Control System of the Establishment

Article.1 - Responsibilities of Quality Control department

A. The Establishment must have an own quality control system to ensure safety and quality of the product. The Quality Control Department shall be responsible for the self-monitoring/inspection and audits of the Establishment

B. The Quality Control department must 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.

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

Article 2 - Own check system (HACCP)

A. There must be a well-documented 'Own Check System (Hazard Analysis and Critical Control Point) implemented in the Establishment.

B. The printed, updated and authorized manual must be available at the Establishment

C. The HACCP manual must be approved by the Competent Authority.

D. It shall be desirable to have an HACCP system audited and certified by a reputed third party (external certifying agency)

E. There must be documented pre-requisite programs (SSOP and GMP) in place with necessary documents and records.

F. The 7 principles of HACCP must be applied for the system implementation.

G. There must be adequate documents and records available to support the effective existence of the system.

H. There must be adequate number of HACCP trained persons in the Establishment to maintain the system.

Article.3 – Internal inspection and audit

A. There must be a systematic and regular inspection program for the raw material. Routine sample must be collected and inspected for organoleptic, microbiological, parasitical and chemical parameters and necessary documents are to be maintained. The Raw material must meet the microbiological specification given in Annexure # 4 and 5

B. Water and ice must be tested for all applicable parameters as stipulated in this manual at the defined frequencies

C. There must be a scheduled on line product inspection in order to ensure the product quality. Necessary online inspection records must be maintained.

D. There must be systematic, regular inspection program for the final product. Random samples must be collected from the final packages from cold store (Frozen store) and inspected for organoleptic, microbiology and chemical parameters and necessary documents are to be maintained. The final product bacteriological specification are given in Annexure # 4

E. There must be systematic regular program for swab test for staff and product contact surfaces to cross verify the level of cleanliness and hygiene.

F. There shall be a National Residue Monitoring Program conducted for Natural Waters, Farms, Raw material and Final Product by AD-MA as well as by the Establishment as per Chapter-9 and necessary records shall be kept.

C. The mercury, lead and cadmium level in the final product must be checked at least once in six months to ensure that the readings are within the limits as per the Annexure # 5 and relevant records must be kept

Article.4 –'Product Recall' and 'Traceability'

A. There must be a proper system for product identification and traceability.

B. There must be a documented recall procedure for products, to facilitate emergency withdrawal of distributed products

C. In case of a product is identified with non-conformity, the Establishment must take a decision on the disposal of the product for Rework/Down Grade/Divert/Discard, based on the type of non-conformity

D. The Establishment shall guarantee that there shall be no possibility of contamination to food being processed in the facility and a documented Traceability system is in place in the Establishment.

Article.5 - Own Laboratory of the Establishment

A. The Establishment must have an own laboratory for routine tests and analysis.

B. There must be adequate equipment's and instruments to conduct routine tests and analysis.

C. The laboratory in the Establishment must be approved by the Competent Authority.

D. The Competent Authority shall approve the technicians who can carry out the routine tests and analysis.

Article. 6 - Inspection/audit reports

A. The Inspection/analysis reports must be stored in hard copies.

B. All test reports must be verified by a senior lab officer and reports must have Name and Signature of concerned staff.

C. If the record and reports are stored in the forms of soft copy, there must be proper backup system to ensure the safety of the stored data. There must be provision in the computer program for approval of the test report by the concerned Lab officer.

D. The Records and Reports must be used as a tool for regular perusal as part of Verification, whenever a problem arises and for management review for different purposes.

E. All records and reports must be kept for a minimum period of 2 years or up to the shelf life of the product whichever is higher

Chapter – 9

National Residue Monitoring Program

The National Residue Monitoring Program shall be controlled by the Aquaculture Department – Ministry of Agriculture. Every year the annual report shall be prepared by AD-MA and the same shall be sent to the CA. The CA shall send the consolidated annual report to the European Union before 31 March of every year.

The annual report shall contain the following elements: (*Based on the direction from concerned office of European Council the elements shall be amended in prescribed Formats/Table and the annual report shall be submitted to DG-SANCO)*

1. General information

1.1. Introduction

1.2. Regulation on shrimp / finfish culture and residue program
1.2.1. Regulation on general aquaculture operation
1.2.3. Regulation on usage of aquaculture drugs/chemicals
1.2.3. Regulation on aquaculture drug/chemical supply

1.3. National residue tolerance limit
1.3.1Prohibited aquaculture drugs/chemicals/pharmacologically active substances
1.3.2. National tolerance limit for aquaculture drugs
1.3.3. National tolerance limits for other substances

1.4. Sampling for “National Residue Monitoring”
1.4.1. Agencies responsible for sample collection

1.4.2. Frequency of sample collection

1.4.3. Types of samples, sampling methods and securing procedures

.5. Laboratories for conducting analysis for “National Residue Monitoring”

1.6. Measures taken when residues are detected above EU admissible limits..

2. Background information on production

2.1. Details of production and products exported to Europe

2.1.1. Species

2.1.2. Products

2.1.3. Process type

2.1.4. Total figures of production

2.1.5. Names of Establishments

2.2 Type of production

2.3 Product proposed to export to Europe in the subsequent year

2.3.1. Species

2.3.2. Products

2.3.3. Process type

2.3.4. Expected quantity for exports

3. Scope of “National Residue Monitoring” plan.

4. Frequencies and levels of controls

5. Targeting criteria (if any)

Part # 3

Annexures

Annexure # 1

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

Annexure # 2

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 μS 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 22^{0}C)	100 cfu/ml
9	Total Plate Count-Colonies (at 37^{0}C)	20 cfu/ml
10	*Escherichia coli (E. coli)*	0 cfu/ml
11	Total Coliform Bacteria	0 cfu/ml

Annexure # 3 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 perfringens* (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

Annexure # 4

Microbiological and Parasitical Standards of shrimp and finfish

(Frequency CA – Every visit, Establishment - Every Day code batch)

A. Microbiological Standards

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 Standards

Parasites - The visual inspection for parasites must be conducted for raw material

(Admissible limit – 0)

Annexure # 5

Chemical Standards of shrimp and finfish

(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), 1.0 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	5.0 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 Annexure # 1, EEC/466/2001 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 annexure EC No. 1881/2006