وزارة البيئة والمياه والزراعة
Ministry of Environment Water & Agriculture
المملكة العربية السعودية Kingdom of Saudi Arabia

الدليل الوطني لتصدير منتجات الأحياء المائية

National Aquaculture Products Export Manual

Revision 3

May 2018

The General Directorate of Fisheries
Ministry of Environment, Water and Agriculture
Kingdom of Saudi Arabia

The General Directorate of Fisheries hereby declares that:

- This manual stipulates the official regulation and procedures concerned with aquaculture product export from Kingdom of Saudi Arabia[1].
- The General Directorate of Fisheries of Ministry of Environment, Water and Agriculture (GDF-MEWA) shall be the Competent Authority in Kingdom of Saudi Arabia in dealing with all matters related to Aquaculture Licensing, Production and Export.
- The agencies involved in the export of Aquaculture products shall be the Fisheries Resource Affairs Division, Saudi Aquaculture Society (SAS) and the exporting units (Establishments).

The General Directorate of Fisheries hereby approves the stated contents of 'National Aquaculture Products Export System Manual' to be followed in all matters related to the export of aquaculture products.

Any interim decision(s) taken by concerned government agencies shall be incorporated in the manual during subsequent revisions.

Director General – General Directorate of Fisheries
Ministry of Environment, Water and Agriculture

[1] Except to EU countries

Foreword

Fish and fishery products have a big share in the modern food industry and the demand for seafood verities for human consumption has grown remarkably in the past few decades across the globe. Apart from that several fisheries product also has other applications in the cosmetic pharmaceutical, industrial and other similar usages. Aquatic organism holds significant share in the total fish and fisheries product large percentage significant share forms culture products forma a major part of comprise

Due to various reasons, there are declines reported in the 'Capture Fishery Sector" and hence aquaculture has emerged out as a potential alternative industry with its evident benefits to consumers, entrepreneurs and society.

The history of aquaculture operation the Kingdom of Saudi Arabia can be traced back from the later years of 1970 and it has proved to be one of the successful industries in the Kingdom.

As in the case of all aquaculture countries, maintaining standards of responsible and sustainable culture practice has become a matter of priority for the Kingdom. The ultimate purpose of the Kingdom in supporting this industry is to supply quality aquaculture products in the domestic as well as international markets.

Aquaculture products have good market potential in international markets. Factors such as proximity to European international markets, passage to the Atlantic Ocean through the Suez Canal etc., provides the industry a sharp edge over other aquaculture countries.

The Kingdom has taken all measures for the sustainable production of aquaculture species in line with the international norms and stipulations under the responsibility of General Directorate of Fisheries of Ministry of Environment, Water and Agriculture (GDF-MEWA).

Responsible production of aquaculture products will enable the Kingdom to rise up to as a major aquaculture product exporting country in the international markets. There is a promising future for the aquaculture product export for the kingdom of Saudi Arabia, in the context of the vast coastal line that promotes aquaculture operation, low cost of energy resources and the capacity to source needed technical man power.

The 'National Aquaculture Products Export System Manual' is prepared with the specific aim to provide a documental basis of national regulation for the export of aquaculture products by defining regulations and stipulations to be followed in the different areas such as production, processing, storage and distribution of aquaculture products from the kingdom of export of aquaculture products

Director General – General Directorate of Fisheries
Ministry of Environment, Water and Agriculture

Section I:Competent Authority Structure and Working Procedures

1. Introduction

Aquaculture in the Kingdom of Saudi Arabia is regulated at the National and regional levels by General Directorate of Fisheries of Ministry of Environment, Water and Agriculture (GDF-MEWA).

1.1 Legal Definition of Aquaculture

Aquaculture is the farming of aquatic organisms, including fish, mollusks, crustaceans and aquatic plants. Farming implies some form of intervention in the rearing process to enhance production, such as regular stocking, feeding, protection from predators including on land and off shore activities. Farming also implies individual or corporate ownership of the stock being cultivated. For statistical purposes, aquatic organisms which are harvested by an individual or corporate body which has owned them throughout their rearing period contribute to aquaculture.

1.2 Competent Authority

General Directorate of Fisheries of Ministry of Environment, Water & Agriculture (AD - MEWA) shall be the competent authority (CA) in all matters of production and export of aquaculture products from Kingdom of Saudi Arabia

1.3 Authorization System – Aquaculture

1.3.1 The GDF-MEWA regulates and licenses aquaculture activities within the Kingdom of Saudi Arabia. All Aquaculture activities including brood stock rearing, hatcheries, farming, harvesting and processing of aquaculture products are subject to the GDF-MEWA regulations. It is unlawful to conduct aquaculture operations or to culture approved species of aquatic plants and animals unless registered with GDF-MEWA. Furthermore, it is unlawful to spawn, incubate, or cultivate, transgenic fish species, or any exotic species of finfish, managed by the GDF-MEWA.

1.3.2 Aquatic plants and animals, including fish, may only be collected by a registered aquaculture specialist, with written approval of GDF-MEWA.

1.3.3 The owner of each aquaculture facility must register with the GDF-MEWA, specifying the identity of the owner, the species grown, and the location of each aquaculture operation.

1.3.4 The broodstock or larvae or fingerlings can only be received from an approved establishment, with the prior approval of the GDF-MEWA.

1.3.5 Applications must include *inter alia*, a legal property description, an actual physical street address, and description of production facilities at each aquaculture facility.

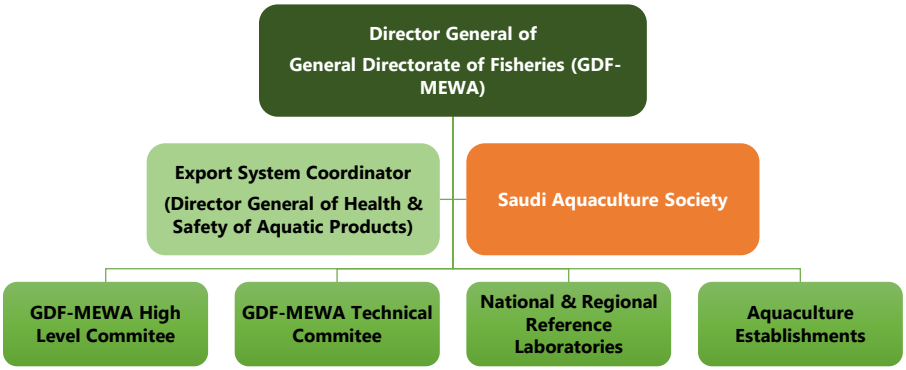
1.3.6 It is unlawful for an aquaculture establishment to commingle any shellfish / finfish aquaculture product with a wild product in the same container. It is also unlawful to transport by vessel over water, wild and aquaculture products of the same species at the same time.

1.3.7 Special regulations apply to the cultivation and processing of shellfish / finfish products as deeded necessary by GDF-MEWA

2. Structure of Aquaculture Export System

2.1 The General Structure

2.1.1 Structure of GDF-MEWA, Export System Coordinator & Saudi Aquaculture Society



2.2 The Functions of the GDF-MEWA – The Competent Authority

The CA shall be responsible for the following:

2.2.1 Over all supervision of all matters related to export of aquaculture products to different countries except to the European Union.
2.2.2 Perform as the communication link between the Kingdom of Saudi Arabia and aquaculture products importing countries.
2.2.3 Coordination between different committees and agencies involved in the export of aquaculture products.
2.2.4 Proper distribution of documents, directives, communications and other relevant information among the committees, agencies and establishments.
2.2.5 Approve all aquaculture establishments and issue licenses for activities of Broodstock Centers, Hatcheries, Farms[2], Processing and storage of aquaculture products.
2.2.6 Final approval of all matters related to export of aquaculture products.
2.2.7 Issue list of tests/analysis to be conducted by Reference Laboratory and Establishment laboratory.
2.2.8 Issuing formats and checklists to be used during establishment inspections and approvals.
2.2.9 Approval of Government Auditors for Establishment audits.
2.2.10 Regular monitoring of overall activities of the Establishments to ensure that the Establishments meet the stipulations of "National Aquaculture Product Export System Manual" of Saudi Arabia.
2.2.11 Ensure that GDF-MEWA and Saudi Aquaculture Biosecurity Technical Group (SABTG) meets annually or as needed.
2.2.12 Allocation of Approval Number to approved Establishments.
2.2.13 Identifying 3rd party laboratories to conduct tests if needed.

2.3 Functions of Saudi Aquaculture Society (SAS)

2.3.1 Represent the Aquaculture Product exporting establishments (who are members of SAS) in Ministry of Environment, Water & Agriculture (MEWA).
2.3.2 Coordinate and communicate on all aquaculture export related matters with the Establishments and GDF-MEWA.

[2] Farming includes on land and offshore operations of Grow out and Harvest

2.3.3 Communicate with institutions, agencies, societies and organizations in matters related to aquaculture products export on behalf of establishments as needed.
2.3.4 Coordinate and facilitate aquaculture establishments for implementation of aquaculture best practices, 3rd party Certifications and any specific exporting country requirements.
2.3.5 Make necessary follow-up with member establishments to meet the GDF-MEWA requirements.
2.3.6 Provide assistance to member establishments for specific needs in export related matters.
2.3.7 Participate in GDF-MEWA's Management committee meetings (AMC).

2.4 Functions and Responsibilities of the Aquaculture Establishments

2.4.1 Initiate the request for export approval as stipulated in this Manual
2.4.2 Abide by all national and international rules and regulations as applicable.
2.4.3 Adopt and practice the stipulations, directives and specific advices officially communicated by the Competent Authority.
2.4.4 Develop and maintain required infrastructure facilities for export of fishery products as stipulated or directed by the Competent Authority.
2.4.5 Bear the cost of tests, analysis, inspection, audits and expenses of certification of the Export procedures as applicable.
2.4.6 Keep all necessary documents and records to a required period of time as stipulated by the CA.
2.4.7 Coordinate and facilitate GDF-MEWA officials to conduct audits and inspections.
2.4.8 Participate in GDF-MEWA's High Level Committee (HLC)

2.5 Structure of GDF-MEWA High Level Committee (HLC)

2.5.1 The following members shall constitute the GDF-MEWA High Level Committee
2.5.1.1 General Directorate of Fisheries (Competent Authority)

- Director General of GDF-MEWA
- Director of production Follow- up Division GDF-MEWA [National Manager of Export Program]
- Representative of Biosecurity Division
- Representative of GDF-MEWA Labs

2.5.1.2 Fisheries Department

- Head of Fisheries and representative(s) of Fisheries Department

2.5.1.3 Saudi Aquaculture Society (SAS)

- Chairman of SAS and SAS General Secretary or his designate
- Representatives of the Establishments as necessary

The above members shall meet once a year for the AMC meeting or as any need arises.
The Director General of GDF-MEWA can invite other agencies, establishment representatives and persons to HLC as needed.

2.6 Functions of the GDF-MEWA High Level Committee (HLC)

The GDF-MEWA High Level Committee Responsible for:
2.6.1 Evaluate the inspection / audit and samples analysis results of establishments.
2.6.2 Evaluate any amendments required in the National Aquaculture Products Export System Manual.
2.6.3 Evaluate the recommendation of Technical Committee and take decision for further plan of action.

2.7 Structure & Functions of the Technical Committee (TC)

The GDF-MEWA Technical Committee Responsible for:

The Technical Committee (TC) shall be comprised of Technical Representatives from GDF-MEWA, Saudi Aquaculture Society and representatives of the Approved Establishment(s).

This technical committee, which supervises the Exports qualification related issues (with almost similar functions) shall supervise exports qualification and hence a better coordination with respect to the compliance of the establishments to the regulations.

Functions of the Technical Committee (TC):

2.7.1 Review & discuss on procedural, scientific updates and Technical matters connected with exports.

2.7.2 Technical committee members of the establishment shall be responsible for closure of inspection / audit comments / observations & submission of reports to GDF-MEWA / during Technical Committee Meetings.

2.7.3 At least a member of Technical Committee of GDF-MEWA shall represent Inspections of the establishments for exports.

2.7.4 This committee also shall be responsible for suggesting amendments in the National Aquaculture Export System Manual and other related matters.

2.8 Functions of GDF-MEWA Audit Team

2.8.1 The specific members of the EFAA Team will be decided by the Director of the Follow-up Production Division

2.8.2 As needed GDF-MEWA may invite competent personnel to be part of Audit team as required to meet specific requirements of the audit.

2.8.3 The Leader of the Audit Team shall be a GDF-MEWA representative.

2.8.4 Members of the Audit Team (including the Team Leader) shall have a bachelor's degree (in Veterinary sciences, Marine sciences or other biological Sciences) as the minimum educational qualification. One of the Audit Team member shall have a minimum experience of 3 years in the field of Aquaculture.

2.8.5 The audit team shall conduct audit as per the Establishment Audit Check List including but not limited to exporting country requirements (as applicable).

2.8.6 Audit team shall collect samples and send to JFRC labs or any 3rd party approved lab for analysis.

2.8.7 GDF-MEWA audit team shall conduct announced / unannounced routine audits / renewal audit of the establishment as per the annual audit calendar.

3. Procedure for Approval of Aquaculture Establishments

3.1 Procedure to add a new country in the list of Exporting Countries

The inclusion of a new country in the list shall be based on the need from the industry.

3.1.1 If an establishment proposes to export its aquaculture products to a new country which is not listed, the establishment shall submit its request to GDF-MEWA through the Saudi Aquaculture Society (SAS).

3.1.2 GDF-MEWA shall;

- 3.1.2.1 Contact the official agency of the importing country directly or through diplomatic channel.
- 3.1.2.2 Provide new country export requirements to SAS.
- 3.1.2.3 Include necessary official monitoring requirements and documentation procedures in to National Aquaculture Export System Manual to cater the requirements of the new country.
- 3.1.2.4 Conduct audit in the establishment to check compliance, if any specific conditions of the new country is to be met by the establishment in addition to the existing requirements.
- 3.1.2.5 Include the new country in the list of importing countries.

3.1.3 SAS shall;

- 3.1.3.1 compile exporting country requirements,
- 3.1.3.2 communicate requirements with requesting establishment
- 3.1.3.3 Draft Export Health Certificate and submit to GDF-MEWA for review and approval

3.1.4 Establishment(s) shall comply with new exporting country requirements

Establishments intending to export aquaculture product from Saudi Arabia must be approved by GDF-MEWA based on their adherence and compliance to the requirements of this manual.

3.2 Application Process

3.2.1 The applicant shall complete Form-01 "Application for the Registration of Aquaculture Establishments for Export" and submit to SAS, with details of the documents as per the application requirement.

3.2.2 The fee for application form and Assessment/ Inspection will be as decided by GDF-MEWA, shall be paid through SADAD system (as applicable).

3.3 Processing applications for approval

3.3.1 The received applications shall be reviewed within 15 working days by GDF-MEWA

3.4 Assessment of the facility

3.4.1 GDF-MEWA shall conduct the inspection of the establishment to verify the compliance against the National Aquaculture Export System manual.

3.4.2 Audit findings (if any) shall be reported to establishment for its closure.

3.4.3 SAS will also get a copy in case of a major non-conformity for necessary follow-up.

3.4.4 GDF-MEWA Audit team shall review closure of audit findings by establishment and submit its recommendations to GDF-MEWA

3.5 The steps of Establishment / Facility Approval process

- Step1. Submission of application along with relevant documents to SAS
- Step2. Scrutiny of the submitted application and documentation by SAS
- Step3. SAS to submit the reviewed application to GDF-MEWA
- Step4. GDF-MEWA to communication audit dates to Establishment and SAS
- Step5. GDF-MEWA to conduct Establishment audit
- Step6. GDF-MEWA to submit audit findings (if any) to Establishment and SAS
- Step7.Closure of audit findings (if any) by the establishment and submit audit finding closure with evidences to SAS for review and submit to GDF-MEWA
- Step8.Granting/denying Approval to the Establishment are subject to the closure of audit findings.
- Step9. GDF-MEWA to allocate of Approval Number.
- Step10. GDF-MEWA issue Approval Certificate of Establishment (including approval of in-house lab and technicians, approval the Food grade chemicals used in the Establishment)

3.5.1 If an Establishment is not granted with an approval to export, it can re-apply again for approval only after three months. Such establishments/ facilities must follow all steps once again while applying for next time and a freshly filled Application Form specifying corrective actions taken (if any) on the audit findings.

3.6 Validity of Approval Certificate

3.6.1 The Approval Certificate is valid for 2 years subject to no critical / major non-conformities during the routine audits.

3.6.2 The Competent Authority has full right to invoke / hold export certification status of any establishment subject to non-closure of critical / major non-conformities or the aquaculture zone / Aquaculture Establishment has effected with shrimp / fish diseases.

3.7 Approval of additional facilities / activities /changes of approved units

3.7.1 The approved Establishments seeking approval of additional facilities / activities such as additional Hatcheries, farms, cages, cold storage, ice plant, freezer, new process activities and or new product lines etc. shall submit request letter to SAS with all details of changes / improvements took place in the Establishment.

3.7.2 The assessment and approval process followed as per the section 5.3 and 5.4 of this manual.

3.7.3 Change in the Name of Establishment:

3.7.3.1 The establishment shall submit official letter with all supporting documents requesting for change of name of the establishment

3.8 Approval of Technicians, Technologists and HACCP team members

3.8.1 The number of technologists required in an approved Establishment / Facility shall be fixed based on the recommendation of Audit Team while assessing the facility, which shall take into consideration the volume of work, number of work shifts, laboratory testing work, the products handled by the facility and the automation in the Establishment.

3.8.2 The minimum number of approved technician (s) in any Establishment shall be one.

3.8.3 The minimum number of approved technologist(s) in any Establishment shall be one.

3.8.4 Qualification Requirement- Technicians, Technologists and HACCP team members

a. Process Technician (for Fish Processing, Farm Operation, Hatchery Operation etc.) b. Quality/ Process Control Technician (on line Quality Control)	Higher Secondary School certificate with 3 years on-floor experience, Or Bachelor's Degree in with one year production Experience
Lab. Technician	Diploma in Lab technology / Bachelor's Degree in biological science / Lab science / chemistry with one year analytical Experience
HACCP Team member	Bachelor's degree in respective area / minimum 3 day HACCP / ISO 22000 training from a reputed training agency

3.9 The Approved Establishment shall be given an Approval Number

3.9.1 The Approval number to be allotted for the Establishment shall be 'Alphanumerical' for example "SA-001E". SA stands for Saudi Arabia and 001 will stand for the serial number of the approved establishment.

- E – Stands for Establishment where major raw materials processed from own farms / cages
- P– Stands for the processing facility (does not have, where raw materials are sourced from approve establishments in KSA.

3.9.2 The approval numbers shall be allotted to units in chronological order and it should be used only once for a particular facility, except In case of change of name where same number is requested by the facility. In case the approval is withdrawn, the approval number of the facility shall not be allotted to a new facility. GDF-MEWA shall maintain proper records for allotment of approval numbers.

3.10 Renewal of approval of the facility

3.10.1 Renewal audit is planned by GDF-MEWA as per the audit calendar, unless Establishment submit official letter through SAS to GDF-MEWA to stop / hold the export license.

3.10.2 Renewal audit, assessment and approval process followed as per the section 5.3 and 5.4 of this manual.

3.10.3 Certificate of renewal of approval shall be issued by GDF-MEWA as per the prescribed format and it shall be sent to the Establishment/ Facility and certificate shall be valid for a period of 2 years from date of expiry of the previous Approval

3.11 Procedure to be followed when an approved facility suspends its production / activities.

3.11.1 When an approved facility decides to suspend its production / processing activities temporarily for more than 3 months for general repairs/ major maintenance / Non-availability of raw materials **OR** improving their hygienic and sanitary conditions **OR** Identifying the cause of contamination and taking corrective action to prevent recurrence. **OR** Major alteration/construction work etc. **OR** Any other activity which may result in change in production flow or give scope for the contamination of fishery products / ice / water / food contact surface, the Establishment shall

intimate GDF-MEWA the date from which it intends to suspend its operation, the purpose and the probable date by which it intends to resume production.

3.11.2 Upon receipt of intimation, GDF-MEWA may discontinue monitoring visit / supervisory visit to the facility.

3.11.3 When an establishment intends to suspend the export totally, this matter shall be specifically informed to GDF-MEWA and the establishment can apply for re-start of export only after one year.

When the unit is ready to restart export activity after 1 year or more, the Establishment shall request GDF-MEWA for permission to commence production. Before granting permission to start export activity, the establishment shall meet all the requirement of a fresh approval from GDF-MEWA.

4. Rapid Alert System

This procedure covers the transmission of information by means of a rapid alert between the Competent Authority of KSA (GDF-MEWA) and Competent Authorities / Government agencies of Exporting countries with regard to Aquaculture Products Exported from Kingdom of Saudi Arabia.

When urgent action is required to protect public health or aquatic animal health / stop spreading of infected aquatic products from sale or to be used in aquaculture. This procedure may also be used product-withdrawals for safety reasons.

GDF-MEWA may form committees with relevant Government Agencies of Saudi Arabia and Aquaculture Associations/ Societies, in order to effectively handle a recall situation post rapid alert.

Product quality related issues do not cover in this Export Manual.

4.1 General

In order to protect public health and aquatic animal health, it may become necessary to implement urgent measures such as the recall of one or more defective batch(es) of an Aquaculture product during its marketing or retail sale or to be used in Aquaculture operations.

This procedure covers the receipt and handling of notifications of suspected defective product(s) and batch recalls from companies or health professionals both during and outside normal working hours.

4.2 Responsibility / Emergency Contact Details

4.2.1 The regional offices GDF-MEWA or Competent Authority where the defect was first identified, GDF-MEWA may review the identified defect / hazard and should issue the rapid alert.

4.2.2 Saudi Aquaculture Society in coordination with Regional GDF-MEWA branches coordinate with Aquaculture Establishments for investigation, testing the products and steps needed to assess an alert situation.

4.2.3 Rapid Alert Contact points:

Dr. Ali AlShaikhi General Director – General Directorate of Fisheries (Fisheries Department) Ministry of Environment, Water and Agriculture Mobile: +966 566886616 Email: ali.alshaikhi@mewa.gov.sa	Mr. Faris Al Ghamdi D.G. Health & Safety of Aquatic Products Ministry of Environment Water and Agriculture Office +966 11 4172000 Ext. 2855; Mobile: +966 509336602 Email: f.alghamdi@mewa.gov.sa

4.3 Cases where notification required

As to the source of the information about the serious risk, although most notifications result from official controls performed by the competent authorities, a notification reporting on a serious risk can also be based on company own-checks. In the latter case, it is for the competent authorities to assess as much as possible the reliability of the information on which the notification is based (e.g special care should be used with analytical results obtained through non-accredited laboratories or methods, and the use of a non-accredited laboratories or methods should be clearly indicated in the notification).

Listed below are cases where Competent Authority have considered that the risk was such as to require rapid action:

4.3.1 An aquaculture product containing substances prohibited or unauthorized substances according to KSA's National Aquaculture Policies and Practices.

4.3.2 An aquaculture product in a contaminated with fungi, bacteria or their toxin, algal toxins; the risk assessment shows an aquaculture product might pose risk to public health.

4.3.3 An aquaculture product contaminated with OIE listed crustacean / fin fish diseases specific to the products exported. A risk assessment shows that, the aquaculture product may act as a medium if used may spread the specific OIE listed diseases.

Section II: Conditions and Procedures for Export

5. Responsibilities of the Approved Establishments

5.1 General

5.1.1 All approved establishments shall also follow requirements as stated in the *National Aquaculture Policies and Practices*.

5.2 Requirements for Processing Plants

5.2.1 As the sole responsibility in maintaining the quality and safety of the products processed / handled in the units, lies with the approved Establishments / facilities, they shall develop and implement HACCP based own food safety check system. The facility shall exercise proper controls at all stages of production / handling starting from raw material procurement to the final dispatch of the cargo and maintain records thereof. The facility shall comply with all the regulatory requirements of the GDF-MEWA Notifications as well as those specified by the importing country.

5.3 HACCP System

5.3.1 The HACCP System shall be developed and managed by Establishment's multi-disciplinary food safety team that includes those responsible for quality, production operations, maintenance, hygiene & sanitation, stores & purchasing, in-house laboratories, Establishment's Management Representative and other relevant functions.

5.3.2 HACCP system shall be developed based on Code of Practice - General Principles of Food Hygiene[3] [CAC/RCP 1-1969, Adopted 1969. Amendment 1999. Revisions 1997 and 2003], using 12 Steps and 7 Principals of Hazard Analysis and Critical Control Point (HACCP) System and guidelines for its application.

5.3.3 Proper identification and monitoring of Pre Requisite Programs (PRPs) and Critical Control Points (CCPs) shall be addressed in the HACCP System Manual.

[3] www.fao.org/input/download/standards/23/CXP_001e.pdf

5.3.4 HACCP system has to be reviewed by the Establishment's HACCP team at least once in a year or in case of any change in the product(s) / process flow / intended use / source of raw material(s)/ change of HACCP team member(s) / in case of customer complaint. The review records shall be maintained for verification.

5.3.5 A copy of signed HACCP Manual shall be submitted to GDF-MEWA audit team during the renewal audit.

5.3.6 All HACCP records shall be reviewed and shall be readily available.

5.4 Product Traceability and Recall

5.4.1 Establishment shall document and implement traceability system for all products including raw material, ingredients, permitted chemicals / additives and traceable back to the source of production.

5.4.2 Establishment shall document recall procedure.

5.5 Plant Hygiene & Sanitation

5.5.1 There must be a scheduled program for cleaning and disinfection, which shall be documented and implemented to ensure that all areas of processing plant are appropriately cleaned and sanitized, including floors, tables, utensils, equipment etc.

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

5.5.3 There must be adequate number of Rest rooms (toilets), Change rooms, Hand washing facilities, Foot dips, Hand sanitizing points available in order to ensure food hygiene in the Establishment.

5.5.4 The toilets/lavatories should not open directly to the processing area. All toilets must be flush lavatories.

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

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

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

5.5.8 All entrance to processing hall must have foot dips with sanitizer

5.5.9 All hand dip bowls must have required level of sanitizer

5.5.10 All waste bins must be non-hand operable

5.5.11 Level of chlorine in water for different purpose must follow as per below table[4]:

#	Location / Type	Chlorine Level
1	Processing	2 ppm or below
2	Glazing	2 ppm or below
3	Ice manufacture	2 ppm or below
4	Hand sanitization dip	20 – 25 ppm.
5	Foot sanitization dip	50 – 100 ppm
6	Washing of tables, equipment and utensils	50 – 100 ppm
7	Washing of floor	100 – 200 ppm

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

5.5.13 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.

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

5.5.15 Establishment shall ensure that the detergents used for cleaning and sanitation do not cause contamination / damage to the food or food contact surfaces and do not create environmental Hazards.

5.5.16 All Hygiene and sanitation chemicals must be stored under lock & key condition.

[4]If an establishment is approved for Export to EU; the chlorination limits shall be applied specific to EU Manual

5.5.17 **Hygiene Requirements for Staff:**

5.5.17.1 All the employees who work in the product handling area(s) must obtain Health Certificates from a Local Government agency / Municipality / Medical Center, as proof of fitness to work in the processing plant.

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

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

5.5.17.4 Staff assigned to the handling and preparation of fishery products must be required to wash their hand at least each time work is resumed; wounds on the hands must be covered with water proof dressing.

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

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

5.6 Raw Materials

5.6.1 Raw materials sourced / procured shall be from approved Establishments

5.6.2 Establishment shall not purchase /procure pre-processed products from unauthorized centers.

5.6.3 Water and Ice (for processing aquaculture products) purchased from outside facilities shall be assessed for potable water requirements prior to use.

5.6.4 Raw material procured from another farm for processing shall be approved by GDF-MEWA. The Establishments shall conduct regular audits if required to ensure that the farms are following good aquaculture and biosecurity practices. Establishment shall maintain records for Raw material quality checks, acceptance and traceability.

5.7 Special requirements for processing of aquaculture products

5.7.1 Establishments shall process aquaculture products procured only from farms registered and recognized by GDF-MEWA.

5.7.2 If live or fresh products are exported, Pre-harvest test (of live animals from concerned ponds) shall be carried out in the Approved Establishment Lab / approved reference lab to prove that the raw material is free from pathogens and contaminants as required by GDF-MEWA and other importing country requirements as applicable.

5.7.3 Test reports pertaining to the quality and safety of the raw material, ingredients and the additives / preservatives used shall be maintained by the Establishment.

5.7.4 **Validation:** Establishment shall validate the processing method(s) used for cooking, retorting etc. and calibrate all the measuring and recording devices at a laid down frequency so as to ensure proper temperature control. Establishment shall also validate the freezing process / equipment.

5.7.5 **Contamination:** Proper control shall be exercised through Pre-requisite Programs to avoid cross contamination of the product processed / handled. Where necessary Establishment shall carryout risk assessments to identify and mitigate hazards.

5.8 Pest Control

5.8.1 Suitable pest control measures shall be adopted to eradicate pests inside the factory premises.

5.9 Storage and Transportation

5.9.1 Fresh fishery products, thawed / unprocessed fishery products, and cooked & chilled products from crustaceans and mollusks must be maintained at a temperature approaching that of melting ice (up to 5^0 C). Proper temperature controls shall be exercised at all stages of processing.

5.9.2 Frozen fishery products, with the exception of whole fish initially frozen in brine for the manufacture of canned food, must be maintained during transport at an even temperature of not more than -180C in all parts of the product, possibly with short upward fluctuation of not more than 30C.

5.9.3 Frozen fishery products during storage shall be kept at a temperature of not more than -180C in all parts of the products; however, whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of not more than -90C.

5.9.4 The transportation and storage facilities used for frozen fishery products should be fitted with temperature recording devices to monitor air temperature at regular intervals.

5.9.5 Fish and fishery products of other facilities shall not be stored in the approved Establishment without proper traceability, document and adhering to applicable government rules and permissions.

5.9.6 A HACCP based risk assessment shall be conducted in case of storage of any other product (including frozen raw materials) stored along with final product in cold store.

5.9.7 Finished products stored outside the establishment's cold store during any emergency / break down / during major maintenance shall be notified to GDF-MEWA. Proper temperature controls shall be exercised at all stages of processing.

5.10 Internal Audits:

5.10.1 Establishment shall conduct internal audits at a defined frequency covering all areas of SOP's, PRP's and HACCP System. Records shall be maintained for verification.

5.10.2 Internal audits shall be conducted by appropriately trained, competent auditors. Audit or shall be independent and shall not audit their own work.

5.10.3 Establishment shall adopt GMP for storage / handling of printed materials and marking materials / articles in order to ensure that printed surfaces or marking ink applied to nonfood contact surfaces will not come in contact with food or food contact surfaces. Regular training shall be imparted to the workers in this regard and records of the same shall be maintained.

5.11 Training

5.11.1 Trainings shall be provided to all relevant staff (including new staff) on the implementation of the HACCP system, Hygiene & sanitation practices, SOP's, Sampling, waste management, Traceability and Recall procedures.

5.11.2 Records shall be available for verification.

5.12 Handling of Imported cargo for re-export

5.12.1 Establishment importing fishery products for further processing and export shall address the processing of the imported cargo in their HACCP plan of the establishment and maintain proper records including traceability.

5.12.2 Any such cargo imported from other countries shall follow all Bio-security protocols before it is taken for re-processing.

5.12.3 Establishment shall inform the GDF-MEWA when an imported raw material is intended for re-export, submitting all details of imported cargo such as

- Type of product
- Quantity details
- Type of pack
- Quality inspection report
- Lab test report for microbiology
- Lab test report for chemical parameters (if any relevant)
- Country of origin certificate
- Health certificate
- Copy of BL
- Bill of entry etc.

5.12.4 If any imported cargo is re-processed in Saudi Arabia and exported to another country, the requirements of the country to which the product is finally exported shall be followed.

5.13 Quality Control

5.13.1 Each aquaculture establishment shall have a functional quality control department. This department should be independent from other departments / management and under the authority of person not reporting to production, who may have in-house establishment laboratories under his disposal.

5.13.2 Adequate resources must be available to ensure that the Quality Control arrangements effectively carried out.

5.13.3 All aquaculture products released for sale / export / samples shall be through an established quality control system for product release.

5.13.4 **Organoleptic Inspections**

5.13.4.1 Organoleptic inspection of raw material, process and product samples shall be conducted by the approved technologist / qualified personnel to ascertain the freshness and other organoleptic qualities of the product.

5.13.4.2 Time- Temperature control shall be exercised at all stages of production, storage and transportation, wherever applicable.

5.13.4.3 For organoleptic checks, the establishments shall develop a sampling plan with adequate sample size, which shall be documented. Organoleptic checks shall also be conducted during processing and after freezing / packing as applicable.

5.13.4.4 For the analysis of finished products, type wise and variety wise samples shall be drawn from the day's production at random, as applicable, as per the documented sampling plan. Defective lots shall not be allowed for export.

5.13.4.5 Ice plants shall check the quality of ice produced

5.14 Microbiological Checks

5.14.1 Fishery products procured by establishments as **raw material** shall be tested (variety wise / source wise) for microorganisms such as TPC, E.coli, Coagulase positive staphylococcus, Salmonella, *V. cholerae*, and *V. parahaemolyticus* in the in-house lab by the approved technologist(s) or at GDF-MEWA-Lab / approved lab for every lot, as per the frequency laid down as documented.

5.14.2 Batch (Code) wise, variety wise, type wise samples of **Frozen fishery products** shall be tested for microorganisms such as TPC, *E.coli*, Coagulase positive staphylococcus, Salmonella,, *V. cholerae*, and *V. parahaemolyticus*, whereas fishery products packed in hermetically sealed containers and heat treated, shall be subjected to sterility tests. Code wise, variety wise, type wise samples of acidified fishery products shall be tested for yeast and mould and dried fishery products for microorganisms such as TPC, *E.coli*, Salmonella, *V. cholerae*, yeast and mold.

5.14.3 For the export of **Fresh / Chilled fishery products**, the establishments shall conduct bacteriological testing of the consignment for TPC, *E.coli*, and Coagulase positive staphylococcus, Salmonella, *V. cholera*, and *V.parahaemolyticus* on post- facto basis.

5.14.4 Consignments of frozen cooked crustaceans meant for export shall be tested batch (code) wise for *Listeria monocytogenes* in addition to the microorganisms mentioned in the previous clause prior to shipment by the Establishments.

5.14.5 If salt is used in processing / ice production, it shall be ensured by the Establishment that all the batches of salt purchased shall be free from S*taphylococcus aureus* and Sulphite reducing clostridium.

5.14.6 Other ingredients such as Oil, Vegetables, Spices etc., if used, shall be tested for microbiological parameters such as TPC, *E.coli*, Coagulase positive staphylococcus, *V. Cholerae* and Salmonella.

5.14.7 Sanitation & Hygiene Control random samples from food contact surfaces and worker's hand shall be tested for TPC, Coliforms and *V. cholerae* a pre-documented frequency to ascertain the effectiveness of cleaning and sanitization.

5.15 Water and Ice

5.15.1 Establishment(s) shall exercise proper quality control on water and ice used in their factory. They shall check the microbiological parameters such as TPC, coliform and *V. cholerae* in water and ice in their in-house lab / GDF-MEWA Lab / GDF-MEWA approved Lab at least once in a month.

5.15.2 Establishments / Facilities which are involved in export of aquaculture products to Russia shall test water used for processing and ice production for all parameters as per Council Directive 98/83/EC of 3 November 1998 in GDF-MEWA Lab / GDF-MEWA approved lab at least once every year and also whenever the source of water is changed. For other exports, SASO national standard for drinking water shall apply.

5.15.3 In case the source of water used for processing and ice production is same, then the ice needs to be tested only for microbiological parameters applicable as per Part-A of Annex - I of Council Directive 98/83/EC.

5.15.4 Water used for processing and ice production shall also be tested in house for the parameters applicable as per clause 1 of Table A of Annex II of Directive 98/83/ECat least once in six months.

5.16 Additives / Color

5.16.1 Crustaceans shall be tested by the Establishment to ensure that residue of additives such as sulphites, phosphates etc., are within the permissible limits. Purity of additives shall also be tested by the Establishment.

5.16.2 Admissible limits shall be followed as per the Annexure -2 Food Additives

5.16.3 The uses of new additives / color (for exports) only when written permission has been obtained by the Establishment from the GDF-MEWA.

5.17 Histamine

5.17.1 Histamine forming fishes shall be tested as per the documented frequency, to ensure that the limits of histamine are not.

5.17.2 Fish shall be tested for histamine shall be carried out in-house on post facto basis as per the importing country's requirement.

5.18 Total Volatile Basic Nitrogen (TVB-N)

5.18.1 If organoleptic evaluation of raw material / finished products reveals any doubt as to the freshness of aquaculture products, the same shall be tested for total volatile basic nitrogen (TVB-N).

5.18.2 A minimum of two samples need to be analyzed (random sample) annually by the Establishment.

5.19 Parasites

5.19.1 Establishments shall ensure that aquaculture products are free from visible parasites.

5.19.2 Every day the raw material shall be subjected to visual examination to check visible parasites before processing.

5.19.3 The daily Raw Material inspection report shall have a specific space to record observation.

5.20 Toxic Fishes

5.20.1 Poisonous fishes / aquatic organisms shall not be processed for export.

5.20.2 Fishery products derived from poisonous fishes belonging to the families like Canthigasteridae, Diodontidae, Molidae and Tetraodontidae shall not be processed for export.

5.21 Residual parameters

5.21.1 Raw materials and finished products shall be tested by the approved facility for antibiotic residue, pesticides, heavy metals, dyes and other contaminants.

5.21.2 The aquaculture feeds shall be tested for antibiotic residue, mycotoxins and relevant aquaculture drugs as per the annual residue-monitoring plan of the establishment.

5.21.3 Approved Establishments shall also test other parameters specified in the documented schedule.

5.21.4 The scheme of analysis and schedules shall be based on the National Residue Monitoring Program

5.22 Other parameters

5.22.1 Dried products / salted & dried products of aquaculture origin shall be tested batch (code) wise for moisture, sand content, percentage of salt (as applicable).

5.22.2 Pickles / Acidified / Marinated aquaculture products shall be tested for pH, salt contents etc. Purity of the salt shall also be tested batch-wise.

5.22.3 If Oil is used in processing, the product shall be tested for rancidity and moisture.

5.23 Records and documents

5.23.1 Proper records shall be maintained by the Establishment at all stages of production, storage and transportation of fish & fishery products shall be made available to the GDF-MEWA officials for verification.

5.23.2 The records shall be legible and accessible. All the records and documents shall be checked, verified and signed by authorized persons.

5.23.3 The documents / formats shall bear the Revision details on it.

5.23.4 All the records and documents shall be kept for a minimum period of 2 years or shelf life of the product + 1 year, whichever is higher.

5.24 Marking of approval number on export packages

5.24.1 The approval number along with the specified Quality Mark shall be legibly printed on all the export packages of Aquaculture products.

5.24.2 The Traceability Code which gives link to the production batch, time and aquaculture pond shall be marked on all export packages of aquaculture products.

5.24.3 If there are any specific requirement of an importing country is to be followed either on packaging material or in other aspects that shall be followed as decided by GDF-MEWA.

Section III: National Sampling & Inspection Program

6. Sampling & Inspection Program by Competent Authority

The CA shall communicate with Establishments regarding annual plan of audit and inspection program, however, CA can make planned and unplanned visits for the inspection and sampling of establishments. Types of audits and sampling program will be followed as per below:

6.1 Types of Audit (Establishment Audit by the Competent Authority)

GDF-MEWA shall periodically conduct audit for:

6.1.1 **Approval Audit** – will be done, as per the requirements of section 4.3 and 4.4 of this manual. The audit team shall inspect the establishment to check the level of compliance to the requirements to this Manual and to approve Establishment, Laboratory Technicians, chemicals and food additives used in processing plant.

6.1.2 **Surveillance Audit**– will be done semi-annual for all approved establishments. The Audit team shall inspect the establishment's compliance to the requirements as per the National Aquaculture Product Export System Manual.

6.1.3 **Renewal Audit** – will be done prior to the expiry of Establishment's approval. The Audit team shall inspect the establishment's compliance to the requirements as per the National Aquaculture Product Export System Manual.

6.1.4 **Special Audit** – will be done in case of any major structural changes to the processing plant (i.e., production process, addition of new product lines, etc.) or as decided by GDF-MEWA. The audit team shall inspect the establishment's compliance to the requirements as per the National Aquaculture Product Export System Manual.

6.2 Sampling Program

The audit team shall carry out sampling activities along with Establishment's audit.

6.2.1 The official samples shall be collected by GDF-MEWA annually as a minimum and tested at National Reference Laboratory / 3rd party laboratory. Establishment shall bear the cost of samples analysis.

6.2.2 In case of failure reported in results of analyzed samples, the matter shall be immediately reported to the foreign buyer and the GDF-MEWA and counter samples shall be re checked and the recall procedures shall be initiated by the establishment as needed.

6.2.3 The Establishment/ Facility shall test self-samples for residues following a documented schedule. The test results shall be communicated to GDF-MEWA as proof of the conducted tests.

6.2.4 **Proficiency testing of the in-house laboratory of the processing establishments -** In order to ascertain the performance of the in-house lab of the establishment, the monitoring officials shall draw aseptically 2 sets of samples (one sample divided into 2 sets) from the selected production code during the monitoring at least once in six months. One set of sample is sent to National Reference Laboratory or approved reference laboratory as decided by GDF-MEWA and the other set is given to the in-house lab of the establishment for testing all microbiological parameters. Details of proficiency testing of in-house labs shall be maintained as per the specified format.

6.2.4.1 The Establishment / Facility shall submit the report to GDF-MEWA and GDF-MEWA shall compare the test results of the official lab and in-house lab. If variation above 10% is observed, GDF-MEWA shall audit the in-house lab of the establishment. In case of minor non-conformities, unit shall undertake immediate corrective action and same shall be verified by GDF-MEWA in the subsequent monitoring visit.

6.2.4.2 However, in case of major non conformities, the establishment shall stop the analysis in the in-house lab and shall send the own check microbiological samples to GDF-MEWA lab for testing till the non-conformities are rectified and same is verified by the GDF-MEWA lab expert.

6.2.5 **Reporting System:**

6.2.5.1 GDF-MEWA auditor shall submit the audit report, details of Non-conformities (if any) and suggestions for improvements to the establishment after the Establishment audit.

6.2.5.2 Establishment shall ensure that:

- Shall submit corrective action plan to GDF-MEWA for non-conformities noted during the Audit.
- All non-conformities shall be closed with in specified time as agreed with GDF-MEWA.
- Any non-conformity effecting food safety shall be addressed immediately to ensure product safety.

6.2.5.3 Analysis reports received from 3rd party labs/GDF-MEWA Reference lab shall be communicated to Establishment.

6.2.6 **Deviations noted in analysis results**

6.2.6.1 GDF-MEWA to do resampling and send to 3rd party lab / GDF-MEWA reference lab for analysis of particular parameter(s) in question. All costs of samples analysis shall be paid by Establishment.

6.2.6.2 The product is noted as non-confirming product until the re-assessment and root cause is rectified.

6.2.6.3 GDF-MEWA to review with Establishment and shall take appropriate decision to put the product on hold from sale / withdrawal from market place / recall.

6.2.6.4 Establishment to identify particular production lot, do the Mass Balance and traceability of the non-confirming product.

6.2.6.5 Establishment to take action as per the decision taken, as per clause 6.2.6.3.

6.2.7 **Guidelines for dealing with non-conformities / unsatisfactory analysis results / violations**

6.3 Non-conformities

6.3.1 **Minor Non-Conformity:** The deficiencies which do not affect the wholesomeness (food safety) of the products.

6.3.2 **Major Non-Conformity:** Those which affect the safety of the food product shall be considered as major non-conformities. A number of minor non-conformities or repeated minor non-conformities indicating a system failure would also be treated as major non-conformity.

6.3.3 **Some of major non-conformities are:**

6.3.3.1 Contamination with pathogens (Salmonella, V. cholera. Listeria etc.) or with hazardous substances like heavy metals, antibiotics, pesticide residues etc. above permissible limits shall be considered as major non-conformities

6.3.3.2 Failure of sanitation & hygiene control samples for Coliforms in three consecutive instances may be considered as major non-conformities.

6.3.3.3 Failure of finished product samples to meet the quality parameters on freshness based on organoleptic examination and / or the test results of TVB-N and TMA-N is also major non-conformities.

7. Details of the Laboratory System

7.1 General

7.1.1 The GDF-MEWA Laboratory in Jeddah shall be referred as National Reference Laboratory for export of Aquaculture products.

7.1.2 The GDF-MEWA Laboratories in other locations shall be referred as Regional Laboratories.

7.1.3 All GDF-MEWA Laboratories / 3rd Party laboratories shall be certified with ISO 17025 Accreditation.

7.1.4 GDF-MEWA shall have a list of Approved Laboratories including GDF-MEWA Labs and 3rd Party Labs for meeting different analytical requirements.

7.1.5 A list of approved laboratories is as per Annexure 6.

7.1.6 The list of approved laboratories shall be reviewed annually and updated list shall be communicated with GDF-MEWA Auditors and Establishments.

7.1.7 The establishment Laboratory shall be the one that conducts day-to-day analysis to ensure the product quality and safety compliance to the analytical requirements and standards as stipulated by GDF-MEWA.

7.2 Responsibilities of GDF-MEWA Laboratories

The responsibility of this GDF-MEWA laboratories(National Reference Laboratory & Regional Laboratories) shall be as follows:

7.2.1 Shall conduct analysis as per the samples sent by Competent Authority (GDF-MEWA Head Office).

7.2.2 In case of any test they are unable to carry out, the National Reference Laboratory shall assign tests and analysis to other Regional Laboratories.

7.2.3 GDF-MEWA Laboratories shall send a copy of all test reports to the establishment andto the Competent Authority (GDF-MEWA).

7.3 Establishment Laboratory

7.3.1 The Establishment shall have its own laboratory to carry out regular analysis and tests. The responsibility of this Laboratory shall be as follows:

7.3.1.1 Conduct regular tests/analysis as per the list issued by the Competent Authority.

7.3.1.2 Keep record of all tests/analysis conducted.

7.3.1.3 Prepare a scientific sampling plan for the collection and analysis of samples. The sample collection for routine self-analysis shall follow this schedule. This should include the sample collection, securing and dispatch details.

7.3.1.4 Send test/analysis reports to the Competent Authority along with other documents to get APEHC and HC (from Competent Authority) for each consignment to be exported.

7.3.1.5 Keep GLP in the Establishment Laboratory.

7.3.1.6 Microbiological lab tests and Analysis to be carried out by the Establishment as per Annexure-3.

7.3.1.7 Contaminants and residual analysis shall be carried out by the establishment / approved 3rd party lab as per Annexure-5.

Section IV: Aquaculture Products Export Health Certification

8. Export certification

8.1 Aquaculture Product Export Heath Certificate (APEHC)

8.2 All the consignments of Aquaculture products meant for export shall accompany an Aquaculture Product Export Health Certificate after undergoing quality control and inspection prior to shipment. The validity of HC issued for every export consignment shall vary from Frozen to Fresh Products. The certificate shall have the following details;

8.2.1 Health certificates shall be issued by GDF-MEWA based on the declaration of the Establishment to the effect that proper precautionary measures have been taken by the establishment to avoid microbiological / residual contamination of the fresh / chilled fishery products intended for export.

8.2.2 Health certificate shall be issued for the export of aquaculture products to fulfill import requirements of the importing country.

8.3 Additional Certificate(s).

8.3.1 If the importing country needs / demands for an additional certificate, the competent authority shall issue the required certificate as an annexure to the HC.

8.3.2 The establishment shall provide the necessary information of the needed additional certificate and GDF-MEWA shall prepare such additional certificate in the prescribed format.

8.3.3 For a certificate in other language, Establishment shall submit a hard and soft copy of the Additional certificate in English and the importing country language to GDF-MEWA.

8.3.4 Additional certificate shall be issued in bilingual languages as requested by the Establishment.

8.3.5 Each additional certificate shall be verified and stamped by the CA / GDF-MEWA branches /GDF-MEWA reference labs.

8.3.6 The format of additional certificate shall be communicated with the establishments as need arises.

8.4 Procedure for issuance of Health Certificate (HC)

8.4.1 Procedures to ensure reliable certification (HC)

8.4.1.1 The certificates shall be issued only once the Establishment submits a request along with all documents as required which include the lab certificates, packing list, product details etc.

8.4.1.2 The certificates shall be serially numbered as per section 8.5 of this manual

8.4.1.3 An official seal and signature shall be put at the bottom of every page.

8.4.1.4 The signature shall not be of the same color of the print of the Certificate. For example if the print color is black the officer shall sign with a blue ink pen.

8.4.1.5 The name of the officer shall be legibly printed on the certificates.

8.4.1.6 One copy of the certificate shall be kept in the local GDF-MEWA office and another shall be sent to GDF-MEWA head office in Riyadh.

8.4.1.7 A register shall be kept in all local GDF-MEWA offices which keep the reference number of the issued Certificates.

8.4.1.8 Prior to an export, the establishment shall submit a request for HC to be issued by GDF-MEWA.

8.4.1.9 The Establishment shall apply for a HC along with the following information;

- Commercial invoice / sample invoice (English and Arabic)
- Packing list
- Bank receipt (if applicable)
- Quality declaration from establishment
- Any additional documents if required

8.4.2 Re-issuance HC / Replacement of a Health Certificate:

8.4.2.1 Replacement certificates may be issued by a competent authority to rectify certificates that have been for example, lost, damaged, contain errors, or where the original information is no longer correct. These certificates must be clearly marked to indicate that they are replacing the original certificate 'reissue'. A replacement certificate should reference the number of the original certificate that it supersedes and the

date the original was signed. The original certificate should be cancelled and where possible, returned to the issuing authority.

8.4.3 Revocation of Health Certificates:

8.4.3.1 When, for good and sufficient reason, there is cause to revoke a certificate, the competent authority or its branch office where Health certificates issued, may revoke the original certificate as soon as possible and notify the exporter or their agent by email and letter. The correspondence should reference the number of the original certificate to which the revocation refers and provide all particulars regarding the consignment and the reason(s) for the revocation.

8.4.4 Invalid Health Certificates:

8.4.4.1 Despite efforts to prevent errors, official health certificates may inadvertently contain incorrect or incomplete information or attestations. Upon discovery of this the Competent Authority or its branch office where Health Certificate(s) issued, should notify exporting country. In such cases the certifying body should, in a timely fashion, issue a replacement certificate as described in paragraph 8.4.2 or revoke the certificate as described in paragraph 8.4.3, as appropriate.

8.4.4.2 Prior to an export, the establishment shall submit a request for HC to be issued by GDF-MEWA.

8.5 Health Certificate Numbering System

8.5.1 Each Export Health Certificate shall bear an alpha numeric numbering system on each page of health certificate.

Below is structure and exemplary definition for export health certificate numbering system.

Regional Office (Health Certificate issuance regional office)	**Type of product**	**Issuance Year**	**Serial No of Health Certificate**
1 – Fish Farms Dept. – Riyadh (Head Office) 2 – Fish Researches Center – Jeddah 3 - Fish Researches Center – Al Qateef 4 –General Directorate of Fisheries– Jazan 5 – General Directorate of Fisheries – Jeddah 6 - General Directorate of Fisheries – Yanbu 7 - General Directorate of Fisheries – Al-Jubeil 8 – General Directorate of Fisheries Amluj 9 - General Directorate of Fisheries– Farasan 10 - General Directorate of Fisheries – Algahma 11 - General Directorate of Fisheries – Dhuba 12 -General Directorate of Fisheries – Al-Qunfuda 13 - General Directorate of Fisheries – Al Lith 14 – General Directorate of Fisheries Tabuk	F – Fresh product Z – Frozen product C - Cooked product L – Live product RP – Reprocessed product	2016 (for example)	Numbering certificates starts from 0001
Example for Health Certificate code: 05-F-2016-0001 (Certificate No. will continue following the series 0001, 0002, Etc.)			

Section V: Annexures

Annexure -1: Abbreviations and Glossary

GDF-MEWA – General Directorate of Fisheries of Ministry of Environment, Water & Agriculture, Saudi Arabia
AMC – GDF-MEWA Management Committee
AOAC – Association of Official Analytical Communities (earlier 'Chemists')
APC - Aerobic Plate Count
APEHC – Aquaculture Product Export Health Certificate (of Saudi Arabia)
APHA -American Public Health Association
AQSIQ-General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China
BAM - Bacteriological Analytical Manual
BL – Bill of Lading
CA – Competent Authority
CCP – Critical Control Point
CFE - Certificate for Export
CITES - Convention on International Trade in Endangered Species
DDT - Dichlorodiphenyltrichloroethane
EDTA – Ethylene Di-amine Tetra Acetic acid
EFAA - Establishment Facility Approval Audit
EU – European Union
F & FP – Fish and Fishery Products
GLP -Good Laboratory Practices
GMP - Good Manufacturing Practices
GHP – Good Hygiene Practices
HACCP – Hazard Analysis and Critical Control Point
HCH – Hexa-Chloro Cyclo-Hexane
INS – International Numbering System
NCR - Non- Conformity Report
NOC - No Objection Certificate
NRMP - National Residue Monitoring Program
PCBs - Polychlorinated biphenyls
PME - Presidency of Meteorology and Environment, Saudi Arabia
PSP & DSP - Paralytic Shellfish Poison and Diarrhetic Shellfish Poison
SAS – Saudi Aquaculture Society
SOP - Standard Operating Procedures
SSOP - Sanitary Standard Operating Procedures
TMA-N – Tri Methyl Amine N-oxide

TPC – Total Plate Count
TVB-N – Total Volatile Base Nitrogen
TVC – Total Viable Count

Annexure-2: List of Approved Food Additives

Additives: In unprocessed fish and fish fillets

Additive	INS* Number	Matrix	Frequency	Test Method	Sample Size/ Number
Ascorbic acid and sodium, calcium, potassium ascorbates	300, 301, 302, 303	Frozen fish fillets (including peeled prawns)	Every Day	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Erythorbic acid and sodium erythorbate	315, 316		Every Day	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Sodium, potassium and calcium phosphates	339, 340, 341		Every Week	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Pyrophosphates, Triphosphates, Polyphosphates	450, 451, 452		Every Week	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Sulphur dioxide and sodium and potassium sulphites	220, 221, 222, 223, 224, 225, 228	Uncooked crustaceans	Every Day	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Ascorbic acid and sodium, calcium and potassium ascorbates	300, 301, 302, 303		Every Week	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Erythorbic acid and sodium erythorbate	315, 316		Every Week	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Citric acid and sodium, potassium, calcium and ammonium citrates	330, 331, 332, 333, 380		Every Week	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Sodium carbonates	500		Every Week	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Magnesium carbonates	504		Every Week	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan

*** INS –** International Numbering System

Additives: In processed products

Additive	INS* Number	Matrix	Frequency	Test Method	Sample Size/ Number
Sulphur dioxide and sodium and potassium sulphites	220, 221, 222, 223, 224, 225, 228	Cooked crustaceans	Every Lot	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Amaranth	123	Roe -all products	Every Lot	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Annatto extracts	160b	Semi-preserved fish	Every Lot	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Sorbic acid and sodium, potassium and calcium sorbates	200, 201, 202, 203		Every Lot	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Benzoic acid and sodium and calcium benzoates	210, 211, 212, 213		Every Lot	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Sulphur dioxide and sodium and potassium sulphites	220, 221, 222, 223, 224, 225, 228	Fully preserved fish (including canned fish products	Every Lot	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Calcium disodium EDTA	385		Every Lot	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Sulphur dioxide and sodium and potassium sulphites	220, 221, 222, 223, 224, 225, 228	Canned abalone (paua)	Every Lot	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan

*** INS –** International Numbering System

Annexure-3: Microbiological and Chemical Standards of Aquaculture products

#	Parameters	Product(s) Matrix	Frequency & Details
1.	TPC, *E.coli*, Coagulase positive staphylococcus, Salmonella, *V. cholerae*, *V. parahaemolyticus*	Raw /process material	Every monitoring visit
2.	TPC, *E.coli*, Coagulase positive staphylococcus, Salmonella, V. cholerae, *V. parahaemolyticus*	Frozen/ chilled Finished products	Every monitoring visit
3.	TPC, *E.coli*, Coagulase positive staphylococcus, Salmonella, *V. cholerae*, *Listeria monocytogenes*	Frozen cooked crustacean	Every monitoring visit on availability
4.	TPC, Coliforms, *V.cholerae*	Water	Every monitoring visit
5.	TPC, Coliforms, *V.cholerae*	Ice	Every monitoring visit
6.	TPC, Coliforms	Swabs from food contact surfaces immediately after cleaning & sanitization)	Every monitoring visit
7.	*V.cholerae*	Swabs from workers hand	Every monitoring visit
8.	Antibiotics (Chloramphenicol, Metabolites of Nitrofuran, Tetracycline, Oxytetracycline, Chlorotetracycline	Raw material / finished products (aquaculture products only)	Once in six months from establishments exporting aquaculture Products
9.	Cadmium, Lead, Mercury	Raw material / finished fishery products	Once in 6 months from each approved establishment
10.	Pesticides (Organochlorine compounds)	Raw material/ finished products (Only for aquaculture products)	Once in 6 months from each approved establishment
11.	Histamine	Raw material/ finished products (only histamine fishes)	Once in 6 months from each approved establishment for the Histamine species fish only
12.	TVB-N &TMA-N	Raw Material/ Pre-processed Material/ processed material	Every monitoring visit. Only when there is a as to the freshness of the fishery product during organoleptic examination, same shall be tested for TVB-N and TMA-N
13.	Sulphite & added Phosphates form crustaceans	Sulphite & added Phosphates finished products	Once in 6 months from each approved department
14.	PSP/DSP	Raw material/finished products of Molluscs belonging to Gastropoda and Bivalvia and also crab species	-do-
15.	Coagulase positive staphylococcus & Sulphite reducing clostridium and purity test	Salt used for processing	-do-
16.	Sterility test	Fishery products packed in hermetically sealed containers and heat treated. (Canned/ retort pouch packed)	Every monitoring visit

#	Parameters	Product(s) Matrix	Frequency & Details
17.	pH, yeast, Mould and salt content	Acidified fishery products	Every monitoring visit
18.	Moisture content, salt content and yeast & mould, TPC, *E.coli*, Coagulase positive staphylococcus, *V.cholerae* Salmonella & Acid insoluble ash	Dried & salted fishery products	Every monitoring visit
19.	Parameters for the other commodities like fish oil	Rancidity/Moisture	Every monitoring visit
20.	Dioxin & PCB	Fishery products	Every one year

Annexure-4: Microbiological Quality Standards for Aquaculture products

Organism	Product Type	Sampling	Test Method	Sample Size/ Number
Aerobic Plat Count at 35^0 C	All Raw Products	Every day Every lot	SASO and AOAC / APHA/ BAM or Specific Country Requirement	As per the Establishment's documented sampling plan
Aerobic Plat Count at 35^0 C	Cooked products	Every day Every lot	SASO and AOAC / APHA/ BAM or Specific Country Requirement	As per the Establishment's documented sampling plan
Escherichia coli	Cooked or ready-to-eat products	Every day Every lot	SASO and AOAC / APHA/ BAM or Specific Country Requirement	As per the Establishment's documented sampling plan
Escherichia coli	Raw molluscan shellfish	Every day Every lot	SASO and AOAC / APHA/ BAM or Specific Country Requirement	As per the Establishment's documented sampling plan
Escherichia coli	All other types	Every day Every lot	SASO and AOAC / APHA/ BAM or Specific Country Requirement	As per the Establishment's documented sampling plan
Coagulase-Positive *Staphylo-cocci*	All types	Every day Every lot	SASO and AOAC / APHA/ BAM or Specific Country Requirement	As per the Establishment's documented sampling plan
Listeria monocytogenes	Cooked products	Every day Every lot	SASO and AOAC / APHA/ BAM or Specific Country Requirement	As per the Establishment's documented sampling plan
Salmonella	All types	Every day Every lot	SASO and AOAC / APHA/ BAM or Specific Country Requirement	As per the Establishment's documented sampling plan
Vibrio cholerae	Cooked or ready-to-eat products	Every day Every lot	SASO and AOAC / APHA/ BAM or Specific Country Requirement	As per the Establishment's documented sampling plan
Vibrio para - haemolyticus	Raw Oyster	Every day Every lot	SASO and AOAC / APHA/ BAM or Specific Country Requirement	As per the Establishment's documented sampling plan

Annexure-5: Contaminants and Residues analysis for aquaculture products

Compound	Matrix	Frequency	Test Method	Sample Size / Sample Number
Diethylstilbestrol	Fish Muscle	Minimum- once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Estradiol	Fish Muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Progesterone	Fish Muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Chloram-phenicol	Shrimp/Fish muscle Fish eggs (roe) Shrimp/Fish feed	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Nitroimidazoles *i. Dimetridazole* *ii. Metronidazole* *iii. Ronidazole* *iv. Ipronidazole*	Shrimp/Fish muscle Fish eggs (roe) Shrimp/Fish feed	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
		Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
		Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
		Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Nitrofurans (including furazolidone)	Shrimp/Fish muscle Fish eggs (roe) Shrimp/Fish feed	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Sulfonamides	Shrimp/Fish muscle Fish eggs (roe) Shrimp/Fish feed	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan

Compound	Matrix	Frequency	Test Method	Sample Size / Sample Number
Neomycine	Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Oxytetracycline,	Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Erythromycin	Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Tetracycline	Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Albendazole	Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Fenbendazole	Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
HCH (α & β)	Natural Water Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Lindane	Natural Water Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
DDT (DDD, DDE, DDT)	Natural Water Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
PCB congeners	Natural Water Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Mercury	Natural Water Shrimp/Fish muscle Fish eggs (roe)	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan

Compound	Matrix	Frequency	Test Method	Sample Size / Sample Number
Cadmium	Natural Water Shrimp/Fish muscle Fish eggs (roe)	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Lead	Natural Water Shrimp/Fish muscle Fish eggs (roe)	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Aflatoxins	Shrimp/Fish muscle Shrimp/Fish feed	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Malachite green & Leucomalachilte green	Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Crystal Violet & Leucocrystal violet	Shrimp/Fish muscle	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan
Dioxine	Feed ingredients	Minimum once every year	SASO and AOAC / APHA or Specific Country Requirement	As per the Establishment's documented sampling plan

Annexure-6: List of Approved 3rd Party Labs

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)

Note: In case of any emergency / non-availability of above laboratories for any specific reason, analysis performed with alternate lab certified by ISO 17025 for ensuring availability of results.