



ပြည်ထောင်စုသမ္မတမြန်မာနိုင်ငံတော်အစိုးရ  
စိုက်ပျိုးရေး၊ မွေးမြူရေးနှင့် ဆည်မြောင်းဝန်ကြီးဌာန  
ငါးလုပ်ငန်းဦးစီးဌာန

ညွှန်ကြားချက်အမှတ် - ၈၇ /၂၀၁၈

၁၃၈၀ ခုနှစ်၊ တန်ဆောင်မုန်းလပြည့်ကျော် ၁၃ ရက်  
၂၀၁၈ ခုနှစ်၊ ဒီဇင်ဘာလ ၅ ရက်

အကြောင်းအရာ။ ငါး၊ပုစွန်ရေထွက်ပစ္စည်းများ တင်ပို့/တင်သွင်းခြင်းလုပ်ငန်းများ ဆောင်ရွက်ရာတွင် လိုက်နာရမည့် စည်းမျဉ်း၊ စည်းကမ်းများ(Technical Regulation For Export and Import Fishery Products) အား ပြင်ဆင်ထုတ်ပြန်ကြေငြာခြင်း

၁။ စိုက်ပျိုးရေး၊ မွေးမြူရေးနှင့်ဆည်မြောင်းဝန်ကြီးဌာန၊ ငါးလုပ်ငန်းဦးစီးဌာန ညွှန်ကြားရေးမှူးချုပ်သည် မြန်မာ့ပင်လယ်ငါးလုပ်ငန်းဥပဒေပုဒ်မ - ၂၃ တွင် အပ်နှင်းထားသော လုပ်ပိုင်ခွင့်ကိုကျင့်သုံး၍ ငါး၊ပုစွန် ရေထွက်ပစ္စည်းများ တင်ပို့/တင်သွင်းခြင်းလုပ်ငန်းများ ဆောင်ရွက်ရာတွင် လိုက်နာရမည့် စည်းမျဉ်း၊စည်းကမ်းများ(Technical Regulation for Export and Import of Fishery Products)အား ဤညွှန်ကြားချက်ဖြင့် ထုတ်ပြန်လိုက်သည်။ (စည်းမျဉ်း၊စည်းကမ်းများ Technical Regulation for Export and Import of Fishery Products အားပူးတွဲဖော်ပြထားပါသည်။)

၂။ ငါးလုပ်ငန်းဦးစီးဌာနသည် ပြည်ပသို့တင်ပို့သော၊ ပြည်တွင်းသို့ တင်သွင်းသောငါး၊ ပုစွန်ရေထွက်ပစ္စည်းများသည် စားသုံးသူများအားဘေးဥပဒ် အန္တရာယ်ကင်းရှင်းစေရန်နှင့် အရည်အသွေးစံချိန်၊ စံညွှန်းပြည့်မီသော ရေထွက်ပစ္စည်းများဖြစ်စေရန်၊ နိုင်ငံတကာမှ သတ်မှတ်ထားသော စည်းမျဉ်း၊စည်းကမ်းများနှင့်ကိုက်ညီစေရန်နှင့် အာဆီယံစီးပွားရေးအသိုက်အဝန်း တည်ထောင်မှုကို အထောက်အကူဖြစ်စေရန်အတွက် ငါး၊ပုစွန်ရေထွက်ပစ္စည်းများတင်ပို့/ တင်သွင်း ခြင်းပြုရာတွင် လိုက်နာရမည့် စည်းမျဉ်း၊စည်းကမ်းများနှင့်အညီဆောင်ရွက်ရန် ညွှန်ကြားချက်အမှတ်- ၂/၂၀၁၅ကို ထုတ်ပြန်ခဲ့ပြီးဖြစ်သော်လည်း အဆိုပါစည်းမျဉ်း၊စည်းကမ်းများ (Technical Regulation for Export and Import of Fishery Products) ကို ပိုမိုပြည့်စုံကောင်းမွန်စေရန်နှင့် ခေတ်နှင့်လျော်ညီစေရန်အတွက် ကုန်သွယ်မှုဖွံ့ဖြိုးရေး အစီအမံ (Trade Development Program) အရ ဥရောပသမဂ္ဂ၏ ပံ့ပိုးကူညီမှုဖြင့် ပြန်လည်၍ ပြင်ဆင်ဖြည့်စွက်တည်းဖြတ်ခဲ့ပြီးဖြစ်ပါသည်။

၃။ သို့ဖြစ်ပါ၍ ရေထွက်ပစ္စည်းတင်ပို့/ တင်သွင်းသောလုပ်ငန်းရှင်များအနေဖြင့် ယခုညွှန်ကြားချက်ပါစည်းမျဉ်း၊စည်းကမ်းများအား ၂၀၁၉ ခုနှစ်၊ဧပြီလ (၁)ရက်နေ့မှ စ၍ လိုက်နာ ကျင့်သုံးဆောင်ရွက်ရန်နှင့် အဆိုပါနေ့ရက်မှစ၍ ညွှန်ကြားချက်အမှတ် - ၂/၂၀၁၅ ကို ဤ ညွှန်ကြားချက်ဖြင့် လွှမ်းမိုးပယ်ဖျက်လိုက်သည်။

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ခင်မောင်မော်

ညွှန်ကြားရေးမှူးချုပ်

ဖြန့်ဝေခြင်း

ရေထွက်ပစ္စည်းတင်ပို့/ တင်သွင်းသည့် လုပ်ငန်းရှင်များအားလုံး

စာအမှတ်၊ ငလ/နပတ-၅ / ၂၀၁၈ ( ၈၅၅၁ )

ရက်စွဲ၊ ၂၀၁၈ ခုနှစ်၊ ဒီဇင်ဘာလ ၅ ရက်

မိတ္တူကို-

- ပြည်ထောင်စုဝန်ကြီးရုံး၊ စိုက်ပျိုးရေး၊ မွေးမြူရေးနှင့် ဆည်မြောင်းဝန်ကြီးဌာန
- ဒုတိယညွှန်ကြားရေးမှူးချုပ်၊ ငါးလုပ်ငန်းဦးစီးဌာန
- ညွှန်ကြားရေးမှူးများ( )၊ ငါးလုပ်ငန်းဦးစီးဌာန
- ပြည်နယ်/ တိုင်းဒေသကြီးငါးလုပ်ငန်းဦးစီးဌာနမှူးများအားလုံး( )
- ဥက္ကဋ္ဌ၊ မြန်မာနိုင်ငံငါးလုပ်ငန်းအဖွဲ့ချုပ်
- ဥက္ကဋ္ဌ၊ မြန်မာနိုင်ငံရေထွက်ပစ္စည်းထုတ်လုပ်သူများနှင့် ပို့ကုန်လုပ်ငန်းရှင်များအသင်း
- ✓ - ရုံးလက်ခံ
- မျှော

# EXPORT REQUIREMENTS

# Chapter I - Legibility to Supply Raw Materials Intended for Export and to Export Fishery Products

## 1 Legibility to Supply and Operate in Export

### 1.1 Primary Production and Allied Areas

1. The primary production and allied areas include fishing vessels, aquaculture farms, ice factories, landing places, collection stations, auction places and hatcheries. Transporting vehicles under the control of, or used by, the primary producer, feed mills and feed and chemical distributors supplying primary producers are also allied areas to primary production. Suppliers of lime for aquaculture farms are not considered allied area.
2. The primary production and allied areas operating in the food chain meant for export shall
  - 2.1. Operate only on the basis of a valid license or registration for operation by the Department of Fisheries of the Ministry of Agriculture, Livestock and Irrigation of the Union of Myanmar or by the State or Region Department of Fisheries or other relevant authorities.
  - 2.2. Be responsible for ensuring the quality and food safety of the products they supply. To this end they shall comply with the hygiene requirements and food safety management principles stipulated in this technical regulation and, where relevant, with any additional requirement requested by specific export markets.
  - 2.3. Give access and offer full cooperation and necessary assistance to the NCA for the purpose of verifying the compliance with conditions stipulated in the chapters 2.1 and 2.2, as per Section 30 of the Myanmar Marine Fisheries Law of 25 April 1990.
3. Business operators in primary production and allied areas, which operate in the food chain intended for export to the EU Market, shall be Listed for that by the NCA, subject to compliance with Department of Fisheries Directive No 3/2009 of 3 April 2009. Such listing may exclude areas with no direct impact on food safety, e.g. lime supplies for aquaculture farms. The procedure for Listing and maintaining of such Listing shall be documented and implemented by the NCA, and informed to the business operator.

### 1.2 Processing Establishments and Allied Areas

Processing and allied activities are operations other than primary production and allied areas, which may include processing facilities, handling and storage in dry or wet warehouses, storage in cold store, freezer vessels and factory vessels. Transporting vehicles under the control of or used for transport of processed products are also to be considered allied areas to production.

1. The processing establishments allied areas operating in the food chain meant for export shall
  - 1.1. Operate only on the basis of a valid license by the NCA of Department of Fisheries of the Ministry of Agriculture, Livestock, and Irrigation of the Union of Myanmar.
  - 1.2. Ensure and be responsible that the food or feed of products produced in and distributed from the establishment are safe for the intended consumers, specifically the compliance with all requirements stipulated in the chapters 2.3-2.11 of this document and additional requirements of the markets which products are intended for.
  - 1.3. Give access to and cooperate with the NCA for inspection, audit, sampling and any other investigations deemed necessary to verify compliance with requirements stipulated in chapter 2.3-2.11 of this document and, where relevant, the also to verify compliance with requirements of the markets which the food business is Listed or Approved for.
2. For export to certain markets, the license may be conditional to further Listing or Approval for such markets, subject to conditions stipulated in chapter 3.2 of this document.
  - 2.1. Listing or Approval, conditional to compliance with specific market criteria, e.g. EU, Vietnam or China shall be established and announced by the NCA when such is required by the competent authority of that market. The term Approval is used only for food businesses allowed to export to EU and the term Listing is used for food businesses allowed to export to other markets where specific requirements apply.
  - 2.2. The NCA shall establish procedures for receiving and handling of applications for Listing or Approval according to the chapters 3.1-3.2 and keep the business operators informed about such procedures and related requirements.
3. The License for export and the related Listing(s) and Approval shall be valid for one year. The NCA shall establish procedures for renewal of the License and the related Listings and Approvals and keep the business operators informed about such procedures and related requirements.
4. The NCA may withdraw or suspend temporarily the permission to export to specific markets if the food business fail to comply with the required food hygiene and food safety and requirements. The NCA shall establish procedures and keep the business operators informed about such procedures and related requirements.
5. The NCA shall comply with requirements stipulated in chapter 3 of this technical regulation when conducting verification activities.

# Chapter II - Hygiene Requirements

## 2 General and Specific Hygiene Requirements

### 2.1 General Requirements – Primary Production and Allied Areas

1. Business operators shall maintain high level hygiene at all stages of production, harvest, storage and transport by minimizing the risk for contaminations from any sources and so to ensure the safety and quality of raw fishery products/feed.
2. Business operators shall ensure that the cold chain are maintained as necessary for control of food safety and or quality of the products.
3. Business operators in the aquaculture sector shall ensure that chemicals and veterinary medical products are used only in compliance with provisions of Department of Fisheries Directive No 2/2014 as amended by Department of Fisheries Directive 1/2017).
4. Business operators of the primary production area shall ensure that the staff do not carry diseases that may be transferred to other humans with the food.
5. Business operators shall conduct regular training to their employees for maintaining personal hygiene and hygiene and food safety conditions in the facilities.
6. Business operators of primary production and allied operations shall maintain and document traceability of all input and output related with their production of food. For this purpose, records of production, harvest/landing, sale, cleaning and sanitation, pond management, use of chemicals, veterinary medicines and feed and treatment of diseases, shall be maintained and made available to the NCA at any time and request.

### 2.2 Specific Requirements – Primary Production and Allied Areas

#### 2.2.1 Hatcheries

- 2.2.1.1 Hatcheries shall have a valid license by the State/Regional Department of Fisheries in reference to Department of Fisheries Notification no. 5/1989 of 28 December 1989.
- 2.2.1.2 Hatcheries shall apply Good Aquaculture Practices in reference to the “Guidelines on ASEAN Good Aquaculture Practices (ASEAN GAqP) for Food Fish”.
- 2.2.1.3 Hatchery operators shall have documented procedures for cleaning and sanitation and maintain records for all operations and keep traceability to all inputs and outputs, including the movements of aquaculture animals.

## 2.2.2 Aquaculture Farms

- 2.2.2.1 Aquaculture farms shall have a valid license by State/Regional Department of Fisheries in reference to Department of Fisheries Notification no. 5/1989 of 28 December 1989.
- 2.2.2.2 While selecting the site for aquaculture farming it shall be ensured that construction of the farm shall not disturb the ecosystem and natural habitats of that locality and undesirable pollutants/chemicals from nearby areas do not contaminate the farm. Prevent the entry of unwanted species into the ponds by screening inlet and outlet of water. The percolation rate / porosity of soil of the pond shall be low enough to hold the pond water satisfactorily. The ponds should be free from harmful chemical and natural pollutants. Quality and chemical composition of water shall be species specific.
- 2.2.2.3 Good Aquaculture Practices (GAqP) shall be adopted at all stages of production to ensure the quality and safety of the aquaculture animals. Farms may adopt international code of practices like OIE's 'Aquatic Animal Health Code' and/or the ASEAN "Guidelines on ASEAN Good Aquaculture Practices (ASEAN GAqP) for Food Fish" to minimize risk for microorganisms that are pathogenic to humans and or aquatic animals.
- 2.2.2.4 The farm shall receive inputs including feed, feed supplements, veterinary medical products and other chemicals, only from suppliers with a valid registration/license to distribute such products. The composition of all inputs must be known, preferably through technical data sheets from the supplier. The farm shall maintain proper stock /utilization register of all inputs and out puts.
- 2.2.2.5 Only inputs allowed to be used in aquaculture shall be stored. All inputs shall be stored and used according to the instructions given by the supplier, either in the label or in related technical data sheets. The storage area shall be clean and neat and maintained properly to avoid contamination. Responsible person for receiving, storage and utilisation of inputs shall be identified.
- 2.2.2.6 Larvae, fingerlings etc. shall be procured only from hatcheries licensed by state and Region Department of Fisheries, after ensuring that they are free from diseases, harmful chemicals and pharmacologically active substances. Proper traceability shall be maintained for all movements of aquaculture animals in and out of the farm.
- 2.2.2.7 Proper water management system shall be introduced to ensure the quality of water. Suitable water filtration system shall be established to minimize risk for organic impurities and pathogenic bacteria. Water shall be tested for presence of pathogenic bacteria, primarily salmonella on a risk based frequency and on request from buyers.
- 2.2.2.8 Waste shall be disposed in a suitable manner to avoid cross contamination. Chemical wastes and non- biodegradable wastes shall be disposed of as per supplier instructions and legal requirement of the relevant City Development Committee or General Administration Departments of State or Regional Ministries.

- 2.2.2.9 Adequate cleaning & sanitation shall be done at all areas of the farm, including machineries and equipment's to minimize the risk for contamination. Employee shall strictly adhere to personnel hygiene practices as applicable for the type of work.
- 2.2.2.10 Chemicals and veterinary medical products may be stored and used in the farm only if they are authorized for aquaculture by Livestock Breeding and Veterinary of Ministry of Agriculture Livestock and Irrigation.
- 2.2.2.11 Withdrawal times for authorized pharmacological active substances shall be at least 500 degree days if not otherwise stipulated for specific products. The input and output records shall be maintained so to document adequate withdrawal times.
- 2.2.2.12 Monitoring shall be done to ascertain the health status of aquatic animals, their movements within the farm, mortality rates and the presence of exotic and non-exotic diseases and records maintained. Information regarding the emerging diseases and actions taken to prevent their potential spreading shall be immediately communicated to Aquaculture Division of Union Department of Fisheries.
- 2.2.2.13 Only aquaculture animals which have reached commercial size and which show no clinical sign of disease may be harvested for distribution as food for human consumption.
- 2.2.2.14 Harvesting shall take place to minimise the risk for contamination of the fish with soil, dust and other environmental contaminants and so the fish is not subject to unduly high temperatures. Immediately after harvest the fish shall be placed in designated clean facilities, protected from contamination and mixed with ice made from clean or potable water or a mix of ice and clean water sufficient to cool the fish to temperature below 4°C.
- 2.2.2.15 Where fish is beheaded and /or gutted before transport, such operations must be carried out hygienically under conditions stipulated in the sections 2.2.5.3-2.2.5.20 and the products must be washed immediately and thoroughly with potable water or clean water.
- 2.2.2.16 Fish intended to be transported alive after harvest shall be kept under conditions that do not affect their viability.
- 2.2.2.17 The farm shall have a documented procedure for the application of Good Aquaculture Practices. The farm shall maintain records as necessary to document traceability of animals including records of all inputs used for the rearing and all outputs from the rearing. Maintaining of GAqP shall be documented through records on pond management, water management, stocking, feed management, chemicals and veterinary medical products managing, mortality, disease investigations, cleaning of equipment, harvesting and transport of fish.



## 2.2.3 Feed Mills and Feed Distribution

- 2.2.3.1 Feed Mills shall have a valid license by the State/Regional Department of Fisheries in reference to Department of Fisheries Notification no. 5/1989 of 28 December 1989.
- 2.2.3.2 Feed mills shall ensure that their products do not contain ingredient, additives or contaminants which may be a source of un-acceptable contamination of the farmed aquatic animals. Therefore, feed mills shall implement Good Manufacturing Practices (GMP), a HACCP based control systems and specifically comply with the following basic requirements.
- 2.2.3.3 Feed mill facilities shall be kept clean and shall have defined curtilage. The factory shall be housed in a building of permanent nature affording sufficient protection from the environment and shall be of sufficient size for the work to be carried out under hygienic conditions.
- 2.2.3.4 The design and layout shall be such as to preclude contamination. The layout of different sections shall be such as to facilitate smooth and orderly flow of work and to prevent possible cross contamination and backtracking.
- 2.2.3.5 Change room(s) with adequate facilities shall be provided for workers and suitable facilities for washing hands shall be provided for workers at entry points.
- 2.2.3.6 Utensils, machineries, conveyors, mills, aspirators, screeners, mixers and other feed contact surfaces shall be smooth, clean and maintained in good hygienic condition to avoid contamination of the feed. Sieves, screens, filters, separators and mixers shall be regularly checked for damages, cleanliness and their effective operation.
- 2.2.3.7 Separate storage facilities shall be provided for storing incoming materials, finished products and also packing materials hygienically. Storage areas shall be hygienically maintained and shall be free from moisture, dust, vermin and birds. Medicated feeding stuff, premix and feed additives shall be stored in suitable, separate and secured rooms or hermetic containers with proper labelling and traceability records on a first in - first out basis. Only authorised person shall have access to these stores. Proper records of storage, with details of incoming and outgoing materials shall be maintained by a responsible person.
- 2.2.3.8 Waste shall be collected promptly and, or stored in dedicated waste containers away from incoming raw material and finished product storage areas and shall be disposed of legally in accordance with the National Environmental Quality (Emission) Guidelines.
- 2.2.3.9 Suitable pest control measures shall be taken to prevent the entry of flies, rodents, lizards etc. into the premises as specified at chapter 2.7.4
- 2.2.3.10 A HACCP based Feed Safety Management System shall be implemented. Critical Control Points shall be monitored on a laid down frequency and in case of deviation, corrective action shall be taken promptly. Traceability of incoming materials and finished products shall be established from the source. Recall procedures shall be

developed to address customer complaints. Control of carry over shall be addressed within the HACCP study.

- 2.2.3.11 Specifications on quality and food/feed safety parameters for incoming ingredients, feed additives, pre-mixtures, and finished products shall be developed and effective quality control to document compliance shall be established.
- 2.2.3.12 Chemicals and pharmacological active substances banned for use in aquaculture products by Department of Fisheries shall not be accepted in any ingredient, pre-mixture or additive.
- 2.2.3.13 Chemicals and pharmacological active substances allowed for use in aquaculture products by Department of Fisheries shall be clearly labelled on the product and on related technical Data Sheet, whether added directly or carried over from other ingredients or pre-mixtures.
- 2.2.3.14 Feed shall comply with criteria stipulated by Department of Fisheries, as regard the content of aflatoxin at the time of distribution.
- 2.2.3.15 A well-documented, effective cleaning and sanitation programme shall be developed and implemented as per the laid down frequency.
- 2.2.3.16 A written procedure shall be developed to ensure regular cleaning of cooler. If air is used for conveying or cooling, it should be checked for microbial contamination. Pelleting conditions must be assessed to ensure stability of the feed additives.
- 2.2.3.17 Employees shall adopt adequate hygiene practices and wear clean protective clothes. The requirements specified at chapter 2.7.2, may be implemented, as applicable.
- 2.2.3.18 Internal audits shall be performed at least once in a year to establish that the HACCP is in place and all the control systems are effective to produce safe feed products.
- 2.2.3.19 Well documented internal standards, specifications, operating procedures etc. shall be developed as a part of the HACCP based Feed Safety Management System. Records pertaining to documentation of monitoring of critical control points, hygiene and sanitation, personal hygiene, pest control, calibration, traceability, training, incoming and outgoing material, stock register, carry over etc. shall be maintained in a way that allows for traceability.
- 2.2.3.20 The labelling of compound feed intended for aquaculture animals shall include at least:
  - a. Commercial Name and unique product code (if it exist)
  - b. Type of feed (“complete” or “complementary”) and target aquatic animal (for example indicated as “complete feed for freshwater fish”)
  - c. Registration number or other unique ID number and name and address of the feed business operator under which name the feed is placed on the market.
  - d. Name and address of the feed business operator that imported/placed the product on the market (where relevant)

- e. Batch or lot reference number
- f. Net quantity per package unit
- g. General instructions for proper use
- h. The minimum storage life indicated as “use before date” or “best before date”
- i. Composition by feed ingredients (materials) in descending order
- j. Feed additives expressed in amount per kg or amount per liter
- k. If any pharmacological active substance is included in the compound feed, the functional substance(s) and the content of the substance shall be clearly indicated on the label.

2.2.3.21 Imported feed shall be labelled as indicated in section 2.2.3.20 and additionally be provided with:

- a. Information about the Importer name and address and, when necessary, a translation of the information on the label to Myanmar or English language.
- b. Information about its approval/listing by the competent authority of the country in which the feed is produced. This information may be provided in separate document if not directly on the label.

## 2.2.4 Fishing Vessels

- 2.2.4.1 Vessels must be designed and constructed so as to avoid contamination of fishery products with bilge water, sewage, smoke, fuel, oil, grease or other objectionable substances.
- 2.2.4.2 Surfaces that come in contact with fishery products must be made of suitable corrosion-resistant material that is smooth, non-toxic and easy to clean.
- 2.2.4.3 Vessels designed and equipped to preserve fresh fishery products for more than 24 hours shall be equipped with holds, tanks or containers for the storage of fishery products at a temperature approaching that of melting ice. These holds shall be separated from the machinery space and the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products. Melt water shall be drained away from fishery products.
- 2.2.4.4 In vessels equipped for chilling fishery products by cooled clean seawater, tanks must be fitted with devices for temperature monitoring in the tanks. The system shall ensure that the mix of fish and clean seawater reaches not more than 3°C six hours after loading and not more than 0°C after 16 hours.
- 2.2.4.5 Equipment's and material used for working fishery products shall be made of corrosion resistant material that is easy to clean and disinfect
- 2.2.4.6 Vessels shall be equipped with facilities that allow crew to wash hands when necessary prior to handling the catch.
- 2.2.4.7 The fish receiving deck shall be smooth, clean and free from engine oil, grease, etc.

- 2.2.4.8 Utmost care shall be taken while catching/ storing/handling of fish to avoid injury or physical damage. Fish should be handled hygienically to avoid contamination at all stages.
- 2.2.4.9 The fishery products should be loaded onto the vessel on a clean surface where risk for contamination with oil, grease and other dirt is minimized. After taken on board, fishery products shall undergo chilling as soon as possible. Ice used for chilling shall be clean and made up of potable water or clean water and kept under clean conditions. Fishery products shall at all times be protected from contamination and from the effect of sun and other sources of heat, when on board the vessel.
- 2.2.4.10 Where fish is beheaded and /or gutted on board, such operations must be carried out hygienically and the products must be washed immediately and thoroughly with potable water or clean seawater.
- 2.2.4.11 Staff assigned for handling of fishery products shall be trained in good handling practices as relevant for the type of vessel and species and they shall be required to maintain a high standard of personal cleanliness. Persons liable to contaminate fishery products due to illness or poor personal hygiene shall not be permitted to handle the products.
- 2.2.4.12 When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in good repair and condition.
- 2.2.4.13 The vessel shall keep records of catches and landings/transfers which allow traceability to the date(s), amount and type of fish caught and transferred/landed.
- 2.2.4.14 The vessel shall demonstrate the effective implementation of SSOPs for pest control, waste disposal, cleaning and sanitation, personal hygiene and GMP for use of sulphites where relevant.
- 2.2.4.15 Carrier vessels shall comply with provisions in points 2.2.4.2 – 2.2.4.7, 2.2.4.9, and 2.2.4.11 - 2.2.4.14.
- 2.2.4.16 Carrier vessels shall not do any other activities than transport, ensuring chilling by ice or refrigeration.

## **2.2.5 Landing Sites and Collection Stations**

- 2.2.5.1 The Landing Sites/Fishing Harbours of fish and fishery products shall be located at a site ideal for the purpose and shall be free from undesirable smoke, dust, other pollutants and stagnant water.
- 2.2.5.2 The layout and design of a landing site shall be so it can be ensured that fishery products are protected from contamination from the environment, such as dirty water, soil, sun light, rain, wind, dust, birds and pest etc. during and after the landing. Adequate working space shall be provided for hygienic handling of fishery products.

- 2.2.5.3 Landing sites operating also a collection stations shall comply with hygiene criteria stipulated in sections 2.2.5.4 - 2.2.5.10.
- 2.2.5.4 Collection stations, carrying out operations such as sorting and re-icing, shall have facilities that allow for hygienic handling and where necessary storage of the products under cool conditions. Floors and walls (if any) shall be smooth and easy to clean and sanitize. The floor shall not allow for stagnant water and have sufficient slope for proper removal waste water through drainage so not to be a risk for contamination of the products. Artificial lighting sufficient for the type of handling shall be provided and the lights shall be protected with suitable covering.
- 2.2.5.5 Adequate quantity of potable water or clean sea water shall be available for cleaning and sanitation.
- 2.2.5.6 Collection stations shall have access to sufficient quantity of ice made of potable water or clean sea water and provision for hygienic handling and storing of the ice.
- 2.2.5.7 The utensils & equipment used to handle fish and fishery products shall be smooth and made of corrosion free, easy to clean and disinfect materials, and kept in a good state of repair and cleanliness.
- 2.2.5.8 Collection stations shall be maintained hygienically. Cleaning and sanitation shall be implemented at all areas on a laid down frequency to minimize the risk for cross contamination. Proper waste management shall be adopted to remove solid and liquid wastes immediately after its formation so as to avoid cross contamination.
- 2.2.5.9 Collection Stations shall take suitable measures to ensure the risk related with pests inside the area of operation, including elimination of shelters and attractants of pest in the surroundings. Records of pest control activities shall be maintained for verification
- 2.2.5.10 Workers on collection stations shall adopt personal hygiene practices to avoid contamination of fishery products. There shall be sanitary facilities at appropriate places for hand washing with sufficient number of washbasins, soap, disinfectants and single use hand towels. Appropriate number of flush lavatories shall also be provided outside the collection station.
- 2.2.5.11 Collection Stations shall maintain a record system that allow for traceability to all incoming materials at least by species, amounts, vessel and date and to all buyers by company name, address, species, date and amount.

## 2.2.6 Auction

- 2.2.6.1 Auction facilities used for the display and sale of fishery products shall be well protected from the entry of dust, pests/insects and other contaminants
- 2.2.6.2 Raised platforms, tables or similar facilities which are smooth, easy to clean and disinfect shall be provided for handling and display of fishery products.

- 2.2.6.3 Vehicles emitting exhaust fumes shall not operate in the fish handling area. Vehicles in immediate vicinity of the fish handling area shall not operate engines emitting exhaust fumes.
- 2.2.6.4 The premises and all the surfaces that come in contact with fishery products shall be cleaned before and after each sale. The crates/utensils shall also be cleaned and rinsed inside and outside with potable water or clean water and disinfected before use. Workers engaged in handling fishery products shall maintain highest degree of cleanliness. They shall wash hands properly before and after handling fishery products, ice and food contact surfaces.
- 2.2.6.5 Fish and fishery products shall be properly iced using good quality ice made up of potable water, compliant with provisions of section 2.7.3 of this regulation, so as to maintain the core temperature of fishery products below 4°C. Refrigerated room of adequate size for storing fishery products may be provided, if required.
- 2.2.6.6 Sign boards prohibiting smoking, spitting, eating, drinking etc. inside the auction area shall be exhibited at prominent positions. Unauthorized person(s) shall not be permitted to enter into the auction area.
- 2.2.6.7 Separate area may be earmarked for storage of fishery products which are unfit for human consumption. Cleaning and sanitation chemicals shall be stored in separate lockable cupboards with proper labelling for identification.
- 2.2.6.8 A person shall be assigned to be responsible for the auction area and shall conduct random checking of fishery products meant for export for organoleptic factors, including the core temperature to ensure chilling of fishery products below 4°C and records maintained.
- 2.2.6.9 Clean sea water or clean water used for cleaning of fishery products/ food contact surfaces. The water shall be sampled and tested as deemed necessary to document compliance with criteria as stipulated in section 2.5.3.
- 2.2.6.10 The auction shall maintain a record system that allow for traceability to all incoming materials at least by species, amounts, vessel and date and to all buyers by company name, address, species, date and amount.
- 2.2.6.11 The auction hall shall have a Food Safety Management system that identify food safety hazards and control measures relevant for the operation, and all related hygiene procedures and controls shall be documented.

## 2.3 General Requirements - Processing and Allied Areas

1. Business operators shall ensure that practices for documenting of purchasing, operation, monitoring, labelling, distribution and record keeping are established and implemented in a way which allow for traceability to all incoming and outgoing materials at any time when the product may be available on the market.
2. If a business operator considers or has reason to believe that a product placed on the market under his/her responsibility is not in compliance with the requirements in this

document he/she shall immediately inform the NCA and initiate measures to withdraw the affected product(s) from the market. The business operator shall allow the NCA full access to facilities, staff and documents and cooperated in all actions to minimize any risk from the food.

3. Business operators shall obtain Health Certificates from NCA, as per the requirement of an import country, or the NCA before the departure of each consignment. The NCA shall establish procedures and keep the business operators informed about such procedures and related requirements.

## 2.4 Requirements to Infrastructure - Processing and Allied Areas

### 2.4.1 Processing Facilities

- 2.4.1.1 The surroundings of the factory shall be free from objectionable odours, smokes, dust and other contaminants. It shall be maintained clean without stagnant water or garbage accumulation. The establishment shall be housed in a building of permanent nature affording sufficient protection from the environment and shall be of sufficient size for the work to be carried out under hygienic conditions. The design and layout shall be such as to preclude contamination. Immediate surroundings of the building shall be with hard surfaces to avoid pest and windblown dust.
- 2.4.1.2 The layout of different sections shall be such as to facilitate smooth and orderly flow of work and to prevent possible cross contamination and backtracking. All the fish handling areas shall be separate from areas used for residential purpose. There shall be adequate lighting and ventilation and light fixtures shall be protected with proper covering. The layout shall ensure sufficient space in different sections for machinery, equipment, personnel etc. without congestion. The building shall provide sufficient protection against the entry and harbourage of rodent, insects, birds etc. Non –operative areas inside the establishment, if any, shall be properly cordoned off to avoid possible cross- contamination
- 2.4.1.3 The floor of fish handling areas shall be smooth, impermeable and easy to clean and disinfect. There shall be no water stagnation on the floor. The floor shall have sufficient slope opposite to the flow of work or sideways. The wall to floor and wall-to-wall junctions shall be rounded off to facilitate easy cleaning. The walls should be durable, smooth, light coloured and easy to clean and disinfect. The ceiling shall be free from cracks and open joints and shall be smooth and easy to clean.
- 2.4.1.4 There shall be adequate drainage facility and slope of the drainage shall be opposite to the flow of work/ material. The drains shall be of adequate size having sufficient slope for easy cleaning.
- 2.4.1.5 The doors shall be tight fitting to prevent the entry of flies. All doors and windows shall be durable and made of corrosion resistant material and windowsills, if any, shall be sloped inwards. The windows/ ventilators opening to the outside shall be

constructed with fly proofing nets to prevent the entry of flies. Mechanical ventilation/exhaust fans shall be provided in areas of air stagnation.

- 2.4.1.6 All the entry points shall have suitable arrangements to prevent the entry of flies/dust. Suitable washing and sanitizing facilities for hands shall be provided at the entry points. Hand washing facilities such as non-hand operated wash basin, liquid soap, nail brush, disinfectants, hand drying facilities shall be provided. Foot baths shall be provided and maintained with disinfection solution to ensure disinfection of boots at entrance to processing areas, where it is deemed necessary for maintaining of food safety.
- 2.4.1.7 All utensils and equipment in contact with food shall be made of non-corrodible food grade materials. Surfaces in contact with food shall be smooth without cracks and crevices and easy to clean and disinfect. Separate colour codes shall be given for utensils/crates/tubs using in the high risk areas to avoid cross contamination.
- 2.4.1.8 Adequate number of change rooms for workers of suitable size having smooth, washable walls and floors shall be provided depending upon the quantum of production and number of workers at duty at the same time. Change room shall have hygienic facilities for changing to the protective clothes and hygienic toilet facilities. There shall be lockable cupboards and facility for keeping gumboots, shoes and uniforms inside the change room.
- 2.4.1.9 Employees shall wear protective clothes only inside the processing establishment. Laundry facilities which ensure that protective clothes are effectively cleaned, dried and kept under conditions so minimize risk for contamination shall be available. Employees shall not be allowed to bring protective clothes outside the processing facility.
- 2.4.1.10 Chill rooms with mechanical refrigeration system to maintain temperature at level (0°C to 4°C) or adequate number of insulated boxes with ice shall be provided for storing fishery products as deemed necessary to keep the raw materials and intermediate products at temperature approaching that of melting ice.
- 2.4.1.11 Freezers shall have sufficient capacity to bring the core temperature of the products to -18°C as quickly as possible and at least within 5-6 hours.
- 2.4.1.12 Establishments processing frozen fishery products shall ensure that the products are placed and kept in cold storage having suitable capacity to maintain the product temperature below -18°C. External cold stores may be used only if Listed or Approved by the NCA and if the business operator achieve documentation that the temperature of products is maintained at -18°C or below.
- 2.4.1.13 Solid wastes shall be collected in identifiable containers/bags designated for the purpose and shall be stored so it is not a source of contamination to the products or the environment. Solid waste shall be disposed of as soon as possible.
- 2.4.1.14 A stable and sufficient supply of water compliant with the requirements referred to in chapter 2.7.3 of this document shall be ensured at all places necessary for the



operations. For this purpose the water supply system may include suitable water purification and disinfection system. The water supply system shall be designed so to minimise the risk for backflow in the pipe system and the taps shall be fitted with non-return valves to avoid back flow of water. Water storage tanks shall be protected from dust, pest by covering with lockable lids and the tanks shall be cleaned on a laid down frequency.

- 2.4.1.15 Plumbing diagrams showing the entire reticulation of the water, identifying each tap with consecutive numbers shall be established and maintained.
- 2.4.1.16 Water not intended for contact with food and food contact surfaces (e.g. for cooling, steam productions etc.) shall be distributed in separate well identified plumbing systems.
- 2.4.1.17 If the ice plant is not integrated to main establishment, it shall be Listed by the NCA separately.
- 2.4.1.18 There shall be separate stores for wet and dry items and the chemicals/ disinfectants should be properly labelled. Packing material store shall be of adequate size with proper fly and dust proofing system. Cartons shall be kept on cleanable pallets away from the walls and covered properly.
- 2.4.1.19 The establishment may have a well-equipped in house laboratory for testing microbiological and other chemical parameters or can test their products in government laboratories.

## **2.4.2 Freezer Vessels and Factory Vessels**

- 2.4.2.1 Freezer vessels/ Factory vessels shall have infrastructure/hygiene requirements in additions to those specified for fishing vessels section 2.2.4 of this regulation, as applicable.
- 2.4.2.2 Vessels shall be equipped with freezing equipment(s) which can achieve core temperature of fish not more than -18°C rapidly.
- 2.4.2.3 Vessels shall be equipped with a cold storage of sufficient capacity to maintain a temperature of not more than -18°C and the store shall be fitted with a temperature recording device. If EU approved vessel, the device shall comply with EN 12830, EN 13485 and EN 13486 standards. The sensor of the device shall be at the warmest area of the store.
- 2.4.2.4 Whole fishes intended for canning only, may be frozen in brine to fish core temperature at least -9°C. The brine used shall be free from contamination.
- 2.4.2.5 Change rooms and hand washing facilities shall be provided at a convenient area.
- 2.4.2.6 Separate area for processing fishery products shall be available, which is sufficiently large for hygienic operation and easy to clean and disinfect. All the utensils and

equipment shall be made of food grade, non-corrodible material and shall be smooth without cracks and crevices and easy to clean and disinfect.

- 2.4.2.7 In factory vessels a separate raw material receiving area shall be identified to receive each fish catch separately. The receiving area shall be kept clean and well protected from environmental hazards and pests. Suitable hygienic system shall be in place to transfer the fish from receiving area to fish processing area
- 2.4.2.8 The processing and storage areas of factory vessel shall be sufficiently large for hygienic handling and storing fishery products. If a waste processing unit is operating on board, that should be well separated from processing areas to avoid cross contamination and the hold must be designed for the storage of such waste separately. Packing materials shall be stored separately in a clean area.
- 2.4.2.9 Factory vessels processing cooked products, shall not process raw products or waste products in the same areas.
- 2.4.2.10 Sufficient quantity of ice made up of potable water or clean sea water shall be made available for chilling fishery products.
- 2.4.2.11 Proper hygiene and sanitation shall be maintained at all stages of production and the workers shall implement strict personal hygiene practices to avoid contamination.

### **2.4.3 Independent Ice Production and Storage Facilities**

- 2.4.3.1 Ice shall at all times be handled as food and as such be protected from contamination from air, dust, soil and any other poor hygiene practice.
- 2.4.3.2 The infrastructure and hygiene requirements specified in section 2.4.1 applies to ice production and storage where applicable; the requirements in clause 2.4.1.1), 2.4.1.5, 2.4.1.6, 2.4.1.7, 2.4.1.3; 2.4.1.4 and 2.4.1.5 shall always apply to ice producers.
- 2.4.3.3 The ice factory shall establish and implement a food safety management system including at least all procedures and records pertaining to cleaning and sanitation of all facilities, personal hygiene, staff training, control of water, and amounts supplied to different operators.

### **2.4.4 Independent Cold Storage Facilities**

- 2.4.4.1 The surroundings shall be reasonably free from objectionable odors, smoke, dust and other contaminants. The refrigerated storages shall be housed in a building of permanent nature affording sufficient protection from the environment and shall be of sufficient size for the work to be carried out under hygienic conditions. The design and layout shall be such as to preclude contamination.
- 2.4.4.2 Good Hygiene practices shall be applied.
- 2.4.4.3 In cold storages, ante-room with suitable size having smooth walls, floor and roof shall be provided, the door of which shall be made of non-absorbent material and

fitted with air curtain / strip curtains. There shall be suitable mechanism to prevent condensation of water inside ante room. Suitable provisions for loading and unloading the cargo hygienically without causing temperature fluctuation shall be provided.

- 2.4.4.4 Cold storages shall have refrigeration system with sufficient capacity to maintain the temperature around product at -18°C or below and equipment and practices for storage of the products shall allow for efficient circulation of the cold air around products in the whole room.
- 2.4.4.5 It shall be ensured that during defrosting, variation in temperature is minimal and the period is short so as to avoid temperature abuse of the products.
- 2.4.4.6 The cold store shall have an automatic temperature recording device with a temperature sensor which shall be located at the warmest place in the cold storage. Cold stores Approved for EU market, shall have an automatic recording device (data logger), which comply with EN 12830 standard to monitor the air temperature in cold store. Thermometers and recording devices used for monitoring in the cold store shall be verified periodically according to EN 13486.
- 2.4.4.7 Chill rooms for storing chilled fishery products shall have a refrigeration system sufficient to maintain the product temperature at 4°C or below.
- 2.4.4.8 Cold Stores shall have a documented Food Safety Management System adequate to their operations. The system shall include at least procedures and record keeping pertaining to Good Manufacturing Practices, cleaning and sanitation, details of loading, unloading and storage of products (for traceability purposes), store temperatures, and calibration of temperature measuring devices and records of actions taken in cases of non-compliance with temperature requirements.
- 2.4.4.9 Cold storages shall ensure that products received for storage are at least -18°C when entering the cold store.
- 2.4.4.10 Temperature recording shall be dated and stored for a period of at least two years, or for a longer period taking into account the nature and the shelf life of the quick-frozen foodstuffs.

## 2.5 HACCP Based Control Systems – Processing and Allied Areas

1. Food business shall control food safety hazards that are reasonably likely to occur in the operation through developing and implementing a HACCP based own check system following at least the ASEAN General Principles of Food Hygiene including the clauses 2a – 2.j below.
2. Pre-requisite programs shall be documented and implemented at least for
  - a. Good Manufacturing Practices
  - b. Control of Raw material supplies

- c. Control of Water and Ice
  - d. Control of contamination from food contact surfaces
  - e. Prevention of cross contamination
  - f. Personal Hygiene
  - g. Employee health
  - h. Control of contamination of pests
  - i. Control of toxic compounds (chemicals)
  - j. Control of packaging materials
3. The Prerequisite Programs shall be documented as adequate for the operation and monitoring and verification shall be defined and implemented, as necessary to ensure the continued control of hygiene conditions.
  4. The seven principles of HACCP shall be applied, documented and implemented as adequate for the operation. The principles are:
    - PRINCIPLE 1: Conduct a hazard analysis.
    - PRINCIPLE 2: Determine the Critical Control Points (CCPs).
    - PRINCIPLE 3: Establish critical limit(s).
    - PRINCIPLE 4: Establish a system to monitor control of the CCP.
    - PRINCIPLE 5: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
    - PRINCIPLE 6: Establish procedures for verification to confirm that the HACCP system is working effectively.
    - PRINCIPLE 7: Establish documentation concerning all procedures and records appropriate to these principles and their application.
  5. Business operator shall ensure that the HACCP system is developed, implemented and maintained under personal with adequate knowledge to identify the hazards and related control measures as they may be applied in the whole organization. The personal shall be understood as the HACCP Team Leader and the HACCP Team.
  6. Business operator shall maintain all the HACCP records including CCP monitoring, corrective action records, verification records, production records, testing records, cleaning and sanitation records, validation records, calibration records, temperature records, review and audit reports etc. for a period as least as long as products may on the market. The records shall be available for verification by NCA at any time.
  7. Business operators shall organize record keeping so they for all products produced allow for traceability to supplier(s) of input and to buyer of the product.
  8. The business operator shall review the HACCP system to verify that it is adequate to control food safety hazards that are reasonably likely to occur at least once in a year and in case of any change in the product/process/ source of raw material or in case of food safety relate complaints from customers. The records of reviews shall be maintained for verification.

9. Business Operator shall ensure that internal audits covering all areas of Sanitation Standard Operating Procedure (SSOP), Good Manufacturing Practices (GMP) and HACCP are conducted at least once in a year.
10. The business operator shall ensure that the NCA has an updated version of the HACCP system documentation. Any deviation in the products produced, process flow changes that influence on the identification of the CCPs shall be brought to the notice of the competent authority immediately.

## 2.6 Product Control – Processing and Allied Areas

### 2.6.1 Raw Material Control

- 2.6.1.1 Business operator shall take utmost care to ensure the quality and safety of all raw materials used for processing.
- 2.6.1.2 A specification for the raw materials shall be agreed with or communicated to the supplier, including at least:
  - a. For fish raw materials, the raw material specification shall include quality criteria typical for the species, temperature criteria at receiving and agreements on hygiene criteria for harvest/landing and transport where such activities are not under the control of the business operator.
  - b. For raw materials from aquaculture, the raw materials specification shall also include provisions for accepting raw materials only from farms that:
    - i. Commit to comply with the regulation on use of veterinary medicines and other chemicals, as per requirements in section 2.6.3.
    - ii. Commit to supply only fish that have no visual signs of diseases.
  - c. The specification for other inputs shall be provided by the supplier and include information about ingredients, information about content of any food additives by name and number according to international harmonised system (E-number or INS-number), and information about storage conditions and use where adequate.
- 2.6.1.3 Traceability to raw material shall be maintained by both of the business operators.
- 2.6.1.4 Business operator shall ensure that fish raw materials are washed with clean water, and that chilling to at least +4°C is initiated immediately after catch or harvest of the raw material. Transportation of fish raw materials shall be done in clean vehicles in clean and properly covered containers.
- 2.6.1.5 Receiving control shall be conducted before accepting the raw material for further processing. The receiving control shall at least include organoleptic evaluation against the specification by a qualified/ experienced employee of the factory. The organoleptic evaluation shall include also assessment of visual signs for diseases.

Sampling for verification or monitoring under the HACCP system may be done on a laid down frequency specified in the HACCP Plan. The sample size shall be documented.

## 2.6.2 Final Product Control – Processing and Allied Areas

2.6.2.1 Under the HACCP system, the food business shall document sampling and testing of final products and raw materials to document compliance with specific food safety requirements of the importing countries. The NCA shall ensure that updated information about requirements of major import markets are available to the business. Annex 3 and 4 of this document provides guidance on sampling and testing where no specific market requirements apply.

1. **Organoleptic evaluation** shall ascertain the freshness of the product before export. If organoleptic evaluation of raw material/ finished products reveals any doubt as to the freshness of fishery products, the same shall be tested for total volatile basic nitrogen (TVB-N) or trimethylamine nitrogen (TMA-N) as specified in Department of Fisheries Directive No 3/2009 of 3 April 2009.
2. **Parasite Check:** Business operators shall ensure that fishery products have been subjected to visual examination and of removal of visible parasites before or during processing, as envisaged in Department of Fisheries Directive No 3/2009 of 3 April 2009.
  - i. Processors should make every effort to achieve parasite check through a non-destructive examination of fish and fishery products during processing by qualified personnel. The checking shall be performed under good light conditions, when adequate, by using candling.
  - ii. When processing conditions do not allow for the examination of each individual fish, the processor must develop a sampling plan for each batch of processed fish. The sampling plan for mechanically eviscerated fish must include a representative number of samples of not less than 10 fish per batch.
3. **Histamine:** Business operators shall ensure that the HACCP system monitoring and verification document compliance with requirements in Department of Fisheries Directive No 3/2009 dated 3 April 2009.
4. **Microbiological criteria:** As a part of verification procedure, fishery products meant for export shall be tested on a laid down frequency to document that microbiological hazards are controlled and, that the product comply with specific market or customer criteria.
5. **Contaminants, residues and other chemicals:** As a part of verification the procedure, fishery products meant for export shall be tested on a laid down frequency to document that environmental contaminants, residues of veterinary

medicines, and additives are controlled as foreseen in the HACCP Plan, and that the product comply with specific market or customer criteria.

## **2.6.3 Special Requirements for Export of Aquaculture Products**

In addition to provisions in section 2.6.2, the following requirements apply for export of products with origin from aquaculture:

- 2.6.3.1 Establishments intending to process aquaculture products meant for export shall have a specific approval given by the National Competent Authority based on their supply of raw materials as specified in section 2.6.3.2.
- 2.6.3.2 Establishments shall export aquaculture products only from raw materials procured from farms Listed and monitored by National Competent Authority.
- 2.6.3.3 Processing facilities shall accept raw materials from aquaculture only after ensuring that the animals have not undergone illegal treatments and, if allowed treatment has been done, that withdrawal period according to section 2.2.2.11 is adhered to. Records of traceability pertaining to each lot of raw material shall be maintained by the establishment.
- 2.6.3.4 Under the HACCP System, business operators shall conduct regular audits of the farms from where they procure aquaculture products to verify that the farms are following Good Aquaculture Practices (GAqP) specifically that they comply with legal requirements as regard are use of veterinary medicines and other chemicals. They shall maintain audit reports for verification by the NCA.

## **2.6.4 Additives and Ingredients**

- 2.6.4.1 Additives and ingredients shall be controlled as per requirements in section 2.6.1.c and the business operator shall further ensure that the additives used are allowed for the type of product on the intended market and shall obtain documentation for such requirements from liable sources, e.g. legislation or guidance from the competent authority of the market.
- 2.6.4.2 The HACCP system shall include control measures ensuring additives to be present in the final product only in concentrations allowed for the specific product at the specific market.
- 2.6.4.3 If additives are used, this shall always appear on the label or on accompanying documents to the final product, according to specific marked conditions.
- 2.6.4.4 Substances used for the protection of plants and plant products or for treatment of animal or human diseases shall never be used as additives in or come in contact with fishery products intended for human consumption.

## 2.6.5 Biotoxins

- 2.6.5.1 For the export of products bivalve molluscs and other filter feeders, business operator shall ensure that biotoxins are within the limit specified by the import market.

## 2.6.6 Toxic Fishes

- 2.6.6.1 Fishery products derived from poisonous fishes belonging to the families like Tetraodontidae, Molidae, Diodontidae, and Canthigasteridae may be processed in the approved establishment/factory vessel/freezer vessel only under the supervision of qualified persons, for which special permission shall be obtained from the NCA. However, poisonous fishes belonging to the above mentioned families are prohibited for export to European Union.

## 2.7 Process Control – Processing and Allied Areas

### 2.7.1 Hygiene and Sanitation

- 2.7.1.1 Business operators of licensed establishment/factory vessel/freezer vessel shall ensure proper hygiene and sanitation throughout the handling, transportation and storage of fish and fishery products to avoid introduction and multiplication of microbial contaminants.
- 2.7.1.2 For this purpose business operator shall develop a written cleaning and sanitation procedure for strict compliance on a laid down frequency, which shall cover all areas of the establishment/factory vessel/freezer vessel including utensils and equipment.
- 2.7.1.3 Cleaning and sanitation procedures shall use only chemicals allowed for food contact surfaces and shall be designed so to avoid risk for contamination of the food with the chemicals.
- 2.7.1.4 Effectiveness of cleaning and sanitation shall be ensured by visual inspection and also by testing of swab samples taken from food contact surfaces for verification, at least where this is deemed necessary to ensure controlling the risk for contamination of ready to eat food. Annex 4 provides further guidance in this regard.
- 2.7.1.5 Records of cleaning and sanitation and also the test results of swab samples shall be maintained for verification by the NCA.

### 2.7.2 Personal Hygiene

- 2.7.2.1 Since employees may be a source of contamination, business operators shall develop proper control measures to ensure their personal hygiene, appropriate movements and behaviour.



- 2.7.2.2 Sufficient number of facilities shall be provided at appropriate places to enable the workers to clean and sanitize their hands and feet and to wear clean work clothes before each entry to the fish handling areas.
- 2.7.2.3 Utmost care shall be taken by the workers to maintain hygiene and sanitation while handling cooked products to avoid microbial contamination and toxin formation.
- 2.7.2.4 Workers shall not eat, talk, cough, sneeze, and spit etc. inside fish handling areas. They shall trim their nails and remove their ornaments before entering the processing areas. They shall wear clean work clothes.
- 2.7.2.5 The movements of employees, utensils and equipment shall be restricted to prevent cross contaminations.
- 2.7.2.6 Workers suffering from injury or disease shall not be permitted to work inside the fish handling area. Each employee working in the processing areas shall have a health certificate issued by an authorized medical practitioner stating that he/she is fit to work in a fish processing establishment and the certificate shall be renewed every year. Employees shall conduct medical examination before joining for duty after taking leave on medical ground.
- 2.7.2.7 Training shall be given to the workers for strictly following personal hygiene and behavioural activities. Records of training shall be maintained for verification.

### **2.7.3 Quality of Water and Ice**

- 2.7.3.1 Business operator shall implement control to document that the quality and safety of water and ice used in their factory comply with required standards.
- 2.7.3.2 Processing factories/factory vessel/freezer vessel approved for export to EU shall sample water used for processing and ice production and have it tested in a laboratory recognised for this by the NCA for compliance with criteria as per EC Directive No.98/83/EC, Annex II and Annex I Part A and C at least four times per year and for compliance with criteria as per EC Directive No.98/83/EC, Annex 1 Part B once per year, or whenever the source of water or ice is changed.
- 2.7.3.3 Establishment/factory vessel/freezer vessel approved for export to countries other than EU shall test water used for processing and ice production as per the Guidance Standard for Drinking Water of Myanmar Food and Drug Authority of September 2014, as amended, and as deemed necessary to document food safety and at least two times per year.

### **2.7.4 Pest Control**

- 2.7.4.1 Business operators shall take suitable measures to ensure a pest free environment inside the factory.
- 2.7.4.2 Methods efficient to exclude and eradicate pests shall be introduced wherever applicable. Air curtains, fly catchers, rodent traps, nets, rodent grills etc. shall be

provided, wherever applicable and so there are no risk that they may cause a risk for contamination of the products

- 2.7.4.3 Elimination of shelters and attractants of pest in the surroundings shall be done to ensure pest free environment.
- 2.7.4.4 Records of pest control activities shall be maintained for verification.

## 2.7.5 Time and Temperature Control

- 2.7.5.1 As a major tool to control contamination by growth of microorganisms and toxin formation, all processing establishments/factory vessel/freezer vessel shall implement time- temperature control starting from the procurement of raw material till shipment of the consignment and as adequate for the related raw materials and products.
- 2.7.5.2 Fish raw materials, intermediate products and final products shall be kept at temperature below +4°C at any time, unless in short periods of processing where temperature practicalities do not allow to maintain the low temperature. Such periods shall be as short as possible and the time-temperature shall be controlled and documented under the GMP/HACCP monitoring as adequate.
- 2.7.5.3 Special precaution shall be taken to avoid temperature abuse while procuring, transporting and processing histamine forming fishes.
- 2.7.5.4 All temperature recording devices shall be calibrated on a laid down frequency.
- 2.7.5.5 Cooking and freezing devices shall be validated to ensure that the applied time-temperature profile is adequate to achieve the intended core temperature.

## 2.7.6 Control of Cross Contamination

- 2.7.6.1 Business operators shall design and implement control measures to prevent cross contamination with biological or chemical contaminants from unsanitary objects to food and /or food contact surfaces. Such measures may include proper maintenance, cleaning and sanitation, employee's hygiene, employee movement and behaviour, pest control, waste management, time and space separation etc.
- 2.7.6.2 A system for collection and disposal of solid waste shall be established in a way so the risk for contamination of products is minimised.
- 2.7.6.3 Only food grade lubricants shall be used inside the factory.
- 2.7.6.4 Establishments/factory vessels/freezer vessels 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 non-food contact surfaces will not come in contact with food or food contact surfaces.

## 2.7.7 Traceability

- 2.7.7.1 Business operators shall develop and implement methods to trace the source of raw materials, ingredients and packing materials, from its origin through all stages of production, processing and distribution. Lot identification is essential in product recall and in stock rotation and shall be applied.

## 2.7.8 Storage

- 2.7.8.1 Fresh fishery products, thawed/unprocessed fishery products, and cooked and chilled products must be stored at a temperature approaching that of melting ice. If fishery products are kept under ice, the ice shall be allowed to melt, but the melt water shall be drained away from the products continuously; containers for such purpose shall therefore be designed with appropriate drainage facility.
- 2.7.8.2 Frozen fishery products during storage shall be kept at a temperature of not more than  $-18^{\circ}\text{C}$  in all parts of the products. This applies also to products that was initially frozen in brine to at least  $-9^{\circ}\text{C}$ , on board freezer or factory vessels, as provided for in section 2.4.2.
- 2.7.8.3 Cleaning and sanitation chemicals, and other chemicals, shall be stored separately under lockable condition with proper labels, including instructions on worker safety during handling.
- 2.7.8.4 Food grade ingredients shall be stored under clean conditions and at temperature and other conditions as prescribed by the supplier and so they are not adulterated due to humidity, dust, vermin etc.

## 2.7.9 Transportation

- 2.7.9.1 Vehicles used for transporting fish and fishery products and ice shall have clean, smooth storage areas made up of non-corrosive material that will not contaminate the product. Cleaning and sanitation of vehicles shall be done before and after the use and the records of cleaning shall be maintained.
- 2.7.9.2 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  $-18^{\circ}\text{C}$  in all parts of the product, possibly with short upward fluctuation of not more than  $+3^{\circ}\text{C}$ .
- 2.7.9.3 Vehicles used for the transportation of fishery products and ice meant for export purpose shall be approved and monitored by the National Competent Authority.
- 2.7.9.4 Refrigerated vehicles approved for transporting fishery products meant for export to EU shall have temperature recording device which shall comply with EN 12830, EN 13485 and EN 13486 standards.

## 2.7.10 Packaging

2.7.10.1 Fish and fishery products meant for export shall be packed in export worthy containers/packets that will not impart contamination or undesirable changes in the product but will give sufficient protection to the product until it reaches the customer.

## 2.7.11 Labelling

2.7.11.1 Proper information about the product shall be given to the consumer through labelling, invoice, or other commercial documents accompanying the goods. However, in no circumstances, false, misleading or illusory information shall be given in the label as regards to the nature, identity, properties composition, quantity, durability, origin, production or processing methods of the product.

2.7.11.2 General Requirements:

The outer packages of fishery products meant for export, that has to undergo further processing at the destination, shall have the following minimum information printed/stencilled/ pasted in English or in the language of the importing country or both.

- a. License No of the establishment
- b. Name of the country of origin
- c. Production date
- d. Name of product (common name)

Additional requirements of importing country, if any, shall also be complied with.

2.7.11.3 Specific Requirements

1. In case of food stuff is packed so to be sold directly to the consumer, following additional information to point 2.7.11.2 shall be given in the label:
  - a. Name under which the product is sold
  - b. Common name and scientific name of the fish included
  - c. List of ingredients in descending order of proportion
  - d. Name and/or E-number or INS-number of additives used in the product
  - e. Net weight and where relevant drained weight
  - f. Date of Production (directly or coded)
  - g. Date of minimum durability or best before
  - h. Storage conditions or condition of use
  - i. Name/business name of the manufacturer or packer
2. Any ingredient known to allergenic shall always be declared. (e.g.: Crustaceans or sulphite). Any ingredient which has been treated with ionizing radiation should also be declared.

3. Notwithstanding the points 1 and 2 above, the business operator shall always ensure that labelling of the products, as a minimum, comply with the legal requirements of the market for which the product is intended. This may be additional or more specific requirements including, but not be limited to:
  - a. Commercial and Scientific name of the fish included in the product.
  - b. Production method for the fish included in the product (Wild catch or Aquaculture and fishing gear).
  - c. Catch area (FAO area code for sea catch, country name for aquaculture and fresh water catch).
  - d. If the name of the product indicate the presence of an ingredient determining for the product, the percentage of that ingredient shall be indicated (e.g. fish in tomato sauce; the amount of tomato sauce shall be indicated).

## 2.8 Special Requirements for Export of Live Fish

1. The export of live fish for human consumption shall take place only from establishments that are under supervision and monitoring of the Aquaculture Section of Department of Fisheries. Only if the Aquaculture Section of Department of Fisheries confirms that the fish and its harvest area, comply with aquatic animal health requirements of the intended market, export shall be allowed.
2. Establishments that intent to export live fish shall be Licensed and, where required further Listed or Approved, for this by the NCA in compliance with provisions in the chapters 1.2 and 3.2. Licensing, Listing or Approval shall be conditional to:
  - a. Implementing of principles of GMP, SSOP and HACCP as provided for in chapter 2.5 and adequate to the type of operations “Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals” and “Standard Operating Procedures for the Responsible Movement of Live Aquatic Animals for ASEAN” of 2015.
  - b. The transport of live fish intended for human consumption shall take place in a way that do not alter the viability of the fish.
3. Health Certificates for food safety of live fish intended for export for human consumption shall be issued by NCA, as provided for in section 3.6.1.2.
4. Certificates pendent to compliance with aquatic animal health and requirements of CITES live fish intended for export for human consumption, shall be issued by the Aquaculture Section of Department of Fisheries as per market requirements and international commitments.

## 2.9 Management Commitment

1. The commitment of the food business Management is the most important aspect of the food safety system. The Management shall be committed to the development, maintenance, operation and continued improvement of the food safety management system as described in chapter 1 and 2 of this document, and to provide resources as necessary for this.
2. The Management shall demonstrate that food safety is one of the business objectives of the organisation.
3. The Management shall be committed to meeting the national and international food safety requirements as well as specific customer requirements relevant for their export.
4. They management be committed to conduct management reviews regularly to ensure that the food safety management system and conditions of implementing are effective to maintain food safety and quality and quality of the exported products

## 2.10 Management Responsibility

1. The Management of the organisation shall ensure that the responsibilities and authorities are well defined within the organisation to establish effective operation and control of the food safety management system.
2. The management shall ensure that all staff and management members, including the HACCP Team and the HACCP Team members has received training as appropriate to the nature of their work and responsibility at any time.
3. Work instructions shall be clearly laid down as to the responsibility in case of failure. All personnel in the organisations shall have the responsibility to report immediately to the management in cases which may lead to or constitute an immediate risk for production or distribution of food that is not safe or in compliance with requirements in this document.

## 2.11 Training

1. The management shall ensure that all staff and management members are trained in food hygiene and food safety management as relevant for their work responsibility. Training may be class room training or hands on training as deemed relevant for different work responsibilities.
2. The management shall define the necessary training methods, times and frequencies and keep records of such training.
3. The staff and management members responsible for development and maintenance of the HACCP system as required in chapters 2.5 and 2.6 shall have received adequate training and/or technical assistance adequate to allow them to undertake this responsibility.

# Official Control Activities

# Chapter III - Official Control Activities

## 3 The National Competent Authority

### 3.1 Requirements to the National Competent Authority

#### 3.1.1 Responsibility

- 3.1.1.1 The assigned National Competent Authority (NCA) shall plan and conduct of official controls to verify that the objectives and technical requirements in this regulation are complied with by all business operators and facilities in the value chain for fishery products produced in and intended for export from Myanmar.
- 3.1.1.2 The assigned National Competent Authority (NCA) shall also assist the Myanmar customs department to control food safety of imported fishery products as provided for in chapter 4.
- 3.1.1.3 The NCA shall ensure that the official controls are carried out regularly on a risk basis and with appropriate frequency, taking account of:
  - a. The specific risk to food safety related with the different type of operations and products
  - b. The facilities past record of compliance with this regulation or specific market criteria
- 3.1.1.4 The official controls shall be carried out without prior warning except in cases where the notification or presence of the business operators is specifically required.
- 3.1.1.5 The official controls shall include provisions for the NCA to require corrective actions towards non-compliances with requirements, as a condition for business operators to maintain their eligibility to export fishery products.
- 3.1.1.6 The NCA may initiate legal actions according to the Marine Fisheries Law Chapter XII, section 35 as amended and the Aquaculture Law section 31 and 32 in cases of business operators' non-compliance with provisions in this technical regulation.
- 3.1.1.7 The NCA shall apply a transparent approach, specifically keep the business operators informed about their procedures and practices and results of official controls.
- 3.1.1.8 The NCA shall keep itself, and related business operators, updated about specific requirements to official controls as required by certain export markets; to this end the NCA shall ensure that:
  - a. The competent authorities of such export markets are timely provided and updated with the required information.



- b. The requirements of the export markets are addressed as appropriate by business operators and by NCA to facilitate the export of fishery products from Myanmar
- 3.1.1.9 NCA may delegate official control tasks to other control bodies on the condition that:
- a. There is an accurate description of the tasks and of the conditions under which it shall be carried out.
  - b. There is and effective communication and coordination between the control body and the NCA.
  - c. There is proof that the control body:
    - i. Has the expertise, equipment and infrastructure required to carry out the tasks delegated to it
    - ii. Has a sufficient number of suitably qualified and experienced staff
    - iii. Is impartial and free from any conflict of interest as regards the exercise of the tasks delegated to it
    - iv. Comply with operational criteria at least as specified by NCA.

## 3.1.2 Operational Criteria

- 3.1.2.1 The NCA shall have legal power to conduct official controls and take the measures provided for in this technical regulation.
- 3.1.2.2 The NCA shall have financial, technical and human resources adequate to perform the official controls efficiently, including at least:
- a. Adequate and proper maintained equipment and facilities
  - b. Access to adequate laboratory facilities operating in line with international standards
  - c. Staff who are trained as appropriate to their duties and able to carry out the controls in a consistent manner
- 3.1.2.3 The staff carrying out official controls shall be impartial and free from any conflict of interest towards the business operators and facilities subject to the official controls.
- 3.1.2.4 The NCA shall operate in line with internationally and regionally recognised quality management and performance standards and/or criteria required by specific export markets. The NCA shall therefore establish and maintain updated internal procedures, work instructions and systems of documentation and communication for the staff and management, which:
- a. Facilitate uniform performance of the official controls, including actions in case of non-compliances:
  - b. Allow for actions to ensure, in due cooperation with the related business operator, the removal of Myanmar fishery products from any market, if such products, after being placed on the market, are found to be unsafe for the consumers.

- c. Allow for internal verification of efficiency all official control activities
- d. Ensure that corrective actions are implemented if the non-compliances with agreed internal procedures or this technical regulation are identified.
- e. Document results by methods that allow for trend analysis of data in context of the risk based approach.
- f. Facilitate transparency, specifically towards communication with the involved business operators and facilities
- g. Ensure maintenance of confidentiality as regard all information and knowledge gained during the official control activities.

### 3.1.3 Methods of Official Control

3.1.3.1 The methods of official control shall be selected and designed so they are suitable to address the objective and scope of each facility.

3.1.3.2 The methods may include, but not necessarily be limited to:

- a. Inspection and audit of hygiene conditions, management of good practices and food safety management procedures in:
  - i. Primary production and allied areas with license to operate and which are Listed to supply the value chain for export of fishery products for specific markets in reference to section 3.2.1, to assess compliance with requirements in this technical regulation and any further specific market requirements.
  - ii. Processing facilities with license to export fishery products, to assess compliance with requirements in this technical regulation and any further specific market requirements.
- b. Assistance to the Department of Customs, to assess fishery products intended for import to Myanmar for the purpose of human consumption, for compliance with food safety requirements in this technical regulation.

3.1.3.3 The inspection and audit may include, but not necessarily be limited to:

- a. Assessment of facilities and practices of operation in the facilities
- b. Assessment of the operators written food safety management systems and materials including their records of monitoring and verification
- c. Interviews with business operators and staff members
- d. Reading of the values recorded by the operators
- e. Measuring of food safety parameters with own test equipment
- f. Sampling and testing for the purpose of official control where deemed appropriate to verify compliance with requirements in this technical regulation. Sampling and testing may include but not be limited to raw materials, semi-

finished products, final products, ice, potable water and surfaces in contact with food.

- g. Defining and implementing of monitoring programs for specific hazards e.g. histamine and environmental contaminants.
- h. Surveillance of specified activities of defined business operators or activities at random frequency and time.

## 3.2 Approval and Listing

### 3.2.1 Listing of Primary Production and Allied Areas to Supply for Export

- 3.2.1.1 The assigned NCA shall keep Lists (register) with reference to a unique identity code of all primary producers and allied areas (as defined in chapter 1) under mandatory official control for verification of compliance with requirements in this regulation. The primary producers and allied areas under mandatory official control are those to be Listed to supply raw materials or other input to the value chain for export of fishery products to certain markets as specified in section 3.2.1.6.
- 3.2.1.2 The NCA shall announce to the business operator(s) which markets that require Listing, including information about the specific requirements or conditions for such Listing of different operators.
- 3.2.1.3 The business operators shall apply to the NCA for Listing to supply for export to different markets. The NCA shall establish procedures, work instructions and checklists as adequate for receiving and assessment of such application, and the business operator shall be informed about such procedures in due time.
- 3.2.1.4 The NCA shall assess an application for Listing on the basis of the application and required supporting documents, and the result of inspection or audit of the practices against the requirements of this regulation or specific export market requirements.
- 3.2.1.5 The supporting documents to an application for Listing shall include, but not necessarily be limited to:
  - a. Documentation related to valid business registration for operation by the relevant authorities and license from of Department of Fisheries as may be required.
  - b. Layout of facilities and description of practices
  - c. Documentation related to procedures and practices for control of hazards related with the operations on the facility.
- 3.2.1.6 Currently Listing of primary producers and allied activities under mandatory official control applies to fishing vessels, aquaculture farms, ice factories, landing sites, collection stations and auctions which provide or distribute raw materials intended for export to the EU market.

## 3.2.2 Listing and Approval of Processing Factories for Export to Specific markets

- 3.2.2.1 Certain export markets require that the NCA establish and maintain lists of export establishments that are specifically designated to export to that market, subject to compliance with specified requirements.
- 3.2.2.2 The markets requiring specific Listing/Approval includes EU (Approval of processing factories, independent cold stores, factory vessels and freezer vessels), China (Listing of fish processing factories, feed processing factories and warehouses), Vietnam (Listing of fish processing factories), and US (Listing of processing factories for export of fish of the order Siluriformes).
- 3.2.2.3 The Listing and Approval may be general or limited to specific products or groups of products.
- 3.2.2.4 Only establishments with a general License to export fishery products, as stipulated in chapter 1.2 of this document, shall be Listed or Approved for the specific markets.
- 3.2.2.5 The Listing and approvals for specific markets according to section 3.2.2.2 and 3.2.2.3 shall be based on application by the business operator and the NCA shall announce and provide guidance in this regard.
- 3.2.2.6 The NCA shall establish procedures and work instructions for the official controls related to assessment of applications and for establishing and maintaining of the Listings and Approvals for specific markets as referred to in section 3.2.2.2.
- 3.2.2.7 The NCA shall assess an application for Listing or Approval on the basis of the application and required supporting documents and the result of inspection or audit of the practices against the requirements of this regulation or specific export market requirements.
- 3.2.2.8 The supporting documents to an application for Listing or Approval shall include, but not necessarily be limited to:
  - a. Any specific documentation required by the related export market
  - b. Documentation related to valid license for export
  - c. Layout of facilities and description of practices
  - d. Documentation related to HACCP system and pre-requisite programs
  - e. Documentation related to raw material suppliers and other stakeholders in the value chain, if so required by the market.
- 3.2.2.9 The Listing or Approval for specific export markets is subject to continued compliance with the stipulated criteria. If the results of official controls, as stipulated in section 3.2.2.7 or in chapter 3.3, show that an establishment do not comply with criteria related with a Listing or Approval, the NCA shall not allow the establishment to export to the market until compliance is re-installed.

3.2.2.10 The NCA shall establish documented procedures and work instructions for permanent or temporarily withdrawal of a Listing or Approval and inform the business operators accordingly

## 3.3 Methods of Official Control

### 3.3.1 Surveillance Visits

- 3.3.1.1 Surveillance visits may be carried out to any establishment at any time.
- 3.3.1.2 Surveillance visits may be announced or un-announced depending of the objective and context of the visit.
- 3.3.1.3 Observations may be carried out as:
  - a. Observations/assessment of practices of relevance when conducting target sampling, e.g. under the residue monitoring program or in context of the pre-export assessment.
  - b. Specific planned activities, e.g. the assessment of raw material quality and practices on landing sites, collection centres and auctions.
  - c. Short visits for gathering of information e.g. in feed distribution centres, Listed or non- Listed landing sites, collection stations and auctions.
- 3.3.1.4 Activities and observations in surveillance visits shall be recorded in context of the key activity, e.g. on the sampling report or the pre-export verification reports or if planned activity on separate records.
- 3.3.1.5 If during a surveillance visit the officer of NCA finds conditions or practices in non-compliance with this regulation, the officer shall take steps as necessary to issue a formal request of Corrective Action in reference to chapter 3.6 and further documented internal procedures.

### 3.3.2 Inspection

- 3.3.2.1 Inspection is a planned activity that may be carried out to any establishment at any time in the value chain, including for example but not limited to primary producers and allied activities, processing establishments, ice factories, cold stores, feed production and distribution establishments.
- 3.3.2.2 The purpose of inspection is to verify that the establishment comply with the general hygiene and food safety criteria which apply to the establishment.
- 3.3.2.3 The NCA shall document and implement procedures and work instructions for frequency of planned inspections to each type of establishments and inform the business operators accordingly. The frequency of inspections shall be decided based on:

- a. The type of establishment (risk based)
  - b. The previous performance of the establishment (past record of compliance)
  - c. The existence of unforeseen events (e.g. market rejections, non-compliant results in sampling and testing)
- 3.3.2.4 Inspections shall be carried out in reference to documented procedures and checklists reflecting the legal requirements which apply to the establishment and its related Listing or Approval.
- 3.3.2.5 Inspections may include but not be limited to:
- a. Assessment of physical facilities
  - b. Assessment of practices
  - c. Interview of management and operators
  - d. Review of written work procedures, instructions and results of monitoring related to control of food safety and hygiene to assess whether they are adequate to control food safety efficiently.
  - e. Sampling of final products, raw-materials, semi-manufacture, water, ice, ingredients, packaging materials and swap test of food contact surfaces.
- 3.3.2.6 Results of inspections shall be recorded in systematic way. The business operator shall be informed about the outcome of and inspection in a written report. The report shall identify the establishment representative, the name of the inspectors, the scope of the inspection and the result of the inspection, specifically identified non-compliances with this regulation or specific market criteria, to which the establishment is Listed or Approved.
- 3.3.2.7 If during inspection the officer of NCA finds conditions or practices of non-compliance as stipulated the officer shall issue a formal request of Corrective Action in reference chapter 3.6 and further documented internal procedures.
- 3.3.2.8 A formal Corrective Action Request following an inspection result shall identify the non-compliance and the related objective evidences with reference to the legal requirements and the request to identify and implement adequate Corrective Action within a time limit.

### **3.3.3 HACCP Audit**

- 3.3.3.1 HACCP is a planned activity that shall be carried out in establishments that apply either mandatory or voluntary HACCP, including specifically processing establishments, freezer vessels and factory vessels and feed establishments.

- 3.3.3.2 The purpose of the HACCP Audit is to verify that the establishment document and implement food safety management measures in accordance with the principles stipulated in chapter 2.5 of this document, and that the implemented measures are adequate to ensure efficient control of food safety.
- 3.3.3.3 Regular HACCP Audits shall be planned implemented and documented according to the principles described in section 3.3.2.3 – 3.3.2.8, however in addition to section 3.3.2.5 include also:
  - a. Assessment of the correct application of the 7 principles and 12 preliminary steps as provided for in chapter 2.5.
- 3.3.3.4 HACCP Audits shall always be conducted in assessment of a request for Listing or Approval to one of the markets identified in chapter 3.2.

### **3.3.4 National Residue Monitoring Program (NRMP) for Products from Aquaculture**

- 3.3.4.1 The NCA shall implement a national monitoring program to verify that residues of veterinary medicines and environmental contaminants, in fishery products from aquaculture in Myanmar, are not present in levels which may harm the consumers (NRMP).
- 3.3.4.2 The NCA shall ensure that the NRMP is managed and supervised by a cross functional Residue Monitoring Committee (RMC) with expertise and management representatives from areas of management of aquaculture, control of authorisation, distribution and use of veterinary medicines, laboratory testing relevant to the program and requirements to food safety requirements/official controls on the EU market.
- 3.3.4.3 Residue Monitoring Committee (RMC) shall decide and ensure enforcement of remedial measures in cases of detection of distribution and use of prohibited veterinary medicines and in cases of misuse or misguidance related to distribution and use of authorised veterinary medicines. Such remedial measures may include but not be limited to suspension of the farm, hatchery and/or feed mill involved in the illegal activity until such time NCA is satisfied that the activity will not re-occur.
- 3.3.4.4 The NCA shall establish and implement documented procedures for:
  - a. Planning, implementing and reporting the results of the program on an annual basis.
  - b. Investigations of cases of non-compliant findings with focus on identifying root causes
  - c. Actions against cases of non-compliant findings, with focus on ensuring that the products are withdrawn or not placed on the market and minimizing the risk for re-occurrence of the case.

- 3.3.4.5 All processing establishments and their related aquaculture farms that are Approved for export of products from aquaculture to the EU Market shall be included in the NRMP. Other processing establishments and their related aquaculture farms may be included by request or by the decision of the NCA.
- 3.3.4.6 The objective of the program shall be to:
- a. Detect the illegal use of prohibited veterinary medicines.
  - b. Detect the illegal or wrong use of allowed veterinary medicines.
  - c. Collect data in support of management towards responsible management of veterinary medicines in animals intended for food.
- 3.3.4.7 The program shall be based on annually plans for sampling and testing considering:
- a. Risks related with potential illegal substances on the market.
  - b. Risk related with potential wrong use of legal substances.
  - c. Risks related with specific potential environmental contaminations in related areas (run off from farming areas, mining, etc.).
  - d. The amount of production in the included farms.
  - e. The necessary laboratory test capacity and capability.
  - f. The results of previous year sampling and testing.
  - g. Any specific market requirements to the program, specifically the EU Directive 96/23/EC.
  - h. Myanmar legislation on authorisation, distribution and use of veterinary medicines in products of aquatic animal origin.
  - i. Myanmar legislation on prohibited and allowed pesticides.
- 3.3.4.8 The program shall provide annual reports on the implementing of the program and the results obtained, with specific focus on actions taken towards non-compliant findings.

### **3.3.5 Laboratory Services for Official Control**

- 3.3.5.1 Sampling and testing of fishery products for the purpose of official control shall be planned and conducted in reference to international recommended standards or method descriptions, e.g. ISO, FDA-BAM, APHA, AOAC, NMKL-NorVal International.
- 3.3.5.2 Where import markets require testing with specific methods or with methods complying with specific performance criteria such methods, or methods that has been demonstrated to be equivalent, shall be used.



- 3.3.5.3 Laboratories used for sampling and testing for purpose of official control shall apply systematic quality management following international standard, specifically the laboratory shall:
- a. Document their validation of all test methods used for purpose of official control, specifically document performance criteria which may be required by specific import markets.
  - b. Participate in internationally recognised proficiency tests on a regular basis for the test methods used for purpose of official control.
  - c. Ensure and document that staff assigned to do testing are qualified and able to conduct the tests in accordance with specified performance criteria.
  - d. Issue analytical reports for all testing, following international standard and be able to document traceability for all data collected from receiving the sample to the issuing of the Analytical report.

### 3.4 Actions in Case of Non-Compliance

1. In case of non-compliance with regulatory requirements as stipulated in this document, the NCA is empowered to take suitable action against the involved Business Operators under Section 24 and Section 45 of Myanmar Marine Fisheries Law 1990 and under section 17 of the Myanmar Aquaculture Law 1989.
2. The actions may include, but not be limited to, levying fee, withholding health certificates, imposing suspension or withdrawing of the Approval or Listing granted for export.
3. The NCA shall establish and implement documented procedures for deciding and managing actions in case of non-compliances and inform the business operators accordingly.

### 3.5 Procedures to Removal of Unsafe Food from the Market

1. The NCA shall establish and implement documented procedures covering their role in prompt removal from the market of fishery products that are deemed to be unsafe for the consumers. Such procedures shall cover cases where:
  - a. The business operator inform the NCA, in accordance with chapter 2.3 of this document, that a product has been deemed unsafe, or for other reasons, rejected from an export market.
  - b. The NCA receive information from the competent authority of an export market, that a fishery product from Myanmar is deemed unsafe and to be rejected for import or to be withdrawn from that market.

2. The NCA shall ensure that all establishments, which are Listed or Approved for export of fishery products from Myanmar, have documented procedures for communicating with the NCA and for taking actions as appropriate to withdraw or recall of their products from the market if and when such is deemed necessary for protection of consumers.
3. The NCA shall oversee and, if deemed necessary for protection of consumers, request specific measures to recover, re-direct or dispose of products that are rejected or withdrawn from an export market. The involved business operators shall have affirmative duty to give effect to request from the NCA in this regard.
4. The NCA shall establish documented procedures for the controls to be conducted and leading to the decisions about measures to recover, re-direct or dispose of products that are withdrawn from an export market.
5. The NCA shall establish documented procedures for their investigation of cases of rejection or withdrawal due to other market complaints. The investigation shall analyse the cause for the market rejection or complaint and lead to decisions on Corrective Actions to be taken by the involved business operator(s) who shall have affirmative duty to give effect to request from the NCA in this regard.
6. In reference to the results of an investigation specified in chapter 3.4 the NCA is empowered to take suitable action against the involved facilities under Section 24 and Section 45 of Myanmar Marine Fisheries Law 1990 and under section 17 of the Aquaculture Law 1989.

## 3.6 Export Certification

### 3.6.1 Health Certificates for Products

- 3.6.1.1 The NCA shall establish procedures to issue Health Certificates or other certificates of compliance with food safety requirements as required from different markets.
- 3.6.1.2 If a market require certification for absence of specific animal diseases, the NCA shall cooperate with the relevant sections of Department of Aquaculture, specifically the aquatic animal health diagnostics laboratory to provide the relevant documentation.
- 3.6.1.3 The NCA shall ensure that certificates are always issued on a valid template provided by the imported country if such exist.
- 3.6.1.4 The NCA shall sign certificates only after assuring, by adequate verification, that the consignment complies with criteria and requirements specified by that market.
- 3.6.1.5 The NCA shall establish documented procedures and work instructions for verification of compliance and issuing of certificates of compliance with food safety criteria. These pre-export verification procedures may include desk verification and/or onsite verification of the compliance with required criteria.

- 3.6.1.6 The pre-export verification procedures mentioned in section 3.6.1.4 shall be decided based on risk and include history of compliance with HACCP requirements and compliance of previous consignments.
- 3.6.1.7 For export markets which do not have own Health Certificates or certificates of compliance with food safety criteria, the NCA will issue Health Certificates on templates in Annex 1 to this technical regulation.
- 3.6.1.8 The NCA shall inform business operators about the requirements to Health Certification, or other certification, including the procedures NCA has established in this regard.

## 3.7 Training

1. The NCA shall establish documented job descriptions for all key job functions related to managing and implementing official controls.
2. The NCA shall identify required key competencies for officers assigned to inspection, sampling or health certification and ensure that all staff members are trained as appropriate to their job function related with inspection, certification, sampling, reporting and administrative functions.
3. The NCA shall keep updated records of all staff members including CVs, training records and assignments for different job functions.

## 3.8 Transparency

1. Transparency is the most important aspect of the official control activity. Development of food safety standards and official control systems shall be done in a transparent manner and all the stakeholders of the food chain shall have equal opportunity to give their contributions. Co-operation of all stakeholders is essential for the success of any food safety system.
2. Public information and public consultation are the major tools in achieving the transparency. Therefore, NCA shall have regular meetings with all the stakeholders to collect their suggestions before finalizing the standards and also to update them with the latest national and international requirements. Information may also be communicated through social media, official letters, websites etc.

# Import of Fish and Fishery Products

# Chapter IV – Import of Fish and Fishery Products

## 4 General and Specific Requirements

### 4.1 General Requirements

1. Fish and fishery products shall be imported as per the requirements in the Myanmar Export and Import Law, (The Pyidaungsu Hluttaw Law No.17/2012), of (17th September, 2012).
2. Establishments, companies or individuals that intend to import fisheries product to Myanmar shall obtain and maintain valid a Registration for this from the Ministry of Commerce and according to administrative procedures stipulated by that ministry.
3. Establishments, companies or individuals with a valid Registration to import shall receive a License to Import fishery products by the Ministry of Commerce and according to administrative procedures stipulated by that ministry.
4. Establishments, companies or individuals with valid Registration and valid license to import fishery products shall comply with all regulatory requirements and administrative procedures for the import as stipulated by the Ministry of Commerce.
5. Department of Fisheries is responsible for food safety control of imported fisheries products as per the Directive 7/2018 issued according to the Marine Fisheries Law. This responsibility shall be implemented as per agreement/decision of the Ministry of Commerce on import of commodities with recommendation from concerned ministries.
6. The NCA shall establish procedures and work instructions for official control of imported fishery products in as provided for in chapter 4.2-4.6 below and under general provision for official control as provided for in sections 3.1.1.1 and 3.1.3.2.

### 4.2 Registration of Overseas Processing Facilities

1. Only those overseas establishments, factory vessels or freezer vessels, which are approved and monitored by the Competent Authority of that country, are eligible for getting registration from Department of Fisheries.
2. For the purpose of registration, the overseas processor shall approach the Competent Authority of that country to forward their request letter to NCA for registration along with the recommendation and a brief description of regulatory control system of the Competent Authority and also the approval details of the facility.
3. The approval details of the facility shall include:
  - a. Name and address of the approved processor and/or exporter
  - b. Approval number of the processing unit
  - c. Scope of approval
  - d. Name of countries/group of countries to where export is permitted

- e. List of products approved for export.
  - f. Flow diagram and HACCP plan of each product intend to import
4. NCA shall consider the recommendation of the overseas Competent Authority after verifying the request letter and related documents. If satisfied, registration shall be granted to the concerned overseas facility/business operator for importing fishery products to Union of Myanmar through a licensed importer.
  5. The details of registration shall be informed to the overseas Competent Authority with a request that any change in approval status of the overseas registered facility shall be intimated to Department of Fisheries for necessary corrections. The list of overseas registered processors/exporters shall be published by Department of Fisheries for information of the importers and other stakeholders.
  6. If necessary, NCA may take necessary steps with the help of overseas Competent Authority to audit the registered processors of that country so as to ensure their compliance with the requirements of Union of Myanmar. Assessment of registered processors may be done by NCA officials directly or through qualified third party auditor(s).
  7. NCA shall publish information about the procedures for registration of overseas processing facilities as adequate and in compliance with the commitments as member of WTO.

### 4.3 Procedures for Import Intended for Domestic Market – Recommendations from Department of Fisheries

1. The NCA shall establish and implement documented procedures for assisting the Ministry of Commerce, Department of Custom to verify the food safety of imported fishery products.
2. The verification according to point 1 shall be planned and conducted based on food safety risk and may include, but not be limited to one or more of the following controls:
  - a. Document check prior to import, specifically verification of Sanitary Certificate from the competent authority in the country of origin.
  - b. Document check, identity check and physical check upon arrival to Myanmar.
  - c. Sampling and testing for compliance with Myanmar food safety criteria.
3. The Sanitary Certificate mentioned in point 2 shall include information about:
  - a. Company Name and address of Exporter, Importer and Producer
  - b. Description of product
  - c. Origin of the raw material (aquaculture/wild caught)
  - d. Weight (Net/Gross)

- e. Scientific Name of species in the consignment
  - f. Temperature required during storage and transport
  - g. Unique ID number of the company processing the products, by the responsible competent authority for food safety in the country of processing.
  - h. Statement by the competent authority, that the product is produced in an establishment that comply with food safety regulations of that country and that product it is fit for human consumption.
4. The NCA shall recommend import only if the document check of the Sanitary Certificate mentioned in point 3 satisfy that the product is safe according to Myanmar food safety requirements.
  5. The document check, identity check and the physical check at arrival to the border inspection point in Myanmar shall be conducted in cooperation and coordination with the Myanmar Custom authorities.
  6. The document check at the arrival as mentioned in point 5 shall always be carried out, and it shall verify that the information on the Sanitary Certificate accompanying the consignment is equivalent to the information received for desk verification.
  7. The verification of identity as mentioned in point 5 shall include:
    - a. Inspection of labels on the arrived products, where information shall match information on accompanied documentation and documentation received prior to arrival.
    - b. Physical inspection of content in packages where the species and type of product shall match information on label.
  8. The physical check mentioned in point 7 shall be planned and conducted considering the food safety risk related with the product and may include sampling and testing for compliance with organoleptic, chemical and microbial quality and food safety criteria as follow:
    - a. One of each ten consignments from the same supplier if it is raw, low risk products for cooking before consumption (routine schedule).
    - b. One of each two consignments from the same supplier if it is high risk products ready to eat (cooked products, histamine sensitive species, cooked dried shellfish) (routine schedule).
    - c. Samples from ten consecutive consignments from the same supplier if results of previous sampling and testing from that supplier showed non-compliant results (sampling on suspicion).
  9. Consignments that do not comply with criteria for document check and identity check as mentioned in points 6, 7 and 8 shall be detained as per procedures of Department of Customs until decided if the consignment may be allowed to enter Myanmar.

10. Consignments from where samples have been taken for organoleptic, chemical and physical test according to point 8 shall be handled as follow:
  - a. If the sample was taken according routine schedule, the consignment shall be released after the sampling, and further distribution do not need to wait for test result.
  - b. If the sample was taken on suspicion, the consignment shall be held in detention until the result of the testing is available.
  - c. If test results from a routine sampling show that the consignment do not comply with requirements, the consignment shall be re-called from the market.
  - d. If the test result from a sample taken on suspicion show that the consignment do not comply with requirements, the consignment shall rejected for entrance in Myanmar.
11. The NCA shall inform the Competent Authority of the country of origin in cases where a consignment is rejected due to the non-compliance with document, identity or physical controls at the border entrance.

## 4.4 Additional Requirements for Import of Fishery Products Intended for Re-Export.

1. Consignments imported for Contract Manufacturing under the “Contract Manufacturing Process System, CMP”, defined by Ministry of Commerce, shall be imported under the same procedures in chapter 4.3, consignments imported for domestic consumptions.
2. The importer shall keep the NCA informed about the products to be produced and the quality and safety criteria which the owner of the consignment has required. If the owner of a CMP consignment has not specified criteria, the consignment shall be processed under an adequate HACCP plan.
3. The importer shall keep the NCA informed about the processing yield of a CMS consignment and NCA shall verify traceability of the raw materials imported for re-processing and that raw materials and final products from contract processing is fit for human consumption and processed in line with related process description and food safety plan.
4. Consignments imported under the CMS, and intended for export to EU, shall come from facilities that are approved or listed for export to EU by the competent authority of the country of origin.
5. The NCA shall establish procedures for the control of products imported and exported under CMP and keep the business operators informed about such procedures.



## 4.5 Additional Requirements for Import of Aquaculture Products

In case of aquaculture products meant for human consumption, the Sanitary Certificate, as mentioned in chapter 4.3 point 2, shall be accompanied by test report proving that the product comply with Myanmar criteria for residues of veterinary medicines as stipulated in Department of Fisheries Directive 2/2014 as amended by Department of Fisheries Directive 1/2017.

## 4.6 Additional Requirements for Import of Live Fishes

Consignments of live fish intended human consumption shall be imported under the procedures provided in chapter 4.3 and 4.5, however only after control and confirmation by the Aquaculture Division of the Myanmar Department of Fisheries that, the consignment may be allowed into the country on the basis of compliance with Myanmar aquatic animal health requirements and status.

Consignments of live fish, where transport conditions have obviously resulted in altering the viability of the fish, shall not be allowed import for human consumption.

Samples for testing food safety parameters as provided for in chapter 4.2 point 8 may not be taken from live fish.

The NCA and the Aquaculture Division shall establish documented and well-coordinated procedures to license importers, list exporters and conduct the necessary controls in line with the principles and guidelines “Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals” and “Standard Operating Procedures for the Responsible Movement of Live Aquatic Animals for ASEAN” of 2015.

# ANNEXES

## ANNEX 1 - Generic Health Certificate for Export of Fishery Products Intended for Human Consumption

1. Name, address and contact number of the Competent Authority issuing the Certificate		1.1. Certificate No
<b>2. Provenance of the fishery products</b>		
2.1. Name, address and contact number of processing establishment/ factory vessel/freezer vessel & Approval Number		
2.2. Country of Origin & ISO code		
2.3. Country of transit		
2.4. Date of Departure		
2.5. Means of Transport.		
2.6. Name and address of consignor & contact Number.		
<b>3. Destination of the fishery products</b>		
3.1. Name, address & contact number of Consignee		
3.2. Country & Place of Destination		
<b>4. Product Identification</b>		
4.1 Product description with HS code		
4.2 Nature of preservation		
4.3 Date(s) of production		
4.4 Net weight in Kg		
4.5 Number of package & Type and nature of pack		
4.6 Storage and transport temperature.		
4.7 Container identification / Seal no.		
<b>5. Health Attestation</b>		
The official inspector certify that the fishery/aquaculture products specified above:		
5.1	have been handled, prepared or processed, identified, labelled, stored and transported under a competent HACCP and sanitary programme consistently implemented and in accordance with the requirements laid down in Codex Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)	
5.2	come from an establishment/factory vessel/freezer vessel which is approved and monitored by the Competent Authority.	
5.3	have undergone health controls in accordance with the laid down health rules and the product is fit for human consumption.	
5.4	come from aquaculture farms which are approved/registered and monitored by the Competent Authority and are free from exotic or non-exotic diseases notified by OIE	

Place:	
Date:	(signature of certifying official, with name, designation and qualification)
(Seal of Competent Authority)	

(Strike whichever not applicable)

## ANNEX 2 - Model Health Certificate for Import of Live Fishes

I.1 Consignor Name, Address and Contact Details  Approval Number (ID number):	I.2 Certificate No:
	I.3. Name, address and contact number of the Competent Authority issuing the Certificate:
I.4. Consignee Name, address & contact details  License Number:	
I.5. Country of Origin	ISO Code
I.6 Country of destination	ISO Code
I.7 Place of Origin Name, Address and Contact Details  Approval Number/Licence Number:	
I.8 Place of Shipment	I.9 Date of Departure
I.10 Means of Transport <input type="checkbox"/> Airplane; <input type="checkbox"/> Ship; <input type="checkbox"/> Railway; <input type="checkbox"/> Road <input type="checkbox"/> Other, Identification:	I.11 Country of Transit
	I.12 Cites Permit Number(s)
I.13 Description of Commodity	I.14 Commodity Code (SH Code):
	I.15 Total quantity/weight:
I.16 Identification of Container/seal number	I.17 Type of Packaging
I.18 Commodities intended for us as: <input type="checkbox"/> Breeding; <input type="checkbox"/> Grow out; <input type="checkbox"/> Slaughter; <input type="checkbox"/> Restocking; <input type="checkbox"/> Ornamental; <input type="checkbox"/> Competition; <input type="checkbox"/> Other; specify	
I.19 For import or admission: <input type="checkbox"/> Definitive Import; <input type="checkbox"/> Re-entry; <input type="checkbox"/> Temporary admission	
I.20 Identification of Commodities: <input type="checkbox"/> Amphibian; <input type="checkbox"/> Crustacean; <input type="checkbox"/> Fish; <input type="checkbox"/> Mollusc; <input type="checkbox"/> Other	
I.21 Origin <input type="checkbox"/> Wild stock; <input type="checkbox"/> Cultured stock	
I.22 Species Scientific name(s)	Number (pcs)

II Health Information	Certificate No:
<p><b>II.1 General requirements</b></p> <p>I, the undersigned official inspector, hereby certify that the aquatic animals referred to in Part I of this certificate:</p> <p>a) have been inspected within 72 hours of loading, and showed no clinical signs of disease;</p> <p>b) are not subject to any prohibitions due to unresolved increased mortality; <u>and</u></p> <p>c) no un-explained mass mortality during the past 3 months.</p> <p>d) are not intended for destruction or slaughter for the eradication of diseases;</p> <p>e) originate from aquaculture farms that are all under the supervision of the competent authority; <u>or</u></p> <p>f) are wild caught from an area which is more than 5 kilometers away from the existing aquaculture farms and is not contaminated from aquaculture.</p>	
<p><b>II.2 Declaration of health information</b></p> <p>I, the undersigned, certify that the animals identified above meet the following conditions: They come from a farm establishment/ zone/ country where they are submitted to a health supervision set up to operate according to the procedures described in the <i>Manual of Diagnostic Tests for Aquatic Animals</i> from World Organisation for Animal Health and that is recognized officially unaffected by the following diseases:</p> <p>a) for fish: epizootichaematopoietic necrosis, infection with <i>Aphanomyces invadans</i> (epizootic ulcerative syndrome), infection with <i>Gyrodactylus salaris</i>, infection with infectious salmon anaemia virus, infection with salmonid alphavirus, infectious haematopoietic necrosis, koi herpesvirus disease, red sea bream iridoviral disease, spring viraemia of carp, and viral haemorrhagic septicaemia</p> <p>b) for mollusc: infection with abalone herpesvirus, infection with <i>Bonamia ostreae</i>, infection with <i>Bonamia exitiosa</i>, infection with <i>Marteilia refringens</i>, infection with ostreid herpesvirus-1 microvariant, infection with <i>Perkinsus marinus</i>, infection with <i>Perkinsus olseni</i>, and infection with <i>Xenohaliotis californiensis</i></p> <p>c) for crustacean: crayfish plague (<i>Aphanomyces astaci</i>), infectious hypodermal and haematopoietic necrosis, infectious myonecrosis, necrotising hepatopancreatitis, taura syndrome, white spot disease, white tail disease, and yellow head disease</p> <p>d) for amphibian: infection with <i>Batrachochytrium dendrobatidis</i> and infection with ranavirus</p>	
<p><b>II.3 Transport and labeling requirements</b></p> <p>I, the undersigned official inspector, hereby certify that:</p> <p>a) the live aquatic animals referred to above are placed under conditions, including with water quality, that do not alter their health status;</p> <p>b) the transport container is clean and disinfected or previously unused; and</p> <p>c) the consignment is identified by a label on the exterior of the container with the relevant information referred to in boxes I.16 of this certificate.</p> <p>This certificate is valid for ten days from the date of issue.</p>	
Place:	Name and address of the Certifying Official
Date:	Official Position of Certifying Official:  Signature of the Certifying Official :
(Seal of Competent Authority)	

## ANNEX 3 – Chemical and Microbial Criteria for Fishery Products

### 1. Chemical Criteria and Additives

The food safety criteria in the tables below shall apply for fishery products imported to Myanmar and for fishery exported from Myanmar, if no other criteria are specified by the customer or by the legislation of the country of destination.

Guidelines on specific market criteria can be found on the NCA web-site.

Parameter		Products	Maximum Level
<b>Residues of veterinary medicines</b>	Prohibited veterinary medicines and veterinary medicines allowed with an MRL	All fish and fishery products originating from aquaculture	As provided for in Department of Fisheries Directive 2/2014 with any further amendment.
<b>Food Additives</b>	Sulphites <sup>1)</sup>	Fresh and frozen, uncooked fish and fishery products	100 ppm
	Phosphates <sup>1)</sup>	<ul style="list-style-type: none"> <li>• Frozen, cooked crustaceans</li> <li>• Other fishery products, fully preserved (canned or fermented).</li> </ul>	150 ppm
<ul style="list-style-type: none"> <li>• Smoked, dried, fermented, and/or salted fish and fish products</li> <li>• Frozen fish, fish fillets, and fishery products</li> <li>• Frozen battered fish, fish fillets, and fishery products.</li> <li>• Frozen minced and creamed fishery products.</li> <li>• Cooked fish and fishery products</li> <li>• Smoked, dried, fermented, and/or salted fish and fishery products.</li> <li>• Fish and fishery products, marinated and/or in jelly, pickled and or in brine</li> <li>• Salmon substitutes, caviar, and other fish roe products</li> <li>• Semi-preserved fish and fishery products, (e.g. fish paste)</li> <li>• Fully preserved, including canned or fermented fish and fishery products</li> </ul>		30 ppm	
			2200 ppm

Parameter	Products	Maximum Level	
	Note: This criteria applies also to products of bivalve molluscs, echinoderms, tunicates, gastropods.		
Sorbates <sup>1)</sup>	<ul style="list-style-type: none"> <li>Smoked, dried, fermented, and/or salted fish and fishery products</li> <li>Semi-preserved fish and fish products</li> </ul> <p>Note: This criteria applies also to products of bivalve molluscs, echinoderms, tunicates, gastropods.</p>	1000 ppm	
Benzoates <sup>1)</sup>	<ul style="list-style-type: none"> <li>Cooked fish and fishery products</li> </ul> <p>Note: This criteria applies also to products of bivalve molluscs, echinoderms, tunicates, gastropods.</p> <ul style="list-style-type: none"> <li>Cooked crustaceans (including mollusks and echinoderms)</li> <li>Semi-preserved fish and fishery products</li> </ul>	2000 ppm	
Other food additives	<ul style="list-style-type: none"> <li>Smoked, dried, fermented, and/or salted fish and fish products.</li> </ul> <p>Note: This criteria applies also to products of bivalve molluscs, echinoderms, tunicates, gastropods</p> <p>Fishery Products in product groups 9.1-9.4 in CODEX STAN 192-1995 as amended 2018.</p>	200 ppm	
		As provided for in Codex Alimentarius CODEX STAN 192-1995 as amended 2018.	
Contaminants	Cadmium <sup>2)</sup>	<ul style="list-style-type: none"> <li>Marine bivalve mollusks</li> <li>Cephalopods without viscera</li> <li>Seafood mix (different fishery products in same unit)</li> <li>Surimi based fishery products</li> </ul>	1,0 ppm
	Lead <sup>2)</sup>	<ul style="list-style-type: none"> <li>Fish</li> <li>Marine bivalve mollusks,</li> <li>Cephalopods without viscera</li> <li>Seafood mix (different fishery products in same unit)</li> <li>Surimi based fishery products</li> </ul>	0,3 ppm 2,0 ppm
	Methyl Mercury <sup>2) and 3)</sup>	<ul style="list-style-type: none"> <li>Marine bivalve mollusks,</li> <li>Cephalopods without viscera</li> <li>Seafood mix (different fishery products in same unit)</li> <li>Surimi based fishery products</li> </ul>	0,5 ppm

Parameter		Products	Maximum Level
		Tuna, whole commodity excl. viscera	1,2 ppm
		Alfonsino, whole commodity excl. viscera	1,5 ppm
		Marlin, whole commodity excl. viscera	1.7 ppm
		Shark, whole commodity excl. viscera	1,6 ppm
	Tin <sup>2)</sup>	Canned food	250 ppm
<b>Other Food Safety Criteria</b>	Histamine	Histamine poisoning fish; Tuna, Mackerel, Sardine, Saba, etc.	100 ppm

Notes:

<sup>1)</sup> As specified in CODEX STAN 192-1995 as amended 2018

<sup>2)</sup> Codex Alimentarius CSX 193-1995 as amended 2018

<sup>3)</sup> If the total mercury concentration is below or equal to the ML for methylmercury, no further testing is required and the sample is determined to be compliant with the ML. If the total mercury concentration is above the ML for methylmercury, follow-up testing shall be conducted to determine if the methylmercury concentration is above the ML.

## 2. Microbiological Criteria for Fresh and Frozen Fish & Fishery Products

Product group	Parameter	<i>n</i>	<i>c</i>	<i>m</i>	<i>M</i>
Raw Fish, crustaceans and molluscs, fresh or frozen: (to be prepared and cooked before consumption)	E. coli; CFU/g	5	3	10	500
	Staphylococcus aureus, CFU/g	5	2	10 <sup>3</sup>	10 <sup>4</sup>
	Salmonella spp.; /25g	5	0	ND	
Prepared fish and fishery products; frozen, ready to cook (to be cooked before consumption; e.g. breaded fish)	TPC; CFU/g	5	2	10 <sup>5</sup>	10 <sup>7</sup>
	E. coli; CFU/g	5	2	10	500
	Staphylococcus aureus, CFU/g	5	1	10 <sup>3</sup>	10 <sup>4</sup>
	Salmonella spp.; /25g	5	0	ND	-
Cooked fish and fishery products, frozen, ready to eat.	TPC; CFU/g	5	2	10 <sup>4</sup>	10 <sup>5</sup>
	E. coli; CFU/g	5	0	<3	-
	Staphylococcus aureus, CFU/g	5	2	10 <sup>2</sup>	10 <sup>3</sup>
	Vibrio parahaemolyticus, CFU/g	5	1	10 <sup>2</sup>	10 <sup>3</sup>
	Salmonella spp.; /25g	5	0	ND	-
	L. monocytogenes; /25g	5	0	ND	-

ND means shall not be detected



References:

- 1) ICMSF, MICROORGANISMS IN FOODS 2 Sampling for microbiological analysis: Principles and specific applications 1986, 2. Ed.; Chapter 17 (modified)
- 2) CAC/GL 50-2004 chapter 3.2.2

### 3. Microbiological Criteria for Traditional Fishery Products

Product	TPC; CFU/g	Yeast & Mould; CFU/g	<i>Staphylococcus Aureus</i> ; CFU/g	<i>Vibrio cholera</i> ; /25g	<i>Clostridium Perfringens</i> /0.1g	<i>Salmonella</i> spp. /25g
Fermented shrimp paste	NT	<1,000	<3	n = 5 c = 0 m = 0	10	n = 5 c = 0 m = 0
Dried cephalopods	NT	<1,000	<100	NT	ND	n = 5 c = 0 m = 0
Dried fish	NT	<1,000	<100	NT	ND	n = 5 c = 0 m = 0
Dried other fisheries product	NT	<1,000	<100	NT	NT	n = 5 c = 0 m = 0
Dried other fisheries product	<50,000	<200	<100	n = 5 c = 0 m = 0	NT	n = 5 c = 0 m = 0
Fermented fish (Ready to eat)	<50,000	<200	<100	n = 5 c = 0 m = 0	ND	n = 5 c = 0 m = 0
Salted fish (Fresh)	NT	<1,000	<100	NT	ND	n = 5 c = 0 m = 0
Traditional other fisheries product	<50,000	<200	<100	n = 5 c = 0 m = 0	ND	n = 5 c = 0 m = 0

ND means shall not be detected

NT means shall not be tested (no criteria applies)

## ANNEX 4 – Sampling and Testing

### 1. General requirements to Business Operators and NCA

The business operators as well as the NCA shall carry out sampling and testing to verify that the HACCP based systems are effective to control identified food safety hazards. The sampling frequencies and test parameters shall be defined within the business operators HACCP systems and within the NCA Technical procedures and the respective related work instructions.

Table 1 overleaf indicates the minimum sampling and testing to be carried out by the two parts, however it is the responsibility of each part to always evaluate if it is deemed necessary to increase frequency of the samplings for efficient verification or if it can be justified, based on risk assessment and trend analysis, to reduce the sampling frequencies.

The NCA and business operators shall keep the results of sampling and testing in formats that allow easy trend analysis and information gathered through this shall be included in the risk assessment when determining frequency of sampling for different parameters.

Results of the business operators sampling and testing shall be available for NCA officials at audit an inspection of the HACCP systems.

### 2. Test Methods and Sampling

2.1 Procedures for sampling and testing, to be conducted for the purpose of official control of food safety of fishery products, as foreseen in sections 3.1.3.3, 3.3.2.5, 3.3.5 and 3.6.1.5 of this technical regulation, shall be documented in quality management systems of the NCA and the laboratories or other control bodies, to which such responsibility is delegated. NCA shall have procedures and where necessary, related work instructions including, but not be limited to:

#### *Test Methods*

- Reference to the test method used
- Performance criteria for the test method used as applicable (detection limit, accuracy, limit of quantification etc.)
- Matrix for which the test method applies/has been validated
- Sample preparation
- Detailed technical test procedure including calculation and presentation of the result

## Sampling

- Identification of the lot sampled from and the size of the lot (a day's production, the products produced from on batch of raw material, a consignment ready for export etc.).
  - Special precautions to be taken to avoid any changes of the substance to be tested for (e.g. sterility, cleanliness or migration of substances from the containers to be used for the sample).
  - Number and size of incremental and aggregate samples where relevant
  - Containers to be used for the sample, including sealing of the container
  - Ensuring of samples to be kept for references
  - Principles for systematic labelling of samples and record keeping of the sampling process which ensure that samples may not be mixed up.
  - Conditions for sample storage, transport and delivery to the laboratory (time and temperature)
  - Sampling plans as adequate for the type of product, size of the consignment and lots/sublots and the purpose of the sampling and testing.
- 2.2 Business operators shall have procedures and related work instructions for verification by sampling and testing documented under the HACCP system. The documentation shall include at least the elements described in section 2.1.2 and information about the laboratory services relied on.
- 2.3 The business operator shall select a laboratory that can provide satisfactory information about the test methods as described in section 2.1.1 above. Business operators shall require the laboratory to inform, where relevant, whether the method(s) to be applied are equivalent with any specific market criteria.

### 3. Specific Requirements – Sampling Plans

Where export markets, for example the EU market, have specific requirements for test methods, sampling methods or sampling plans, such methods shall always be applied for the purpose of official control of consignments intended to be exported to these markets.

If there is no specific marked requirements, the principles in relevant international standards, as indicated in section 6 – 7 below shall be applied.

### 4. Sampling Plans for microbial testing

When a consignment for export or import is to be tested for compliance with microbial criteria stipulated in Annex 3 of this Technical regulation, or with specific market criteria, a two or three

attribute sampling plan shall be applied <sup>Ref. 1)</sup> and the number of samples and acceptance level shall be determined based on the risk as indicated in the Table 2 below, where it is not already defined in Annex 3.

**Table 2: Classification of sampling plans for microbial criteria, including histamine, according to nature of concern and hazard**

Nature of Concern	Decreased hazard	Unchanged hazard	Increased hazard
No direct health hazard (spoilage and shelf-life)	n=5, c=3	n=5, c=2	n=5, c=1
Low indirect health hazard (indicator organism)	n=5, c=3	n=5, c=2	n=5, c=1
Moderate direct health hazard (limited spread)	n=5, c=2	n=5, c=1	n=10, c=1
Moderate direct health hazard of potential extensive spread in food.	n=5, c=0	n=10, c=0	n=20, c=0
Severe direct health hazard.	n=15, c=0	n=30, c=0	n=60, c=0

Examples:

- If Salmonella in a ready to eat products is considered to be “A moderate direct health hazard (limited spread), hence the sampling should be done with n=5 and c=0
- E. coli in raw fish is considered to be of “A low indirect health hazard (Indicator organism) with decreased hazard (because the product will normally be cooked before eating) hence the sampling should be done with n=5 and c=3.

Ref. 1 CAC/GL 50-2004 chapter 3.2.2 and section 10 in this Annex for definitions.

## 5. Sampling for of control of net weight/drained weight

When control of net weight/drained weight of lots/consignments ready for export or lots/consignments intended for import the tolerable error for a given net weight/ drained weight as indicated in Table 2 below shall be applied and the number og samples depending of the size of the consignment shall be determined as per Table 3.

*Example:* If the consignment have 500 master cartons of 10 kg, 81 samples shall be taken (Table 2) and 4 of the samples may have a negative tolerance of up to 150 g (table 3).

**Table 2: Sampling for net weight/drained weight control**

Lot size (units)	Number of samples to be taken	Number of packages allowed with the error in Table 3
20	all	0
40	32	1
60	35	1
80	47	2
100	49	2
200	64	3
300	67	3
400	81	4
500	81	4
600-100000	98	5

Reference: OIML R 87 (2016).

**Table 3: Tolerable negative error of weight/drained weight**

Nominal weight/drained weight ( An g)	Tolerable Negative Error (TNE)	
	% of An	g
5 to 50	9	-
50 to 100	-	4.5
100 to 200	4.5	-
200 to 300	-	9
300 to 500	3	-
500 to 1 000	-	15
1 000 to 10 000	1.5	-
10 000 to 15 000	-	150
Above 15 000	1	

Reference: OIML R 87 (2016).

## 6. Sampling for control of environmental contaminants

6.1 Sampling for control of environmental contaminants (heavy metals, dioxin and dioxin like substances) in a lot/consignment intended for export or import shall be based on the following principles.

- a. A number of incremental samples shall be taken randomly in the consignment, however focus may be given to the biggest fish in the consignment.
- b. The incremental samples shall be pooled to one aggregate sample, from where the laboratory sample(s) shall be drawn.
- c. The result of the sampling and testing is the result from the laboratory sample.
  - i) If the result for the bigger fish is below the criteria in Annex 3, the consignment shall be considered compliant.
  - ii) If the result for the bigger fish is higher than the criteria in Annex 3, new samples shall be taken from smaller fish. If the result from this testing is below the criteria in Annex 3, the fish of this size and smaller sizes shall be considered compliant while the bigger fish shall be non-compliant and sorted out of the consignment for other purposes.

6.2 The number of incremental samples shall be determined depending of the size of the lot.

- a. A lot/consignment or a subplot can consist of only one species of marine fish or freshwater fish.
- b. A lot/consignment which is more than 15 tonnes shall be divided in sublots of 15-30 tonnes
- c. The number of incremental samples from a lot or subplot shall be determined as follow

**Table 3: Minimum number of incremental samples to be taken from the lot or subplot**

<b>Weight or volume of lot/sublot (in kg or litre)</b>	<b>Minimum number of incremental samples to be taken</b>
< 50	3
≥ 50 and ≤ 500	5
> 500	10

Reference: EU Regulations (EC) 333/2007 and (EC) 644/2017

If the lot or subplot consists of individual packages or units, then the number of packages or units which shall be taken to form the aggregate sample is given in Table 4.

**Table 4: Number of packages or units (incremental samples) which shall be taken to form the aggregate sample if the lot or subplot consists of individual packages or units**

Number of packages or units in the lot/sublot	Number of packages or units to be taken
≤ 25	at least 1 package or unit
26-100	about 5 %, at least 2 packages or units
> 100	about 5 %, at maximum 10 packages or units

Reference: EU Regulations (EC) 333/2007 and (EC) 644/2017

## 7. Sampling for control of residues of veterinary medicines

Sampling for control of residues of veterinary medicines in a lot/consignment intended for export or import shall be based on the principles for environmental contaminants as described in section 6 above, however the incremental samples shall include all sizes of the fish in the lot/consignment.

## 8. Hygiene control of food safety surfaces

Hygiene control of food safety surfaces shall or may be carried out as required in the sections 2.7.17 and 3.1.3.3 of this technical regulation and Table 1 of this Annex. The controls shall be carried out with methods described by international standards such as ISO 18593:2018 or other methods where validation proves their efficiency for purpose.

The operator and the NCA shall make work instructions for implementing the method the chose to use, including at least, but not limited to the instructions for use, surface area to be controlled, the incubation temperature and the criteria for acceptable and not acceptable. Records shall always include details of time and place of the testing.

The routine hygiene control shall as be based on total count; however it may be made specific for specified pathogenic bacteria (e.g. salmonella, E.coli, Listeria spp.) in cases where causes for specific are to be analysed.

## 9. Special conditions

If it is not possible to carry out the sampling as set out in this Annex because of unacceptable commercial consequences (e.g. damage to the lot or package forms) or where it is practically impossible to apply the above mentioned sampling methods, alternative methods may be applied provided that they are sufficiently representative for the sampled lot or subplot and fully documented.



## 10. Definitions that apply to this Annex

N	The number of samples to be tested in microbial analysis
m	The lower limit which determine compliance (microbial analysis)
M	The higher limit which may apply in determining compliance (microbial analysis)
c	Is the number of samples that are permitted to have results above <b>m</b> (single limit) or between <b>m</b> and <b>M</b> if the two are different
Two attribute sampling plan	If only one limit <b>m</b> applies to the product, or if <b>m = M</b> .
Three attribute sampling plan	If two limits <b>m</b> and <b>M</b> applies to the product and if <b>m &lt; M</b>
Lot:	An identifiable quantity of food delivered at one time and determined to have common characteristics, (such as origin, variety, type of packing, packer, consignor or markings). The size of fish shall be comparable.
Sublot:	Designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separated and identifiable.
Incremental sample:	A quantity of material taken from a single place in the lot or sublot
Aggregate sample:	The combined total of all the incremental samples taken from the lot or sublot; aggregate samples shall be considered as representative of the lots or sublots from which they are taken
Laboratory sample:	A sample intended for the laboratory

**Table 1: Framework for sampling of water, ice, products and raw materials for verification of efficiency of the HACCP systems – Minimum requirements**

Parameters and Products	Establishments own sampling (mandatory for the establishments <u>and</u> to be verified during NCA inspections)	Official Control  Samples to be taken by ALU or ICU inspectors
Microbiological testing of Potable Water (E. Coli, coliforms, Enterococci ) + Clostridium perfringens	As a part of SSOP internal verification:  - 1 sample/month and if non-compliances at least 1 sample/week until solved	<ul style="list-style-type: none"> <li>- At least 1 sample on the line <u>at each regular inspection/audit</u> (= 2-4 samples per year). If the results of the establishment own monitoring indicates systematic non-compliances, more samples may be taken.</li> <li>- Samples may be taken also as part of verification and before closing a CAR, if deemed necessary.</li> </ul>
Microbial testing of ice (E. Coli, coliforms, Enterococci,)	As a part of SSOP internal verification:  - 1 sample/month and if non-compliances at least 1 sample/week until solved	<ul style="list-style-type: none"> <li>- At least 1 sample on the line <u>at each regular inspection/audit</u> (= 2-4 samples per year). If the results of the establishment own monitoring indicates systematic non-compliances, more samples may be taken.</li> <li>- Samples may be taken also as part of verification and before closing a CAR, if deemed necessary.</li> </ul>
Chemical Testing of potable water and ice  (full testing according to Annex I, Part B in Directive 98/83/EC)		<ul style="list-style-type: none"> <li>- 1 sample/year and if non-compliances further sampling as deemed necessary</li> </ul>
Chemical and physical testing of potable water and ice  (Testing of relevant Indicator Parameters Annex I, Part C in Directive 98/83/EC, <u>following</u> Annex II,	As a part of SSOP internal verification:  - 1 sample/3 months and if non-compliances at least 1 sample/week until solved	<ul style="list-style-type: none"> <li>- 1 sample/year and if non-compliances further sampling as deemed necessary</li> </ul>

Parameters and Products	Establishments own sampling (mandatory for the establishments <u>and</u> to be verified during NCA inspections)	Official Control  Samples to be taken by ALU or ICU inspectors
check monitoring)		
Testing hygiene of food contact surfaces	<p>As a part of SSOP internal verification:</p> <ul style="list-style-type: none"> <li>- Conduct swap analysis or similar microbiological testing of surfaces in contact with ready to eat products (i.e. in areas after or during their processing but before packing).</li> <li>- Frequency to be specific in HACCP pre-requisite program, depending of trend analysis; it may be weekly or monthly.</li> </ul>	<p>May be carried out as a verification of visual inspection during HACCP audit or inspection (however only after normal cleaning and disinfection and when no processing takes place).</p>
<p>Products/Raw materials</p> <p>Heavy Metals <u>in wild caught species</u> (Pb, Cd, Hg)</p>	<p>As a part of HACCP verification: At a frequency determined by species and result of trend analysis (see section 1 of this Annex).</p> <p>Cephalopods (squid, cuttlefish): all consignments intended for export to EU unless trend analysis for the size of the animal in the consignment show that levels below the EU criteria is common.</p>	<p>Target Monitoring Program (in line with current program). Samples to be taken with reference to catch or production area at level factory raw material receiving or vessel.</p> <ul style="list-style-type: none"> <li>- Freshwater Fish (Rohu)</li> <li>- Freshwater Prawn</li> <li>- Marine Fish</li> <li>- Squid</li> <li>- Mud Crab</li> <li>- Black Tiger Shrimp</li> <li>- Pink Shrimp</li> </ul> <p>Sampling may be conducted at pre-export verification if risk assessment indicates that level may be above level accepted by the importing country.</p>

Parameters and Products	Establishments own sampling (mandatory for the establishments <u>and</u> to be verified during NCA inspections)	Official Control  Samples to be taken by ALU or ICU inspectors
Products/Raw materials  Histamine	For HACCP/GMP verification:  <i>Hilsa</i> : at determined frequencies for monitoring/verification of CCP  <i>Dried Anchovies</i> : HACCP System verification - all consignments intended for export to EU (at least 9 samples)  <i>Dried Loti</i> : all consignments intended for export to EU (9 samples)	For freshness at landing:  Hilsa, anchovies, spanish mackerel and lotia to be sampled for histamine if doubt about freshness.  Sampling at level pre-export verification at least 1/10 consignments. If non-compliance or level close to non-compliance initiate further sampling.
Products Microbial Testing	For HACCP/GMP verification:  <u>Raw Products for cooking before consumption:</u>  E. Coli, Staphylococcus Aureus at determined frequencies, (app. 1 time per month)  <u>Breaded, not pre-fried, products:</u>  E. Coli, Staphylococcus Aureus, total count at determined frequencies, (at least 1 time per month)  <u>Cooked products or other ready to eat products:</u>  – E. Coli, Staphylococcus Aureus, Salmonella, Listeria monocytogenes and other species depending of determined risk; frequency	For raw products and for breaded products for cooking before consumption:  - At inspections and pre-export verification <u>if</u> deemed necessary for verification of hygiene standard.  <u>For cooked products and other ready to eat products:</u>  - At each regular inspection and at pre-export verification on a risk based frequency.

<b>Parameters and Products</b>	<b>Establishments own sampling (mandatory for the establishments <u>and</u> to be verified during NCA inspections)</b>	<b>Official Control Samples to be taken by ALU or ICU inspectors</b>
	depending of risk assessment; could be daily or weekly.	