SCOPE

This standard sets out the requirements for HACCP of Fish and Fishery Products which includes essential needs in managing hygienic controls of food processing, analysis of food safety hazards relating to products and processing, and appropriate control measures of identified hazards. Fish processors are required to commence the operations in compliance with this requirement. This standard will cover the following sections:

1. Sanitation Standard Operating Procedures
2. HACCP plans
3. Training
4. Quality manual

DEFINITIONS

1. Good manufacturing practice means whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

2. Hazard means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

3. Hazard analysis means an analysis of the risks and severity of each of the hazards to determine the significance of the food-safety hazards. All potentially significant hazards must be considered in the HACCP plan.

4. HACCP Plan means the written document based upon principles of HACCP that delineates the procedures to be followed to ensure the control of a specific process or procedure.

5. Critical control point means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.

6. Critical limit means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

7. Validation means the element of verification that involves the collection and evaluation of information to determine if the HACCP plan, when properly implemented, will effectively control significant food-safety hazards.

8. Monitoring means a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.
9. Corrective action means procedures followed when a deviation from a critical limit occurs at a critical control point

10. Verification means the application of methods, procedures, tests and evaluations other than monitoring to validate the adequacy of and compliance with the HACCP plan.

SECTION 1: SANITATION STANDARD OPERATING PROCEDURES

1. A processor must meet the pre-requisite requirements specified in "Conditions laying down for Operating Practices of Fish and Fishery Products"

2. A processor must develop a written sanitation standard operating procedure (herein referred to as SSOP) and implement it effectively.

3. A processor must monitor the conditions and practices of its hygiene during processing with sufficient frequency.

4. The written SSOP must include
   (1) Hygienic processing plant's structure and equipment.
   (2) Safety of water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice.
   (3) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments.
   (4) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product.
   (5) Maintenance of hand washing, hand sanitizing, and toilet facilities.
   (6) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants.
   (7) Proper labeling, storage, and use of chemical and toxic compounds.
   (8) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces.
   (9) Exclusion of pests from the establishment.

5. SSOP documents should have in details the procedures of hygienic practices and their controls to meet the SSOP requirements. The

documents should also include description of monitoring procedures for those SSOP 9 areas as mentioned above.

6. Whenever non-compliance is found, the processor must correct it in an appropriate time-frame.
7. Records of SSOP monitoring and corrective actions must be maintained for a period as specified in section 2 item 3.7. 2 (3.7).

SECTION 2: HACCP PLAN

1. Hazard analysis

   A processor must conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information.

   Every processor must record hazards analysis and preventive measures that processor designed to control those hazards.

2. The HACCP plan

   A processor must have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph 1. A HACCP plan must be specific to each location where fish and fishery products are processed by that processor and each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in the contents of HACCP plan are identical for all fish and fishery products so grouped or for all production methods so grouped.

3. The contents of the HACCP plan.

   The HACCP plan must, at a minimum:

List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (1) of this section. Consideration

should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

1) Natural toxins, e.g. biotoxin
2) Chemical contamination, e.g. Heavy metal
3) Microbiological contamination, e.g. *Listeria monocytogenes*, *Salmonella*
4) Pesticides
5) Drug residues
6) Decomposition in scombroid toxin-forming species
7) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites
8) Unapproved use of direct or indirect food or color additives
9) Physical hazards

List the critical control points for each of the identified food safety hazards. Processor may use CODEX Decision tree or others proper methods to decide the critical control points. Preventive measures must prevent or eliminate a food-safety hazard or reduce it to an acceptable level.

Critical limits should conduct or information gather from sources such as scientific publications, regulatory guidelines. Critical limits must proper validate.

List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits by who have adequate training or experience.

Corrective action

(1) Processors must develop written corrective action plans, by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps.

(2) Segregate and hold the affected product to determine the acceptability of the affected product for distribution.

All corrective actions taken in accordance with this section must be fully documented in records that are subject to verification in accordance with item 3.6 and the recordkeeping requirements of item 3.7.

Verification

A processor must verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented.

(1) Verification must include, at a minimum:

(i) *Reassessment of the HACCP plan.* A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment must be performed by an individual or individuals who have been trained. The HACCP plan must be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements.

(ii) *Ongoing verification activities.* Ongoing verification activities including: a review of any consumer complaints, the calibration of process-monitoring instruments and the performing of periodic end-product or in-process testing.

(iii) *Records review.* A review, including signing and dating, by an individual who has been trained. The following records must be review:

- *The monitoring of critical control points.* The purpose of this review must be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review must occur within 1 week of the day that the records are made and before transportation of products.

- *The taking of corrective actions*. The purpose of this review must be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken. This review must occur within 1 week of the day that the records are made.

- *The calibrating*. The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process

testing that is part of the processor's verification activities. The purpose of these reviews must be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews must occur within a reasonable time after the records are made.

(2) A processor must immediately follow the corrective action plan whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

Documentation and record keeping

(1) A processor must keep records and HACCP related documents. Examples of records required e.g. monitoring records, corrective action and calibrations records. Documents required to be maintained such as HACCP plan and scientific data that are used to support the plan.

(2) Monitoring records must include
   (i) Name and location of the processor.
   (ii) Date and time of the activity that the record reflects.
   (iii) Signature or initials of the person performing the operation.
   (iv) Where appropriate, the identity of the product and the production code.

(3) Record retention. All records required by this part must be retained at the processing facility at least
   (i) 1 year after the date they were prepared in the case of refrigerated products and traditional product.
   (ii) 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

SECTION 3: TRAINING

The following functions must be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing and sanitation; developing a HACCP plan, monitoring at CCP, verification and Reassessing and modifying the HACCP plan.

SECTION 4: HACCP MANUAL

A processor must have a written HACCP manual and cover the following essential areas:

1. Background information specific to the name and address of processing plant, tel./fax no., document no., date of submission, and management commitment.

2. Organization chart of the company.

3. Job responsibility of HACCP - related personnel outlined in the organization chart.

4. Product description which includes product name, product characteristic, intended use of the product, packaging, shelf-life, where the product will be sold, labeling instruction, and special distribution control.

5. Product flow diagram must cover processing steps at which affects to safety of product.

6. Standard operating procedures must be specific to operation practices and quality control of each step.

7. Hazards analysis and their control measures.

8. HACCP plan, when a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, must include:
    1) Identified potential hazard that need to be controlled.
    2) Critical control point.
    3) Critical limits.
    4) Monitoring procedures.
    5) Corrective actions.
    6) Verification procedures.
    7) Name of each monitoring record.

9. Standard sanitation operating procedures as specified in section 1.

10. Other pre-requisite requirements:
    1) System verification; outlining the verification procedures, frequency, and responsible person.
    2) Record keeping procedures including documents as described in section 2 item 3/3.7(1) and retention period and place.

3) Recall procedures; demonstrating operation steps when products are recalled, responsible person, and detail of product code used for tracing back the target lot.
4) Training; specifying training program, subject, date and trainee.

11. HACCP manual must be signed and dated by top management or authorized person. Signing will demonstrate the company's acceptance of the developed manual and this must be done when the manual is first accepted and prior to its implementation or whenever any changes occur.