LEGAL NOTICE NO 41/1998

THE FISHERY PRODUCT HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP) REGULATIONS

PART I

PRELIMINARY

Art. 1 Citation

These Regulations may be cited as to "the Fishery Product HACCP Regulations Legal Notice No 41/1998".

PART II

PRINCIPLES OF HACCP

Art. 2 Principles

It is recommended that a model of a logical approach be followed of which the following principles form the essential components:

1) identification of hazards, analysis of risks and determination of measures necessary to control them;

2) identification of critical points;

3) establishment of critical limits for each critical point;

4) establishment of monitoring and checking procedures;

5) establishment of corrective action to be taken when necessary;

6) establishment of verification and review procedures; and

7) establishment of documentation concerning all procedures and records.

Such a model or the principles on which it is based should be used with the flexibility appropriate to each situation.

PART III

RECOMMENDATION FOR PROCEEDING WITH ACTIVITIES IN SEQUENCE REGARDING IDENTIFICATION OF CRITICAL POINTS

.Art. 3 Assembly of a multidisciplinary team

1) The team which involves all parts of the enterprise concerned with the product, needs to include the whole range of specific knowledge and expertise appropriate to the product under consideration, its production (manufacture, storage, and distribution), its consumption and the associated potential hazards.

2) Where necessary, the team will be assisted by specialists who will help it to solve its difficulties as regards assessment control of critical points.

3) The team may consist of :

   (a) A quality control specialist who understands the biological, chemical or physical hazards connected with a particular product group.

   (b) A production specialist who has responsibility for, or is closely involved with the technical process of manufacturing the product under study.

   (c) A technician who has a working knowledge of the hygiene and operation of the process plant and equipment.

   (d) Any other person with specialist knowledge of microbiology, hygiene and food technology.

   One person may fulfil several of these roles, provided all relevant information is available to the team and is used to ensure that the own-checks system developed is reliable. Where expertise is not available in the plant, advice should be obtained from other sources (consultancy, guides of good manufacturing practice, etc.

Art.4 Description of the product

The end product should be described in terms of:

1) composition (e.g. raw material ingredients, additives, etc);

2) structure and physico-chemical characteristics (e.g. solid, liquid, gel emulsion, pH, Aw etc.);

3) processing (e.g. heating, freezing, drying, salting, smoking, etc and to what extent);

4) packaging (e.g. hermetic, vacuum, modified atmosphere);

5) storage and distribution conditions;

6) required shelf life (e.g. sell by date and best before date);

7) instruction for use; and

8) any microbiological or chemical criteria applicable.

Art. 5. Identification of intended use

The multidisciplinary team should also define the normal or expected use of the product by the customer and the consumer target groups for which the product is intended .In specific cases, the suitability of the product for particular groups of consumers such as institutional caterers, travellers etc and for vulnerable groups of the population may have to be considered.

Art. 6 Construction of a flow diagram (Description of manufacturing process)

1) Whatever the format chosen all steps involved in the process, including delays during or between steps, from receiving the raw materials to placing the end product on the market, through preparation, processing, packaging, storage and distribution should be studied in sequence in a detailed flow diagram with sufficient technical data.

2) Types of data may include but are not limited to:

- plan of working premises and ancillary premises;
- equipment layout and characteristics;
- sequence of all process steps (including the incorporation of raw materials ingredients or additives and delays during or between steps.);
- technical parameters of operations (in particular time and temperature including, delays);
- flow of products (including potential cross-contamination);
- segregation of clean and dirty areas (or high /low risk areas); and
- personnel routes.

Art. 7 On-site confirmation of flow diagram

After the flow diagram has been drawn up, the multidisciplinary team should confirm it on site during operating hours. Any observed deviation must result in an amendment of the original flow diagram to make it accurate.

Art. 8 Listing of hazards and control measures.

Using the confirmed flow diagram as a guide the team should:

1) List all potential biological, chemical or physical hazards that may be reasonably expected to occur at each process step (including acquisition and storage of raw materials and ingredients and delay during manufacture).

A hazard is a potential to cause harm to health and is anything covered by the hygiene objectives of the Fishery Product Regulations Legal Notice No 40/1998. Specifically, it can be any of the following:

(a) unacceptable contamination (or recontamination) of a biological (micro - organisms, parasites) chemical or physical nature of raw materials, intermediate or final products;

(b) unacceptable survival or multiplication of pathogenic microorganism and unacceptable generation of chemicals in intermediate products, final products, production line or environment; and

(c) unacceptable production or persistence of toxins or other undesirable products of microbial metabolism.

For inclusion in the list, hazards must be of a nature such that their elimination or reduction to acceptable levels is essential to the production of safe food.

2) Consider and describe what control measures, if any, exist which can be applied for each hazard.

(a) Control measures are those actions and activities that can be used to prevent hazards, eliminate them or reduce their impact or occurrence to acceptable levels.

(b) More than one control measure may be required to control an identified hazard and more than one hazard may be controlled by one control measure. For instance, pasteurization or controlled heat treatment may provide sufficient assurance of reduction of the level of both *Salmonella* and *Listeria*.

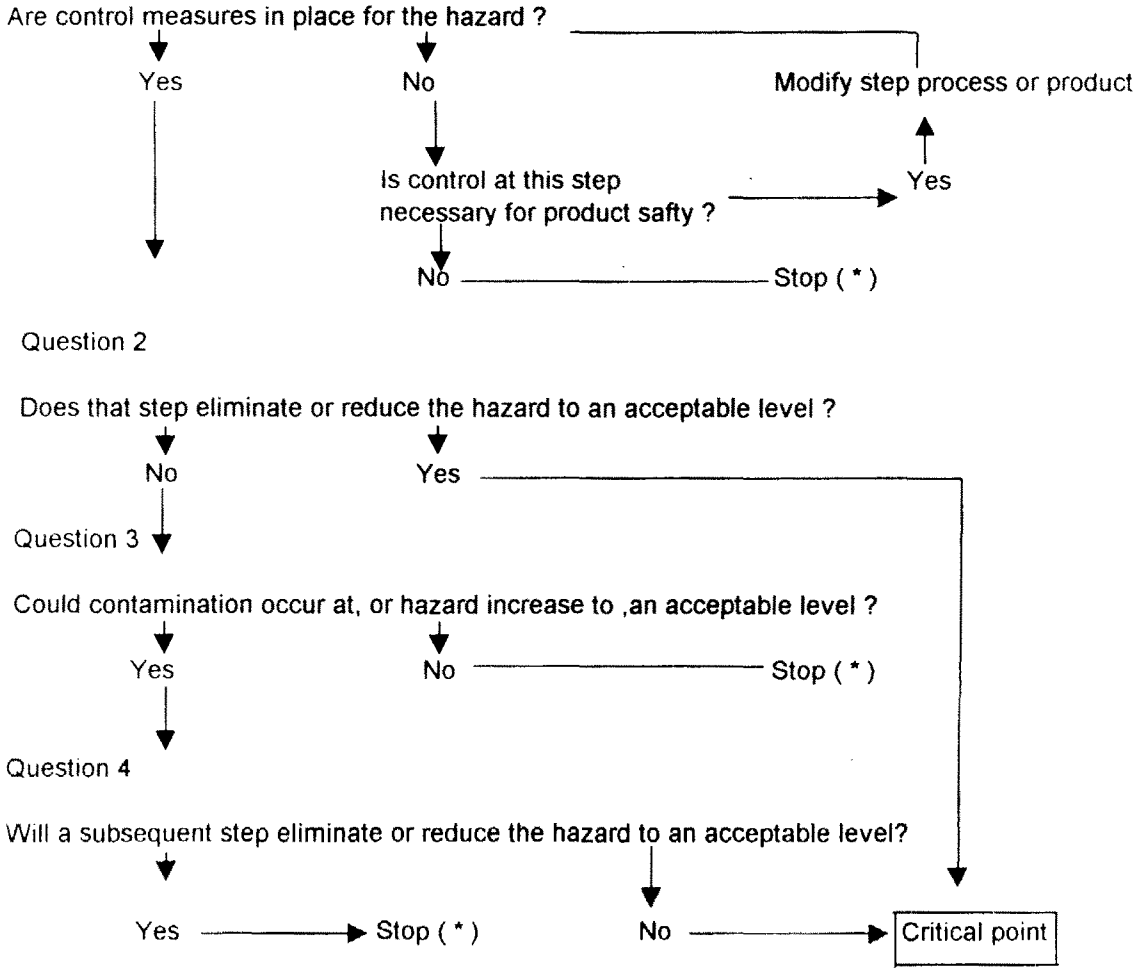
(c) Control measures need to be supported by detailed procedures and specifications to ensure their effective implementation. For instance, detailed cleaning schedules, precise heat treatment specifications, maximum concentrations of preservatives used in compliance with the applicable legislation on additives.

Art. 9 Methods for identification of critical points

The identification of critical point for the control of a hazard requires a logical approach. Such an approach can be facilitated by the use of the following decision tree (other methods can be used by the team, according to their knowledge and experience).

1. Decision tree for the identification of critical points

Answer each question in sequence, at each step and for each identified hazard.



(*) The step is not a critical point. Proceed to next step.

2) For the application of the decision tree, each process step identified in the flow diagram should be considered in sequence. At each step, the decision tree must be applied to each hazard that may be reasonably expected to occur or be introduced and each control measure identified.

3) Application of the decision tree should be flexible and requires common sense, having consideration for the whole manufacturing process in order to avoid, whenever possible, unnecessary critical points.

Art. 10 Action to be taken following identification of a critical point

The identification of critical control points has two consequences for the multidisciplinary team, which should then:

1) Ensure that appropriate control measures are effectively designed and implemented. In particular, if a hazard has been identified at a step where control is necessary for product safety and no control measure exists at that step or at any other, then the product of process should be modified at that step, or at any other, than the product or process should be modified at that step or later stage, to include a control measure.

2) Establish and implement an appropriate monitoring and checking system at each critical point to ensure effective control thereof and proceed to the activities specified in Part IV herein below.

PART IV

ESTABLISHMENT AND IPLEMENTATION OF MONITORING AND CHECKING CRITICAL CONTROL POINTS

Art. 11 Establishment of critical limits for each control measures associated with each critical point

1) Each control measure associated with critical control points should give rise to the specification of critical limits.

2) Those critical limits correspond to the extreme values acceptable with regard to product safety. They separate acceptability from unacceptability. They are set for observable or measurable parameters that can readily demonstrate that the critical point is under control; they should be based on substantiated evidence that chosen values will result in process control.

3) Examples of such parameters include temperature, time, pH, moisture level, additive, preservative or salt level, sensory parameters such as visual appearance or texture ...etc.

4) In some cases, to reduce the risk of exceeding a critical limit due to process variations, it may be necessary to specify more stringent levels (i.e. target levels) to assure that critical limits are observed.

5) Critical limits may be derived from a variety of sources. When not taken from regulatory standards (e.g. frozen storage temperature) or from existing and validated guides of good manufacturing practices, the team should ascertain their validity relative to the control of identified hazard and critical points.

Art. 12 Establishment of a monitoring and checking system for each critical point.

1) An essential part of own-checks is a program of observations or measurements performed at each critical point to ensure compliance with specified critical limits. The program should describe the methods, the frequency of observations or measurements and the recording procedure.

2) Observations or measurements must be able to detect loss of control at critical points and provide information in time for corrective action to be taken.

3) Observations or measurements can be made continuously or discontinuously. When observations or measurements are not continuous, it is necessary to establish a frequency of observations or measurements, which provides reliable information.

4) The program of observations or measurements should properly identify for each critical point:

-who is to perform monitoring and checking;

-when monitoring and checking is performed; and

-how monitoring and checking is performed.

Art.13 Establishment of a corrective action plan

1) Observations or measurements may indicate:

(a) that the parameter monitored tends to deviate its specified critical limits, indicating a trend toward loss of control. Appropriate corrective action to maintain control must be taken before the occurrence of hazard; and

(b) that the parameter monitored has deviated from its specified critical limits,

indicating a loss of control. It is necessary to take appropriate corrective action to regain control.

2) Corrective action has to be planned in advance by the multidisciplinary team, for each critical point so that it can be taken without hesitation when a deviation is observed.

3) Such corrective action should include:

   (a) proper identification of the person(s) responsible for the implementation of the corrective action;

   (b) description of means and action required to correct the observed deviation;

   (c) action to be taken with regard to products that have been manufactured during the period when the process was out of control; and

   (d) written record of measures taken.

PART V

VERIFICATION OF OWN-CHECKS SYSTEMS

Art.14 Own -checks system

Own -checks system verification is necessary to ensure that they are working effectively. The multidisciplinary team should specify the methods and procedures to used:

1) Usable methods may include in particular random sampling and analysis, reinforced analysis or tests at selected critical points, intensified analysis of intermediate or final products, surveys on actual condition during storage, distribution and sale and on actual use of the product.

2) Verification procedures may include: inspection of operations, validation of critical limits, review of deviations, corrective action and measures taken with regard to the product, audits of the own -check system and its records.

3) Verification should provide for confirmation of the suitability of the own-checks system established and ensure, afterwards, with an appropriate frequency, that the provisions laid down are still being properly applied.

4) In addition, it is necessary to review the system, to ensure that it is (or will be) still valid in case of change.

   Examples of change include:

   - change in raw material or in product, processing conditions (factory layout and

environment, process equipment, cleaning and disinfection program);

- change in packaging, storage or distribution conditions;
- change in consumer use; and
- receipt of any information on a new hazard associated with the product.

5) When necessary, such a review must result in the amendment of the provision laid down.

6) Any change to the own-checks system arising should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available.

7) Where criteria are specified in regulations, such criteria are to be used as reference values for the verification process.

PART VI

FINAL PROVISIONS

Art. 15 Entry into Force

These Regulations shall enter into as of the date of their publication in the Gazette of Eritrean Laws.

Done at Asmara, this 25th day of May, 1998

Petros Solomon,

Minister of Fisheries.