FI:TCP/BGD/4555
Field Document 2

TECHNICAL COOPERATION PROGRAMME

# PREPARATION OF A HACCP-BASED FISH QUALITY ASSURANCE PROGRAMME

BANGLADESH

# PROPOSALS FOR A HACCP-BASED FISH INSPECTION SYSTEM

based on the work of

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## 1. Executive Summary

The report details draft regulations to meet the requirements of the principal importers of fish and shellfish products from Bangladesh. These rules cover sanitation, operating procedures, facilities, and revised export certification based on 'own-checks'. These are exemplified by HACCP (Hazard Analysis Critical Control Point) systems. The report also addresses current problems of rejection of exports and suggests how to avoid these. It contains a review of the structure, facilities and operations of the Department of Fisheries of the Ministry of Fisheries and Livestock of the Government of Bangladesh (DoF) and suggestions for changes as well as a plan for the implementation of the new rules with timescales.

## 2. Introduction

The consultant carried out in August 1996 an initial survey on the current fish inspection and quality assurance system operated by DoF (FI:TCP/BGD/4555 field document 1). His second mission took place from 13 to 25 November 1996 with the following terms of reference:

- review, along with government representatives, the existing fish inspection structures and give advice to enable the drafting of the final text of the new regulations, based on the project proposals;
- advise on the policy and framework improvements needed, in particular to meet the new sanitary and quality requirements of major importing countries of fishery products of Bangladesh, and;
- assist in the drafting of a national HACCP-based quality assurance programme.

The main objectives of the consultant's terms of reference have been met. The consultant had a series of meetings with senior representatives of the main trade associations, the Bangladesh Frozen Fish Exporters Association and the Bangladesh Fisheries Development Association. During these meetings, general aspects were first discussed in considerable depth with regard to conditions in the country, and then the draft regulations were discussed line by line. There was agreement on virtually all points and the change in the philosophy in inspection systems was accepted and, indeed, welcomed. At the technical session of the workshop organized by DoF on 24 November 1996, a talk was organized on HACCP for industry and for inspectors and there was some discussion on the draft rules. The consultant also prepared documents on implementing the regulations, training requirements, a new operating structure for the inspection service with options for its organization, and laboratories.

The consultant expresses his thanks to all those he had contact with, for their helpfulness, co-operation and willingness to accept that change is inevitable and should be welcomed.

## 3. Main Findings

### 3.1 Regulations

The main objective of the present regulations is to license production of fish/shrimp products and certify them as of export quality by means of end product testing. This has been the world method until recently, when international opinion has moved towards a system of preventative quality assurance based on the HACCP-concept, or 'own-checks' for the E.U. The new approach has been written into the European Union (EU), United States of America (USA) and Canadian legislation and will soon be in that of Japan. Countries exporting to these markets will have to show that they have an equivalent or harmonized system for quality assurance and safety. This has been the driving force for changing the regulations for fish inspection in Bangladesh.

The most detailed legislation is from the EU and, as there are Memoranda of Understanding between the EU and the other principal markets, then compliance with their Directives will give access to all markets. They describe the requirements of HACCP.

The draft regulations prepared by the consultant are in Annex 1. The most important innovation is to replace the health certificate which must accompany any export lot with a declaration certificate completed by the producing company that it has an approved HACCP, all appropriate records indicating hygienic production of a safe and quality product. Then the inspector countersigns to the effect that he has seen the HACCP and the records. Thus the onus is on the producer who, as the owner of the goods, takes the responsibility. Much of the regulations lay down how to achieve the product and are regarded as an operating manual, or the alternative, a prohibition list of undesirable practices.

There is a major problem with the water directive, EEC/80/778, which has only recently been activated in many EU countries. This places a requirement for some 57 analyses to be done on each water supply, annually, and will stretch the resources of the country. Water is used in many ways in factories. It is used for glazing, as about 500ml is added to each 2 kg batch of peeled shrimp. As this water can be regarded as an ingredient, the consultant recommends that a separate pure supply of water, either specially purified by treatment with ion exchange resins or nano-filtration, or even bottled water be used. Pure water could be supplied by DoF or the export association.

DoF should remain as the competent authority for these regulations. It is assumed that the Bangladesh Standard and Testing Institute (BSTI) will be the competent authority for laboratory standards.

The draft regulations do not cover the bivalve molluscan shellfish Directive (EEC/92/492 and subsidiary regulations). The consultant was told that the bivalve industry was very small at present. Enforcement of this directive is extremely expensive in time and manpower as it requires continuous monitoring of production areas for *E. coli* and of wider areas for shellfish toxins. Toxins at present are assayed in animals; tissue culture cell line assays should be available in the near future. It is recommended that, if certification is required for bivalve shellfish, samples be sent to the reference laboratory in the receiving country.

Copies of the general food laws of Bangladesh have not yet been made available to the consultant and, accordingly he is unable to comment on them nor determine how the draft fish regulations will interact with them.

### 3.2 Sanitary requirements

A HACCP plan can cover all aspects of factory operation and their requirements, but from the consultant's experience and views expressed at an International Conference on Fish Inspection and Quality Control, held in the USA in May 1996, many potential critical control points (CCPs) are best tackled by means of Standard Sanitation Operation Procedures (SSOP) and other factory operations by Standard Operating Procedures (SOP). These have been written into various schedules of the regulations. They cover, for example, factory cleaning as an SSOP and freezer operational specifications as an SOP.

### 3.3 Current export problems

The Project Team Leader - Mr. Oscar Do Porto - obtained a copy of the list of lots of shellfish originating in Bangladesh and rejected by the authorities in the USA. The reasons given were presence of (i) *Salmonella arizonae*, (ii) decomposition and/or (iii) filth/insects.

3.3.1 Presence of *Salmonella arizonae*

The DoF laboratory asked why the USA authorities had been able to report the presence of *S. arizonae* from lots which they had found negative. The consultant made enquiries to contacts in the USA and obtained precise details of the methods used and compared them with those used by DoF. In the USA, the conventional Salmonella assay used includes enrichment on three media. DoF only uses two. *S. arizonae* behaves atypically on one of these media (XLD) and would be missed. It behaves normally on the third medium, Hektoen agar, which DoF does not use because of lack of supplies. So the discrepancy lies in the methodology. It is recommended that the laboratories use exactly the same methods as applied by the importing authorities.

*S. arizonae* is an unusual Salmonella. The consultant made enquiries about the incidence of human disease caused by this organism and these confirmed his view that it rarely causes illness, that any illness is rarely associated with consumption of shellfish. The major sources traced in the UK and confirmed in other countries are 'tourists', but none reportedly from Bangladesh, and reptiles, including frogs. His hypothesis at present is that *S. arizonae* is endemic in the ponds due to the presence of snakes and frogs, that it is not a contamination from within the factories, and that it is not a serious risk to human health. When the HACCP inspection system is in operation, it is expected that inspection and laboratory effort will be applied to tracing the source of these Salmonellas and devising control or elimination procedures. There should be interaction with the incipient FAO/TCP project "Disease Prevention and Health Management in Coastal Shrimp Culture" which will also examine possibilities of control of pathogens in aquaculture, and the consultant has some ideas to contribute in due course.

3.3.2 Decomposition

The second problem is decomposition, as determined by sensory analysis and high bacterial counts. This is entirely preventable and the incidence should be reduced by HACCP and SOPs. Bacteria grow to high numbers when given sufficient time and suitable temperatures. Processors must get the starting material to factories as quickly as possible and then ensure that there is the minimum delay in processing before freezing. There was discussion about heading and peeling of shrimp before they reach the factory and, in the schedules, the consultant recommends that only whole unpeeled shrimp be delivered, otherwise the peelers would need a HACCP. To be practical, especially during the transition period, factories should have the choice of how they want their supplies.

3.3.3 Presence of filth

The problems of filth and insects will also be reduced with application of the SSOP and building requirements.

## 4. Organization of Inspection Service

The functions of the DoF service will change under the new regulations. The structure of the inspection service will also have to change and proposals are given in **Annex 2**. The nature of the duties of staff will also change and these are reviewed in Annex 2. Because of anticipated changes in staffing, the service should take the opportunity for a radical restructuring, reducing the number of layers of management and introducing specialists at a higher level than at present. The role of the laboratories will change and end product testing will no longer be mandatory and testing will be done at earlier stages in processing, and initially, much more extensively. Laboratories are reviewed in **Annex 3**. The objective of the proposals is to suggest a choice of structures and facilities and organization to be progressive and be flexible enough to meet the needs of Government and industry for some time.

## 5. Auditing

For the correct implementation of HACCP in the fish/shrimp industry of Bangladesh there is a need to train DoF inspectors on auditing procedures. The consultant gave DoF staff a document on auditing - a totally new activity for DoF inspectors.

The essential features of auditing HACCP are that audits are planned, that they are constructive and not overtly critical, and that action points are followed up. There should be a meeting in advance of the audit to decide on the scope, for example one production line, or the SSOP for the factory of landing centre environment, the time of the visit (day or night shift), and the reference point (for example the appropriate part of the HACCP plan). Auditing a whole operation at one time is not usually practical, especially if the factory is in 24 hour operation. The personnel involved should be identified and must be present. The auditors should arrive at the agreed time and place and start work. They are the 'fresh eyes' to assess an operation and it is better if they had not approved the plan. They assess how well the plan is functioning, what are the deviations, but do not discuss them in the plant. Ample time should be set for a round-up meeting where there can be full and frank discussion of what was seen and the factory staff can indicate what was typical and what was unusual. At the meeting, an action plan should be agreed and a timescale set. The date for a further meeting should be set, at which all the amendments to the plan should be presented. Inspectors should allow 2-3 days per audit, including reporting and record keeping. Audits are confidential.

## 6. Study tour

Part of this TCP project involves representatives from industry and DoF in a study tour to see how their counterparts in other countries do similar work. The tours could include visits to other producing countries, such as Thailand, and importing countries, such as in the EU and USA. The project team leader identified some people and the consultant agreed on the list, excluding those known to be retiring. For maximum benefit, he strongly recommended that the tour party include a guide or tutor.

## 7. Workshop

A workshop was held on 24 November, attended by DoF staff from all centres and industry. A synopsis of the presentation by the consultant is given in **Annex 5**. The draft rules, as amended by the consultant, should have been available for discussion, but for technical reasons they were not. There was a lively discussion on practical aspects of HACCP, laboratory analysis, and the self certification proposals.

## 8. Costs

The shrimp export industry earns US$ 300 million in foreign exchange each year. Quality used to be regarded as free but now costs 3-5% of the market value. A new document from the Laboratory of the Government Chemist, UK, states that analytical measurements cost 3% of the GDP in Western Europe. The consultant recommended that some form of funding at this level be found to support the fish industry, perhaps by a levy on exports. The moneys should be used initially for replacing/improving facilities for the service; then for research and development for trouble shooting and to expand the industry and introduce added value products, as well as for training, including an expansion in food science education at a university. The consultant was involved in a similar HACCP project in Chile three years ago, and since then, the value of their fish related exports has increased by one third.

## 9. Implementation of a National HACCP-based Quality Assurance Programme

### 9.1 Initial considerations

It is clear to the consultants, from the missions already completed, that HACCP-based systems can be introduced to the fish export industry of Bangladesh but that additional assistance, more than has been allowed for in this project, will be required, especially with the very short timescale for implementation

The main need rests with trainers to train the inspection service staff in more depth, to give them confidence in imparting information to industry, to make them accepted by and credible to industry and importing authorities, and to instruct laboratory specialists with up to date skills and knowledge.

The essence of HACCP is to have a database containing test results of all types - times, temperatures, bacteriology, etc., against which performance can be rated, for sensible control limits to be set for each Critical Control Point (CCP), for sampling levels to be determined, for frequency of inspection of each plant, etc. This gives the information for validation of the plan and the audit requirements. Moreover, after a HACCP plan is devised and installed, it has to run for some time to show that production is in control and that safe products are being produced. This takes time. It is noteworthy that the Department of Agriculture of the USA has allowed 42 months for small meat processing companies to comply with their new HACCP requirements.

How can HACCP be implemented in the short term? There have been training workshops run by the FAO project in which representatives of industry and government were trained and carried out practical exercises in model factories. How much was learned and applied to real work situations will become evident during the next visit by the project team leader (February 1997) and confirmed when the FAO Headquarters senior officer makes his next backstopping visit (May 1997).

### 9.2 Workplan and Time Schedule

a) The first step for HACCP implementation in Bangladesh requires the joint development by DoF and Industry of an agreed national workplan ("the new rules of the game"), i.e. under HACCP, which are the new roles expected to be played by the DoF and the Industry; who should do what, how and when

b) The joint effort government-industry must start with the development of National Guidelines for the designing and application of the HACCP system at industry level. Once this is achieved, producers should set a timescale to present to the inspection service the first draft of their plan, carrying out the steps listed in the notes in **Annex 2**. They should also produce a list describing their SSOPs. The time limit should be of maximum 3 months for the larger processors and less for smaller facilities.

c) The inspectors should make an assessment of the plan within two weeks of receiving it. Ideally, they should visit the plant, but from their existing knowledge and their existing categorization of each plant, they should be able to give an assessment of how well it complies with the proposed regulations and how practical it will be.

d) The industry will then go through a three-month transition period to implement their proposals and, during this period, there should be at least two visits by inspectors, preferably by different persons. As inspectors will still be carrying out their current duties, they may not have much time to spend at each plant, but if plants are already scheduled for visits for export certification purposes, efforts should be made to find time during these visits for HACCP studies and, especially, discussions. Then, approved plants will be able to carry out self-certification for exports.

e) During this six-month period, the trade association should be encouraged to exchange information between members and perhaps temporarily engage experts to assist the factories. Confidentiality could be assured. While each HACCP is plant-specific and a separate plan is required for each factory, there is some commonality that can be shared. Also, some aspects of risk assessment of the products can be done centrally and the information pooled. Preprinted forms for recording the action points of the plans and records of observations and measurements have been provided in the training manuals, but with experience, the association members may collaborate and produce versions more appropriate to their working practices. There is an international requirement that records be kept in English.

f) Shortly after implementation, the revamped inspection service should carry out an audit of at least part of each plant. An audit is a two-way procedure, and must not be regarded as an imposition or inquisition by authority. It is a friendly learning procedure for both parties, the company and the auditor. The suggested procedure, starting with a meeting to decide on the scope and finishing with an agreed plan of action, will improve the practicalities of the plan and highlight any deficiencies. This is standard as numerous decisions, perhaps some of an arbitrary nature, have been made while carrying out the HACCP steps and principles, and some may no longer be valid, sometimes due to changes in operating procedures further down the line. Each party must have an open mind. If the audit leads to a major change in, for example layout of a production line to overcome, say, a contamination problem, then the date for the next review should be set at this time to determine the effectiveness of the action taken.

g) It is extremely important at this time that companies notify the inspection service of any rejections of lots by importers so that the reasons can be investigated and the HACCP modified. Without prejudicing commercial interests, the trade association should circulate such information so that all the industry can learn from the problem.

h) Other problems will have been identified and will need resolving. For example, the causes of any deviations should be investigated. By this time, the laboratory facilities should have been improved so that far more samples can be analyzed each day. End product testing will probably continue, based on the experience and practices of other countries in the region, but there will be scope for problem tracing. There have been three reasons given for import rejection: the presence of *Salmonella arizona*, decomposition presumably with high bacterial counts, and insect fragment. There should be detailed investigations including analyses from final product back to source to determine the reasons for the defect, and to refine the flow through the factory. While there may be some common reasons for a particular defect, most will be site-specific and require investigations at each plant. The costs of such investigations should be borne centrally at least for the first year to ensure that they are properly addressed, and hopefully solved.

9.3 Handling and processing operations at production level (outside the plants)

During the workshop, there was some discussion as to whether only whole shrimp be delivered to factories. In the first implementation phase of HACCP, it will be easier if all operations are done in the factories under supervision. At a later stage, HACCP can be extended to earlier stages including heading and peeling before delivery, and in due course a similar quality management tool applied to the growth and harvesting of shrimp. The latest draft CODEX (1996) states that "prior to application of HACCP to any sector of the food chain, that sector should be operating according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation". At the factory level, there was evidence as witnessed by the consultants that such efforts were being made, but there was insufficient opportunity to survey the hygienic status and controls of the sectors handling shrimp before delivery to the factories. Thus, it is recommended that a start be made soon, or at the latest when factory HACCP is implemented, on such a survey so that appropriate Codes of Hygienic Practice be devised and applied.

## 10. Conclusions

At this stage in the project, conclusions are best regarded as tentative.

10.1. If the draft legislation is adopted substantially, it will meet the requirements of importing countries.

10.2. There is sufficient staff for DoF to implement the changes but retraining is necessary and additional training is needed for the specialists.

10.3. The present DoF facilities must be upgraded soon.

10.4. The representatives of industry were in agreement with the draft proposals.

10.5. Further international support is desirable.

## 11. Recommendations

It is recommended that:

11.1. the technical aspects of the draft regulations be adopted; that the rules for bivalve filter-feeding shellfish are omitted, and; that DoF be the competent authority;

11.2. where water is an ingredient, a pure source be found and used;

11.3. for compliance with the EEC/80/778 Water Directive, a water sample from each area be tested in an EN45000 laboratory;

11.4. many potential CCPs of the HACCP plan be covered by SSOPs;

11.5. the laboratories use the same analytical methods as the importing authorities;

11.6. factories reduce decomposition problems by using whole specimens;

11.7. the structure, organization and laboratories of DoF be revamped;

11.8. industry follow the procedures in the operating manuals and training manuals;

11.9. audit procedures be adopted;

11.10. the study tour be accompanied by a tutor;

11.11 a means be found to fund developments;

11.12. the implementation proposals are adopted.

Annex 1

# PROPOSED DRAFT REGULATIONS

(exposed hereunder in the same order as original DoF draft)

In exercise of the powers conferred by Action 3 and 15 of the Fish and Fish Products (Inspection and Quality Control) Ordinance, 1983, the Government is pleased to make the following rules, namely:-

1. Short title:-

   (i) These rules may be called the Fish and Fish Products (Inspection & Quality Control) Rules, 1996.

   (ii) These rules shall come into force on such date as the Government may, by notification in the Official Gazette, decide.

   (iii) In pursuance of these rules, any rule and sub-rule promulgated before about this subject and context by Government, will be treated as cancelled.

2. Definitions:-

   In these rules, unless there is anything repugnant to the subject or context:

   (i) 'Ordinance' means the Fish and Fish Products (Inspection and Quality Control Ordinance, 1983).

   (ii) 'Unwholesome' fish, means fish that has in or upon it micro-organism of public health significance or substances toxic or aesthetically offensive to human beings, or hanging meat, or any other part of the fish which is not meant for export, which encourages bacterial growth and deterioration of the quality of the fish or fish products.

   (iii) 'Container' includes as defined in section 2(a) of the Ordinance, 1983.

   (iv) **Deleted. All references to canned fish are deleted, pending review of general food laws.**

   (v) 'Authorized Officer' means and includes any officer of the Fish Inspection and Quality Control division of the Department of Fisheries or any person

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"Bold text reflects the consultant's recommendations"

mentioned in Schedule-S who may be delegated authority by an Authorised Officer.

(vi) 'Schedule' means any schedule in these rules.

(vii) 'Drained weight' means the weight of the edible solid contents of a container of fish after the liquid has been drained through an appropriate device using a standard method such as those approved by FAO.

(viii) 'Prescribed fees' means fees included in the rules.

(ix) **Delete (covered in 2 (v) )**

(x) 'Processing plant' means any place (land or sea based) where fish are processed or partially processed.

(xi) 'Processing' is defined in section 2(g) of the Ordinance, 1983.

(xii) 'Form' means any form described in the Schedule.

(xiii) 'Fish' includes 'Fish and Fish Products' as defined in section 2(c) and (d) of the Ordinance, 1983.

(xiv) 'Lot' means the quantity of fish of the same type being exported at one time to a single customer.

(xv) 'Licence' defines when appropriate rules agreed.

(xvi) 'Health' Certificate means the Certificate defined under rule ***

(xvii) 'Quality Control' means the techniques and procedures to be adopted so that the products are in conformity with the standards specified under section 2(4) of the Ordinance, 1983.

(xviii) 'Tainted' means that the fish is not wholesome or has an abnormal odour, flavour and/or texture.

## QUALITY CONTROL RULES

**Amendments suggested in Para.2(xix):-**

(xix) 'Landing Centre' means any designated primary or secondary place where fish are landed from fishing vessels, carrier vessels, vehicles, for shipment

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or transfer to processing plants. **(Note: All handling and preservation is to be done in HACCP factories).**

(xx) 'Service Centres' mean primary landing places within the shrimp farming zones from which iced shrimp are sent to landing centres or factories.

(xxi) 'Inspection' means the examination of fish processing and packaging plant, harvesting centre, landing centre, service centre, with regard to hygiene and sanitation, including requirements of the HACCP plan.

(xxii) 'Person' includes any company, people, Association, dealing in fish.

(xviii) 'Cured fish' means fish that have been pickled, dried, salted, smoked, marinated or fermented, or any combination of these procedures.

(xxiv) 'Potable Water' means water conforming with Ordinance ***

(xxv) 'Chilled fish' means fish at a temperature approaching that of melting ice and less than 5° C.

(xxvi) 'Decomposed' means fish that have offensive or objectionable odour, flavour, colour, and/or textural defects and not of the nature expected of the fresh product.

(xxvii) 'QAP' means the measures adopted for the hygienic handling, processing, and distribution of fish. **(Note: This includes HACCP).**

(xxviii) 'Review Authority' **This will be defined when the service is restructured.**

(xxix) 'Appellate Authority' (see xxviii).

## PART 1 - GENERAL

2. These rules shall apply to all stages of handling and processing of fish.

3. A licence is required to carry out fish processing.

4. Prohibition of fish processing:-

(i) No person shall process any tainted or decomposed fish.

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(ii) Fish shall be processed only in establishments which have an approved HACCP plan.

(iii) The requirements of Schedule B must be followed.

(iv) Tainted or decomposed fish shall be disposed of in such a manner not to be available for human consumption.

(v) Materials, chemicals, or containers which may contaminate fish shall not be used.

(vi) Only materials, chemicals and utensils approved for food use shall be used in fish processing.

(vii) **Delete.**

(viii) Each processing plant shall have a self-regulatory quality assurance/management programme conforming with HACCP requirements and with access to/contract with a testing laboratory.

5. Health Certificate:-

(i) A Certificate as laid down in Schedule * is required for exporting any fish.

(ii) The exporter shall apply for such a Certificate as laid down in Schedule E.

(iii) When a person has prepared a lot for export, he will furnish and duly sign a statement that the fish are of satisfactory quality and safety, that the plant has an approved HACCP plan, that the product has been produced in accordance with the requirements of the plan and all records have been taken and kept, any corrective actions taken. An authorised person will countersign that they have approved the plan, that they have seen the records and believe that they are an accurate reflection of the quality and safety characteristics of the products and the conditions under which they were produced and stored.

(iv) Fees shall be paid for each Certificate as per Rule 16.

6. Identification markings of cartons etc:-

(i) Cartons shall be labelled in accordance with the General Food Regulations of Bangladesh and the requirements of the importing country.

(ii) **Metallic can... Deleted.**

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7. Conditions for fish carrying vehicles:-

Conditions laid down in Schedule E shall be observed for transporting fish.

8. Inspection:-

(i) An inspector can inspect at any reasonable time the processing plant and its environment, any ship or vehicle used to carry and/or store fish, the processing methods, finished products, packaging, and related documents.

(ii) An inspector can instruct any relevant person not to process, or to destroy any specified fish, or give any instructions to ensure compliance of 8 (i) and the person instructed must carry out the instructions.

(iii) The inspector must carry a relevant identity card.

9. Fish inspection and sample collection:-

(i) An inspector can draw any reasonable number of samples for any kind of examination from any stock or lot in the processing plant. Such samples can be used to verify the effectiveness of the HACCP plan and its operation and the results of any tests be taken into account by the inspector before he agrees to countersign the self certification document from the plant management. The inspector must put a tag on the sample with his signature and date and an identification number and brief description of the sample.

(ii) The inspector must collect the prescribed fees from the owner of the fish or his representative and give a receipt stating the information on the tag.

(iii) The inspector shall send any sample taken under sub rule (i) to any Government laboratory or any other laboratory accredited under the BSTI EN45000 Scheme. The results of analysis shall be given or sent to the owner or his representative as soon as practical. **(Note: Results including confirmation of the identity of suspect bacterial isolates cannot be given within seven days; it is better not to specify the time).**

(iv) **Delete. (Note: 'Resampling' is deprecated.)**

10. Application for a licence:-

(i) Applications shall be made in accordance with Schedule F. They shall include the approved layout plan of the processing establishment, the HACCP plan, and an insurance certificate.

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(ii) An authorised person can inspect the establishment and can request further information.

(iii) If the authorised person is satisfied he can issue the licence as in Schedule G. If he is not satisfied he must give reasons for refusal of the licence within thirty days.

(iv) All licences can be issued at any time of the year and renewable in January for a calendar year.

11. Conditions for obtaining a licence:-

(i) For a land-based plant, the establishment shall meet the relevant conditions of Schedules A, B, and L.

(ii) For a factory vessel the vessel shall meet the requirements of Schedule I and the hygienic and sanitary requirements of Schedules J and L.

(iii) For an ice-plant the establishment shall meet the requirements of Schedule K and the water requirements of Schedule L.

(iv) For a landing and/or service centre the establishment shall meet the requirements of Schedules M and M-1, and be operated under the hygiene requirements of Schedules N and N-1.

(v) Fish vendors or suppliers shall meet the conditions laid down in Schedule C.

(vi) Exporters must have a permanent/registered establishment/office with a known address and must produce a certificate from a licensed processor to use his registered brand name.

(vii) For fish-curing, the establishment shall meet the requirements and specifications of Schedule O.

12. Cancellation of licence:-

As per Food Law.

13. Destruction of fish:-

Any unwholesome or tainted fish unfit for human consumption shall be totally segregated as per instructions of an authorised person and shall be removed and destroyed.

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14. Re-Inspection of certified fish:-

If there are any reasons to believe that there is some cause to justify re-inspection of fish for which a health certificate has already been issued, the authorised person can inspect the fish as per rule (9) and if necessary take action as per rules 8 and 9. **(Note: Reasons for re-inspection should be defined).**

15. Review Appeal:-

As per Food Law.

16. Prescribed fees:-

As per legal requirements.

17. Violation of rules:-

As per Ordinance 1983.

18. Penalty:-

As per legal requirements.

19. Jurisdiction:-

As per legal requirements.

20. Delegation of powers:-

To be decided after restructuring of organisation of inspection service.

21. Indemnity:-

As per legal requirements. **(Note: This should be strengthened to protect inspectors).**

22. Implementation of Quality Assurance Programme (QAP):-

**Section 22 is suggested to be covered in the schedules. If this proposal is not accepted, then section 22.1 (c) requires change:-**

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"Bold text reflects the consultant's recommendations"

Samples taken for analysis for any purpose under the HACCP plan shall be analyzed by a laboratory approved by the competent authority for this purpose. **(Note: This means that, for example, for cleaning/sanitation purposes the inspector will accept data from any laboratory but for the presence/absence of *Salmonella*, then a BSTI EN45000 accredited laboratory should be used both for analytical competence and safety to the analyst as well as to the plant site. This complies with 'flexibility' in the latest draft CODEX report.)**

## SCHEDULE A

Construction Specifications and Equipment Requirement for Processing Plants

1. Floors shall have a reasonable slope for drainage purposes and be constructed of impervious materials such as cement, concrete, and mosaic.

2. Drains shall be of a size and type sufficient to carry all effluent and water from cleaning operations and shall be equipped with traps or other devices to prevent entry of vermin to the plant.

3. Interior walls must be covered with impermeable mosaic or equivalent materials to a height of at least 1.8 metres. Other parts of the walls shall be of sound construction and washable.

4. Ceilings of work areas shall be of reasonable height and sound.

5. Stairs, lifts and other auxiliary structures such as platforms, ladders, chutes etc. shall be constructed and situated so as not to contaminate fish.

6. Windows and other openings shall be constructed so as to avoid the accumulation of dirt and shall be fitted with fly-proof nets or screens. Sills shall be sloped.

7. (i) Doors shall have smooth non-absorbent surfaces and, where appropriate, be self-closing, have close fittings, and fly-proof netting or screens.

   (ii) All entrances to processing areas shall have foot disinfecting facilities and have wash-hand basins.

8. An adequate number of hygienic toilet facilities must be provided.

9. Hand-washing facilities fitted with hot and cold water supplies and detergent/disinfectant shall be provided adjacent to the toilets and entrances. Taps must be foot or knee operated.

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"Bold text reflects the consultant's recommendations"

10. Water supply:-

(i) There shall be a supply of water meeting the requirements of Schedule L sufficient to cope with all the operations of the establishment.

(ii) There shall be a supply of hot water adequate for personal and factory sanitation and be available in suitable locations.

(iii) Water storage tanks shall be covered, kept clean and hygienic. Their capacity should be no more than adequate for the purpose.

11. There shall be sufficient lighting in the working areas to facilitate close examination of the fish and other materials. The lighting fixtures must be fitted with covers to contain any breakage and not be located directly over work benches or storage bins. They should be electrically insulated and capable of being safely washed and disinfected.

12. (i) Buildings and facilities shall be designed and constructed in such a way as to minimise any chance of cross-contamination of fish.

(ii) The design of the processing plant shall be such as to permit easy and adequate cleaning and to maintain regular flow in the processing area from reception of raw materials to finished products.

(iii) Frogs, tortoises, turtles etc. shall be processed in an area completely separate from fish processing.

13. Adequate, suitable and conveniently located dress-changing facilities with washing facilities shall be provided for males and females separately. Living/sleeping facilities on site shall be located remote from the processing area with appropriate toilet facilities draining away from the processing area.

14. Adequate facilities for cleaning and disinfecting utensils and equipment as laid down in Standard Sanitation Operating Procedures shall be provided.

15. The frames, legs and surfaces of all equipment used for fish processing shall be constructed of stainless steel or equivalent impervious, non-corrodible materials approved for food contact use.

16. Separate hygienic facilities shall be provided for the storage of wastes and inedible materials prior to removal from the establishment. Bins provided for this purpose should be equipped with foot-operated close-fitting covers.

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"Bold text reflects the consultant's recommendations"

17. (i) No wooden furniture or fixtures should be used within the processing area unless approved by an authorised person. **(Note: This allows for impervious or impermeable wood to be used in block ice plants).**

(ii) Conveyor-belts which are in contact with fish, other than packaged fish, shall be constructed so that they can be easily cleaned and disinfected.

18. (i) Equipment used to extract fish meat shall be constructed of non-corrodible material, and be easily and properly cleaned and disinfected.

(ii) **Delete.**

19. **Delete.** See 17 (i)

20. Containers for holding fish shall be constructed so as to provide drainage.

21. (i) Wire-mesh utensils shall not be used in processing except for shellfish and crustaceans.

(ii) Enamelled or galvanized utensils shall not be used.

22. (i) Stores for frozen fish shall maintain a constant temperature of -20 +/-2 C or colder.

(ii) Each cold store shall be fitted with an accurate thermometer or other temperature device located in the warmest part of the store and easily visible from the outside.

(iii) Ice holding rooms shall have a temperature of 0 - 5° C.

23. The working area shall be sufficient to allow for proper and satisfactory performance of all operations.

24. **Delete.**

## SCHEDULE B

Operational Requirements for a Processing Plant (Land based)

1. (i) No person known or suspected to be suffering from, or a carrier of a disease, or with infected wounds, skin infections, sores, or diarrhoea, shall be permitted to enter a processing plant.

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(ii) No person with an open cut or wound shall be allowed to work unless it is covered with a close-fitting waterproof dressing of a bright and contrasting colour.

(iii) Every person employed shall be medically examined by a registered medical practitioner regularly to ensure that he/she is healthy and fit for work, and a record be maintained.

2. (i) Every person shall maintain a high degree of personal cleanliness.

(ii) No persons shall wear ornaments or jewellery except for closed sleeper-type ear-rings and wedding bands.

(iii) Eating, drinking, chewing, spitting, smoking, or any other act which may contaminate fish shall be prohibited.

(iv) No person shall be allowed to enter the plant unless he/she has cleaned their hands in running water with disinfecting materials. After using the toilet, hands must be similarly cleaned.

(v) Notices describing these subsections shall be conspicuously displayed. There shall be Standard Sanitation Operating Procedures describing the protective clothing requirements for operators for each type of work in the plant and their cleaning and disposal procedures.

3. Standard Sanitation Operating Procedures shall be prepared and approved by the inspector to cover the following:-

(i) The area surrounding and under the control of the establishment.

(ii) The buildings and their fittings, including equipment and utensils, and services including water supply and drains.

(iii) Cleaning of the plant interior, the frequency of which shall be at least every shift.

(iv) Items and materials in contact with unpacked fish.

4. Only disinfectants approved by a competent authority as suitable for food contact use can be used. They must be used in accordance with the instructions provided by their supplier.

5. Sewage, offal, and other waste materials including liquid waste from processing operations shall be disposed of hygienically.

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6. Fish shall be stored in locations and manners approved by the authorised person. Frozen fish shall be protected from oxidation and dehydration.

7. Cold stores and chill rooms as per Schedule A. **(Note: Should the temperatures be repeated here?).**

8. No odorous substance shall be stored in the same room as fish.

9. The cold chain shall be maintained at all times during storage and transportation.

10. Water shall meet the requirements of Schedule L.

11. Ice shall only be made from approved water and stored so as to protect it from contamination. It shall not be stored on floors.

12. Fish shall be adequately but not excessively washed during processing.

13. Fish must be kept chilled (below 5° C ) throughout processing and before freezing.

14. Heat processing of fish shall be to a standard approved by a competent authority.

15. All curing ingredients shall be of food grade standard.

16. Only new packaging materials approved for contact with fish shall be used.

17. Frogs, crabs, turtles, shall be slaughtered in a manner approved by the competent authority.

## SCHEDULE C

Requirements for conveyances used for transporting fish

1. (i) Vessels used for harvesting or transporting fish shall have facilities for protecting the fish from sun and weather, and from bilge and other contamination.

   (ii) Bulkheads used for separating fish holds from the engine-room or other quarters shall be water-tight and well insulated.

   (iii) Fish holds, pen boards, and shelf boards shall be smooth and impervious and capable of being properly cleaned.

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(iv) Fish shall be stored in such a way as to prevent damage such as bruising or crushing.

2. No person shall transport fish unless it is under cover and fully protected from sun and weather, dust, dirt, animals, insects, and any other form of contamination.

3. (i) All conveyances and containers shall be cleaned and disinfected before use. Standard Sanitation Operating Procedures shall be devised for this purpose and approved by the authorised officer.

(ii) Decks, holds, pen boards and shelf boards shall be thoroughly cleaned and disinfected as soon as fish have been discharged.

4. Fresh fish while under the control of the carrier shall be chilled within 2 hours to less than 5° C.

5. (i) Refrigerated carriers shall be capable of maintaining the temperature of the fish during transport.

(ii) Frozen fish while under the control of a carrier shall be kept well refrigerated at all times. **(Note: This is covered in Schedule A).**

(iii) **Deleted.**

6. Fish shall be protected from the weather and contamination during loading and unloading.

## SCHEDULE D

Health Certificate for Fish for Export

**Note: This Schedule requires complete reappraisal in view of the implications of HACCP.**

The Certificate will consist of a signed statement by the owner of the fish to the effect that-

(1) In his opinion the fish are of satisfactory quality and safety and meet the Bangladesh specification

(2) His establishment has an approved HACCP plan

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(3) The requirements of the plan were met throughout the production of the lot and adequate records were kept, and all corrective actions taken.

The certificate will then be endorsed by an authorised person that the HACCP plan is in order and that records have been seen and agreed as accurate.

**The other requirements of the certificate concerning origin of product etc are of an administrative and not technical nature and outwit the expertise of the consultant.**

SCHEDULES E, F and G

**These also outwit the expertise of the consultant**

SCHEDULE O

Requirements/specifications for dried/dehydrated (sun) salted fish

1. The fish drying yard should be clean and covered. Measures shall be taken to eliminate and exclude rodents, insects, birds and animals from the premises.

2. Products shall be processed and produced hygienically.

3. The drying yard must have raised platforms and have sufficient air circulation, natural or forced, and light, either natural or artificial.

4. Common salt (NaCl) of food grade must be used.

5. The fresh fish should be gutted and split. The head may be removed.

   (i) For the production of dried fish the product shall be rinsed with potable water and dried under hygienic conditions in the sun or under artificial dryers until a satisfactory product is obtained.

   (ii) In the case of salted dried fish the fish shall be rinsed with potable water and then dosed with salt, the ratio of salt to fish being not less than 1 : 4. The salting period shall be for a minimum of 12 hours. Salting must be done in covered waterproof, for example, cement tanks fitted with drains. The salted fish should be washed with potable water and then dried hygienically in the sun or in artificial dryers until a satisfactory product is obtained.

   (Note: **The water content or salt content or water activity should be defined for "satisfactory", or place rule 10 earlier).**

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6. The flesh and skin of the dried fish shall have a colour characteristic of the species and shall not show any 'pink' or 'brown' microbial discoloration. The flesh shall be firm and fibrous and not yield to finger pressure. The flesh shall not be crumbly, nor mealy, or pasty.

7. The dried products shall be free of any offensive odours indicative of spoilage.

8. The products shall be substantially free of insects and insect fragments, infestation and of visible mould, fungal and/or bacterial growth.

9. The maximum limit for broken pieces shall be 5% by mass or as otherwise agreed between purchaser and vendor.

10. The composition of the products with regard to water, salt and ash shall conform to the standards of BSTI.

11. Unless otherwise agreed by the purchaser and vendor the products shall be packed uniformly in suitable polythene bundles, bagged or in other containers capable of withstanding the ingress of insects, dust, dirt, and moisture during storage and transport.

12. Insecticides and/or pesticides are not permitted unless they are at levels not hazardous to public health.

13. Dried products packaged as in Rule 11 may be stored at low temperature.

**(Note: The procedure for salting described above is called 'dry salting'. Small fish of high fat content are often 'brined ', that is salted in a saturated salt solution. Should this be permitted?).**

## SCHEDULE I

Special conditions applicable to factory vessels

**(Note: Does Bangladesh have any factory vessels to which this Schedule applies? If there are none, it is recommended that the Schedule be omitted).**

1. Conditions concerning design and equipment:-

   (i) Each vessel shall have a reception area solely for taking fish on board. It shall be designed and arranged into pounds or pans, each large enough to accommodate a catch. Each catch shall be kept separate. The area must be designed so as to be easy to clean, and to protect the fish from the sun or weather or any source of contamination.

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(ii) There shall be a system for hygienically transferring the fish from the reception to work areas.

(iii) The work areas shall be of sufficient size for their purpose and be designed to permit hygienic processing and prevent contamination.

(iv) The storage areas for finished products shall be of sufficient size for their purpose, be easy to clean and prevent contamination. If the vessel has a waste processing unit, there must be a separate hold for the by-products.

(v) There must be a separate store for packaging materials.

(vi) For disposal of waste or fishery products that are unfit for human consumption, there shall be special separate equipment to move the materials into the sea or into a water-tight tank specifically reserved for that purpose. All waste storage and processing must be done in separate areas specifically allocated for the purpose.

(vii) There should be a supply of potable water for human consumption meeting the requirements of Schedule L and a supply of pressurised clean sea water. The sea water intake must be suitably located such that discharges of waste of any type and effluent from engines are avoided.

(viii) A suitable number of changing rooms, wash-hand basins and toilets shall be provided. The toilets shall not open directly on to fish working or storage areas. The wash-hand basins shall meet the requirements of Rule 9, Schedule A.

2. Areas used for the preparation, processing or freezing of fishery products must have:-

(i) A non-slip floor that is easy to clean, disinfect, and from which water drains easily. Drains shall be fitted with traps so that they are not obstructed by fish waste and allow water to drain freely.

(ii) The walls and ceilings shall be easy and safe to clean, particularly where there are pipes, chains, or electrical fittings.

(iii) Hydraulic circuits must be fitted or protected such that any leakage of oil cannot contaminate fishery products.

(iv) There shall be adequate ventilation, and where necessary, efficient vapour extraction.

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(v) There shall be adequate lighting.

(vi) There shall be facilities and equipment for cleaning and disinfecting tools, utensils, equipment and fittings.

(vii) Wash-hand basins meeting the requirements of Rule 1 (viii) shall be provided.

3. Equipment and tools including cutting benches, containers, conveyors, gutting and filleting machines, etc. must be so constructed as to be resistant to corrosion, easy to clean and disinfect, and to maintain.

4. Factory vessels which freeze fishery products must have:-

(i) A refrigeration plant capable of lowering the product core temperature to - 20 C within 4 hours.

(ii) Refrigeration plant capable of maintaining maximum load in the storage holds at - 20 C. Each storage room shall be fitted with a temperature monitoring and recording device, the sensor being located in the warmest part of the room, and the temperature displayed outwith the room.

## SCHEDULE J

Conditions of hygiene relating to onboard handling and storage of fishery products

1. There shall be on board each factory vessel a qualified person designated as responsible for applying good manufacturing practices for all production. The person shall have the authority to ensure that all provisions of these rules are applied and shall make available to authorised persons any records of production. **(Note: The draft rule contains a requirement for HACCP. Is this intended? If so, there should be cross-reference to Schedule O-1).**

2. The general conditions of hygiene applicable to processing areas and equipment shall be equivalent to those laid down in the various Schedules.

3. The hygiene requirements for staff shall be equivalent to those laid down in the various Schedules.

4. All processing including heading, gutting and filleting, must be carried out hygienically as laid down in the various Schedules.

5. Fishery products must be packaged hygienically as laid down in the various Schedules.

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6. Storage of fish on board must be carried out hygienically as laid down in the various Schedules.

## SCHEDULE K

Construction and equipment requirements for ice plants

1. The floors shall have reasonable slope for drainage purposes and be constructed of suitable waterproof material such as smooth cement, concrete, mosaic, or similar materials.

2. The interior walls or wall-linings shall be constructed of smooth, waterproof, light-coloured materials which are easy to clean and disinfect.

3. Ceilings should be of reasonable height, easy to clean and disinfect, with insulated electrical fittings.

4. Doors and other openings should be constructed with durable, non-corrodible, washable materials and be fly-proofed with nets or screens.

5. Drains must be covered and the external end netted to prevent entry of vermin.

6. All furniture and equipment in the ice plant shall be constructed of non-corrodible materials and be free of cracks and crevices.

7. For the manufacture of block ice the cans shall be made of non-corrodible materials approved for food contact use and be fitted with lids.

8. The water used to assist in removal of ice from cans must be potable (Schedule L).

9. For the manufacture of flake, tube or particle ice, the equipment shall operate continuously and the receiving receptacles be clean and then covered with clean lids when full. Ice must not be allowed to collect on the floor nor be stored on the floor.

10. Ice should be carried on non-corrodible trolleys or conveyor belts.

11. There shall be adequate space provided to allow for the satisfactory performance of all operations.

12. An adequate number of toilet and hand-washing facilities meeting the requirements of Schedule A, Rule viii, shall be provided nearby.

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13. The temperature of ice-holding rooms shall be maintained in the range 0 - 5° C.

14. Potable water conforming with Schedule L shall be used for making ice.

## SCHEDULE L

### Water Quality

**This Schedule is a copy of EEC/80/778. During my visit to BSTI, the Deputy Director told me that the current Bangladesh water regulations are to be changed to conform with the Directive. Accordingly, it is recommend that Schedule L refer to this new regulation, and the draft version can be omitted.**

## SCHEDULE M

Construction, specifications and equipment for fish landing/service centres

**(Note: Define landing/service centre so that they are or are not covered by a HACCP).**

1. Service/landing centres where fish are displayed for sale must be suitably constructed and accessed by hard-surface road and:

   (i) Have raised waterproof platforms to a minimum height of **(specify).**

   (ii) Be covered and have walls which are easy to clean.

   (iii) Have waterproof flooring which is easy to clean and disinfect and made so as to facilitate drainage of water and have a hygienic waste disposal system.

   (iv) Be equipped with toilets and wash-hand basins conforming with Schedule A, Rule viii.

   (v) Have an adequate water and ice supply and ice storage facility, the water conforming with the requirements of Schedule L.

   (vi) Have ceilings over working areas of a reasonable height.

   (vii) Have signs prominently located prohibiting smoking, spitting, eating and drinking.

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(viii) Have access to be restricted solely to persons having business.

(ix) Have, for the purposes of the competent authority, a lockable room for the sole use of authorised persons.

(x) Have ice-crushers, weighing apparatus, and unloading and landing equipment constructed of non-corrodible materials which are easy to clean and disinfect, and kept in a good state of repair.

(xi) Have adequate natural or artificial lighting, the fittings being covered and insulated.

## SCHEDULE O - 1

Own-checks

1. The Government of Bangladesh will designate a competent authority for controlling own-checks.

2. The owner or manager of any establishment where fish are handled, transformed, wrapped, re-wrapped, packed or stored shall take all measures necessary to ensure that at all stages of production, the health rules are observed.

   For this purpose, the person responsible shall, depending on the manufacturing processes used, the size of the establishment and the product concerned, establish a permanent programme of own-checks based on the following principles:-

   (i) Analysis of hazards and identification of the critical points in the establishment.

   (ii) Establishment and implementation of appropriate methods of monitoring and checking these critical points.

   (iii) Taking samples for analysis in a laboratory approved by the competent authority, for the purposes of checking, cleaning and disinfection methods and verifying compliance with health standards.

   (iv) Keeping a written or indelibly registered record of the above actions for presentation to the competent authority. The results of the checks and tests shall be kept for at least two years.

   (v) Without prejudice to the measures provided, if the results of own-checks or any information available to the responsible persons referred to in

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paragraph 1 reveal the existence or suspicion of a health risk, taking the appropriate measures, under official control.

(vi) In the event of an immediate risk to human health, withdrawal from the market of any fish obtained under technologically similar conditions and likely to present the same risk. Such fish shall remain under the control and responsibility of the competent authority until they are destroyed, used for purposes other than human consumption or, after authorization by the competent authority, treated in such a way as to ensure their safety.

At the request of the competent authority, the owner or manager shall amend the own-checks programme, or increase the frequency of own-checks or laboratory tests where this is deemed necessary in order to guarantee the safety of the fish.

3. The owner or manager of the establishment shall apply or organize a training programme for staff, adapted to the production system and enabling them to comply with the particular conditions of hygienic production, except for staff who already have an appropriate qualification. The official authority responsible for the establishment shall be associated with the design and implementation of this programme or, when an existing programme is involved, with its control.

Official checks

1. Any establishments where fish are handled, transformed, wrapped, re-wrapped, packed or stored shall be subject to the approval by the competent authority which shall issue licences as per Schedule F.

2. The competent authority shall approve an establishment only if it meets the health requirements. The competent authority shall draw up a list of its approved establishments, each one having an approval/licence number.

## SCHEDULE O - 2

Implementation of Own-checks

GENERAL PRINCIPLES

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

- identification of hazards, analysis of risks and determination of measures necessary to control them,
- identification of critical points,
- establishment of critical limits for each critical point,

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- establishment of monitoring and checking procedures,
- establishment of corrective action to be taken when necessary,
- establishment of verification and review procedures,
- 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.

## IDENTIFICATION OF CRITICAL POINTS

It is recommended to proceed to the following activities in sequence:

1. Assembly of a multidisciplinary team

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

Where necessary the team will be assisted by specialists who will help to solve difficulties as regards assessment and control of critical points.

The team may consist of:

- a quality control specialist who understands the biological, chemical or physical hazards connected with a particular product group,
- a production specialist who has responsibility for, or is closely involved with, the technical process of manufacturing the product under study
- a technician who has a working knowledge of the hygiene and operation of the process plant and equipment,
- 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 establishment, advice should be obtained from other sources (consultancy, guides of good manufacturing practices, etc.).

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**(Note: The 1996 Draft Codex gives an alternative version which should be considered:-**

**"The food operation should assure that the appropriate specific product knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes)."**

2. Description of the product

The end product should be described in terms of:

- composition (e.g. raw materials, ingredients, additives, etc.)
- structure and physico--chemical characteristics (e.g. solid, liquid, gel, emulsion, Aw, PH, etc.)
- processing (e.g. heating, freezing, drying, salting, smoking, etc. and to what extent),
- packaging (e.g. hermetic, vacuum, modified atmosphere),
- storage and distribution conditions,
- required shelf life (e.g. sell-by date and best before date),
- instructions for use,
- any microbiological or chemical criteria applicable.

3. 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.

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4. Construction of a flow diagram (Description of manufacturing process)

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 and presented in a detailed flow diagram with sufficient technical data.

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),
- cleaning and disinfection procedures,
- hygienic environment of the establishment,
- personnel routes and hygienic practices,
- product storage and distribution conditions.

5. 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.

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6. Listing of hazards and control measures

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

(a) 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 delays during manufacture).

A hazard is a potential to cause harm to health and is anything covered by the hygiene objectives of Schedules A, B, J, K & M. Specifically, it can be any of the following:

- unacceptable contamination (or recontamination) of a biological (micro-organisms, parasites), chemical or physical nature of raw materials, intermediate products or final products,
- unacceptable survival or multiplication of pathogenic micro-organisations and unacceptable generation of chemicals in intermediate products, final products, production line or line environment,
- 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.

(b) consider and describe what control measures, if any, exist which can be applied for each hazard.

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.

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.*

Control measures need to be supported by detailed procedures and specifications to ensure their effective implementation (Standard

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Sanitation Operating Procedures), for instance, detailing cleaning schedules, precise heat treatment specifications, maximum concentrations of preservatives used.

7. Methods for identification of critical points

The identification of a 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).

*Decision tree for the identification of critical points*

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

Question 1

Are control measures in place for the hazard?

Yes — No → Modify step, process or product

Is control at this step necessary for product safety? Yes → STOP (*)

No

Question 2

Does that step eliminate or reduce the hazard to an acceptable level?

No — Yes

Question 3

Could contamination occur at, or hazard increase to, an unacceptable level?

Yes — No → STOP (*)

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Question 4

Will a subsequent step eliminate or reduce the hazard to an acceptable level?

Yes STOP(*) No Critical point

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

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.

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. The decision tree is not specific to all food operations and should be used in conjunction with professional judgement, and modified in some cases.

8. Action to be taken following identification of a critical point

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

- 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, or at an earlier or later stage, to include a control measure.

- establish and implement a monitoring and checking system at each critical point.

## ESTABLISHMENT AND IMPLEMENTATION OF MONITORING AND CHECKING CRITICAL POINTS

An appropriate monitoring and checking system is essential to ensure the effective control of each critical point.

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To develop such a system, it is recommended to proceed to the following activities:

1. Establishment of critical limits for each control measure associated with each critical point.

   Each control measure associated with a critical point should give rise to the specification of critical limits.

   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 which 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.

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

   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.

   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.

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

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

   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.

   The programme of observations or measurements should properly identify for each critical point:

   - who is to perform monitoring

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- when monitoring and checking is performed
- how monitoring and checking is performed.

3. Establishment of a corrective action plan

Observations or measurements may indicate:

- that the parameter monitored tends to deviate from 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,
- 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.

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.

Such corrective action should include:

- proper identification of the person(s) responsible for the implementation of the corrective action,
- description of means and action required to correct the observed deviation,
- action to be taken with regard to products that have been manufactured during the period when the process was out of control,
- written record of measures taken.

VERIFICATION OF OWN-CHECKS SYSTEMS

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

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.

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"Bold text reflects the consultant's recommendations"

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.

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.

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

Where necessary, such a review must result in the amendment of the provisions laid down.

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

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

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"Bold text reflects the consultant's recommendations"

Annex 2

# PROPOSED ORGANISATION AND STRUCTURE OF INSPECTION SERVICE

## Present situation

The inspection service in its current form is part of the Department of Fisheries under the Ministry of Fisheries and Livestock. The Secretary of the Ministry has overall responsibility. Under him there is a Director-General, then the *de facto* head of the service, the Principal Scientific Officer, based in Dhaka. He has responsibility for units at Dhaka, Chittagong and Khulna. These units have inspectors, laboratories and support staff.

The service has endeavoured to meet the requirements of the existing legislation, especially with regard to export certification but has not been wholly successful, as judged by the level of rejection of lots by importers. Deficiencies in the operational mode are mentioned elsewhere; they are not solely attributable to the service.

With the changing legislation, there is a need for a different service with new objectives. It is understood that there will be a number of retirements of present senior staff in the near future and this provides an opportunity for a new structure. In addition, the experience of other countries which have introduced modern inspection methods has been that there is a loss of trained staff to industry. This is beneficial to the country, in that their industry becomes more technically minded, but the structure must allow for a reasonable number of persons in training grades. This increases costs.

## New type of organisation proposed

At present the service is best described as conventional government service, with direct responsibility on a daily basis to Ministers. This is being replaced in many countries by more independent arrangements. There are three possibilities: firstly, to continue much as at present; secondly, to form an executive agency; and thirdly to privatise the service.

(1) Inspection as a Government Department.

This would be a continuation of the present setup. It has the advantage to government of direct control, to importers of an accountable head of service accessible to them through embassies etc. The disadvantages are seen as a lack of independence, possible government interference, and a continuation of a system which has been somewhat discredited by being party to the export of substandard produce. The service is financed by central government and all income goes to central funds.

(2) An Agency.

There is a trend towards agency status for many technical functions of government. These are functions for which there is no need for continuous contact with or monitoring by government, as would be the case in enacting the proposed legislation. An example is the Food and Drugs Administration (FDA) of the USA, or the Laboratory of the Government Chemist in the UK. The head of the agency is recruited external to the service, although staff are eligible to apply, appointed by a government department for a fixed period, and is responsible to the department for carrying out agreed functions. Financing is by means of an annual grant and charges to customers (the industry) for services provided. There is thus an incentive to give the best and maximum high quality service to the industry so as to maximize income without prejudicing standards.

(3) Wholly privatised service

Government would prepare a specification of requirements and outputs and put it out to tender. A contract would be time limited. One or more organizations could be selected. A trade association might bid in that as they are the customers of the service they have most to gain from being in control and ensuring that the work is done to highest rather than minimum standards. The organization(s) selected would provide the total infrastructure and operating systems compatible with the legislation. The financing would be by fee income and the tender. In practice, privatised services tend to be a joint company comprising the present staff and specialists (technical and managerial) from the private sector. Government audits the performance against the agreed criteria and can withdraw the contract at any time. This may be a way to attract foreign investment for construction and operation of modern sophisticated laboratories and an inspection service to cover all foods at minimal government cost.

For the short term, the consultant would recommend that the first option is taken, but the internal organisation be such that the service could be made an agency at a later date. This requires that it be a 'stand-alone' unit and not fully integrated with other functions of the Ministry.

**Location**

At present, the service is head-quartered in Dhaka. Most of the industry is elsewhere, especially in Khulna and there is a case for locating the administration there. As there are plans to upgrade the facilities at Khulna, consideration should be given to the eventual location of the service there, especially if the type of organisation changes.

**Basic structure**

The organisation consists currently of a Director-General (part-time?), a Principal Scientific Officer (full-time), three Deputy Directors, two Fish Inspection and Quality Control Officers, nine Inspectors, three technologists, three microbiologists, a biochemist, four technical staff and office staff.

The actual job descriptions of the professional staff are as follows:-

Principal Scientific Officer

The Principal Scientific Officer (Project Director) will be placed in Dhaka under the Ministry of Agriculture, Dhaka and Fisheries & Livestock Division, will be overall in charge and responsible for monitoring the whole programme policy, planning, training of staff, with other organisations, local and International bodies and authorities of importing countries, drafting of regulation, code of practice manual of good manufacturing practice, methods of lot identification, methods of sampling, and resampling, methods of reporting results, method of payment of fees.

Deputy Director of Fisheries (Inspection and Quality Control)

He will be in charge of the laboratory, will be responsible for inspection of fish and fish products and control the quality, issue licences and certificates. He will assist the additional Director on respect of legal, planning and drafting of regulation and code of practice. He will guide and motivate trade and industry for production of quality products.

Inspection and Quality Control Officer

He will be responsible for supervision of the work of Fish Inspectors, issue licences to the Fish Traders and motivating fish trade and industry.

Biochemistry

He will be responsible for analysing and Food additives in fish and fish products, trace element and residual effect of insecticide in fish and fishery products.

Fish Technologist

He will be responsible for routine chemical analysis of fish and fish products, sample of water, ice, checking processing of fish and their storage, and guide in right direction.

Fish Microbiologist

He will be responsible for routine microbial analysis of fish and fish products, sample of water, ice, swabs and other tests as and when necessary.

Fish Inspector

He will be responsible for inspection of fish processing, factory, assembly centres, fish market etc. He is the main force of fish inspection service. He will enforce the Fish Inspection Act and Regulation and bring the fish industry and trade up to standard.

There is obvious overlap in these functions as described but this may not happen at the operational level.

**New structure and new job descriptions**

Under the proposed legislation, the main functions of the inspection service is to supervise the HACCP-based quality assurance plans implemented by the industry. Each HACCP plan should be assessed and approved by the person who visits the plant or facility, taking advice from his superior officer. The consultant recommends that the person who carries out the visit to the factory and who has seen the HACCP records, signs the certificate; and that this person or post holder in case of change also be a signatory to acceptance of the HACCP plan. Thus authority is delegated to the people who have done the actual inspections and their activities are checked by their superior who should not be wholly office based.

The consultant recommends that the operational head of the service be directly responsible to the Secretary. He is currently called **'Principal Scientific Officer'**, a misnomer at present but perhaps not historically. The job title should be **'Head/Chief of Inspection Service'**. He would be responsible for the operation of the whole service, and based at present in Dhaka. He would also be head of the Dhaka unit. He would have two **Deputy Chiefs**, one based in Chittagong and the other at Khulna, and two **Assistant Chiefs**, one based in Dhaka reporting to him directly, and the other in Cox's Bazaar, reporting through the Chittagong Deputy. A Deputy should be kept fully informed of all matters in the service, and an Assistant on a 'need-to know' basis.

Staffing at each location should be in proportion to the level of work. Thus, from the information received, about half the industry is in the Khulna area, and if this also represents half the work in terms of production for export, then the staff numbers should reflect this.

Specialization

At present, there are some specialist posts in the organisation chart for microbiologists and chemists. The consultant was told that all inspectors are expected to turn their hand to these scientific skills when the demand arises. This is not good practice nowadays.

The consultant recommends that there be a **microbiology specialist** and a **chemistry specialist** with responsibility for the relevant work throughout and across the service. The specialists would require additional training and recommendations for this are given in Annex 4. They would have responsibility for their laboratory service, facilities, quality control, analysts and their training. They would be encouraged to be members of international scientific societies to keep up to date with developing knowledge and skills, techniques and equipment, and to attend appropriate training course and seminars. They would provide a service of acceptable international standard and be credible internationally. They should be based at the site where their workload is maximum, but must travel to the other sites. They will be the operational managers for the laboratory staff who will be administratively managed by their local Deputy.

Training of staff, who then train industry, will become more important. There should be a **Training Officer** for the whole service. The responsibilities include organising and carrying out a substantial part of the skills training of the **Inspectors**, arranging for the training of other staff including the specialists, running training courses for industry, especially on hygiene and HACCP initially, but later, on product and market development. As this officer will be involved at all sites, the location is flexible.

These specialists should be appointed at Assistant Chief level and managed by the Head of Service, not by their local Deputy.

**Inspectors** have a key role in enforcing the new regulations but their function will change. Instead of policing, they will have a more educational role and work with the industry, in a spirit of co-operation. They will require a wide and deep knowledge of fish technology, processing and quality management systems, especially HACCP, and be able to impart this to industry. Each inspector, or each inspection team, will have responsibility for a group of factories and have to work closely with them, especially for the first two years of HACCP. Thus, inter-personal skills, including communication, will be important. Some inspectors will have junior staff and a responsibility to train them.

**New job descriptions**

Head/Chief of Service

The incumbent would be an experienced man either with extensive knowledge of the existing inspection service or, to accommodate the changes, appropriate skills and experience gained in an inspection service/quality control function in another industry. He/she should be scientifically qualified with a good track record but a research background is not a prerequisite. Management, including financial, experience is required. As the legal framework for the service will be stable for some time, he/she will not be required to take on policy matters. He/she would maintain awareness of changes in inspection requirements, inspection schemes for other commodities, specialist facilities including laboratories, and develop the service to enhance its efficiency and the performance of the industry especially in export markets.

Deputy Chief

The incumbent would take responsibility for one of the major operational units of the service, reporting directly to the Head/Chief.

Annex 3

# MICROBIOLOGY LABORATORIES

Present situation

DoF has laboratories at three centres, Dhaka, Chittagong and Khulna. The consultant has seen the first two only. They are not of modern standard and would not pass any accreditation inspection. He saw plans for a new laboratory for Khulna and made some comments, mainly regarding the flow of samples and analysis in a logical and safe manner.

The problems with the current laboratories are structural, including the use of wood for benches, hygiene, both with regard to potential contamination of samples from the environment and of staff from culture, air supply and movement, and breaks in the electricity supply.

On the operational side, they lack sufficient materials and equipment and quality control, and do not fully use internationally accepted methods. As an example, mentioned elsewhere, many lots are rejected due to the presence of *Salmonella arizonae*, but the method used, which omits one part of the AOAC method, would generally fail to detect this organism.

The laboratories can only process a few samples per day due to lack of pipettes, petri dishes, etc, and therefore are expensive to run. Even with more materials, they are space limited and have insufficient incubators and no modern homogenisers. They obtain media supplies from India and while these are cheaper than international brands, they are not quality controlled to the same necessary standard. Some control cultures are run but these are not appropriate. For example, for *Salmonella* assays, the control culture in use is *Salmonella typhi*. This should not be used as the organism should only be handled in a special high containment laboratory, and it is not typical in its growth and reactions of the types of *Salmonella* spp. found on foods.

Many companies were building laboratories in their factories. This is not a requirement of the importing authorities. Access to a laboratory may be requested, but there is no need for the facility to be on site. No laboratory seen had sufficient space, materials, equipment nor trained personnel to be effective and none had any quality control scheme.

Recommendations for improvement

Bearing in mind that one effect of HACCP is to remove the need for end product testing, and that testing effort should be done earlier in processing and concentrate on the environment, there is a need for a good laboratory in each area. It is worth mentioning that other countries in the region (and even in most industrialized countries) have increased the level of testing and have not given up end product testing as they feel that it would be commercial suicide to do so.

As certification is not dependent on DoF laboratory testing, there is no requirement for DOF to carry out the testing. The consultant was told that there will be a new large government laboratory soon. Reportedely, there may also soon be a commercial laboratory built and operated to EU standards.

In order to solve the current quality problems which lead to rejection of lots, there is a need for extensive screening of products **during production and of their environment, and for hygiene testing**. This can best be met by having access to a large facility which can take 100 samples at a time, or by investing in automated instruments. In the meantime, it would be preferable for the industrial laboratories to combine their facilities and equipment and have one good laboratory in each area, perhaps under the aegis of the trade association. This could be combined with the DoF laboratories so that good laboratory practice can be done and there are sufficient resources for consumables, so that full methodologies can be followed.

The laboratories should participate in external quality control schemes. Under these, coded samples are sent regularly to the laboratories for analysis for counts, isolations, or identifications. 'Correct' results lead to some form of accreditation for the laboratory and credibility. The laboratories should aim for registration under the EN45000 standard when this is available in Bangladesh, said by BSTI to be in 1997.

Taking all these considerations into account, the consultant recommends that in due course: microbiological analyses in Dhaka be done in the new government laboratory or contracted out to a commercial laboratory if it meets EN45000 standard; those in Khulna be done in the new DoF laboratory in collaboration with industry; and in Chittagong, consideration be given to upgrading the laboratory. From his experience, he recommends that consideration be given to automated analyses. The specialist microbiologist would supervise all analyses. In the meantime, there should be better provision of consumables, a specialist should attend the WHO course (Annex 4) and the laboratories should participate in a quality control scheme. Some funds should be made available for these purposes. The staff should read chapters 11 and 12 of '**Making Safe Food**' by Harrigan and Park and apply as much of the information as possible.

The consultant did not see any operational chemistry laboratories. If chemical analysis is to be undertaken, then it should be done at one centre only and probably the best solution would be to use, or have space, in the new government laboratory.

Annex 4

# RECOMMENDATIONS FOR TRAINING ACTIVITIES

## Food Microbiology

The curriculum below was taken from: "**Joint IUMS/ICFMH and UNESCO consultation on postgraduate training in advanced food microbiology with recommendation of a core curriculum**" RWA Park, International Journal of Food Microbiology, vol 11, (1990) 107-118. The curriculum components must be included in any course leading to a professional qualification in food microbiology. It must last for at least one full year.

1. *Introduction*
   Fundamentals of modern food processing, microbiology and molecular biology.

2. *Contemporary basis for advanced food microbiology*
   (a) Modern approaches to microbial classification and identification as applied to relevant bacteria, fungi, viruses and parasites.
   (b) Microbial chemistry and physiology with particular reference to: the cellular determinants of microbial resistance to food processing procedures; destruction and survival of microbes.
   (c) Foodborne pathogens and virulence factors.
   (d) Microbial ecology of foods: raw food; storage; processing; impacts of innovation in processing methods on the microbiology of foods.
   (e) Predictive modelling of microbiological effects of interactions between various processing procedures.

3. *Analytical food microbiology*
   (a) Traditional techniques for detection, enumeration, isolation and identification of microbes and their toxins.
   (b) Modern techniques and their bases.
   (c) Applied mathematics and statistics; probability distributions; sampling plans; analysis of data; guidelines and standards; effective use of computers.
   (d) Types of microbial reduction in quality.
   (e) Good laboratory practice and quality management systems.
   (f) Epidemiology and case studies.

4. *Quality assurance of food products*
   (a) Longitudinally integrated safety assurance (LISA), good manufacturing practice (GMP) and hazard analysis of critical control points (HACCP).
   (b) National and international legislation and codes of practice.
   (c) Role of the International Commission on Microbiological Specifications for Foods (ICMSF).

5. *Food biotechnology*
   (a) Fermented foods; industrially fermented foods; indigenous fermented foods; immobilized cultures and enzymes.
   (b) Industrial starter cultures; principles of preservation, preparation and use of starters; improvement by classical and molecular biological techniques; safety and legislation relating to industrial use and release of genetically manipulated organisms.
   (c) Bioreactors and upstream and downstream processing.
   (d) Treatment of waste and other environmental considerations.
   (e) Microbial protein as a food.

6. *Laboratory design and safety*
7. *Case Studies*
8. *Project*

Note:

Every second year, there is a WHO Recognised Advanced Course in Food Microbiology, held at the University of Surrey, UK. About half the participants are from developing countries. The programme for the 1997 course, will be held from 15 June to 5 July. The consultant strongly recommends that a microbiologist from DoF attends this course and that another attends the next one as well.

All aspects of on-site practical training will be of particular importance when new laboratory facilities are available. If the recommendation concerning laboratory automation is adopted, then the manufacturers include comprehensive training for the proper and optimal use of their equipment.

**Chemistry training courses**

At present there is no requirement as no chemical assays were being done. The main requirements for the future would be for water analysis, for residues of compounds used therapeutically or contamination by pesticides and other agrochemicals. unless these are done centrally by, for example, BSTI or the new government laboratory, A well trained analytical chemist, with a post-graduate qualification, and 5 years experience using modern instruments is required. Specific training would be given by the suppliers of equipment. The post holder would train support staff.

**Training for Inspectors**

A number of curricula for the training of fish inspectors are available from several sources. FAO/INFOFISH recommend a training programme based on FAO experience in training fish inspectors for more than 25 years ("**The need for fish inspection and quality assurance**", 1991).

**Training materials**

In addition to the Training Manual developed by this project, the following materials are also recommended:

1. "**The Food Hygiene Handbook for Scotland**" training manual, in Bengali, produced in association with the health institutes of the UK. This booklet is designed to train factory operatives in good hygienic practice. Training, under the instruction of a leader, takes 6 hours. It is better that the material is given in small amounts, each session lasting less than half an hour, and interspersed with videos. The REHIS of Scotland from whom the booklet was obtained also produce aids for trainers but these are not produced in Bengali. The consultant can obtain full details about these and the syllabuses of the advanced courses, if required. The course materials are used in other EU countries, apparently with success. The aim is to have every operative trained in hygiene practices within 6 months of starting work. The certificates issued on successful completion of the course, as judged by a short multiple choice examination, are transferable so that if operatives move to another employer, they take their certificates.

2. "**Making Safe Food**", WF Harrigan & RWA Park. This short book is a management guide for microbiological quality and safety of foods and requires no previous knowledge of microbiology. It is especially suitable for those planning facilities as there are good chapters on the layout and use of laboratories and making the most of the resulting data. The consultant has checked with one author who confirms that there is no new edition planned.

3. "**How to HACCP**", M Dillon & C Griffith, 2nd edition. Dillon has worked in the fish industry and has also published extensively on microbiological aspects of fish. The book is well presented with more illustrations than text. The consultant has not been able to contact the authors to enquire about any upgrades and the possibility of parts of the manual being translated into Bengali.

4. In addition to the videos being used by FAO during training programmes for fish inspectors, the Consultant obtained information on a new video on HACCP. It is designed for operatives and supervisors as part of the requirement to involve everyone in a factory in the HACCP and to motivate them. The producers are sending the consultant a preview copy. They would produce, for a fee, a Bengali

version. They have told the consultant that producing versions in other languages is not usually a commercial proposition but they can translate the script or may permit a public body such as FAO to do so. The script of the video is by Carol Wallace who has published books on HACCP and is an experienced trainer. She is a co-author of "**HACCP. A Practical Approach**", S Mortimer & C Wallace, Chapman & Hall, London, a useful book but too comprehensive for the project. It would be worthwhile supplying one copy under the project. It will be more relevant if the fish industry moves into added-value, ready-to-eat chilled products.

5. The service should have a copy of the latest edition of the "**Bacteriological Analytical Manual**", and the 16th Edition of the "**Official Methods of Analysis**" of the Association of Official Analytical Chemists (AOAC International). The consultant found out that some copies are given to FAO, Rome, and has requested that a set be given to DoF. These detail the methods used for the analysis of samples taken by importing authorities and they have legal status in the USA and Canada.

6. To maintain current awareness, the service should subscribe to or have access to the following international scientific journals:-

Journal of Applied Microbiology (formerly Bacteriology)
Letters in Applied Microbiology
Journal of Food Protection
International Journal of Food Microbiology
Food Microbiology
Applied and Environmental Microbiology
Journal of Food Science
International Journal of Food Science and Technology

as well as fish industry magazines such as The Fish Inspector, Seafood International, Fish Farming International, Infofish, etc.

Annex 5

# FISH AND SHELLFISH HACCP - THE NEW APPROACH

(Synopsis of lecture given at workshop on 24 November 1996)

Traditional methods for the control of the safety and quality of food and the prevention of food-borne disease have not given consumers the assurances they demand. A more structured approach has been developed, one example of which is HACCP - Hazard Analysis Critical Control Points- or "Own Checks" or "Autocontrol". The philosophy for manufacturers is quite simple - do it right and the product will be all right. The producer knows most about his product, from the choice of raw material, his staff, his factory, and his customer's requirements, so most responsibility is given to him. He has to prove to any relevant person such as a food inspector or import authority that he has taken all reasonable care in production, as shown by adequate records, and so the products should be good and safe. Inspectors will have a monitoring and second level checking role in future. In this talk, I want to review the HACCP procedure, emphasizing aspects of particular interest to the conditions faced by your industry, how they fit in with the draft legislation, what the effects should be, and also I will try to answer your questions.

HACCP is a management tool or technique. There are seven principles involved and implementation is best covered in 14 stages. It is basically the same for all sizes of companies but there is some flexibility as to the degree of application. It is most onerous on companies making 'ready-to-eat' products which are regarded as 'high risk' to the consumer, compared with those doing simple fish cutting and freezing. HACCP is being applied to all industries worldwide. When introduced, companies find that they become more efficient, because they know exactly what they are doing, losses are reduced and they attract more customers. HACCP can be a step in company development, for example, in devising 'added value' products with a high cost return.

## What is HACCP?

HACCP is a set of ideas and principles for ensuring the safety (and quality) of foods by carrying out a systematic approach to the identification and control of real and potential hazards in the production, processing and distribution of foods. A hazard is defined as anything that may cause a food to be unsafe or unfit fit for consumption. With every hazard, there is a risk - how likely is the hazard to happen. The risk of food poisoning is very small but it must be minimised. Outbreaks of food poisoning, or illness traced to eating a food, have enormous financial effects on companies and their countries. Some examples will be given.

## Where is HACCP applied?

HACCP is applied throughout all stages of food production. from selection of stock or fry, feeding, harvesting and processing. The FAO project is concerned at present with fish and shellfish after harvesting; other projects are being planned for aquaculture. With the present processing technology being rather simple, the introduction of HACCP is not too difficult. Note that I have used the word 'food' and not 'fish'. Fish and shellfish have moved in trade and commerce into the food market and are no longer handled by fish specialists in EU and USA.

## How is HACCP applied?

HACCP is a management system and so requires an active management on site. This has been identified as a potential problem for this country as many factories do not have an integrated management structure. Quality and safety management have got to be regarded as being of equal importance as financial management and skilled personnel have to be employed.

## Is HACCP just more inspection?

No. HACCP changes the whole nature of inspection by giving the factory control of their production. Inspectors then have the following tasks:

1. to check if a HACCP plan is in place.
2. to check if it is satisfactory.
3. to check that records are made and kept.
4. to audit the HACCP plan and its implementation.

Thus, inspectors are more 'educators' than 'police'.

## Why are HACCP plans not available for purchase?

HACCP plans are specific for each establishment and its products. They are all different as every factory is different. From experience, it is seen that one operation in one plant may be a critical control point, but a similar operation in another apparently similar factory is not. Generic plans are a guide only. Some from the USA are totally inapplicable for Bangladesh as they apply to fully automated factories with many machines and few people.

**What is a good plan?**

A HACCP is the result of a process of evaluating the total operation of a factory, its products and its surroundings. From the information gathered, managers should devise Standard Sanitation Operating Procedures (SSOP), Standard Operating Procedures (SOP) to control production, link these to Good Manufacturing Practice (GMP), and then conduct a hazard analysis to identify real or proper CCPs and produce the HACCP plan. A good plan is therefore comprehensive but easy to use and guarantees that all aspects of operation of the factory are under control.

**The Principles of HACCP**

Full details have been given in the Training Manual Part 2 and will be only summarized here. This will refresh the memory of those who took part in the course but not be enough to train new people in sufficient depth.

Step 1 Assemble the HACCP team.

Team? This could be six people or one person. It may have advisors or consultants, or perhaps the Association in each area may provide the services of a skilled person to assist. It is best that the MD or owner is not a member of the team. It is often good to have a young person from production in the team.

Step 2 Describe the food and its distribution.

It really is necessary to know what the factory actually makes and where it goes to.

Step 3 Identify intended use.

From the hazard/risk aspect, it is essential to know if the product is a raw material for another product, is to be thawed and sold to housewives, is to be used in restaurants, and, especially, if it is likely to be eaten without cooking. By the way, cooking does not kill all germs.

Step 4 Develop a flow diagram, the route or path of processing.

In fact, I prefer a set of flow diagrams, drawn on a scale plan of the factory floor. There should be the product flow, the people movement routes, the water and drains plan, air movement, insect/vermin pathways, equipment location, time-temperature figures, and the hygiene and contamination diagram. I usually survey or stand in the factory all through the shift to get accurate flows.

Step 5 Verify the flow diagram(s).

OK, maybe reduce them! But confirm that they are an accurate representation of what really happens and where people really go.

Step 6 Conduct a hazard analysis

So, Step 6 is **Principle 1** of HACCP

**Principle 2** Identify Critical Control Points (CCP)

A CCP is a point, place, step, procedure, or operation (a "do something") at which control can be applied so that a hazard can be prevented, eliminated or removed, or reduced to a less hazardous state or acceptable level. Plenty of choice here! So, go through the flow diagrams from beginning to end, or vice versa, which is sometimes easier.

**Principle 3** Set the critical limits for the preventative measures at each CCP.

The preventative measures could be washing, chilling, heat treatment, etc. You may need a more expert person than you have on staff to advise on practical limits. Limits are often given in terms of time (no more than 30 min at reception) and/or temperature (core/centre temperature to be less than 5° C., or if cooked, 70° C).

**Principle 4** Monitor CCP

Decide how and when to measure if the product is within the limits of the CCP. The plan must state who is to do the measurement, how they do it, and the instructions must be given in full practical detail.

**Principle 5** Corrective actions.

This means what to do if the results of the measurements are outwith the limits. They can be simple. For example, if the temperature of shrimp is too high in the step before peeling, the corrective action is to chill them with ice until they are within the specification.

**Principle 6** Record keeping

All measurements taken must be properly written down and recorded. Prepared forms are needed and some are given in the manual. These become the records which inspectors from Government, or importing countries, or your customers need to see, so keep them clean, but not too clean or no one believes you!

**Principle 7** Verification

This means deciding if the plan is working, and that the factory operations have not changed since the plan was devised. If changes have taken place, for example if a new freezer is installed, or the layout has been changed, then the plan is reconsidered and a record of this is kept.

Responsibility

Someone has to be given overall responsibility for the HACCP system and he should have direct access to the factory manager. He should be on site all the time. Other persons should be given responsibility for individual CCP. This works well for a major part of the success of HACCP is motivation of staff. Every one should become a quality controller so that they never pass on an inferior product, and they should be motivated to take a positive attitude to this aspect of their work. The more people in a factory involved in HACCP, the better the success. Good training is essential in all craft skills.

**The new draft rules**

Copies of the draft rules have been circulated. (Note: Participants of the Workshop did not receive advance copies). They are intended to form the basis of evidence for a Memorandum of Understanding (MOU) between your country and the countries you sell to. The rules are based on EU Directives because they are the most detailed. As the EU has MOU with the USA and many other countries, then such a MOU should automatically clear the way for others. One effect of the rules is that any shrimp can be traced back to its origins. The trail from plate to farm is complete and if there are any problems, investigation is likely to be successful.

Many of the Schedules are for hygiene and operational reasons, factors which I hope you will be able to cover with SSOPs and SOPs. Schedule L deals with water quality. This is based on an EU Directive of 1980 which is only now being activated and it is causing major problems in many European countries. I would recommend that the water added to the products for glazing be of the highest quality available because it is really an ingredient and perhaps a different source of supply or even bottled water should be used.

The main change is in Certification. At present, at the factory owner's request, an Inspector takes samples for analysis and if the results are satisfactory, issues a certificate. But there is no traceability of the product or real evidence that the sample (and results) are representative of the lot. So, with 'own checks', the factory has the responsibility. After all, they know their product! When a consignment is ready for export, the factory will review their records and the results of any tests, and then sign a statement to the effect that they have a HACCP plan, that the plan has been obeyed, that appropriate records exist, and that they are of the opinion that the products are of the quality and safety standard required. The inspector countersigns that he agrees and that he has seen the records. Total self control!

Another change is that all processing should be within the factory. This means that heading and peeling of shrimp have to be done under control. Otherwise, the farms and peelers will need a HACCP.