Chapter 21

GMP/GHP and GLP practices relevant to fish and marine food processing

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Fish and fishery products are invaluable food commodity for human being. A high-quality protein and vital nutrients available resulting increment in consumption every year. The high nutritional quality and easy digestibility of fish favours almost all living organisms including bacteria. As a result, all organisms compete to consume fish and fishery products. Careless handling can become a source of toxic residues, poisons and different kinds of public health spoilage organisms like *Salmonella* species, pathogenic *Vibrio* species like *V. cholerae*, *V. parahaemolyticus*, *Listeria monocytogenes Staphylococcus aureus* etc. and cause various kinds of infectious diseases and food poisoning.

Various hazards associated with fish and fishery products are concern which must be taken care to avoid health problems. There are several quality assurance programmes evolved to keep fish and fishery products safe. Various kinds of quality standards like Codex standards, USFDA (United States Food and Drug Administration) standards, BSI (British Standards Institution) standards, FSSAI (Food Safety and Standards Authority of India) etc., HACCP (Hazard Analysis Critical Control Points) system of USA, European Commission Norms aimed to ensure safety and quality of fish and fishery products. The chance of failure to ensure both safety and quality, probably due to certain mistakes exempted in calibration, good laboratory practice, good hygienic practices etc. Certain measures need to be taken seriously at different steps in food production system ensures to achieve quality and safety of fishery products.

Quality system in India

Quality control began in India as a pre-shipment inspection before the products were exported to the other country. But, this inspection on quality was only based on random sampling of finished products. When the samples did not satisfy the quality standards, the entire lot of consignments were rejected resulting in great losses. The recent quality monitoring has the major difference, in that quality is monitored all through the steps of processing so that quality could be traced, or the system has traceability. In the initial stages of export of fishery products from India, heavy losses resulted since entire consignments were rejected by some countries due to bacterial contamination and spoilage. These prompted the Government of India to set up a fully equipped fish processing technology laboratory at Cochin (Kerala) in 1957 to initiate research on quality control and thus provide the much needed support for the seafood processing industry. The Govt. of India brought out a scheme

of voluntary pre-shipment inspection in 1963. At the same time, the Export Act (1963) was enacted by the Parliament of India under which Export Inspection Council was constituted under the Ministry of Commerce, Govt. of India. All export goods including the fishery products came under the purview of the Act resulting in compulsory pre-shipment inspection. The Export Inspection Council created the Export Inspection Agency to deal with the pre-shipment inspection of all fishery products as well as other agricultural products.

In any system of food production, possible sources of health risks or hazards arise from one or a combination of the following:

1) Raw materials

2) Production Process

3) Production facility (Plant and Machinery)

4) Personnel involved in Production

5) Cleanliness of direct/indirect food contact surfaces

6) Personnel hygiene

7) Pest control, and

8) Risk/hazard monitoring facilities (Laboratory)

All the possible areas that can contribute to physical, chemical or biological hazards into the food handled in a food processing establishment includes above factors. Therefore, the best method to achieve quality shall be stream lining and critically evaluating each one of the above sources to ensure that health hazards are not introduced at any of the above sources. This exercise needs the support and skill of a team of experts with a thorough knowledge of the raw materials, production processes, hygiene, sanitation and quality assurance. Careful selection of persons responsible for purchase, production, quality, etc. can help in fulfilling this responsibility. The team shall have the skill and expertise to identify possible significant hazards like physical, chemical and biological that can be associated with the raw materials, processing steps, plant and workers. The team shall also be in a position to provide suitable remedial measures to exclude possible hazards from each and every source.

The CODEX of GMP/GHP includes specific aims and objectives:

• To identify the essential principles of food hygiene, applicable throughout the food chain (including primary production through to the final consumer), to achieve the safety of food and suitability for human consumption

• To recommend a HACCP-based approach as a means to enhance food safety

• To indicate how to implement its principles

• To provide a guidance for specific codes which may be needed (for all sectors of the food chain) and to amplify the hygiene requirements specific to those areas.

Good Manufacturing Practice (GMP)/Good Hygienic Practices (GHP)

GMP/GHP is defined as all practices regarding conditions and measures necessary to ensure safety and suitability (quality) of food at all stages of the food chain. This is largely the procedure laid down for achieving safety from plant, machinery and other infrastructure used in the production. The important elements of Good Manufacturing Practice are listed below:

1) Plant design, construction and layout:

In any production plant, there will be raw materials and finished products as well as one or many intermediate products. The plant design shall be such that the movement of edible materials from raw materials stage to the finished products stage is unidirectional and opposite to the movement of waste materials like solid wastes and liquid effluents. Another aspect of the plant design and construction is the nature of the materials used for the construction and the type of construction. All materials used shall be water resistant, washable and with a smooth surface. Further, the construction shall be such that there is no sharp corners, and all wall to wall, wall to floor and wall to roof joints are round and smoothened. The design shall take care to provide fly proofing of all external openings like doors, windows, ventilators, chute doors and drain outlets. In fact, the safety at drain outlets shall be such that there is no chance for any solid particles to go out as well as no fly can enter into the food handling areas. The plant will also need several electrical and mechanical fittings. All such items shall be washable and laid out in such a way that there is no scope for pest/microbial harbourage.

2) Machinery design, construction and layout

Like plant, machinery too shall be designed, constructed and installed to facilitate unidirectional movement of food materials and that the machinery is water resistant, washable and subitizable. All the machinery shall also be in a position to achieve criteria for good manufacturing practice. For example, the machinery for quick freezing shall be in a position to freeze the food in such a way that the core of the food attains $-18\pm2^{o}C$ in 90 minutes. Similarly, equipments for cooking shall be able to attain the validated cooking temperature and time without causing under or over cooking. Selection and installation of processing machinery in this way will exclude all possible health risks from machinery.

3) Provision for pest control

The provision for pest control is often a neglected item. Pest can be the cause for both dirt and contamination with microbes of public health significance. Exclusion of pests is best done by providing fly proof netting for all windows and ventilators as well as providing automatic air curtain and self-closing shutters for all doors and chutes directly opening to outside. There shall also be fly proof netting for drain outlets. Further, to take care of any pest by-passing these facilities, there can be electrical fly catchers and rodent traps at strategic locations. Effective operation of these facilities will make food-handling areas free from pests.

For pest control, there shall not be any chemical based pest control procedures. In rodent traps, the baits shall be only food items like dried and baked coconut or fish. Poison baits shall never be used for rodent control in food processing plants. In case, there is any unusual fly population, fumigation with formaldehyde followed by defumigation with ammonia can be followed. However, there shall not be a regular schedule for fumigation as it may introduce unwanted chemical residues into the food material handled in the plant.

4) Personnel Involved in Production

Workers or plant personnel are the most dynamic source of various type of microbial contamination in any food-processing establishment. In case of food materials from land and inland water bodies, there is every chance of occurrence of organisms of public health significance. But in case of seafood, the occurrence of Public Health Indicator organisms is a sure indication of poor hygiene and sanitation. To exclude such contamination from workers, all personnel in the production unit shall follow good hygiene practice.

a) Medical Fitness of workers- Medical examination to certify the workers is an exercise to be done without failure once in a year. Workers must be examined by a qualified medical

practitioner to rule out that the worker is not suffering from any disease. A doctor can do this by physical examination and certain investigations on blood, urine and stool. These tests exclude the possibility of the worker as a carrier of certain pathogens especially *Salmonella* and *Vibrio cholerae*, and it will ensure that the worker is fit to handle food materials.

b) Use of clean uniform including gum boots, head cover, face mask and gloves

c) Removal of ornaments and other beauty aids

d) Scrubbing of hands with soap and clean water

e) Sanitized footwear using a foot dip containing 100 ppm

f) Hand sanitizing by dipping the full palm of both hands in 20 ppm of chlorine water

5) Cleanliness of Direct/Indirect Food Contact Surfaces

The cleanliness of direct and indirect food contact surfaces is responsible for contamination of food. There shall be identification and listing of all food contact and non-contact surfaces followed by a cleaning procedure and cleaning schedule. All these operations are popularly known as “Standard Sanitation Operation Procedure” (SSOP).

The following are the main elements of SSOP:

- Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice
- Condition and cleanliness of food contact surfaces, including utensils, gloves and outer garments
- Prevention of cross-contamination from insanitary objects to food; food packaging material; and other food contact surfaces including utensils, gloves and outer garments; and from raw product to cooked product
- Maintenance of hand washing, hand sanitizing and toilet facilities
- Protection of food, food packaging material and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants
- Proper labelling, storage and use of toxic compounds
- Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials and food contact surfaces
- Exclusion of pests from the food plant

6) Risk/Hazard Monitoring Facilities

The success of all the above processes and procedures in a food plant will depend on the facilities of the laboratory. In fact, the laboratory shall have all test methods and testing equipment in par with the national and international requirements.

7) Traceability and recall procedures

A system for tracing all raw materials and finished products is a necessary component in a prerequisite programme. No process is fail-safe and traceability that includes lot identification is essential to an effective recall procedure. A crisis response plan should be in place to handle any incidents.

Appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf life of the product. Where there is a health hazard, products produced under similar conditions may be withdrawn. The need for public warning should be considered. Once retrieved, products must be held under supervision until the manner of product disposition e.g. rework or destruction has been determined.

8) Training

All employees should receive documented training on personal hygiene, GHP, cleaning and disinfection procedures, product handling and protection, the HACCP-system and process control. Periodic refresher training should be part of the overall training programme. Training in basic food hygiene is fundamentally important. All personnel should be aware of their roles and responsibilities in protecting fish and the fish products from contamination and deterioration.

Good Laboratory Practices (GLPs)

Good Laboratory Practices (GLPs) define the rules and criteria for a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded and reported.

General Principles of the good laboratory practices-

a) Management's Responsibilities

Most of the responsibilities of test facility management are of a general nature, such as the requirements that test facility management has to ensure the availability of qualified personnel and of appropriate facilities and equipment for the timely and proper conduct of the study. Furthermore, it has to ensure that health and safety precautions are applied according to national and/or international regulations; appropriate Standard Operating Procedures are established and followed, etc.

b) Laboratory Head's Responsibilities

The study director continues to be the single point of study control and has the responsibility for the overall conduct and reporting of the study. He/she should agree to the study plan and ensure that the procedures specified in the study plan are followed.

c) Personnel Responsibilities

Personnel should exercise safe working practice and health precautions; the chemicals should be handled with suitable caution until their hazard(s) has been established. Personnel known to have a health or medicinal condition that is likely to have an adverse effect on the study should be excluded from operations that may affect the study.

d) Facilities

The GLP Principles mandate in general that test facilities should be of suitable size, construction and location to meet the requirements of the studies performed therein, and an adequate degree of separation should be provided between the different activities to ensure the proper conduct of each study.

e) Apparatus, material, and reagents

Apparatus should be suitably located, be of appropriate design and adequate capacity, and should be periodically inspected, cleaned, maintained and calibrated according to SOPs. Apparatus and materials should not interfere with the test systems, and reagents should be properly labelled.

f) Test Systems

All the methods used by the lab shall be approved methods by national or international agencies, like BIS standards (Bureau of Indian Standards), EU (European Union) Norms, US FDA (United States Food and Drug Administration) Guides and Codex. Under no circumstances, unapproved procedures shall be used for monitoring any process/quality parameter.

In case of physical/chemical test systems, the used apparatus should be properly located and have appropriate design and capacity. Reference substances should be used to ensure the integrity of the test systems and considering biological test systems the housing, handling and care of animals, plants, microbial as well as other cellular and sub-cellular systems should be carried out under proper conditions to ensure the quality of the data.

- Test and Reference Substances

All the records referring to test and reference substances should be maintained; handling, sampling, and storage procedures as well as the test and reference substances should be identified. The stability of test and reference substances under storage and test condition should be known.

Standard Operating Procedures

Standard Operating Procedures (SOPs) should be elaborated for test facilities, and there should be immediately available SOPs for each separate laboratory unit.

- Performance of the Study

Prior to initiation of a study, a study plan should exist. It should be retained as raw data, and the study should be conducted according to it. The proper form and content of a study plan is specified in the Principles of GLP.

- Reporting of Study Results

For each study a final report should be prepared by using the International System of Units (SI). It is the task of the Study Director and perhaps of principal scientists from co-operating disciplines to sign and date the final report.

- Storage and Retention of Records and Material

The proper way of storing and retention of any records and material (e.g. study plans, raw data, final reports, samples and specimens, etc.) must be in place.

Conclusion:

The increasing demand of consumers for fish and fishery products, and the internationalization of the food supply generally have created an increased need for regulatory inspection and control of imported foods. The establishment of GMP in a plant will make organized and documented system for whole production along with Improvement of the quality of products. The final product will meet consumer requirements and improves the efficiency. Proper management of waste will protect the environment. GLP sets good practice to perform work in compliance with standardize procedures worldwide. The food production chain must be included in the planning and implementation of comprehensive food safety efforts. Government officials should develop and support partnerships and joint activities with the food industry and with consumers in pursuit of the goal of delivery of safe food to consumers.

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