CHAPTER 5
Planning and Developing for Safe Products

The organization shall plan and develop the processes needed for the realization of safe products. The organization shall implement, operate and ensure the effectiveness of the planned activities and any changes to those activities. This includes PRP(s) as well as operational PRP(s) and/or the HACCP plan

5.1 Prerequisite Programmes (PRP's)

The organization shall establish, implement and maintain PRP(s) to assist in controlling
a) The likelihood of introducing food safety hazards to the product through the work environment,
b) Biological, chemical and physical contamination of the product(s), including cross contamination between products, and
c) Food safety hazard levels in the product and product processing environment.

The PRP(s) shall
a) Be appropriate to the organizational needs with regard to food safety,
b) Be appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled,
c) Be implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or operational line, and
d) Be approved by the food safety team. The organization shall identify statutory and regulatory requirements related to the above.

When selecting and/or establishing PRP(s), the organization shall consider and utilize appropriate information [e.g. statutory and regulatory requirements, customer requirements, recognized guidelines, Codex Alimentarius Commission (Codex) principles and codes of practices, national, international or sector standards].
Annex C of the ISO manual gives a list of relevant Codex publications.

The organization shall consider the following when establishing these programmes (PRP's):
a) Construction and lay-out of buildings and associated utilities;
b) Lay-out of premises, including workspace and employee facilities;
c) Supplies of air, water, energy and other utilities;
d) Supporting services, including waste and sewage disposal;
e) The suitability of equipment and its accessibility for cleaning, maintenance and preventative maintenance;
f) Management of purchased materials (e.g. raw materials, ingredients, chemicals and packaging), supplies (e.g. water, air, steam and ice), disposals (e.g. waste and sewage) and handling of products (e.g. storage and transportation);
g) Measures for the prevention of cross contamination;
h) Cleaning and sanitizing;
i) Pest control;
j) Personnel hygiene;

k) Other aspects as appropriate.
Verification of PRP(s) shall be planned and PRP(s) shall be modified as necessary. Records of verifications and modifications shall be maintained. Documents should specify how activities included in the PRP(s) are managed.

5.2 Primary Steps to Support Hazard Analysis

All relevant information needed to conduct the hazard analysis shall be collected, maintained, updated and documented. Records shall be maintained.
The success of a HACCP system depends on educating and training management and employees in the importance of their role in producing safe foods. This should also include information the control of foodborne hazards related to all stages of the food chain. It is important to recognize that employees must first understand what HACCP is and then learn the skills necessary to make it function properly. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring each CCP.
Management must provide adequate time for thorough education and training. Personnel must be given the materials and equipment necessary to perform these tasks. Effective training is an important prerequisite to successful implementation of a HACCP plan.

5.3 Developing a Food Safety Team

A food safety team shall be appointed. The food safety team shall have a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system. This includes, but need not be limited to, the organization's products, processes, equipment and food safety hazards within the scope of the food safety management system. Records shall be maintained that demonstrate that the food safety team has the required knowledge and experience.

The first task in developing a HACCP plan is to assemble a HACCP team consisting of individuals who have specific knowledge and expertise appropriate to the product and process. It is the team's responsibility to develop the HACCP plan. The team should be multi-disciplinary and include individuals from areas such as engineering, production, sanitation, quality assurance, and food microbiology. The team should also include local personnel who are involved in the operation as they are more familiar with the variability and limitations of the operation. In addition, this fosters a sense of ownership among those who must implement the plan. The HACCP team may need assistance from outside experts who are knowledgeable in the potential biological, chemical and/or physical hazards associated with the product and the process. However, a plan which is developed totally by outside sources may be erroneous, incomplete, and lacking in support at the local level.

Due to the technical nature of the information required for hazard analysis, it is recommended that experts who are knowledgeable in the food process should either participate in or verify the completeness of the hazard analysis and the HACCP plan.
Such individuals should have the knowledge and experience to correctly:
a) Conduct a hazard analysis;
b) Identify potential hazards;
c) Identify hazards which must be controlled;
d) Recommend controls, critical limits, and procedures for monitoring and verification; (e) recommend appropriate corrective actions when a deviation occurs;
f) Recommend research related to the HACCP plan if important information is not known; and
g) Validate the HACCP plan.

5.4 Product Characteristics - Raw Materials, Ingredients and Product-Contact Materials

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the hazard analysis, including the following, as appropriate:
a) biological, chemical and physical characteristics;
b) composition of formulated ingredients, including additives and processing aids;
c) origin;
d) method of production;
e) packaging and delivery methods;
f) storage conditions and shelf life;
g) preparation and/or handling before use or processing;
h) food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses.
The organization shall identify statutory and regulatory food safety requirements related to the above.
The descriptions shall be kept up-to-date including, when required, in accordance with relevant clause.
The HACCP team first describes the food. This consists of a general description of the food, ingredients, and processing methods. The method of distribution should be described along with information on whether the food is to be distributed frozen, refrigerated, or at ambient temperature.

5.5 Characteristics of End Products and Intended Use

The characteristics of end products shall be described in documents to the extent needed to conduct the hazard analysis, including information on the following, as appropriate:

a) product name or similar identification;
b) composition;
c) biological, chemical and physical characteristics relevant for food safety;
d) intended shelf life and storage conditions;
e) packaging;
f) labelling relating to food safety and/or instructions for handling, preparation and usage;
g) method(s) of distribution.

The organization shall identify statutory and regulatory food safety requirements related to the above. The descriptions shall be kept up-to-date including, when required, in accordance with relevant clause.

The intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documents to the extent needed to conduct the hazard analysis.

Groups of users and, where appropriate, groups of consumers shall be identified for each product, and consumer groups known to be especially vulnerable to specific food safety hazards shall be considered.

Describe the normal expected use of the food. The intended consumers may be the general public or a particular segment of the population (e.g., infants, immunocompromised individuals, the elderly, etc.)

5.6 Preparing of Flow Chart / Diagrams, Process Steps and Control Measures

Flow diagrams shall be prepared for the products or process categories covered by the food safety management system. Flow diagrams shall provide a basis for evaluating the possible occurrence, increase or introduction of food safety hazards.

Flow diagrams shall be clear, accurate and sufficiently detailed. Flow diagrams shall, as appropriate, include the following:
a) the sequence and interaction of all steps in the operation;
b) any outsourced processes and subcontracted work;
c) where raw materials, ingredients and intermediate products enter the flow;
d) where reworking and recycling take place;
e) where end products, intermediate products, by-products and waste are released or removed.

In accordance with verification planning, the food safety team shall verify the accuracy of the flow diagrams by on-site checking. Verified flow diagrams shall be maintained as records

The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process. The scope of the flow diagram must cover all the steps in the process which are directly under the control of the establishment. In addition, the flow diagram can include steps in the food chain which are before and after the processing that occurs in the establishment. The flow diagram need not be as complex as engineering drawings. A block type flow diagram is sufficiently descriptive, a simple schematic of the facility is often useful in understanding and evaluating product and process flow.

5.7 Description of Process Steps and Control Measures

The existing control measures, process parameters and/or the rigorousness with which they are applied, or procedures that may influence food safety, shall be described to the extent needed to conduct the hazard analysis (see in next chapter).

External requirements (e.g. from regulatory authorities or customers) that may impact the choice and the rigorousness of the control measures shall also be described.

The descriptions shall be updated in accordance with updating of plans.