

Chapter 3: Prerequisite Programs and Preliminary Steps

Overhead 1

Objective:

In this module, you will learn:

- Prerequisite programs to have in place before starting HACCP, and
- Preliminary steps involved in developing a HACCP plan.

Prerequisite Programs

HACCP is *not* a stand-alone program but is one part of a larger system of control procedures. For HACCP to function effectively, it should be accompanied by the prerequisite programs discussed in this chapter.

Overhead 2

GMP — Good Manufacturing Practice

SCP — Sanitation Control Procedures

SSOP — Sanitation Standard Operating Procedure

HACCP — Hazard Analysis and Critical Control Point

HACCP systems are designed to prevent and control food-safety hazards associated with food from the time a company receives raw material through production to distribution to the consumer. HACCP systems must be built upon a firm foundation of compliance with current Good Manufacturing Practices (GMPs) (Code of Federal Regulations, Title 21, Part 110) and acceptable Sanitation Control Procedures (SCPs). GMPs and sanitation procedures affect the processing environment and should be considered prerequisite programs to HACCP.

Overhead 3

Definition:

Prerequisite Programs: Procedures, including GMPs, that address operational conditions providing the foundation for the HACCP system.

Explanatory Note:

This chapter is not intended to be an exhaustive discussion of all elements of what could be included in prerequisite programs.

Instructor's Note:

See Appendix VI for a copy of the GMPs (21 CFR 110)

Continued

Chap 3 - Prerequisite Programs and Preliminary Steps

Notes:

Explanatory Note:

Although written SSOPs are not mandated by FDA, eight areas of sanitation are identified in the seafood HACCP rule (discussed in Chapter 12). These areas must be monitored and documented by all processors regardless of whether a firm has a written SSOP or is required to have a HACCP plan.

The Good Manufacturing Practices define measures of general hygiene as well as measures that prevent food from becoming adulterated due to unsanitary conditions. The GMPs are broadly focused and encompass many aspects of plant and personnel operations. The SCPs are usually specified as Sanitation Standard Operating Procedures (SSOPs). SSOPs are procedures used by food processing firms to help accomplish the overall goal of maintaining GMPs in the production of food. Typically, SSOPs describe a particular set of objectives associated with sanitary handling of food and the cleanliness of the plant environment and the activities conducted to meet them.

When SSOPs are well-designed and fully and effectively implemented, they are valuable in controlling hazards. Identification of critical control points may be influenced by the effectiveness of a GMP program, including industry SSOPs. For example, SSOPs can help control bacterial hazards by specifying procedures to: 1) avoid product cross-contamination by proper product flow and limiting employee tasks and movement; 2) locate handwashing and sanitizing stations near the processing area to facilitate proper handwashing; 3) ensure appropriate equipment maintenance and cleaning and sanitizing procedures. SSOPs can likewise be used to help control chemical contamination from sanitizer and other chemicals found in food processing operations.

In some situations, SSOPs may reduce the number of critical control points in HACCP plans. Relegating control of a hazard to SSOPs rather than the HACCP plan does not minimize its importance or indicate lower priority. In fact, hazards are typically controlled effectively by a combination of SSOPs and HACCP critical control points. For instance, plant sanitation, employee hygiene and strict handling procedures are often as important for controlling *Listeria monocytogenes* in cooked food operations as the actual cooking and refrigeration steps that might be identified as critical control points in HACCP plans.

When SSOPs are in place, HACCP can be more effective because it can concentrate on the hazards associated with the food or processing and not on the processing plant environment. If sanitation controls are included as part of a HACCP plan, they must lend themselves to all aspects of a critical control point (CCP) such as establishing critical limits, monitoring, corrective actions, verification and record-keeping procedures.

A Clean-in-Place (CIP) system for equipment is a good example of sanitation controls that could be handled as a CCP within a HACCP plan. A CIP system's effectiveness can be monitored, critical control points can be established, monitoring records can be maintained, and appropriate corrective actions can be established when the critical limits are not met. On the other hand, a processor's pest-control program should be included in its SSOP rather than its HACCP plan.

Even without HACCP, the level of plant sanitation and GMPs must comply with the law. Contrary to popular perception, sanitation control is not limited to cleaning equipment. Although clean equipment and a clean working area are essential for producing safe foods, so are personnel

practices, plant facilities, pest control, warehouse practices, and equipment and operation design. Each should be addressed in a complete written sanitation program designed to comply with existing regulations. An important component in any sanitation program is monitoring. Methods for monitoring sanitation practices will vary according to the type and size of a food-processing operation. Typically, a checklist can be used to record conditions and sanitation procedures. The frequency of checks will vary to assure the SSOPs remain in control. For example, in certain processing plants, the safety of the processing water may be checked annually. However, the location of other plants may require more frequent inspection. Grounds around a plant may require monthly checks to discourage attraction of pests, but cooler-storage areas and floor drains may need daily inspection. Multiple daily checks would be important for work surfaces, hand-wash stations and employee attire. FDA's HACCP regulations require records to cover at least eight key sanitation concerns.

Overhead 4

Eight key sanitation conditions and practices:

- Safety of water
- Condition and cleanliness of food-contact surfaces
- Prevention of cross-contamination
- Maintenance of hand-washing, hand-sanitizing and toilet facilities
- Protection from adulterants
- Labeling, storage and use of toxic compounds
- Employee health conditions
- Exclusion of pests

Most importantly, any correction necessary to maintain control of the SSOPs should also be documented so that it can accompany or be referenced to any noted problem. This corrective action is part of the SSOP records. An example of an SSOP checklist is given in Chapter 4.

• *Examples of Common Prerequisite Programs*

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This had traditionally been accomplished through the application of GMPs. These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. Common prerequisite programs may include but are not limited to:

Notes:

Continued

Chap 3 - Prerequisite Programs and Preliminary Steps

Notes:

- **Facilities:** There may be specific state or local code requirements for food handling or processing establishments in your area that specify where your operation should be located, and how it is constructed and maintained. You may also need to obtain specific permits or licenses from state or local authorities.
- **Production Equipment:** All equipment should be constructed and installed according to established sanitary design principles, manufacturer recommendations, and any state or local codes. Preventive maintenance and calibration schedules should be established and documented using manufacturer and other information as appropriate.
- **Standard Operating Procedures:** Procedures that describe how routine operations such as receiving, storage, labeling, shipping, etc. are to be conducted may need to be established to ensure that products and packaging materials are handled and processed appropriately to ensure their safety and wholesomeness.
- **Supplier Controls:** You may need to establish controls to ensure that your suppliers have effective GMP, HACCP, or other food-safety programs in place.
- **Production Specification:** You may need to develop written specifications for all ingredients, products and packaging material and send them to your suppliers. These specifications may include quality requirements, acceptable portion sizes, or other requirements not related to safety.
- **Personnel Policies:** Policies and procedures for employees and other persons who enter the manufacturing plant should be established. These policies may cover a variety of things related to employee behavior and performance and could include training requirements for GMPs, sanitation procedures, personal safety, HACCP, etc.
- **Traceability and Recalls:** Procedures that ensure that raw material and finished products are coded and labeled properly and meet the requirements of all appropriate federal, state, and local food labeling and/or weights and measures regulations. A recall system should also be in place so that rapid and complete traces and recalls can be done when product retrieval is necessary.

Other examples of prerequisite programs might include quality-assurance procedures, standard processing procedures, and product formulations and recipes.

Preliminary Steps in Developing a HACCP Plan

HACCP is often thought of in terms of its seven basic principles. However, it also includes preliminary steps. Failure to properly address the preliminary steps may lead to ineffective design, implementation and management of the HACCP plan.

In preparation for developing a HACCP plan, a firm must have a solid foundation.

Overhead 5

Notes:

Preliminary Steps

- HACCP team assembly,
- Description, food and distribution
- Identify intended use and consumers of food
- Develop flow diagram
- Verify flow diagram

• *HACCP Team Assembly*

Assembling a HACCP team is an important step in building a HACCP program. The team should consist of individuals with different specialties. The team may include personnel from maintenance, production, sanitation, quality control and laboratory. The HACCP team should include members who are directly involved with the plant's daily operations.

The team develops the HACCP plan, writes SSOPs, and verifies and implements the HACCP system. The team should be knowledgeable about food-safety hazards and HACCP principles. When issues arise that cannot be resolved internally, it may be necessary to enlist outside expertise.

Although one person may be able to analyze hazards and develop a HACCP plan successfully, many industries find it helpful to build a HACCP team. When only one person develops the HACCP plan, some key points can be missed or misunderstood in the process. The team approach minimizes risk that key points will be missed or that aspects of the operation will be misunderstood. It also encourages ownership of the plan, builds company involvement and brings in different areas of expertise.

In small companies, the responsibility for writing the HACCP plan may fall to one person. If it is possible to build a HACCP team in a small company, employees knowledgeable of various divisions, including owners, should be members. Universities, cooperative extension, consulting groups, Sea Grant programs, model plans and published guidance can provide additional assistance.

• *Description and Intended Use of Product*

Once a HACCP team is established, the members first describe the product, the method of distribution, the intended customer (e.g. general public, infants, elderly) and consumer use of the product (e.g., consumed without further cooking, heat-and-serve, cooked).

Example:

Frozen, cooked, ready-to-eat shrimp, distributed and sold frozen, to be used by the general public.

Chap 3 - Prerequisite Programs and Preliminary Steps

Notes:

In this example, the presence of certain pathogens is likely to be a significant hazard in cooked, ready-to-eat shrimp because the product may not be heated by the consumer. However, growth of the same pathogens is unlikely to be a significant hazard in raw shrimp because it will be cooked by the consumer before consumption.

• *Development and Verification of the Product's Flow Diagram*

A flow diagram shows in simple block or symbol form the steps required to manufacture and distribute a food product. This step provides an important visual tool that the HACCP team can use to complete the remaining steps of the HACCP plan development. Only a clear, simple, but complete, description of the process is needed.

It is important to include all the steps within the facility's control, including receiving and storage steps for all raw materials. The flow diagram should be clear and complete enough so that people unfamiliar with the process can quickly comprehend your processing stages.

Since the accuracy of the flow diagram is critical to conduct a hazard analysis, the steps outlined in the diagram must be verified at the plant. If a step is missed, a significant safety issue may not be addressed.

Overhead 6

Explanatory Note:

This depicts a generic flow diagram. An actual flow diagram needs to be much more detailed.

The following is an example of a basic flow diagram:

Incoming Materials



Processing



Packaging



Storage



Distribution

The HACCP team should walk through the facility and make any changes required in the flow chart. The walk-through allows each team member to gain an overall picture of how the product is made. It may be helpful to invite additional plant personnel to review the diagram during the walk-through.

In addition to the above, experience has shown that the following items need to be addressed in establishing a HACCP system.

Overhead 7

Notes:

Management Commitment
HACCP Training

- *Management Commitment*

For a HACCP plan to work, it is extremely important to have the support of top company officials such as the owner, director and chief executive officer. Without it, HACCP will not become a company priority or be effectively implemented.

- *HACCP Training*

Education and training are important elements in developing and implementing a HACCP program. Employees who will be responsible for the HACCP program must be adequately trained in its principles. This course is designed to meet that need.

Chap 3 - Prerequisite Programs and Preliminary Steps

Notes:

