

Hazard Analysis Critical Control Points (HACCP)—Prerequisite Programs¹

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In addition to the preliminary steps that should be followed when putting together an HACCP plan, there are certain programs that help provide a solid foundation for the plan. Some of these programs are required for certain food processing segments under HACCP regulations under the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS). With the advent of HACCP regulations, some HACCP experts have suggested that the phrase "Prerequisite Programs" be used only for those programs required under regulation in order to distinguish them from "Precursory Programs," which are programs that have been deemed necessary but are not required under regulation. In this discussion, however, the term Prerequisite Programs will be used to designate programs specified under regulations, as well as others deemed important to the HACCP system.

It is important to differentiate between practices and programs. There are many day-to-day practices (e.g., sanitation practices, management practices, employee hygiene practices, chemical handling and storage practices, and other practices) important to food safety in any food processing and handling facility. A program (broadly defined in the HACCP system) embodies these practices. In addition, programs must be written in a useable format, involve training of personnel, and define monitoring and documentation requirements. They must also include corrective actions (where appropriate to control food safety) and provide for the verification of the requirements and their effectiveness.

General Programs and Practices

There are many general programs and practices that apply to the entire facility. General programs that are important to the manufacture of a safe food product may be considered a part of HACCP prerequisite programs. Some examples of general programs and practices follow.

Good Manufacturing Practices (GMPs)

Every food facility should develop Good Manufacturing Practices (GMPs) tailored to that specific operation. GMP requirements must be followed by all employees (including nonproduction personnel, such as those in

management or maintenance) as well as by all visitors to the facility. In addition, food facilities under FDA regulations must follow Current Good Manufacturing Practices (CGMPs) (21CFR117) and any other GMPs codified under FDA regulations for their specific commodities (see <https://www.fda.gov>).

Good Agricultural Practices (GAPs)

Food handling facilities that receive raw agricultural commodities should require that their suppliers follow Good Agricultural Practices (GAPs) as described in the "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," published jointly by the FDA and the USDA (see <https://www.fda.gov>). It may be necessary to modify these GAPs so that they apply to the specific operation.

Other General Programs and Practices

Certain other terms and acronyms (e.g., Good Sanitation Practices [GSPs], Good Hygienic Practices [GHPs], and Good Handling Practices [GHPs]), have been used for general programs and practices related to sanitation throughout food handling facilities. However, these terms are now being used less frequently, since these general programs are being replaced with more specific standard operating procedures (SOPs), as described below.

Specific Programs and Practices: Standard Operating Procedures (SOPs)

A successful HACCP system is not achievable without well-conceived, well-written, and properly implemented Standard Operating Procedures (SOPs). These SOPs must be specific to specific functions within the facility. They should be written in a useable, step-by-step format, and they must be able to be monitored and documented. Finally, they should have sufficient detail to be clearly understood and effectively used by employees.

General Categories of SOPs

Examples of specific functions where SOPs may be developed include

- Facilities and equipment
- Raw materials handling and control
- Suppliers
- Ingredients and use
- Chemical control
- Pest management
- Extraneous matter control
- Production and quality assurance
- Receiving, storage, and distribution
- Consumer complaints
- Recall and traceability
- Food defense
- Food allergen control
- Sanitation
- Labeling
- Training

For food processing systems that fall under federal HACCP regulations, Sanitation Standard Operating Procedures (SSOPs) are required for certain sanitation conditions. For example, U.S. Department of Agriculture/USDA Food Safety and Inspection Service (FSIS) HACCP regulations (9CFR417) require that meat and poultry facilities develop, implement, and maintain SSOPs. In addition, these regulations include provisions for corrective actions, recordkeeping, and verification of SSOPs by FSIS inspectors. Under FDA HACCP regulations for seafood (21CFR123) and fruit and vegetable juice (21CFR120), SSOPs must be developed, implemented, monitored, and maintained with appropriate recordkeeping. FDA HACCP regulations further stipulate that these SSOPs address, at a minimum, the following sanitation conditions:

- Safety of water sources
- Food contact surfaces
- Prevention of cross-contamination
- Maintenance of handwashing and toilet facilities
- Protection from contamination
- Proper labeling, storage, and use of toxic materials
- Control of employee health
- Exclusion of pests

SOP Program Goals

To be effective, an SOP program should

- Describe the procedures
- Provide a schedule
- Provide a foundation to support routine monitoring
- Involve prior planning to ensure that corrections are taken
- Identify trends and prevent reoccurrence
- Enhance understanding by personnel
- Provide consistency in training and application
- Demonstrate commitment to buyers, auditors, and inspectors

Writing and Developing SOPs

A well-written SOP should include

- A clear identification of the SOP
- Responsibilities for specific activities defined
- A description of all procedures that will impact food safety
- A specified frequency
- The timing sequence or order in which things are done
- Materials used, where appropriate
- Descriptions of corrective actions
- Daily records that must be maintained
- Safety or health considerations
- Expected outcomes

1. Identify the SOP

The name of the SOP should be clearly identified using descriptive language and either a revision number or effective date. In larger operations with many SOPs that may be similar, it may be appropriate to assign code numbers to SOPs to make it easier to reference them to defined requirements. The scope of the SOP (e.g., what specifically is covered, to whom it applies) should be well-defined.

2. Use Active Language

SOPs should be written in active (rather than passive) language. The actor (or person who performs the tasks) should be clearly identified. Here is an example of the difference between active and passive language:

Active: *Apply warm detergent solution (120°–140°F) and scrub to remove soil.*

Passive: *Warm detergent solution (120°–140°F) will be applied and the equipment will be scrubbed.*

3. Avoid Vague Terminology

Since SOPs must be followed, vague terminology should be avoided and more specific terminology should be used. For example:

- Temperature: Temperatures should be specific (give the temperature range, or the maximum or minimum temperature), rather than vague (e.g., "warm," "hot," "cold").
- Concentration: Concentrations should be specific (give the actual concentration range, or the maximum or minimum concentration), rather than vague (e.g., "dilute," "concentrated").
- Time: Times should be specific (give the actual time range, or the maximum or minimum time), rather than vague (e.g., "a few minutes").

4. Be Aware of Length and Amount of Detail

It is important to outline the requirements clearly and concisely. An SOP must include enough detail to be effective. However, long and overly detailed SOPs are cumbersome and may not be useable. In general, an SOP that is more than 10 to 12 steps long could probably be split into two SOPs.

SOPs must be written such that the specific information included is appropriate and practical. For example, if an SOP for cleaning a piece of equipment states that the exact temperature of the wash water shall be 130°F, this requires the employee to check and record the exact temperature and to take corrective actions if the temperature falls below (or goes above) 130°F. Thus, it is recommended that a range, a maximum value, or a minimum value be given, rather than precise values.

SOP Corrective Actions

The SOP plan should include a planned sequence of corrective actions to be followed whenever the requirements of the SOP have not been met, resulting in a potentially unsafe product. Such corrective action shall include procedures to ensure the appropriate disposal of product(s) that may be contaminated, to restore sanitary conditions, and to prevent a recurrence of the contamination or adulteration of product(s). In addition, when corrective actions are needed, the HACCP team should re-evaluate the SOPs and make appropriate modifications or appropriate improvements in their implementation.

SOP Records and Documentation

SOP records provide documentation that the functions are being adequately performed and that there is appropriate supervisory documentation. Keep in mind that records demonstrate compliance to specified requirements. The format of the records should follow the format of the SOPs as closely as possible. (The appropriate format depends on personal choice and the specific situation or application.) Checklists are often used to provide confirmation that the person responsible for the SOP has completed all required tasks. In addition, forms should be signed (initialed) to provide for documentation and to verify that the tasks are being performed by both the responsible employee and the supervisor.

Verification

Records must be maintained to provide verification that SOPs and other appropriate prerequisite programs included in the HACCP plan are being followed in accordance with the goals and defined requirements. Further, if an SOP is being used to control a significant food hazard as part of the HACCP plan, its effectiveness in controlling the specified hazard must be validated.

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