HACCP , GMPs, SSOPs

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I. HACCP, Pre- and Post-harvest

Traditionally, the safety of food products, including meat and poultry commodities, has been controlled (and still is) by inspection of the final product. More recently, and with the introduction of the Hazard Analysis and Critical Control Points (HACCP) system, the process of food inspection is being modernized (especially in the meat and poultry area). The emphasis is being directed to detecting food safety hazards upstream in the production or manufacturing process rather than in the finished product. Thus, similar to traditional inspection systems, the HACCP system was devised to provide safe food for consumers. However, the HACCP concept focuses on controlling the *methods of food manufacturing* rather than controlling the *final product*. HACCP is not a stand alone system. It is complemented by other programs such as GMPs, SOPs, and SSOPs (discussed in an earlier lecture).

HACCP was first developed for NASA's space program in 1959 by Pillsbury. For many years the HACCP was voluntarily used by the food industry. In 1996, HACCP was mandated by USDA-FSIS in meat and poultry slaughter and/or processing facilities in an attempt to enforce more strict food safety measures. Later, it was mandated by FDA as a control system for seafood and, recently, for juices. Currently, there is a growing interest in using HACCP to control the safety of live animal production as well as produce production (i.e., pre-harvest food safety).

HACCP and ISO 9000

HACCP is a preventive system to food contamination. It is a systematic approach for assuring production and processing of safe foods. The focus in the HACCP program is on food safety, not quality. The International Standards Organization 9000 series system (ISO9000) is not directed towards safety. The ISO9000 system is set to provide common standards of quality during production or manufacturing of products to assure that two or more trading partners (nationally or internationally) agree on quality of the product.

New Food Safety Management System – ISO 22000

The Food Safety Management System combines Good Management Practices, Hazard Analysis and Critical Control Point (HACCP) principles and effective supplier verification and validation, ensuring that all actions possible are taken, recorded and verified to ensure safe food, which is based on the HACCP principles.

This requires a company policy definition and quality manual, with definition of responsibilities for management and employees, prerequisite programs and HACCP plan implementation, and preparing SSOP programs and measures for implementing the food safety program. Preparing the HACCP team and effective recording systems, and a combination of self-assessment with application of internal auditing, management review, application of all legal requirements and supplier evaluation, are other concerns in this system.

ISO 22000 comprises the completed HACCP program in addition to the harmonized applicable quality management systems and prerequisite programs. ISO 22000 specifies a food safety management system that includes interactive communication between supplier, producers and customers, answers the growing demand for the certification of suppliers and devotes more attention to quality aspects. It extends the approach of the ISO 9001:2000 quality management systems standard, which does not specifically address food safety.

HAZARD ANALYSIS & CRITICAL CONTROL POINTS
Definitions:
(1) *Acceptable level* refers to the presence of a hazard, which does not pose the likelihood of causing an unacceptable health risk**.**
(2) *Control point* (CP) is any point in a specific food system or process at which loss of control does not lead to an unacceptable health risk.
(3) *Critical control point* (CCP) is a point in a specific system or process at which loss of control may result in an unacceptable health risk.
(4) *Critical limit* (CL) is the maximum or minimum value to which a biological, chemical, or physical parameter must be controlled at a critical point to minimize the risk that the identified food safety hazard may occur.
(5) *Deviation* means failure to meet a required critical limit for a critical control point.
(6) *HACCP* plan is a document that presents the formal procedures for following the principles.
(7) *Hazard* is a biological, chemical or physical property that may cause an unacceptable consumer health risk.
(8) *Monitoring* refers to a planned sequence of observations, or measurements of critical limits designed to produce an accurate record, and intended to ensure that the critical limits are maintained.
(9) *Preventive measure* is an action to exclude, destroy, eliminate or reduce a hazard.
(10) *Risk* is an estimate of the likelihood and severity of a hazard occurrence.
(11) *Sensitive ingredient* is any ingredient historically associated with a known biological hazard.
(12) Verification means methods, procedures and tests used to determine if the HACCP system in use is in compliance with the HACCP plan.

HACCP Principles:
There are **seven** principles of HACCP. They are summarized below.

Principle #1: Hazard analysis
The hazard analysis accomplishes three purposes:
(i) Hazards of significance are identified
(ii) Likely hazards are selected
(iii) Identified hazards can be used for developing preventive measures
Hazards can be biological, chemical or physical in nature, and the potential risk of each hazard is assessed based on its likelihood of occurrence and its severity. Hazard assessment is based on a combination of experience, epidemiological data and information in the technical literature.

Principle #2: Identify the critical control points (CCPs)
A CCP is a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. It is important to identify potential CCP(s) in food preparation. CCPs can be cooking, chilling, sanitation procedures, product formulation control (pH, salt, water activity), prevention of cross contamination or employee and environmental hygiene. Different facilities preparing the same food may differ in the risk of hazards depending on the operation. A CCP *Decision Tree* is helpful in assigning CCPs — see diagram.

Principle #3: Establish critical limits for preventive measures associated with each CCP
Critical limits are the boundaries for safety for each CCP and may be limits with respect to temperature, time, meat patty thickness, water activity, pH, available chlorine, etc. Critical limits may be derived from regulatory standards or guidelines, literature, experiments and expert opinion.

Principle #4: Establish procedures to monitor CCPs
Monitoring is a planned sequence of observations and measurements to assess whether a CCP is under control and to produce an accurate record. This record can be used in case of complaints about the product, and is also used in the verification of HACCP. The measurements for monitoring are visual observations, temperature, time, pH, water activity, etc. The measurements must be done "on-line"; there is no time to wait for lengthy laboratory tests. There must be written documentation for who has the responsibility for monitoring.

Principle #5: Establish corrective actions
Corrective actions are taken to get the process under control when monitoring shows a deviation has occurred and a critical limit has been exceeded There must be written instructions for actions to be taken (re-process, condemn, etc.) when critical limits have been exceeded. Additionally, the instructions should indicate who has the authority for the action. Sometimes regulatory agencies must be consulted.

Principle #6: Establish record keeping system
This system is established to document the HACCP system. This is necessary for internal audits and for verification of the HACCP system sometimes by third parties. It is also important in case of consumer complaint.

Principle #7: Establish verification procedures
Verification procedures indicate whether the HACCP system in place is working properly or not. Verification is based on the HACCP documentation, and may include internal audits and/or verification done by a third party (e.g., outside consultant). Additionally, verification may include validation studies (i.e., laboratory testing of samples of food and/or the environment).

II. Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs), and Sanitation Standard Operating Procedures (SSOPs) — Prerequisites to HACCP

Good Manufacturing Practices (GMPs)
GMPs are practices and procedures that are conducted by food processors to insure the safety of food for human consumption. GMPs take into account personnel, equipment, process or operation, and the environment of food production. The GMPs are not plan or process specific. One can probably say that they are "one size fits (almost) all." GMPs fall under the jurisdiction of the Food and Drug Administration (FDA).
GMPs are listed in the Code of Federal Regulations (CFR 21, Part110), and the following is a summary of GMPs as per CFR 21.

1. Personnel:
According to GMP regulations, plant management shall take all reasonable measures and precautions to ensure:

• Disease Control
Excluding individuals who might pose a risk of contamination of food, food-contact surfaces, or food-packaging materials from any operations that might lead to product contamination. Examples include sick individuals, and people with open lesions, boils, sores, infected wounds, etc.

• Cleanliness
Exercising proper hygienic practices while on duty to protect against contamination of food. This includes, but is not limited to, wearing outer garments (e.g., aprons), maintaining adequate personal cleanliness, washing hands thoroughly, sanitizing hands if necessary, removing all unsecured jewelry, wearing gloves and maintaining them clean, use of impermeable gloves, wearing effective hair restraints, hair nets, headbands, caps, and beard covers, storing personal belongings in areas away from food, food-contact surfaces and food-packaging materials, confining eating food (e.g., snacks, lunches), drinking beverages, chewing gum, or using tobacco to areas other than where food, food-contact surfaces and food-packaging materials may be exposed, and taking precautions against foreign substances such as cosmetics, chemicals, or medicines applied to skin from contaminating food, food-contact surfaces, and food-packaging materials.

• Education and Training
Provide a level of understanding regarding production of clean and safe food. This includes understanding consequences of sanitation failures, appropriate food handling techniques, food protection principles, and the danger of poor hygienic practices.

• Supervision
This involves assigning competent individuals to assure compliance by all personnel with all requirements of GMPs.

2. Equipment

Plant equipment and utensils need to be made of adequately cleanable and corrosion-resistant materials. They should withstand the action of food, intended use, and cleaning compounds and sanitizing agents. Equipment should be installed in locations that facilitate their cleaning. Also, the design of the equipment should not allow adulteration of food with metal fragments, lubricants, fuel, contaminated water, etc. Seams on contact surfaces should be smoothly bonded to reduce accumulation of food matter or dirt and minimize microbial proliferation. Non-food-contact equipment as well as holding, conveying and manufacturing systems should have designs that enable maintenance of proper sanitary conditions. Food freezers or cold storage areas should be equipped with thermometers, or temperature monitoring devices to indicate that the temperature is properly controlled in those area. Temperature monitoring devices should be equipped with automatic alarm systems to alert for any deviations. Compressed air and other gases introduced to food or used to clean food-contact surfaces need to be clean and fit for that use to avoid contamination of food.

3. Processing Operations
All food processing operations including receiving, segregating, preparing, manufacturing, packing, inspecting, storing, and transporting should be conducted under adequate and controlled sanitary conditions to ensure that food is fit for human consumption. Chemical, microbial and physical testing procedures should be conducted to prevent possible food contamination. Possible food contamination can be prevented by identifying and addressing sanitation failures during food processing operations. Adulterated food shall be rejected, treated or processed (if allowed by law) to eliminate contamination.

4. Environment (plant and grounds)
Food plants and the grounds about them should be adequately maintained and kept under conditions that will minimize and protect the contamination of food. As such, roads, yards, parking lots, draining areas should be maintained clean. Any litter or waste within the facility and immediate vicinity should be removed because it can attract pests and become their breeding grounds. Plant construction and design should be of proper size for the operation and easy to maintain and clean.
Sufficient space should be provided for equipment, materials (including packaging, cleaning supplies, etc.), and raw ingredients and finished product. In addition, light bulbs, fixtures, and skylights should be adequately installed to prevent food contamination if glass breaks. Additionally, proper lighting and ventilation should be provided in work areas.

Standard Operating Procedures (SOPs)
Similar to GMPs, standard operating procedures (SOPs) fall under FDA's rule. However, SOPs are plant-specific. They are designed to assure the protocols for performing a certain job during manufacturing or processing of food are closely and properly followed. They are used with GMPs. An SOP should define who is doing the job, why this job is done, what it is, the steps involved in completing the job, any critical time limits for the task, and what are the corrective actions that must be taken if the job was performed incorrectly.

Sanitation Standard Operating Procedures (SSOPs)
Sanitation standard operating procedures (SSOPs) are plant-specific operations. Unlike GMPs and SOPs, which fall under FDA's jurisdiction, SSOPs are regulated by the United States Department of Agriculture (USDA). Cleaning and maintenance of sanitary conditions are vital for providing consumers with wholesome and safe food. Thus, it is important to keep buildings, fixtures, equipment, utensils, and food-contact surfaces properly cleaned and sanitized (if necessary) to prevent food from becoming adulterated. Food- contact surfaces, in particular, should be cleaned frequently to prevent microbial proliferation and biofilm formation. Cleaning and sanitizing compounds should be stored away from food; in separate areas. An effective sanitation system would entail a variety of cleaning procedures that account for the type of food soils and the proper cleaning or sanitizing chemicals. Such a system also should include effective measures for control of pests on the premises, and proper water supply.
To maintain a sanitary water supply, an adequate plumbing system must be in place. This should allow sufficient quantities of water to be moved into and throughout the plant as needed with proper drainage, release or discharge of excess or waste water. Thus, a proper sewage disposal system must be in place. Additional sanitary controls include maintaining toilet facilities, keeping the premises in good repair, providing hand-washing stations and refuse receptacles (in strategic locations).
Furthermore, air quality should be addressed.

Additional Reading:
For more information on Meat Sanitation Regulations and Poultry Sanitation Regulations, refer to 9 CFR Part 308, 9 CFR Part 381, respectively.
For more information on procedures for the safe and sanitary processing and importing of fish and fishery products, refer to 21 CFR Parts 123 and 1240.

Recommended websites for food safety information:
(1) Centers for Disease Control and Prevention at:
http://www.cdc.gov
(2) Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition at: http://vm.cfsan.fda.gov/list.html
(3) United States Department of Agriculture (USDA) Food Safety and Inspection Service at: http://www.usda.gov/agency/fsis/homepage.htm
(4) USDA/FDA Foodborne Illness Education Information Center at:
http://www.nal.usda.gov/fnic/foodborne/foodborn.htm
(5) US Environmental Protection Agency (EPA) at:
http://www.epa.gov

CRITICAL CONTROL POINT DECISION TREE — APPLY TO EACH STEP

Does a control measure exist at this step?

yes

no

Modify step, process, or product

Does this step eliminate or reduce hazard?

Is control necessary at this step?

yes

no

no

yes

not CCP

CCP

Could contamination occur or increase to an unacceptable level at this step?

yes

not CCP

yes

no

Will subsequent step eliminate hazard?

yes

not CCP