PURDUE UNIVERSITY
Food Safety Issues

Controlling Food Safety Using the HACCP Approach and Prerequisite Programs

Richard H. Linton, Ph.D.
Food Safety Extension Specialist

Food Safety and Food Quality Programs

Food safety (prevention of foodborne illness) and food quality (increased shelf-life and improved texture, flavor, and color of food) can be controlled in the food industry by developing and implementing in-house food safety and quality programs. The programs that are used most often to enhance food safety and quality fall into three categories: Good Manufacturing Practices (GMPs), sanitation, and Hazard Analysis Critical Control Points (HACCP) programs. HACCP programs specifically reduce food safety risks, while GMPs and sanitation are "prerequisite" programs to the HACCP approach (Figure 1).

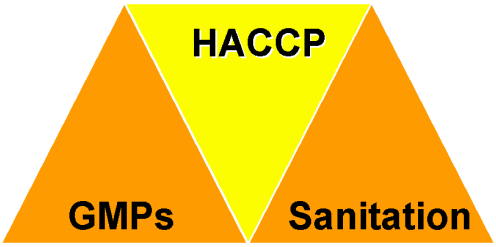

Figure 1. GMPs and Sanitation are Prerequisite Programs for HACCP Programs

GMPs

GMPs refer to the minimum sanitary and processing requirements necessary to ensure the production of safe and wholesome food. The Food and Drug Administration (FDA) requirements for GMPs are listed in Section 21 of the Code of Federal Regulations, Part 110. This document contains requirements for a) personnel, b) building and facilities, c) equipment and utensils, and d) production and process controls. When implemented properly, GMPs help control the possibility of contamination from poor personal hygiene (hand washing, gloves, hairnets) and from inanimate objects (pest control, equipment cleaning, facility design). They also help to ensure proper cleaning and sanitizing.

Sanitation

Sanitation is broadly defined by "all precautions and measures, which are necessary in the production, processing, storage and distribution, in order to assure an unobjectionable, sound and palatable product which is *fit for human consumption*." (Bakka, 1997). Sanitation is a multistep process that involves cleaning and sanitizing as two very

important and separate steps. Cleaning and sanitizing can apply to various aspects of a food plant such as equipment, packages, walls, and floors.

Cleaning removes visible soil and organic matter and more than 90% of harmful microorganisms. A sanitizer is applied after a surface has been properly cleaned. The sanitizer further reduces the level of microorganisms to a safe and acceptable level. Common sanitizers in the food industry include chlorine, iodophors, and quaternary ammonium compounds.

HACCP

The Hazard Analysis Critical Control Point system (HACCP) is a preventative system used by the food industry to help ensure food safety. Properly applied, the system controls hazardous elements in the food system such as contaminants, pathogenic microorganisms, physical objects (glass, metal, bone), chemicals (toxins, heavy metals, pesticide residues), raw materials, processing conditions, use directions for the consumer, or storage conditions.

HACCP is a *systematic approach* to assure food safety. Workers using HACCP systematically examine each step in a process flow and ask the questions:

- *Does a potential hazard exist in a particular step in the process (from ingredients, food handlers, equipment, process environment)?*
- *Can your eliminate or prevent those potential hazards through preventative measures (thermal processing, refrigeration, etc.)?*
- *Since it may be difficult to monitor for the specific hazards, can you instead monitor preventative measures (time, temperature, filter pore size, etc.)?*

If the answers to all of the above questions are "yes," this is a "stop sign" or critical control point (CCP) in the process. At each CCP, a food company must establish parameters to ensure food safety. If these parameters are not within established limits, based on science or experience, the process is considered "out of control" and cannot continue.

GMPs, sanitation, and HACCP collectively make a food product safer and improve quality. HACCP is not a stand-alone program; GMPs and sanitation procedures are important foundations for a successful HACCP program.

How HACCP Started

HACCP started in 1959 when the National Aeronautic and Space Agency (NASA) approached Pillsbury to produce a food that was safe for astronauts in zero gravity conditions in the space capsules. In 1959, they knew essentially nothing of how foods might react under zero gravity. The most difficult and perhaps most important aspect of the project was to develop a system that assured nearly 100 percent freedom from contamination by microbial, chemical, or physical hazards. A food contamination problem could abort a space mission.

The Pillsbury Company, in cooperation with NASA, the Natick Laboratories of the U.S. Army (now called Natick Soldier Center), and the U.S. Air Force Space Laboratory Project Group collectively worked on a project to produce food for the space program. Their primary objective was to develop a food safety system that would reduce the likelihood of microbial, chemical, and physical hazards. The system required control over all aspects of food production such as raw material, processing, environmental conditions, personnel, storage, and distribution. This effort resulted in a set of three HACCP principles, which has since been expanded.

Today, there are seven principles associated with development and implementation of the HACCP system (Figure 2).

- ☑ Analyze hazard analysis
- ☑ Determine critical control points
- ☑ Establish critical limits for critical control points
- ☑ Monitor critical control points
- ☑ Take corrective action
- ☑ Keep records
- ☑ Verify that the system works

Figure 2. The Seven Steps of the HACCP System

The Seven Principles of the HACCP System

Before a food company can develop a HACCP program, they should assemble a multi-disciplinary team that includes individuals involved with food safety, food quality, and food processing operations. This team could include personnel from quality assurance, quality control, management, front line workers, and maintenance. The group also could include an external food safety consultant.

After the team has been assembled, they begin developing a HACCP program. HACCP is "product specific," which means that a plan is developed for

each specific product manufactured by a company. Before proceeding with the seven principles, the team describes the product and draws a flow diagram of the entire process. The flow diagram should represent receipt of incoming ingredients, as well as all the processing, packaging, and storage steps. The team applies the seven principles of HACCP to each step of the flow diagram.

1) Analyze hazards

In this first step, the team assesses hazards associated with growing, harvesting, raw materials and ingredients, processing, manufacturing, distribution, marketing, preparation, and consumption of the food. They identify all significant hazards (biological, chemical, and physical) that need to be controlled to assure food safety throughout each step in the process.

2) Determine critical control points

After identifying the significant hazards, the team establishes preventative measures to control the identified hazards. The team identifies areas or points in the flow of a food product with critical limits that must be met to control the identified hazards. These are the CCPs. If loss of control occurs at a CCP, it likely will lead to an unacceptable health risk.

3) Establish critical limits for critical control points

At each CCP, teams define boundaries or limits of safety to assure that the CCP is in control. They establish upper/lower limits for CCPs. CCP limits are usually based on time, temperature, pH, and moisture content of a food.

4) Monitor critical control points

CCP and CCP limits are only effective if they are monitored during food processing. Monitoring ensures that the process is in control. Monitoring also can identify processing or formulation problems that could lead to food safety risks.

5) Take corrective action

Whenever food companies note a deviation in the critical limits for a CCP, they must correct the deviation. Corrective action may include changing the process, reprocessing, or discarding the product.

6) Keep records

Food companies must keep records of the results of monitoring critical control points. These records are the only proof a company has that the process is in control and that they are complying with the HACCP plan. Depending on the commodity, records should be accessible for one to three years.

7) Verify that the system works

Once the HACCP system is in place, a company must be sure that it is effective. They may request an internal or external food safety audit to verify that the HACCP plan is working. It also may include testing for absence of foodborne hazards in the finished product. An example of a HACCP plan is provided (Figure 3).

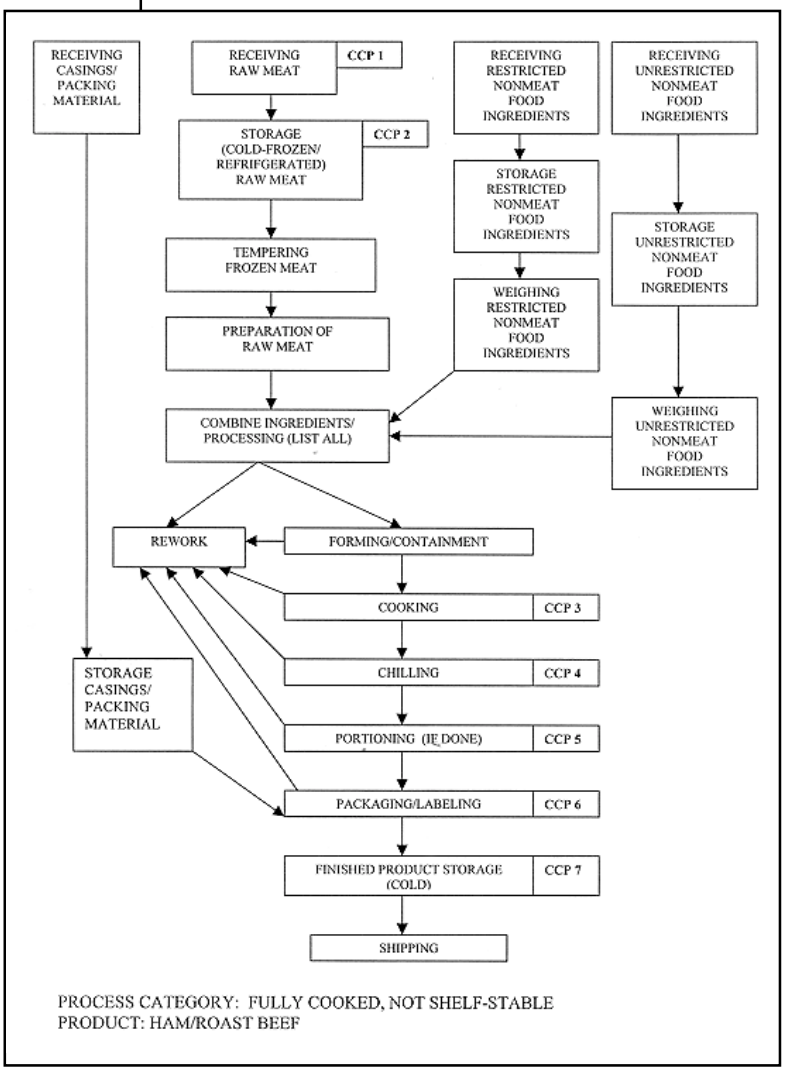

Figure 3. Example of a USDA Generic HACCP Plan for Fully Cooked, Not Shelf-stable Foods

HACCP Regulations in the Food Industry

During the past few decades, several food industries have adopted HACCP programs. In the past few years, HACCP has become a mandatory regulatory requirement in selected food industries as described below.

Meat and Poultry Industries

The Food Safety Inspection Service (FSIS) of the United States Department of Agriculture (USDA) is responsible for inspection of meat and poultry slaughtering/processing facilities. In the past, inspection procedures were based mainly on visual observation or smell of animal carcasses and processing conditions. Recently, this changed with the adoption of the final rule of the Pathogen Reduction Act (also called the "Mega-Reg"), which was first published in the Federal Register on July 25, 1996. Now HACCP plays a large part in the process.

There are four major elements of the rule.

1. All slaughter and processing plants are required to adopt the system of process control to prevent food safety hazards known as HACCP. For the first time, slaughter plants and plants that produce raw ground meat and poultry are required to systematically target and reduce disease-causing bacteria.
2. Slaughter plants are required to conduct microbial testing for generic *Escherichia coli* to verify that their control systems are working as intended to prevent fecal contamination, the primary avenue of contamination by disease-causing bacteria.
3. FSIS has set pathogen reduction performance standards for *Salmonella* spp. that plants must meet for raw products.
4. Every plant must adopt and carry out a written set of sanitation standard operating procedures (SSOPs) to meet basic sanitation responsibilities.

The rule went into effect in stages.

By January 27, 1997:

- All meat and poultry plants had to develop and implement SSOPs.
- Slaughter plants began testing for generic *Escherichia coli.*
- FSIS began testing to set performance standards for *Salmonella* spp.

By January 26, 1998:

- HACCP plans were implemented in large establishments (> 500 employees)

By January 25, 1999:

- HACCP plans were implemented in small establishments (< 500, >10 employees)

By January 25, 2000:

- HACCP plan were implemented in very small establishments (<10 employees, or annual sales <$2.5 million)

Seafood Industry

The National Marine Fisheries Services (NMFS) of the National Oceanic and Atmospheric Administration, U.S. Department of Commerce (USDC), conducts a voluntary inspection program for fishery products on a fee-for-service basis. About 20 percent of seafood products are currently inspected by NMFS. Under this inspection, many services are offered including food sanitation and food safety (HACCP) inspections, product grading, laboratory analysis, training, and other forms of consultation.

As in meat and poultry industry, inspection of seafood products has undergone a significant change. On December 18, 1995, the Food and Drug Administration (FDA) set forth provisions for HACCP inspection of seafood products. These provisions became effective December 18, 1997.

The rule basically states the following:

1. All commercial seafood in interstate commerce must be processed under HACCP controls. This includes domestically produced and imported seafood. Foreign processors that export to the United States must also operate under HACCP.
2. A hazard analysis must be completed for each product and process that involves de-heading or evisceration. If a hazard exists and is likely to cause harm if preventative controls are not in place, a processor must draft a HACCP plan. Those operations that only harvest seafood (e.g. aquaculture) are exempt from the HACCP regulation.
3. SSOPs must be implemented throughout the plant as a foundation for the HACCP program.
4. Special requirements:
   - Mulluscan shellfish must be tagged and harvested from approved waters.
   - Smoked fish must show that the HACCP plan ensures zero toxin production by *Clostridium botulinum.*

Juice Industry

Proposed FDA fresh-juice safety guidelines were released April 21, 1998. Later, FDA required product labeling and recommended HACCP procedures. On January 18, 2001, the final rule was published in the Federal Register for labeling and HACCP requirements for fresh juice.

The rule requires warning labels on all packaged juice products that have not been pasteurized or otherwise treated to eliminate harmful microbes. FDA's warning label reads: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria which can cause serious illness in children, the elderly, and persons with weakened immune systems." The label is required on all packages of untreated juices, with the exception of unpackaged juice sold for immediate consumption. The latter includes freshly squeezed juice served at a restaurant, a juice bar, or a child's lemonade stand.

It is now mandatory for processors of packaged fruit and vegetable juices to implement HACCP plans at their plants to prevent microbiological, chemical, and physical contamination of their products. Additionally, this provision requires makers of unpastuerized juice to document a 5-logarithm (5-log) reduction in the number of pathogens in the finished juice product. This "5-log" step is equivalent to a 99.999 percent kill rate on the "most resistant" harmful microbes found in the juice.

At present, heat pasteurization and use of ultraviolet light are the only known single treatments that can achieve the 5-log reduction. However, juice processors could alternatively use methods such as washing, scrubbing, anti-microbial solutions, and alternative technologies, or a combination of techniques, as long as they can document the 5-log reduction requirement. For citrus products, the 5-log reduction can be done on the surface of the fruit rather than the juice. Shelf-stable products, some concentrates, and juice bars are exempt from the new rules.

As with the meat and poultry HACCP rule, implementation of this rule will be based on size. Large operations will have 12 months, small operations 24 months, and very small operations 36 months to meet the requirements. FDA has defined large processors as those who have more than 500 employees and small processors as those who have fewer than 500 employees. They define very small processors as those who:

(1) have total annual sales of less than $500,000, or

(2) have total annual sales of greater than $500,000 but total annual food sales of less than $50,000, or

(3) employ fewer than 100 full-time equivalent employees and annually sell less than 100,000 units of the juice in the United States.

For More Information on HACCP and HACCP Regulations

Bauman, H. 1990. HACCP: Concept, development, and application. *Food Technology*. 44(5) 156-158.

Corlett, D. A., Jr. 1998. *HACCP User's Manual.* Aspen Press, Gaithersburg, MD.

Deibel, K. 1994. *Enhanced food safety with HACCP*. Medallion Laboratories. Vol. 11, No. 1.

Bakka. 1997. *Making the Right Choice – The Sanitation Process.* Ecolab Food and Beverage Division, St. Paul, MN.

Pierson, M. D. and D. A. Corlett. 1992. *HACCP Principles and Applications.* Van Nostrand

Reinhold:New York.

The final rule on pathogen reduction and hazard analysis and critical control point (HACCP) systems, July 1996, update March 2000, http://www.fsis.usda.gov/OA/background/finalrul.htm

Pathogen reduction and HACCP systems… and beyond, January 1998, updated December 1998, http://www.fsis.usda.gov/OA/background/bkbeyond.htm

Procedures for the safe and sanitary processing and importing of fish and fishery product, final rule, December 1995, http://vm.cfsan.fda.gov/~lrd/searule3.html

HACCP regulations for fish and fishery products: questions and answers, January 1999, http://vm.cfsan.fda.gov/~dms/qa2haccp.html

Food labeling: warning and notice statements; April 1998, http://vm.cfsan.fda.gov/~lrd/fr98424b.html

Food labeling, nutrient content claims – general provisions, May 1998, http://vm.cfsan.fda.gov/~lrd/fr980515.html

Current good manufacturing practice in manufacturing, packing, or holding human food, 2000 edition, http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr110_00.html

FDA publishes final rule to increase the safety of fruit and vegetable juices, January 2001, http://vm.cfsan.fda.gov/~lrd/hhsjuic4.html

Hazard analysis and critical control point (HAACP); Procedures for the safe and sanitary processing and importing of juice; final rule, http://vm.cfsan.fda.gov/~lrd/fr01119a.html