

# AN INTRODUCTION TO HACCP

## The Hazard Analysis & Critical Control Point System for Food Processors

By A.V. RISWADKAR

**A**ccording to a 1996 U.S. Dept. of Agriculture (USDA) report, foodborne microbiological contamination in the U.S. causes an estimated 9,000 deaths and 33 million human illnesses annually. The cost of these human illnesses and lost productivity is estimated to be \$9.3 to \$12.9 billion annually (*Bacterial Foodborne Diseases*).

Recent headlines have reported food safety problems. "Hot dogs blamed for Listeria outbreak" (AP-Detroit, MI, June 1999). "12th death is linked to tainted meat at plant" (*New York Times*, Jan. 27, 1999). "Armed with E-coli horror stories, consumer groups demand safer meat" (CNN, Nov. 10, 1999).

Due to this increased attention, consumer expectations about food quality and safety have grown, prompting food processors to seek systems and programs that will both bolster consumer confidence and improve food safety.

Traditional quality assurance programs and facility inspections focus pri-

marily on finished product testing and general sanitation; these have proven to be inadequate in controlling many foodborne illnesses, such as salmonellosis, e-coli and listeriosis in meat and dairy products. Meanwhile, the Food and Drug Administration (FDA), USDA and other food regulatory agencies are seeking alternative approaches that will effectively and comprehensively evaluate a food plant's ability to produce consistently safe, high-quality foods.

### HAZARD ANALYSIS & CRITICAL CONTROL POINT

The Hazard Analysis and Critical Control Point (HACCP) system is one such alternative. It focuses on identifying and preventing hazards that could cause foodborne illnesses rather than relying on spot-checks of manufacturing processes and random sampling of finished food products to ensure safety. Combined with an effective hazard analysis technique, HACCP allows safety and quality to be built into each step within the process—from product formulation specifications

to distribution. Even potential consumer abuse and misuse can be considered under HACCP principles.

With HACCP in place, a food processor can identify and monitor specific foodborne hazards that are biological, chemical or physical in nature. A systematic hazard analysis is used to identify critical control points (CCPs) in the process; these points must be controlled in order to ensure food safety and prevent adverse health impact on the consumer. This enables the processor to focus control efforts on specific critical points, which also prevents the inefficiency associated with overapplication of extraordinary sanitation measures.

In the drive to ensure food safety, HACCP is becoming a necessity for all food processors; it is now widely accepted as an effective part of a total quality program. In addition, FDA has incorporated HACCP into its 1999 Food Code, a guidance document that is a model regulation for state and local agencies responsible for licensing and inspecting food service

# HACCP follows a basic risk management philosophy.

## By identifying critical risk factors, a firm can focus its prevention and mitigation resources to maximize its risk management efforts.

establishments, retail food stores and vending operations. USDA now requires all meat and poultry processors to implement an effective HACCP system and reassess its adequacy at least annually.

### HISTORY OF HACCP

HACCP emerged as the result of several joint projects conducted during the 1960s to develop food for the space program. The approach was presented at the 1971 Conference on Food Protection, where it was viewed as a solution to microbiological problems with low-acid canned foods, particularly mushrooms. This led to promulgation of Low-Acid Canned Foods regulation by the FDA in 1974.

The original HACCP (1971) was based on three principles:

- 1) Comprehensive hazard analysis and risk assessment.
- 2) Determination and identification of CCPs.
- 3) Monitoring of CCPs.

By 1986, subcommittees of both the National Conference on Food Protection and National Academy of Sciences had recommended that the HACCP approach be adopted by both the U.S. food industry and regulatory agencies. These recommendations led to formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in 1987. This committee expanded the HACCP protocol to include the seven principles now widely accepted as the standard.

- 1) Conduct hazard analysis and risk assessment.
- 2) Identify critical control points in food preparation.
- 3) Establish critical limits for each CCP.
- 4) Establish procedures for monitoring the CCPs.
- 5) Establish corrective action protocol for each CCP.
- 6) Establish procedures for effective recordkeeping.
- 7) Establish procedures for an effective verification (audit).

Today, many HACCP programs and studies are in progress. One of the system's greatest strengths is its adaptability to widely varied processes. For example, USDA's Food Safety and Inspection Service (FSIS) is applying HACCP principles to meat and poultry product safety. These principles are also the center of an ongoing joint seafood inspection program of the FDA and the National Marine Fisheries service (NMFS). The dairy industry's

approach to HACCP systems is taking the form of workshops, manuals and training videos developed under the sponsorship of the International Dairy Foods Assn., National Cheese Institute and American Butter Institute. Many generic HACCP programs have also been developed; for example, FSIS has developed several generic HACCP models.

### THE SEVEN PRINCIPLES

#### **Conduct Hazard Analysis & Risk Assessment**

This first principle may be the most important. Effective controls cannot be considered until hazards have been identified and their risks assessed. This can be an involved process, since all potential hazards should be evaluated. Furthermore, failure to recognize a potential hazard can lead to an unacceptable risk, even if controls and monitors for identified hazards are implemented correctly.

In 1992, in its "Hazard Principles for Food Production" report, NACMCF defined a hazard as "any chemical, physical or biological property that could cause an unacceptable consumer health risk." This report introduced a food risk categorization process that forms a basis for this first principle. To ensure uniformity, food risk assessment should encompass the following six hazard characteristics.

A) **Food intended for consumption by at-risk population.** This category accounts for risk factors introduced when consumers are very young, elderly or otherwise unusually susceptible to potential hazards of the evaluated food product.

B) **Product contains sensitive ingredient(s).** This accounts for any ingredient that may be a source of a hazard or might be a carrier of a microbiological hazard (e.g., eggs).

C) **No process step to eliminate hazard.** For example, raw milk is still sold in the U.S. Elimination of the pasteurizing step is an example of this factor.

D) **Recontamination potential before packaging.** Aseptic packaging has several control advantages over traditional packaging. One key benefit is the reduction of the recontamination potential.

E) **Potential for product abuse.** Does a real potential exist for abuse to the product during distribution or consumer handling that could lead to an unsafe product?

F) **No terminal heat process.** This encompasses ready-to-eat foods that typically do not require reheating. In other

words, one cannot depend on the advantage of consumer cooking to eliminate remaining microbiological hazards.

Based on these factors, food risk categories are assigned as "0" to "VI," with "VI" being the highest risk. Foods that fall into risk factor "A" (e.g., infant formula, baby food) automatically become a risk category "VI," while foods with no risk factors (B-F) are categorized as "0." Foods with one risk factor (other than "A") are risk category "I." Those with two factors (other than "A") are category "II" and so on.

Risk categories can also be assigned to ingredients, incoming raw materials, in-process foods and finished products. These categories are useful indicators for priority identification in the next task—the specific hazard identification and analysis.

The focus on consumer safety is fundamental to HACCP. However, the program can be effectively extended to include other potential problem types, provided food safety hazards remain separate and distinct from those unrelated to food safety. A flow diagram can be used to document the production and distribution processes and help identify hazards at each step.

Risk hazard analysis helps identify potential types of hazards and their sources. Biological hazards in food processing include bacterial, viral, or enteric and parasitic organisms. Chemical hazards include naturally occurring elements (such as mycotoxins from mold), toxic mushrooms, plant toxins and chemicals added during food processing (such as pesticide residues, food additives and lubricants). Physical hazards come in different forms, such as glass, stones or metal fragments, with the most likely outcomes ranging from a chipped tooth to choking.

#### **Identify CCPs in Food Preparation**

Many points in food processing can be considered control points, but few are critical control points (CCPs). According to NACMCF, a CCP is any controllable point in a specific process where loss of control may result in unacceptable risk. It is a point, step or procedure in food preparation where a food safety hazard can be prevented, controlled, reduced or eliminated. For example, time-temperature relation in pasteurization is a CCP.

As noted, NACMCF defined CCPs based on the need to protect the consumer. Other control points have also been identified.

## Hazard Analysis Questions

Appendix C of the "Hazard Analysis and Critical Control Point Principles and Application Guidelines," adopted Aug. 14, 1997, by the National Advisory Committee on Microbiological Criteria for Foods, contains a list of questions to be considered when conducting a hazard analysis. Examples are printed below.

### INGREDIENTS

- 1) Does the food contain any sensitive ingredients that may present microbiological hazards, chemical hazards or physical hazards?
- 2) Are potable water, ice and steam used in formulating or handling the food?

### INTRINSIC FACTORS

- 1) What hazards may result if the food composition is not controlled?
- 2) Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing? During subsequent steps in the food chain?



•**CCP1 and CCP2.** The International Commission on Microbiological Specifications for Foods (ICMSF) divides CCPs into "major" (1) and "minor" (2). CCP1 requires that a hazard be completely eliminated to ensure food safety, whereas CCP2 requires that a hazard be reduced to ensure control. CCP2 is less critical to food safety and, thus, requires less monitoring.

•**Universal CCPs.** As applied in the ABI/NCI *Total Quality Systems Handbook*, these refer to potential hazards that are universal to all manufacturing sites. Specifically, these are hazards that may be common throughout a plant rather than located specifically within a single process or piece of equipment. Sanitation is a universal CCP.

•**Physical hazard CCPs.** Also defined by the ABI/NCI *Handbook*, physical hazards in the production process within the food industry are often controlled through filtering, metal detection or visual inspection. This type of control point has been designated to differentiate it from microbiological CCPs that typically cannot be easily monitored during production.

•**Manufacturing, economic, production, quality, regulatory CCPs.** These can be defined as any controllable point at which failure to control may result in unacceptable quality; improper portion control or waste; or productivity, yield or regulatory problems. However, since these points are not usually food-safety-related, most HACCP programs do not encompass them.

### **Establish Critical Limits (Specifications) for Each CCP**

Critical limits must be established for each CCP to ensure that the system effectively controls identified hazards. Critical limits are the tolerance limits or safety margins for each CCP to ensure prevention or control of a hazard. These limits may be derived experimentally through validation process, regulatory standards and codes, or by other reliable sources.

### PROCESSING PROCEDURES

- 1) Does the process include a controllable processing step that destroys pathogens? If so, which pathogens?
- 2) If the project is subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging, which biological, chemical or physical hazards are likely to occur?

### MICROBIAL CONTENT OF FOOD

- 1) What is the normal microbial content of the food?
- 2) Does the microbial population change during the normal time the food is stored prior to consumption?

### FACILITY DESIGN

- 1) Does the facility's layout provide an adequate separation of raw materials from ready-to-eat (RTE) foods (if this is important to food safety)? If not, what hazards should be considered as possible contaminants of the RTE products?
- 2) Is the traffic pattern for people and moving equipment a significant source of contamination?

### EQUIPMENT DESIGN & USE

- 1) Is the equipment properly sized for the volume of food that will be processed?
- 2) Is the equipment reliable or is it prone to frequent breakdowns?

### PACKAGING

- 1) Does the package include instructions for the safe handling and preparation of the food by the end user?
- 2) Are tamper-evident packaging features used?

### EMPLOYEE HEALTH, HYGIENE & EDUCATION

- 1) Can employee health or personal hygiene practices impact the safety of the food being processed?
- 2) Do employees understand the process and the factors they must control to ensure the preparation of safe foods?

To obtain a complete copy of the guidelines, visit <http://vm.cfsan.fda.gov/~comm/nacmcfp.html>.

Examples of criteria used for CCPs include time, temperature, humidity, water activity and pH level.

### **Establish Procedures for Monitoring of CCPs**

Monitoring is defined as a planned sequence of observation, testing or measurement to ensure that the CCP is under control. Monitoring requirements should be carefully defined; responsibility for observation or testing clearly assigned; and test results accurately recorded for future verification. Monitoring can be performed at defined time intervals or continuously, and visual observation, calibrated instruments and recording charts may be

used to document the monitoring process. Monitoring tracks the process and detects adverse trends that, left uncorrected, could lead to loss of control. Signatures and initials on monitoring records protect the integrity of the process.

### **Establish Corrective Action Protocol for Each CCP**

This protocol is implemented when monitoring indicates that deviation at a CCP has exceeded the critical tolerance limit. A critical deviation (CD) is a deficiency that could result in an unacceptable consumer health risk and must be addressed promptly. This may involve adjustment to the process upstream or

addition of corrective steps in the subsequent process. In addition, the plan must address disposition of any product produced during CD. In some cases, the product must be placed "on hold" pending investigation and appropriate corrective action. Additional monitoring and sampling may be necessary to ensure implementation of corrective action.

#### **Establish Procedures for Recordkeeping**

Future regulatory inspections will likely shift from physical plant/product inspection to review of the HACCP system and associated documentation. It is already a key component of the voluntary FDA/National Oceanic and Atmospheric Administration's Fish and Fishery Products Program.

Documentation should be systematic and thorough. It should include the HACCP-based plan; modifications to the process or the plan; raw material procurement records; CCP limits and monitoring records; records of action taken to address CDs; disposition of products affected by CDs; quality assurance/control records; and consumer complaint records. Appropriate monitoring records should be documented with signature as necessary.

The level of detail in recordkeeping will vary according to the complexity of the food preparation process. For efficiency, HACCP documentation may be integrated into operational recordkeeping.

#### **Establish Procedures for an Effective Verification**

These procedures ensure that the HACCP-based system implemented complies with the HACCP plan designed for that process. Verification may include documentation checks as well as testing, and the manufacturer or regulatory agency may perform audits. Verification activities and procedures may include review of CCPs and monitoring records, deviations and corrective actions, as well as periodic verification inspections. Focused verification can be initiated to investigate and follow-up specific foodborne disease outbreaks and other incidents.

In addition to a periodic program review and audit, it may be necessary to review and verify the integrity and scientific basis for critical limits established for each CCP. Any significant change in the process, materials or packaging will require an appropriate review. The key is to ensure that the program remains effective and current.

#### **CRITICAL CONTROL POINTS & RISK ASSESSMENT**

Due to lack of expertise or adequate training in comprehensive risk assessment, many food processors rely on off-the-shelf generic HACCP systems. While this is a good start, full benefits of an effective HACCP program cannot be realized until a comprehensive risk assess-

ment has been performed and the program customized to meet site-specific needs. However, the HACCP principles do not mandate or suggest any particular methodology for hazard analysis.

In the author's experience, one effective technique is to use a team-based gross hazard analysis method that systematically identifies hazards and their trigger mechanisms, and assesses their associated effects in terms of likelihood and severity. This information is recorded to create a hazard catalog.

Each hazard can then be assessed qualitatively for its relative risk, including comparative probability of occurrence and severity of effects, with due consideration for effectiveness of downstream controls. For example, the potential detrimental effect of a specific hazard in milk production (e.g., inadequate storage temperature and potential for temperature abuse of raw milk) may be somewhat reduced if the downstream process includes a pasteurization step.

The assessor must then determine the desired risk tolerance level and compare this level to the potential frequency and severity of catalogued hazards in order to determine unacceptable risks. The result is a risk profile, which facilitates the identification of CCPs with unacceptable risks to help the facility set priorities; it also simplifies completion of the HACCP program.

#### **CONCLUSION**

An effective HACCP program provides a systematic approach to food safety. With dramatic increases in the variety of prepared foods, an effective food safety program is an important element of public health protection. FDA has already added HACCP to its Food Code and is recommending HACCP system implementation throughout the food industry. USDA has introduced HACCP into its regulations for meat and poultry processors.

HACCP follows a basic risk management philosophy with an emphasis on reducing the potential hazards inherent in food safety. By identifying critical risk factors, a firm can direct its prevention and mitigation resources to maximize its risk management efforts.

HACCP principles are not limited to food safety; they can be applied to other products and processes as well. For example, in 1985, the National Academy of Sciences recommended that all regulatory agencies adopt HACCP principles. FDA's Center for Devices and Radiological Health is working on adopting HACCP for the medical device industry. In 1995, former FDA Commissioner David Kessler stated, "Our safety inspections should focus on prevention rather than on chasing the horses after they are out of the barn. HACCP is the system that will make that possible."

Successful food processors understand the importance of their reputation and "brand value" in the marketplace. This status can be best protected through a well-implemented "total quality" system focused on prevention. ■

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