HACCP is a prevention-focused food safety tool that identifies and monitors specific foodborne hazards that are biological, chemical, or physical in nature.

**OVERVIEW**

The Food Safety Modernization Act of 2011 requires that all companies that handle food have a science based food safety program. HACCP (Hazard Analysis Critical Control Points) programs fit this definition. The CDC has cited that foodborne pathogens are responsible for 48 million illnesses, 128,000 hospitalizations and 3,000 deaths annually.

Daily headlines in news media declare: “Peanut processor found to be the cause of salmonella contamination in peanut butter”; “Cantaloupe being withdrawn because they have the potential to be contaminated with Listeria.” Headlines like these continue to show up in newspapers across the nation. The result? Consumers are raising their concerns and expectations about food quality and safety while processors scramble to find systems and programs that will bolster consumer confidence and safety. Meanwhile, the Food and Drug Administration (FDA) and other food regulatory agencies are looking at alternatives to the old inspection-oriented approach that will effectively and comprehensively evaluate a food plant’s ability to produce consistent safe, high-quality foods.

Traditional quality assurance programs and facility inspections focus primarily on finished-product testing and general sanitation. These have proven to be inadequate in controlling many of the less understood hazards such as Salmonella enteritidis in meat products and Listeria monocytogenes in fresh fruit and dairy products. Most food processors now know that an alternative system already exists – it is the HACCP system.

The HACCP system is becoming a necessity for all food processors since it is now widely accepted as an effective part of a Total Quality Program and an answer to the food industry’s current need. When combined with a good hazard analysis technique, it allows safety and quality to be built into each step in the process – from product specifications to product distribution. Even potential consumer abuse and misuse can be considered under HACCP.

A systematic hazard analysis is used to identify critical control points in the process. These points must be controlled to ensure safety of the food and adverse health impact on the consumer.

HACCP allows the user to focus hazard control efforts on specific critical points in a process. This helps the processor avoid the inefficiency that comes from the over application of extraordinary sanitation measures. The processor gains efficiency and a greater assurance of food safety. One of HACCP’s many strengths is its flexibility and adaptability to widely varied processes. As a result, HACCP can be applied to a variety of products throughout the food industry. This Risktopic will introduce the currently accepted HACCP principles and discuss some of the variations.
HISTORY OF HACCP

Early origins of HACCP lie in several joint projects focusing on developing foods for the space program in the 1960’s. This approach to controlling microbiological hazards in foods was presented at the 1971 Conference on Food Protection. Work with HACCP in the early 1970’s was seen as a solution to microbiological problems with low-acid canned foods, particularly mushrooms. This led to the U.S. FDA’s promulgations of the Low-Acid Canned Foods regulation in 1974 by the U.S. Food and Drug Administration.

The original HACCP of 1971 was based on three principles:

1. Hazard analysis and risk assessment
2. Determination and identification of critical control points (CCPs)
3. Monitoring of CCPs

By 1986, both the National Conference on Food Protection and two reports by the National Academy of Sciences subcommittees (NAS. 1985) had recommended that the HACCP approach be adopted by both the American food industry and the regulatory agencies. These recommendations led to the 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 that are now widely accepted as the standard. Today, many HACCP programs and studies are in progress. The USDA’s Food Safety and Inspection Service (FSIS) has accepted HAACP’s application to meat and poultry product safety. In April 2011, the FDA Center for Food Safety and Applied Nutrition updated its Fish & Fishery Products Hazards & Controls Guidance. The Dairy Industry’s approach to HACCP systems is taking the form of workshops, manuals, and training videos sponsored and developed by two organizations of the International Dairy Foods Association (IDFA), the National Cheese Institute (NCI), and the American Butter Institute (ABI). Food Marketing Institute also has developed a program for supermarkets.

HACCP’S SEVEN PRINCIPLES

The seven widely accepted principles of HACCP are:

1. 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 CCPs
5. Establish Corrective Action Protocol for Each CCP
6. Establish Procedures for Effective Recordkeeping
7. Establish Procedures for an Effective Verification (Audit)

A brief discussion of each of these principles follows.

1. **Hazard Analysis is a Risk Assessment**

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

   NACMCF (1992) defined hazard to be “any chemical, physical, or biological property that could cause an unacceptable consumer health risk.” This report has introduced a food risk categorization process that forms a basis for this first principle. In the interest of uniformity, the food risk assessment should include the following six hazard characteristics:

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

   B. Product contains sensitive ingredient or ingredients: This is intended to account for any ingredient that may be a source of a hazard or that might be a good carrier of a microbiological hazard, i.e., eggs.
C. No process step to eliminate hazard: Raw milk is still sold and consumed in America today. The elimination of the pasteurizing step is a good example for this factor.

D. Recontamination potential before packaging: Aseptic packaging has several obvious hazard control advantages over other traditional packaging. Reduction of the recontamination potential is an important one.

E. Potential for product abuse: Is there a real potential for abuse to the product during distribution or consumer handling that could lead to an unsafe product?

F. No terminal heat process: This is intended to account for ready-to-eat foods that typically do not require reheating. In other words, we cannot depend on the advantage of consumer cooking to eliminate remaining microbiological hazards.

Food risk categories are assigned as “0” – “VI” with “VI” as the highest risk. Foods that fall into risk factor “A”, such as infant formula or baby food, automatically becomes a risk category “VI”, while foods with none of the risk factors are categorized as “0” risk category. Foods with one of the risk factors other than “A” are risk category “I”. Those with two factors other than “A” are category “II” and so on for “III,” “IV,” and “V”.

Food risk categories can be assigned to ingredients, incoming raw materials, in-process foods, and finished products. These categories become useful indicators for priority identification in the next task, the specific hazard identification and analysis. This focus on consumer safety is fundamental to the HACCP system. Still, many HACCP experts agree that the program can be effectively extended to include other potential problem types as long as food safety hazards remain separate and distinct from those unrelated to food safety.

A flow diagram can help in documenting the production and distribution process and assist in identification of hazards at each step.

**2. Identify CCPs in food preparation**

Many points in food processing can be considered control points, but very few are CCPs, defined as any controllable point in a specific process where loss of control may result in an unacceptable risk. As previously noted, NACMCF defined CCPs around the need to protect the consumer. Many organizations and HACCP authorities have defined additional types of control points. Custom names and symbols have accompanied the development of these new types. The following are samples of the many possible types:

- **Critical Control Point:** The original as defined by NACMCF (1987). Any controllable point in the process where a loss of control may result in an unacceptable consumer health risk. A CCP is a point, step, or a 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.

- **CCP1 and CCP2:** Specified by the International Commission on Microbiological Specifications for Foods (ICMSF 1988). CCPs are divided into “major” (CCP1) and “minor” (CCP2). CCP1 requires complete elimination of a hazard to ensure food safety, whereas CCP2 requires a hazard reduction to ensure control. CCP2 is less critical to food safety and hence 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. More specifically, these identify hazards that may be common throughout a plant rather than those located specifically at 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 food industry are often controlled in the production process through filtering, metal detection, or visual inspection. This type of control point has been designated to differentiate it from the Microbiological CCPs that cannot typically be easily monitored during production.
• Manufacturing, Economic, Production, Quality, Regulatory CCPs: Might be defined as any controllable point at which failure to control may result in a product of unacceptable quality, portion control, product waste, productivity, yield, or a regulatory problem. These points are not usually food safety related.

Most HACCP programs focus on food safety only and, consequently, do not include regulatory and other CCPs.

3. Establish critical limits (specifications) for each CCP
Critical limits must be established and met for each CCP to ensure that the system effectively controls the 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 a validation process, regulatory standards, and codes or by other reliable sources. Examples of criteria used for CCPs include time, temperature, humidity, water activity, and pH level.

4. 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. The requirements for this monitoring should be carefully defined, the responsibility for observation or testing clearly assigned, and the test results accurately recorded for future verification. Monitoring can be at defined time intervals or continuous and may use visual observation, calibrated instruments, and recording charts to document the monitoring process. Monitoring helps to track the process and assists in detecting adverse trends that, if not corrected, can lead to a loss of control. Signatures and initials on CCP monitoring records protect the integrity of the entire process. A Critical Deviation (CD) is a deficiency noted through the monitoring of a CCP that could result in an unacceptable consumer health risk.

5. Establish corrective action protocol for each CCP
Establish a protocol for corrective action to be implemented when monitoring indicates deviation at a CCP has exceeded the critical tolerance limit. A Critical Deviation (CD) must be addressed promptly by a clearly defined and assigned plan of action. This may involve adjustment to the process upstream or the addition of corrective steps in the subsequent process. The plan must address disposition of any product that was produced during critical deviation in control. Sometimes a hold must be placed on this product and identified lots pending investigation and appropriate corrective action. Additional monitoring and sampling may be necessary to ensure implementation of corrective action. Specific action plans are needed for each CCP.

6. Establish procedures for effective recordkeeping and documentation of HACCP system
It seems inevitable that future regulatory inspections will shift from a direct physical inspection of plants and products to a review of the HACCP system and associated documentation. A study completed by the U.S. Department of Commerce reported that correcting problems without recordkeeping could lead to a recurrence of the same problems. This is probably the primary reason for the addition of this principle to the HACCP protocol. This aspect of HACCP is already a key component of the voluntary FDA/NOAA Fish and Fishery Products Program. Documentation should be very systematic and thorough. It should include a HACCP-based plan, any modifications or changes 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, additional quality assurance/control records, and consumer complaint records. Appropriate monitoring records should be documented with signature as necessary.

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

7. Establish procedures for an effective verification (audit) that the HACCP system is working as intended
These procedures are necessary to ensure that the HACCP-based system implemented complies with the HACCP plan as designed for that process. This verification may include documentation checks as well as testing, and the manufacturer or the regulatory agency may perform audits. It should be noted that there are many acceptable methods of completing both this and the recordkeeping components of the program.

The verification activities and procedures may include a review of CCPs and monitoring records, deviations, and corrective actions as well as periodic verification inspections. Additional focused verification can be undertaken to investigate and follow up specific foodborne disease and other incidents.

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

Hazard Analysis and HACCP: Hazard Analysis techniques can be as varied as the many types of hazards. HACCP does not mandate or suggest any particular methodology for hazard analysis. Zurich Services Corporation Risk Engineering
relies heavily on Zurich Hazard Analysis (ZHA) for this purpose. It is a gross hazard analysis method, which systematically and comprehensively identifies the hazards, their trigger mechanisms, and assesses their associated effects in terms of frequency and severity. This information is recorded to create a catalog of hazards. Each hazard can then be assessed qualitatively for its relative risk including comparative probability of occurrence and severity of effects with due consideration for downstream controls. For example, the potential detrimental effect of a specific hazard in milk production, such as the inadequate storage temperature and potential for temperature abuse of raw milk, may be somewhat lessened if the downstream process includes a pasteurization step. In contrast, the potential adverse effect of a hazard such as inadequate sanitation procedures and storage temperatures for unpasteurized milk may be increased when the milk is likely to be consumed without any cooking or other terminal heat process. For meat processing, addition of irradiation in the process will have similar effects.

ZHA then calls for the user to determine the desired tolerance level and to compare this level to the potential frequency and severity of the catalogued hazards. The result is called a risk profile. The next HACCP principle, “Identification of Critical Control Points,” becomes much clearer once the risk profile has been generated. This profile helps to prioritize the hazards and simplify the completion of the HACCP program.

SUMMARY
Implementation of an effective HACCP program provides a systematic approach to food safety. With dramatic increases in and variety of prepared foods, an effective national food safety program is an important element of public health protection. FDA is recommending the implementation of an HACCP program throughout the food industry, and dramatic improvements are expected in the level of food safety with a successful implementation of such a program.

Risk managers understand the need to identify exposures, to identify risk management techniques that may address these exposures, to select the best technique or solution, to implement the solution, and to monitor the effectiveness of the risk management effort. HACCP includes much of this basic risk management philosophy with an emphasis on the severe potential hazards inherent in food safety.

Food processors understand the importance of their reputations in the marketplace. These easily damaged reputations can only be effectively protected through a well-implemented “total quality” system. Even for processors who must comply with stringent ordinances and other regulations, HACCP can bring an additional level of effectiveness and protection to that “total quality” system.

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