CHAPTER 21

The HACCP System and Food Safety

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Among the desirable qualities that should be associated with foods is freedom from infectious organisms. Although it may not be possible to achieve a zero tolerance for all such organisms under good manufacturing practices (GMP), the production of foods with the lowest possible numbers is the desirable goal. With fewer processors producing more products that lead to foods being held longer and shipped farther before they reach consumers, new approaches are needed to ensure safe products. Classic approaches to microbiological quality control have relied heavily on microbiological determinations of both raw materials and end products, but the time required for results is too long for many products. The development and use of certain rapid methods have been of value, but these alone have not obviated the need for newer approaches to ensuring safe foods. The hazard analysis critical control point (HACCP) system is presented in this chapter as the method of choice for ensuring the safety of foods from farm to table. When deemed necessary, microbiological criteria may be established for some ingredients and foods, and these in connection with sampling plans are presented as components of the HACCP system.

HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM

The concept and early history of the HACCP system are presented in the previous edition of this text. The presentation that follows is not intended to be used alone to establish an HACCP program in either a food production plant or food service establishment. For these purposes, a more detailed HACCP reference should be consulted.[5,8,11,15,16,27] Also, additional references may be consulted for meat and poultry plants and they include references 1, 20, and 29; and for seafoods, references 9 and 17. More general information and background can be found in references 6, 21, 25, and 26.

The objective of this section is to provide a general overview of what HACCP is, and examples of how one might go about setting up an HACCP system.

HACCP is a system that should lead to the production of microbiologically safe foods by analyzing for the hazards of raw materials—those that may appear throughout processing and those that may occur from consumer abuse. It is a proactive, systematic approach to controlling foodborne hazards. Although some classic approaches to food safety rely heavily on end product testing, the HACCP system places emphasis on the quality of all ingredients and all process steps on the premise that safe products will result if these are properly controlled. The system is thus designed to control organisms at the point of production and preparation. The five leading factors that contributed to foodborne illness in the United States for the years 1961–1982 are noted in Table 21–1, and it may be noted that events associated with the handling and prepa-

Table 21–1 Leading Factors Contributing to Outbreaks of Foodborne Illness in the United States

Factors	*1961–1982*
Improper cooling	44%
Lapse of 12 or more hours between preparation/eating	23
Contaminated by handlers	18
Raw ingredient added without subsequent heating/cooking	16
Inadequate cooking/canning/heating	16

Note: $N = 1{,}918$.

Source: From Bryan.[2,3]

ration of foods were significant.[3] Mishandling of foods in food service establishments in Canada in 1984 was involved in about 39% of foodborne incidents.[28] Proper implementation of HACCP in food service establishments and the home will lead to a decrease in foodborne illness.

A subcommittee of the U.S. National Research Council, National Academy of Sciences, made the following recommendation in 1985[18]: Because the application of the HACCP system provides for the most specific and critical approach to the control of microbiological hazards presented by foods, use of this system should be required of industry. Accordingly, this subcommittee believes that government agencies responsible for control of microbiological hazards in foods should promulgate appropriate regulations that would require industry to utilize the HACCP system in their food protection programs. Before an HACCP program is developed, there are some prerequisite programs that should be in place.

Prerequisite Programs

Prerequisite programs include a wide range of activities and events that may have an impact on an HACCP system for a specific food product even though they are not parts of the HACCP system per se. Some examples of prerequisite programs are noted in reference 16, and they are explained in more detail in reference 24.

Briefly stated, prerequisite programs include concerns and aspects of the entire food environment *before* the HACCP system is initiated. They include the suitability of facilities, control of suppliers, safety and maintenance of production equipment, cleaning and sanitation of equipment and facilities, personal hygiene of employees, control of chemicals, pest control, and the like. These prerequisites include good manufacturing practices,[14] and they should be brought up to acceptable standards before the HACCP system is initiated.

Definitions

The following terms and concepts are valuable in the development and execution of an HACCP system and are taken from International Commission on Microbiological Specifications for Foods (ICMSF)[10] and/or National Advisory Committee on the Microbiological Criteria for Foods (NACMCF)[16]:

CP

Control point: Any point in a specific food system where loss of control does not lead to an unacceptable health risk

Critical control point (CCP): Any point or procedure in a food system where control can be exercised and a hazard can be minimized or prevented

Critical limit: One or more prescribed tolerances that must be met to ensure that a CCP effectively controls a microbiological health hazard

CCP decision tree: A sequence of questions to assist in determining whether a control point is a CCP

Corrective action: Procedures followed when a deviation occurs

Deviation: Failure to meet a required critical limit for a CCP

HACCP plan: The written document that delineates the formal procedures to be followed in accordance with these general principles

Hazard: Any biological, chemical, or physical property that may cause an unacceptable consumer health risk (unacceptable contamination, toxin levels, growth, and/or survival of undesirable organisms)

Monitoring: A planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety

Risk category: One of six categories prioritizing risk based on food hazards

Validation: That element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the hazards

Verification: Methods, procedures, and tests used to determine whether the HACCP system is in compliance with the HACCP plan

HACCP Principles

Although interpreted variously, the ICMSF and NACMCF view HACCP as a natural and systematic approach to food safety and as consisting of the following seven principles:

1. Assess the hazards and risks associated with the growing, harvesting, raw materials, ingredients, processing, manufacturing, distribution, marketing, preparation, and consumption of the food in question.
2. Determine the CCP(s) required to control the identified hazards.
3. Establish the critical limits that must be met at each identified CCP.
4. Establish procedures to monitor the CCP(s).
5. Establish corrective actions to be taken when there is a deviation identified by monitoring a given CCP.
6. Establish procedures for verification that the HACCP system is working correctly.
7. Establish effective recordkeeping systems that document the HACCP plan.

Each of these principles is discussed in more detail below.

Principle 1: Assess Hazards and Risks

Hazards and risks may be assessed for individual food ingredients from the flow diagram or by ranking the finished food product by assigning to it a hazard rating from A through F. A plus sign (+) is assigned when a hazard exists. Six hazard categories have been defined, representing an expansion of the three proposed by the National Research Council (NRC)[19] for salmonellae control. However, this system of ranking and hazard category assignment is not popular in the late 1990s and it may be ignored (see reference 16 for alternative). It is presented here for historical purposes:

A. This is a special class of foods that consist of nonsterile products designated and intended for consumption by individuals at risk, including infants, the aged, infirmed, and immunoincompetents.
B. The product contains "sensitive" ingredients relative to microbiological hazards (e.g., milk, fresh meats).
C. There is no controlled processing step (such as heat pasteurization) that effectively destroys harmful microorganisms.
D. The product is subject to recontamination after processing but before packaging (e.g., pasteurized in bulk and then packaged separately).

E. Substantial potential for abusive handling exists in distribution and/or by consumers that could render the product harmful when consumed (e.g., products to be refrigerated are held above refrigerator temperatures).
F. There is no terminal heat process after packaging or when cooked in the home.

Next, the formulated product should be assigned to one of six hazard categories, expanded from four suggested by the NRC[18]:

VI. A special category that applies to nonsterile products designated and intended for individuals in hazard category A
V. Food products subject to all five general hazard characteristics (B, C, D, E, and F)
IV. Food products subject to any four general hazard characteristics
III. Products subject to any three of the general hazard characteristics
II. Products subject to any two general hazard characteristics
I. Products subject to any one of the general hazard characteristics
0. Products subject to no hazards

Principle 2: Determine CCP(s)

The ICMSF[11] recognized two types of CCPs: CCP1, to ensure control of a hazard, and CCP2, to minimize a hazard. Typical of CCPs are the following:

- Heat process steps where time–temperature relations must be maintained to destroy given pathogens
- Freezing and time to freezing before pathogens can multiply
- The maintenance of pH of a food product at a level that prevents growth of pathogens
- Employee hygiene

Principle 3: Establish Critical Limits

A critical limit is one or more prescribed tolerances that must be met to ensure that a CCP effectively controls a microbiological hazard. This could mean keeping refrigeration temperatures within a certain specific and narrow range or making sure that a certain minimum destructive temperature is achieved and maintained long enough to effect pathogen destruction. Examples of the latter include adherence to the temperatures noted in Table 21–2 for the control of the respective organisms.

Principle 4: Establish Procedures To Monitor CCPs

The monitoring of a CCP involves the scheduled testing or observation of a CCP and its limits; monitoring results must be documented. If, for example, the temperature for a certain process step should not exceed 40°C, a chart recorder may be installed. Microbial analyses are not used to monitor since too much time is required to obtain results. Physical and chemical parameters such as time, pH, temperature, and water activity (a_w) can be quickly determined and results obtained immediately.

Principle 5: Establish Corrective Actions

Establish corrective actions to be taken when deviations occur in CCP monitoring. The actions taken must eliminate the hazard that was created by deviation from the plan. If a product is involved that may be unsafe as a result of the deviation, it must be removed. Although the actions taken may vary widely, in general they must be shown to bring the CCP under control.

Principle 6: Establish Procedures for Verification

Establish procedures for verification that the HACCP system is working correctly. Verification consists of methods, procedures, and tests used to determine that the system is in compli-

ance with the plan. Verification confirms that all hazards were identified in the HACCP plan when it was developed, and verification measures may include compliance with a set of established microbiological criteria when established. Verification activities include the establishment of verification inspection schedules, including review of the HACCP plan, CCP records, deviations, random sample collection and analysis, and written records of verification inspections. Verification inspection reports should include the designation of persons responsible for administering and updating the HACCP plan, direct monitoring of CCP data while in operation, certification that monitoring equipment is properly calibrated, and deviation procedures employed.

Principle 7: Establish Effective Recordkeeping Systems

Establish effective recordkeeping systems to document the HACCP plan. The HACCP plan must be on file at the food establishment and must be made available to official inspectors upon request. Forms for recording and documenting the system may be developed, or standard forms may be used with necessary modifications. Typically, these may be forms that are completed on a regular basis and filed away. The forms should provide documentation for all ingredients, processing steps, packaging, storage, and distribution.

Some Limitations of HACCP

Although it is the best system yet devised for controlling microbial hazards in foods from the

- HACCP requires the education of nonprofessional food handlers, especially in the food service industry and in homes; whether this will be achieved remains to be seen. The failure of these individuals to get a proper understanding of HACCP could lead to its failure.
- To be effective, this concept must be accepted not only by food processors but also by food inspectors and the public. Its ineffective application at any level can be detrimental to its overall success for a product.
- It is anticipated that experts will differ as to whether a given step is a CCP and how best to monitor such steps. This has the potential of eroding the confidence of others in HACCP.
- The adoption of HACCP by industry has the potential of giving false assurance to consumers that a product is safe, and, therefore, there is no need to exercise the usual precautions between the purchase and consumption of a product. Consumers need to be informed that most outbreaks of foodborne illness are caused by errors in food handling in homes and food service establishments and that no matter what steps a processor takes, HACCP principles must be observed after foods are purchased for consumption.

Flow Diagrams

The development of an HACCP plan for a food establishment begins with the construction of a flow diagram for the entire process. The diagram should begin with the acquisition of raw materials and include all steps through packaging and subsequent distribution.