

Management of Microbial Control in HACCP Systems

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An effective management program must be established for the control of pathogens in food processing and production, or the food operation is vulnerable to significant liability. Microbial control processes are only as good as management control of the stability of the processes. When the safety parameters of the process have been established through research and development, the key to evaluating the safety of a process is to measure its stability.

I. HACCP AS A BASIS FOR SYSTEM CONTROL

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (1) describes the Hazard Analysis Critical Control Point (HACCP) program and how it should be documented. The two important components of the NACMCF-HACCP program are prerequisite program controls and food process controls. Prerequisite program controls are listed in Table 1.

For food process control, the NACMCF program lists seven principles of HACCP (see Table 2). These principles are actually a seven-step sequence for

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Table 1 Prerequisite Controls for a HACCP Program

Listing of HACCP management team and responsibilities
 Description of the food and its distribution
 Description of the intended use and consumers of the food
 Facility construction and maintenance
 Linear product flow
 Supplier controls: GMPs, supplier guarantees, HACCP
 Specifications written for ingredients, products, and packaging
 Production equipment construction, installation, preventive maintenance, calibration
 Cleaning and sanitizing procedures; master sanitation schedule
 Personal hygiene; all employees and visitors
 Training documentation covering personal hygiene, GMPs, cleaning safety, HACCP, food and ingredient handling
 Chemical control and segregation
 Receiving, storage, shipping procedures, temperature, humidity
 Traceability and recall; lot coding
 Pest control
 Quality Assurance (QA) procedures
 Process and recipes
 Product formulation
 Labeling
 Glass control

Source: Ref. 1.

Table 2 NACMCF Seven Principles of HACCP for Process Control

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1. Conduct the hazard analysis. Identify steps in the process with hazards.
 2. Apply HACCP decision tree to each step with hazards. Determine which steps are critical control points.
 3. Establish critical limits for preventive measures associated with each CCP (critical control point).
 4. Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.
 5. Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.
 6. Establish procedures for verification that the HACCP system is working correctly.
 7. Establish effective record keeping procedures that document the HACCP system.
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Source: Ref. 1.

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developing a validated, safe process. These principles are used only after the system and all prerequisite programs are specified by a process authority and a HACCP team (a group consisting of management and line employees).

II. THE INTEGRATION OF NACMCF-HACCP WITH TOTAL QUALITY MANAGEMENT FOR FULLY FUNCTIONAL MICROBIOLOGICAL INACTIVATION ASSURANCE

While the NACMCF-HACCP (1) document provides a listing of some necessary elements of a HACCP program, it does not provide a method or approach for documentation of a complete HACCP program. A number of management components are not specified. There is no emphasis on continuous improvement of the program. It is implied that monitoring and record keeping are just for government review. However, it is even more important that operators use the monitoring data to continually improve the processes and reduce variability.

Table 3 lists 12 sections of a fully functional HACCP-TQM continuous improvement program as developed by the Hospitality Institute of Technology and Management (2) for foodservice operations. This program incorporates NACMCF-HACCP components together with management elements necessary for system control.

III. ESTABLISHING CRITICAL LIMITS FOR A PROCESS: HACCP DOCUMENTATION OF THE RECIPE/FOOD PROCESS

In order to simplify the documentation of the NACMCF-HACCP food process chart, it is convenient to combine a flow chart and HACCP analysis into one form, as shown in Table 4. When all prerequisite programs are functioning, the product can be produced in accordance with this HACCP procedure.

The Process Step column lists the steps for the production line preparation/processing of the product sequentially. Typically, this is written just as a computer flow chart is written. The first steps are the "get-ready" steps (e.g., turn on equipment and make sure that the process line is functioning correctly). Then, each process step is listed, beginning with preparation. The inactivation process follows, and finally, cooling (if necessary), packaging, labeling, and final storage for shipment of the food.

Table 3 HACCP-TQM Retail Food Operations Manual: Table of Contents

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- I. Food Safety Policy
 - II. Organization for HACCP-based TQM
 - A. Organization chart
 - B. HACCP-TQM team
 - III. System Description
 - IV. Good Manufacturing Practices
 - A. Management
 - 1. Senior management commitment and involvement for food safety
 - a. Policies and procedures
 - b. PIC (Person in Charge)
 - 2. Hazard analysis and control
 - 3. Manager communication and employee training
 - 4. Handling emergencies
 - 5. Facility improvement
 - B. Personnel
 - 1. Employee responsibility
 - 2. Disease control
 - 3. Cleanliness
 - C. Environment
 - 1. Area around facility or grounds
 - 2. Water
 - 3. Sewage
 - 4. Pest control and materials used
 - 5. Poisonous (toxic) materials
 - D. Facilities
 - 1. Facility design
 - 2. Floors, walls, and ceilings
 - 3. Lighting
 - 4. Plumbing
 - E. Equipment
 - 1. Equipment and utensil construction
 - 2. Equipment operation
 - 3. Food contact surface equipment
 - 4. Non-food contact surface equipment
 - F. Supplies and materials
 - 1. Purchasing
 - 2. Supplier certification
 - 3. Ingredient specification
 - G. Food production and service
 - 1. General production policy
 - 2. Home-prepared food
 - 3. Milk
 - 4. Receiving
 - a. Inspection of incoming products
 - b. Substandard products
 - c. Food containers
 - d. Container disposal
 - e. Labeling
 - f. Use-by date
 - g. Food storage areas
 - 5. Pre-preparation
 - a. Ingredient inspection and control
 - b. Food thawing
 - c. Chemical additives
 - d. Raw food handling

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Table 3 Continued

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- 6. Preparation
 - a. Potentially hazardous food
 - b. Hard foreign objects
 - c. Food pasteurization
 - 7. Holding, serving, and transporting
 - a. Food holding temperatures
 - b. Conveyors
 - c. Serving, packaging, and transporting
 - 8. Storing prepared food
 - a. Food cooling time
 - b. Storage to prevent cross-contamination
 - c. Storage time
 - d. Storage containers
 - e. Leftovers
 - H. Consumer
 - 1. Consumer information
 - 2. Returned food
 - 3. Food sabotage
 - V. Supplier HACCP
 - A. Supplier HACCP Qualification Standards
 - B. Supplier HACCP/QA Qualification List by Ingredients Purchased
 - C. Ingredient Specifications
 - VI. Recipe HACCP
 - A. Quality-assured Product/Recipe Procedures
 - B. Product Specifications
 - VII. Cleaning and Sanitizing Schedule and Instructions
 - A. Cleaning and Sanitizing Schedule
 - B. Sanitation Procedures and Standards
 - VIII. Maintenance Schedule and Instructions
 - A. Maintenance Schedule
 - B. Maintenance Procedures and Standards
 - IX. Pest Control Schedule and Instructions
 - A. Pest Control Schedule
 - X. HACCP-TQM Employee Training Program and Record
 - A. Employee Training Record
 - 1. New Employee Training Record
 - 2. Continuing Education Training Record
 - XI. Self-inspection, Continuous Quality Improvement
 - A. New Product/Process Development
 - B. Product Process Monitoring/Sampling Plan
 - C. Daily Self-inspection
 - D. Weekly, Yearly Self-inspection
 - XII. Food Safety Program Verification and Certification
 - A. Performance Verification and Capability Certification
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Source: Ref. 2

Table 4 HACCP Analysis and Flow Chart

Process step, control measures, and linear process flow chart	Hazard and critical limit	Monitoring procedure frequency, record, and person responsible	Corrective action, record, and person responsible	Verification procedure, record, and person responsible
1. Get ready. Start the production line. Verify that process controls are working. ↓	Not a CCP			
2. Get raw ingredients. Unpackage, cut, and make ready to process. ↓	Not a CCP			
3. Process. Using an inactivation method, reduce pathogens to a safe level. ↓	CCP 1	Cook takes 5 random product temperatures.	If product is not greater than _____, continue to process. Record on _____.	QC (Quality Control) check and record on _____.
4. Cool if necessary. Do not let the product come in contact with contaminated surfaces. ↓	CCP 2			
5. Package. Avoid cross-contamination. Label with lot number and consumer handling. ↓	CCP 3			
6. Store.	Not a CCP			

Source: Adapted from Ref. 1.

IV. DECIDING ON THE PROCESS PERFORMANCE STANDARDS

Each country has its own microbiological inactivation process (lethality) performance standards. For example, in the United States the commercial sterilization process standard for low-acid canned food is processing at temperatures for times

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that assure a 10^{12} reduction in *Clostridium botulinum* (proteolytic types A and B) spores.

A key starting point for the design of pasteurized food processes is to use U.S. Department of Agriculture (USDA) requirements for the reduction of pathogens in food. Decimal reduction values (D-values) are used to indicate the time required to destroy populations of microorganisms. One D-value is the time necessary to destroy 90% of a population of cells (or spores) at a given temperature. The Code of Federal Regulations, Title 9 and Title 21 (3,4), provides current requirements for pathogen reduction in food processes. The USDA requires that large cuts of red meat (e.g., beef roasts) receive a 6.5D *Salmonella* reduction. Poultry requires a 7.0D *Salmonella* reduction. For fruits, the U.S. Food and Drug Administration (FDA) has tentatively established a requirement of 5D *Salmonella* reduction. There is no established thermal reduction for fish, but the FDA 1999 Retail Food Code (5) requirement for a heat treatment of 63°C (145°F) for 15 seconds would only be sufficient for inactivation of parasitic worms that may be present in the center of fish.

It is essential to understand that these government process recommendations are "safe harbors." They assume that the processor is starting with normally contaminated ingredients. If a processor uses HACCP, these critical limits are not required if the processor can show that the production line is starting with a product that has a much lower level of contamination than the government-assumed contamination level used to establish government process performance standards.

V. DEVELOPING THE MANAGEMENT PROGRAM

When management decides to use a new technology for processing food and understands government critical limits for surviving microorganisms (especially *Salmonella* in the food), management can implement a hazard control program to assure that, "from farm to fork," the food will be safe when consumed. The input is the specification of ingredient contamination level from the farm and slaughtering operations. For example, the deep muscle tissue of meat and poultry from healthy animals is basically sterile; however, contamination can occur during and after slaughter. The output is the product that the consumer receives, which may either require some preparation or be ready-to-eat food. Thus, the operator's process must produce a product that meets each product's specifications with zero defects.

The more an operator can work with a supplier to reduce the numbers of bacteria on incoming supplies by using microbial specifications, the less processing will be required to achieve the government specification for pasteurized food of no detectable salmonellae, *Escherichia coli* O157:H7, or *Listeria monocy-*

togenes. Current government recommended process reductions are based on the assumption that there are approximately 1000 *Salmonella* per gram of raw poultry and meat. Within the limits of statistical variation, these pathogenic bacteria must be reduced to approximately 1 *Salmonella* spp. per 250 of food. Processing to achieve this microbial standard is actually more than adequate to assure food safety.

VI. IMPLEMENTATION

After the processes are planned and validated, management designs and checks the processing facility, selects the equipment, and provides for cleaning, maintenance, and employee training (all prerequisite programs), so that the processes will reliably deliver food that is safe when consumed. Six steps used in the management cycle of a process operation are listed in Table 5.

VII. WHAT SIGNIFIES A SAFE PROCESS?

The best way to assure a safe process is to verify the capability of the process. When the critical process is designed, process variables with target values are determined that, when met, assure adequate pathogen reduction. These process variables may include achieving a designated center temperature for a specified period of time, use of ionizing radiation, or heating the product in steam under pressure for a specified period of time. As the process runs, the critical process

Table 5 Steps in the Management Cycle of Process Operation

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1. Management commitment of time and resources so that an effective program is developed
 2. Hazard analysis of process
 3. Documentation of procedures and standards and validation that the operating plan is effective
 4. Training of employees and calibration of the processes so that they are as stable as possible for the production of the product
 5. Operation of the process that includes monitoring and using corrective action to keep the process in control
 6. Analyzing the data in order to revise operating procedures and the operating manual to achieve better stability; repeating the cycle the following day (i.e., begin with #1)
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control target values are monitored and charted, and process capability (C_p) is determined (6). The process capability can be calculated with the following formula.

$$\text{Process capability } (C_p) = \frac{\text{upper control} - \text{lower control limit}}{6 \text{ sigma deviation in the process}}$$

This formula is widely used in manufacturing facilities to judge the capability of a process to produce a standard-performing product. When the process capability is 1.0, it can be expected that in a two-tailed statistical analysis, there will be 28 excursions in 10,000 beyond the upper or lower control limit. If the C_p is >1.3 , the excursion will be only 96 times in 1,000,000. Therefore, the objective of management is to determine the common and special causes of process fluctuation and to minimize those causes with continuous improvement. Thus, process stability and capability are improved. The improvement in process stability becomes a standard goal of a company's quality control department.

A. Risk Management and HACCP

To establish any national and international standards for microbiological, chemical, or physical hazards in food, it is essential to understand that there will always be a risk factor associated with some contamination of ingredients. Food grown in the ground may be contaminated with pathogens such as *Bacillus cereus*, *C. botulinum*, and *L. monocytogenes*, as well as molds, parasites, and viruses. Rodents, insects, and wild birds are known to carry pathogenic microorganisms to farm animals, poultry, and fish. Hence, meat and poultry products produced in a typical farm environment may be contaminated with *Salmonella* spp., *Campylobacter jejuni*, *E. coli*, and other pathogens. Fish and shellfish are likely to be contaminated with *Vibrio* spp. Using methods of farming and harvesting that reduce or minimize contamination can reduce microbial levels in raw food items.

One method of controlling pathogens in meat and poultry items in the future may be the development of vaccines to be used for meat animals and poultry so that they are not colonized with pathogens. Another method of control is to raise animals and poultry in pathogen-reduced environments. One way to do this is to use potable water (e.g., water treated with chlorine) to raise animals and to wash field soil off of vegetables. However, raising animals without some degree of environmental contamination is very costly. This means that the processor must reduce pathogenic microorganisms in foods to low-risk levels. This can be accomplished by pasteurization, cooking food, addition of acid, fermentation, or by washing food items. When these controls are effectively applied in a stable process, the risk of consumers becoming ill is dependent on the functioning im-

immune system of each person and the extent to which consumers follow safe food-handling procedures.

Risk, as related to food consumption, is the likelihood that individuals or a population will incur an increased incidence of adverse effects such as foodborne illness, disease, or death as a result of consuming a food (7). The risk can be further defined by defining the specific cause of illness or disease (e.g., the risk of salmonellosis due to consumption of underheated shell eggs or the risk of foodborne illness due to *E. coli* O157:H7 in ground beef).

In order to estimate how much illness or injury can be expected from exposure(s) to a given risk agent, and to assist in judging whether these consequences are great enough to require increased management or regulation, a risk assessment or analysis should be conducted as a part of a HACCP program. Risk assessment can be used as a tool to determine sources of the most serious hazards and apply action to reduce the presence of these hazards. A risk assessment can also be used to ensure that operational risk management decisions are rational and are based on the best available science (8).

After a risk assessment is completed, risk can be expressed in quantitative probability terms or in qualitative terms. An example of the use of quantitative probability terms is the number of illnesses over a lifetime in a population of 1 million exposed people. A risk of 1 illness in 10,000 is described as " 10^{-4} risk," while 1 illness in 1 million is described as a " 10^{-6} risk." Historically, risks of less than 10^{-6} in magnitude have not been the object of concern. Risk can also be expressed in qualitative terms of "low," "medium," and "high." These terms are used when quantification is either not feasible or unnecessary.

Table 6 shows an organizational chart for integrated risk management. Integrated risk management can be divided into risk analysis, management risk control, and risk communication.

B. Components of Risk Analysis

When the process is specified, the following components of risk analysis can be used:

1. Hazard analysis is based on quantitative epidemiology, expert knowledge, data, or research evidence that shows that an agent associated with the consumption of a particular food may cause human illness or injury.
2. Risk assessment evaluates the chance that a hazard will be in the food. This type of assessment includes consumers, what they eat, and in what type of environments. For example, "Is the product take-out food? How do consumers handle the food? Is there consumer abuse? What is the amount, frequency, and source of the hazard in food?" It is also

important to assess the effectiveness of the controls of the hazard from food production to consumption.

A part of the assessment is the "dose response," or the probability of consumers becoming ill at various dose intakes. For example, the level that normally healthy people can consume and still remain healthy and possibly even develop some immunity must be known, as well as the levels known to cause probable illness or injury.

3. Risk characterization is the severity and cost of a hazard. For example, the development of listeriosis in pregnant women and their fetuses is a severe and costly hazard, while the incidence illness due to consumption of *C. perfringens* in improperly cooled food will only cause an illness of short duration and consequence and virtually no cost.
4. Hazard control assessment is the fourth component of risk analysis. This type of assessment is generated by the HACCP team through evaluation of the effectiveness of the current process, consumer controls, and estimates of the probability of failure. The HACCP team also estimates the probable cost to the business in the event of possible incidents related to an expected failure of control at this step.

C. Management Risk Control

If the risk of financial loss and human suffering is unacceptable after the risk has been assessed, management can take measures to control or reduce the risk to an acceptable level. This can be accomplished through application of Good Manufacturing Practices (GMPs) and the use of a HACCP-based Total Quality Management (TQM) program in the improvement of prerequisite programs and the production of food products.

D. Risk Communication

Risk is never "zero." For example, microbial spores in food survive food preparation processes in retail operations. Consumers must be aware of this risk in foods that they take out of the food operation to consume at a later time. Also, many people desire undercooked/raw food such as beef, eggs, and fish. While the operators can buy these kinds of items from highly reliable suppliers with HACCP programs, there is still risk. Producers and operators of retail food establishments should communicate the amount of residual risk associated with food items to consumers through labels on containers or other various media presentations. Communicating the risk and consumer control responsibilities after the food leaves food operations control does not relieve management of all liability, but it does help in a "due diligence" defense.

Table 6 Integrated Risk Management

1. Operations process step description	2. Risk analysis			
	A. Hazard analysis	B. Risk assessment	C. Hazard control assessment	3. Management risk control
Employee procedures and controls	Hazard identification	Exposure assessment	Analysis of effectiveness of current unit controls	If the risk is acceptable, certify the step
Get ready	Hazard quantification	Dose-response assessment	Analysis of consumer control	If the risk is not acceptable, improve control
Do _____	Critical limits	Risk characterization (dollars)	Failure mode effect analysis	
Until _____			Expected cost per year from failure of this step	
Check _____				
If _____				
Then _____				
Else _____				
Record if _____				
Clean up				
Put away				
				4. Risk communication
				Consumer is informed how to control remaining risk

Source: Ref. 8.

products, the risk of liability can be controlled, and new inactivation processes will continually evolve.

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