

Advanced HACCP Course

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Why HACCP?

The Pathogen Reduction: Hazard Analysis and Critical Control Points (HACCP) Systems, Final Rule-July 25, 1996 requires that each meat and poultry establishment develop and implement a system for preventive controls designed to improve the safety of their products, which is known as the "Mega Reg". The HACCP program is a preventive approach to safe food production. It is based on the two important concepts of safe food production, which are prevention and documentation. The major thrusts of HACCP are to determine how and where safety hazards may exist and their prevention. The documentation concept is essential to verify that potential hazards have been controlled. HACCP is required in the meat industry and is the basis for federal meat inspection in the United States.

HACCP is a proactive, prevention-oriented program based on sound science. It focuses on the prevention or control of food safety hazards that are classified as biological, chemical, and physical. This program focuses on safety (not quality) and should be considered separate from a supplement to quality assurance. The primary objective of HACCP is to ensure that effective sanitation and hygiene and other operational considerations be conducted to produce safe products and to provide proof that safety practices have been followed.

The HACCP concept was developed in the 1950s by the National Aeronautics and Space Administration (NASA) and Natick Laboratories for use in aerospace manufacturing. This rational approach to process control for food products was developed jointly by the Pillsbury Co., NASA, and the U.S. Army Natick Laboratories in 1971 as an attempt to apply a zero-defects program to the food processing industry. HACCP was incorporated to guarantee that food used in the U.S. space program would be 100 percent free of microbial pathogens. Because it is designed to prevent, rather than detect food hazards, HACCP has been identified by the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) as a tool to prevent or control food safety hazards during meat and poultry production. This concept has been embraced and

recommended for use by various scientific groups such as the National Academy of Sciences.

The HACCP concept has become a valuable program for process control of microbial hazards. This approach is a harbinger of the trend toward more sophistication in meat sanitation and inspection. It has been legitimized by governmental regulators and adopted by other progressive food companies.

The HACCP program is divided into two parts: (1) hazard analysis and (2) determination of critical control points (CCP). Hazard analysis requires an extensive knowledge of food microbiology, including which microorganisms may be present and factors that affect their proliferation.

The HACCP process describes a product and its intended use and identifies potentially hazardous items subject to microbial contamination and proliferation during processing or preparation. Then, the entire process is observed. Hazard analysis is a procedure for conducting risk analysis for products and ingredients by the development of a flow diagram to reflect the manufacturing and distribution sequence and microbial contamination, survival, and proliferation capable of causing foodborne illness. Critical Control Points (CCPs) are identified from a flow diagram, preferably with the use of a Decision Tree. Monitoring steps are established to evaluate effectiveness.

The HACCP concept provides a more rational approach to the control of microbial hazards than does traditional inspection. HACCP should be incorporated as a quality assurance function and as a systematic approach to hazard identification, risk assessment, and hazard control in food processing and/or foodservice facilities and distribution channels to ensure a hygienic operation.

Although HACCP was implemented by the industry, this program has been monitored by regulatory agencies. The Food and Drug Administration has adopted the HACCP philosophy because this "systems approach" permits it to utilize its resources more efficiently. This program provides management with tools to protect the consumer's health.

HACCP Development

The essential steps in the development of HACCP plans are: (Steps 6 through 12 are known as the 7 HACCP principles.)

1. HACCP team assembly
2. Description of food and its distribution
3. Ingredients list development

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Proceedings of the 54th Reciprocal Meat Conference (2001)

5. Flow diagram verification
6. Conduct a hazard analysis
 - a. Identify steps and in the process where hazards of potential significance may occur
 - b. List all identified hazards associated with each step
 - c. List preventive measures to control hazards
7. Identification and documentation of the CCPs in the process
8. Establishment of critical limits for preventive measures associated with each identified CCP
9. Establishment of CCP monitoring requirements, including monitoring frequency and those responsible for the specific monitoring activities
10. Establishment of corrective action to be taken when monitoring reveals that a deviation from an established critical limits exists
11. Establishment of procedures for verification that the HACCP system is working correctly
12. Establishment of effective record-keeping procedures that document the HACCP system and update the plan when a change of products and manufacturing conditions occur or if evidence of new hazards exists.

HACCP Program Implementation

CGMPs—the building blocks for HACCP

The Current Good Manufacturing Practices (CGMPs) regulations, as revised in 1986, were promulgated by the FDA to provide for complying with provisions of the Federal Food, Drug, and Cosmetic Act, which mandates that all human foods be free from adulteration. All HACCP plans must be developed based on GMP principles. Good Manufacturing Practices should be selected and adopted before HACCP is implemented. Without the application of CGMP principles, an effective HACCP program cannot be conducted. Furthermore, CGMPs must be applied to the development of sanitation standard operating procedures (SSOPs). Compliance with specific CGMPs should be included as part of HACCP.

Good Manufacturing Practices and SSOPs are interrelated and an important part of process control. CGMPs are the minimum sanitary and processing requirements necessary to ensure the production of wholesome meat. The areas that should be addressed through CGMPs are personal hygiene and other practices, buildings and facilities, equipment and utensils, and production and process controls. CGMPs should be broad in nature.

SSOPs—the cornerstones of HACCP

Although SSOPs are interrelated with CGMPs, they detail the specific sequence of events necessary to perform a task to ensure sanitary conditions. Standard Operating Procedures (SOPs) are either SSOPs or manufacturing SOPs. CGMPs should guide the development of SSOPs. SSOPs contain a description of the procedures that an establishment will follow to address the elements of pre-operational and operational sanitation relating to the prevention of direct product contamination.

Federally and state-inspected meat and poultry plants are required to develop, maintain, and adhere to written SSOPs. This requirement was established because the USDA-FSIS concluded that SSOPs were necessary in the definition of each establishment's responsibility to consistently follow effective sanitation procedures and to minimize the risk of direct product contamination or adulteration.

SSOPs cover daily pre-operational and operational sanitation procedures that establishments implement to prevent direct product contamination or adulteration. Establishments must identify the officials to monitor daily sanitation activities, evaluate whether the SSOPs are effective, and take appropriate corrective action when needed. Also, daily records that reflect completion of the procedures in the SSOPs are required. Deviations and corrective actions taken must be documented and maintained for a minimum of six months and must be available for verification and monitoring. Corrective actions: 1) include procedures to ensure appropriate disposition of contaminated products, 2) restore sanitary conditions, and 3) prevent the recurrence of direct contamination or product adulteration, including the appropriate re-evaluation and modification of the SSOPs and the procedures specified therein.

Written SSOPs contain a description of all cleaning procedures necessary to prevent direct contamination or adulteration of products. SSOPs must be signed on initiation or any modification. SSOPs must be evaluated and modified, as necessary, to reflect changes in the establishment facilities, personnel, or operations to ensure that they remain effective in the prevention of direct product contamination and adulteration.

Sanitation SOPs are a prelude to HACCP. They transcend specific processes and can serve as a preventive approach to direct product contamination and/or adulteration.

The HACCP plan should be formulated for each specific process or product. The plan should include the objective of the analysis, whether it is safety or spoilage. Documentation should include the objectives. The HACCP Report forms a record of the plan and should be presented in a way that is readily available to anyone who needs to use the report. It is an important resource when any changes are proposed for the process.

Previous HACCP Developments

The following examples relate other HACCP courses that have been developed and presented during the past:

- AMSA—3-day Development and Implementation Short Course
- FSIS—3-day Short Courses
- FSIS—3-day Implementation Conferences
- State Inspection—2 or more Short Courses
- Consulting Firm Short Courses
- International HACCP Alliance Accredited Courses presented by:
 - Trade Associations
 - University Scientists
 - Consultants

Course Objectives

This advanced course is a follow-up to the original HACCP course that was developed in 1995 by the American Meat Science Association (AMSA) and is being developed by the AMSA Continuing Education Committee. The content of this course will emphasize verification and validation. Verification is defined as the use of methods, procedures, or tests in addition to those used in monitoring, to determine whether the HACCP plan is operating as intended. Validation is considered to be the scientific and technical process for determining that critical control points and associated critical limits are adequate and sufficient to control likely hazards.

This short course is sanctioned and will be accredited by the International HACCP Alliance. Advanced HACCP courses

have been, will be, or are currently being developed by other organizations such as consulting firms, educational institutions, and professional and trade organizations (i.e. AMSA).

Course Development Process

The AMSA Continuing Education Committee decided to develop the AMSA Advanced HACCP Short Course at the committee meeting during the 2000 RMC. The committee, which consists of: Bill Childers, Catherine Cutter, Kerri Harris, Benjy Mikel, Michelle Schwenk, and Norman Marriott, worked in concert to develop a course outline. After the outline was created, the committee members contacted scientists that were willing to develop the topics that were selected. The proposed course outline is:

Proposed Advanced HACCP Course

	Time	Topic	Topic Developer
Day 1	8:00-8:15 a.m.	Introduction of Course Objectives and Participants	N. G. Marriott
	8:15-9:00 a.m.	Overview of HACCP Prerequisite Programs, Five Preliminary Steps, and Seven Principles	N. G. Marriott
	9:00-9:45 a.m.	Verification of HACCP Prerequisite Programs	Melissa Neuman
	9:45-10:00 a.m.	Break	
	10:00-10:45 a.m.	HACCP Prerequisite Program Validation	J.N. Sofos
	10:45-11:30 a.m.	Is the process under control?	A. E. Reynolds
	11:30-12:45 p.m.	Lunch	
	12:45-1:15 p.m.	Components of CCP Verification	E. A. E. Boyle
	1:15-1:45 p.m.	How to Conduct CCP Verification Activities	M. A. Tolbert
	1:45-2:15 p.m.	CCP Verification Records	M. A. Tolbert
	2:15-3:00 p.m.	The Role of Microbial Testing in CCP Verification	J. N. Sofos
	3:00-3:15 p.m.	Break	
	3:15-3:45 p.m.	The Relationship of Recalls to Verification and Validation	A. E. Reynolds
	3:45-5:15 p.m.	Validation/Verification Group Exercise	W. B. Mikel
5:15 p.m.	Adjourn		
Day 2	8:00-8:30 a.m.	Differences Between a HACCP Plan and HACCP System	W. B. Mikel
	8:30-9:00 a.m.	Components of a HACCP System Verification	D. T. Bartholomew
	9:00-9:30 a.m.	How to Obtain HACCP Verification Records	W. R. Henning
	9:30-10:00 a.m.	Interpretation and Utilization of Results from a HACCP System Verification	R. W. Rogers
	10:00-10:15 a.m.	Break	
	10:15-10:30 a.m.	HACCP System Verification vs. HACCP Plan Validation	J. C. Cordray
	10:30-11:00 a.m.	HACCP Plan Assessment	N.G. Marriott
	11:00-11:30 a.m.	HACCP Plan Validation Components	K. L. Kotula
	11:30-12:00 p.m.	Interpretation and Utilization of Results from a HACCP Plan Validation for Profit Optimization	A. E. Reynolds
	12:00-12:30 p.m.	Regulatory Requirements Related to Verification and Validation	K. B. Harris
	12:30 p.m.	Adjourn	

The advanced HACCP short course material was submitted simultaneously to Dennis Burson and Thomas Powell on February 22, 2001 for peer review. At the time that these proceedings were prepared, no feedback has been received. Following peer review input, the PowerPoint presentations will

be standardized by the AMSA office. Following this standardization, the PowerPoint presentations and handout material will be placed on file in the AMSA office and become available for use by the membership.