Basic Food HACCP Course

Presented By: David Rosson

In Accordance with the International HACCP Alliance

An Overview of HACCP

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Introduction to Hazard Analysis and Critical Control Point (HACCP) Systems

Chapter 1

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What is HACCP?

I'm sure you have some ideal.

Think about it.

Not the Meaning.

What is HACCP?

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HACCP

HACCP is an Acronym

Hazard
Analysis
Critical
Control
Point

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HACCP Concept

- Food Safety Management system
- Based on the application of science and technology to
  - plan
  - control and
  - document

the safe production of foods.

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HACCP Concept (cont.)

- Covers all 3 types of potential food safety hazards:
  1. Biological-Bacteria, Viruses, Parasites & Prions
  2. Chemical-Allergens, Additives, Toxins, Drugs
  3. Physical-Glass, Metal
- Hazards may be naturally occurring in food, contributed by environment, or generated by a mistake during processing.

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HACCP Concept (cont.)

- Focuses on the prevention of problems that could lead to foodborne illness or injury.
- Can be applied throughout the food chain

Boat to Throat

Nip to Lip

Farm to Fork

- Commonly applied in manufacturing settings.
- Is required more and more by purchasing customers

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Origin of HACCP

- HACCP was developed for NASA in response to the food safety requirements for production of foods for the space program.
- The Pillsbury Company, U.S. Army Natick Laboratories were involved in the development

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We can't test our way out of this!

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Adapted
"Modes of Failure" Concept
to Production of Foods

Developed by US Army

By knowing ever detail about everything you do all the time it is possible to predict what might go wrong (hazard) but not only that but how and where it will occur.

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Original HACCP Principles

1. Identify/Assess Hazards
2. Determine Critical Control Points
3. Establish Systems to Monitor CCPs

The HACCP concept was first introduced to the public in 1971 at the National Conference on Food Protection

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Early Uses of HACCP

- FDA inspections
- Low-acid (21 *CFR* 113) and acidified (21 *CFR* 114) canned foods regulations based on HACCP concepts
- Some large food companies (Pillsbury)

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1985 NAS Report

- Provided a strong endorsement of HACCP
- Recommended regulators and industry utilize HACCP
  - most efficient and effective means of assuring the safety of food supply

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1985 NAS Report

- Recommended forming a commission to further define HACCP. This group is now known as the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

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NACMCF

- Encouraged adoption of the HACCP approach to food safety.
- In 1989, adopted a document describing 7 HACCP principles and a systematic approach for application of HACCP to food production.
- Revised HACCP documents in 1992 and 1997.

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Codex Alimentarius Committee on Food Hygiene

- Actively involved in developing HACCP guidelines for use in international trade.
- Worked in concert with NACMCF to revise and refine HACCP.
- Most recent revisions - 2003.

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HACCP Mandatory in US for:

- Fish and Fishery (Seafood) Products (21 *CFR* 123)
- Meat and Poultry Products (9 *CFR* 417)
- Juice Products (21 *CFR* 120)

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HACCP is Mandatory for:

- Third Party Audits
- Customer demands

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International Uses

- EU mandates that all food business operators implement procedures based on HACCP principles.
- Many other countries have adopted or are adopting HACCP.

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HACCP - Definition

A systematic approach to the identification, evaluation and control of food safety hazards.

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Guidelines for Application of HACCP Principles

- Prerequisite Programs
  - The HACCP system is built upon a foundation of prerequisite programs.
  - GMPs
  - SSOPs
  - Policies and Procedures
- Education and Training
  - Effective training is a prerequisite to successful implementation of the HACCP plan.

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Preliminary Tasks in the Development of HACCP Plans

1. Assemble the HACCP team.
2. Describe the food and its distribution.
3. Describe intended use and consumers.
4. Develop a flow diagram.
5. Verify the flow diagram.

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Principle 1

Conduct a Hazard Analysis.

Hazard Analysis: the process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan

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Principle 2

Determine the critical control points (CCPs).

A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

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Principle 3

Establish critical limits.

A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard

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Principle 4

Establish monitoring procedures.

To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification

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Principle 5

Establish corrective actions.

Procedures to be followed when a deviation occurs.

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Principle 6

Establish verification procedures.

Those activities, other than monitoring, that determine the validity of the HACCP Plan and that the systems is operating according to the plan.

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Principle 7

Establish record-keeping and documentation procedures.

With HACCP if you don't have a record then you probably didn't do it. Keep Records!!!

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Implementation and Maintenance of the HACCP Plan

- Need commitment from management. $$, Time
- Establish a plan. Fail to Plan- Plan to Fail
- Assure employees are properly trained. (Probably required)
- Develop forms and policies & procedures. (for everything)
- Implement the plan - continually apply the activities described in the HACCP plan.
- Schedule verification activities and update and revise the HACCP plan as needed.

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SUMMARY

- HACCP is a preventive system for managing food safety.
- HACCP provides the framework for producing foods safely and the records to prove that they were produced safely.

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Questions?

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Prerequisites to HACCP and SSOPs

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Prerequisites to HACCP and SSOPs

Chapter 2

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HACCP is a Food Safety Management System

It is NOT "stand-alone"

It's a System

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System

Merriam Webster- defines system a regularly interacting or interdependent group of items forming a unified whole

Solar System

Digestive System

The System (80's Pop Duo)

HACCP System

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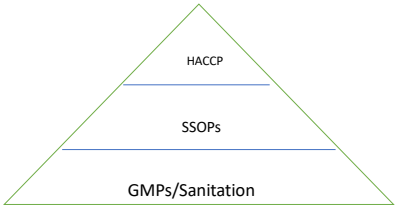

HACCP is built on a solid foundation of GMPs & Sanitation

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SSOP's
Sanitation Standard Operating Procedures

Basic Elements

1. What is covered
2. How often
3. Step by Step instruction how to perform the activity correctly including corrections what to do when things aren't performed correctly
4. Recordkeeping
5. Who is responsible

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Prerequisite Programs

A range of programs that are necessary to set the stage for HACCP-based systems and to provide on-going support for these systems.

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Prerequisite Programs Based on:

USDA
FSIS sanitation regulations
9 CFR 416

FDA

21 CFR 117 subpart B

FDA current Good Manufacturing Practices (cGMPs)

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Prerequisite Programs Based on:

- FDA current Good Manufacturing Practices (cGMPs)
- USDA/FSIS sanitation regulations

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History

AAFC, 1993 -	Canadian Food Safety Enhancement Program
FDA, 1995 and 2001-	Seafood HACCP, Juice HACCP
USDA-FSIS, 1996 -	Meat/Poultry HACCP
NACMCF, 1997 -	Revised HACCP guidelines
Codex, 2003 -	HACCP guidelines
FSIS, 2003 -	*Listeria* rule (interim final)

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Prerequisite Programs

Provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome foods.

(NACMCF)

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Examples of Common Prerequisite Programs

- Facilities
- Production equipment
- Cleaning & sanitation
- Chemical control
- Pest control
- Personal hygiene
- Training
- Supplier control
- Specifications
- Traceability & recall

(NACMCF)

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Examples of Prerequisite Programs

- Consumer complaint management
- Sanitation Standard Operating Procedures (SSOPs)
- Environmental monitoring program

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Facilities

- Layout
  - Buildings, premises, equipment, and personnel movements
- Segregation
  - Clean and unclean zones
  - Wet and dry zones
  - Air handling

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Personnel

- Health and hygiene
  - Disease control and personal hygiene/dress code
- Hygienic practices
  - Handling of materials
  - Movement in facility
- Education and Training

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Poor employee practices may result in microbiological, physical or chemical contamination of foods.

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Production Equipment

- Sanitary design principles
- Scheduled maintenance
- Calibration, where applicable

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Control of (Raw) Materials

- Written specifications
  - Certificate of analysis
  - Letter of guarantee
  - Certificate of conformance
- Supplier approval program
- Inspection and appropriate storage on receipt

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Sanitation and Environmental Monitoring

- Written procedures and schedules
  - Master sanitation schedule
- ATP swabs or microbial testing may be used to monitor effectiveness of sanitation
- Environmental monitoring programs are common for certain products, e.g., RTE meats, infant formula
  - Designed to find “niches” or harborage sites

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Traceability and Recall Program

- Crisis response plan and team
- Lot coding and records
- Distribution records
- Product disposition
- Mock recalls
- FDA regulation (21 *CFR* 7, 21 *CFR* 117, 21 *CFR* 507)
  - Requires records identifying immediate previous source and immediate subsequent recipient

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Sanitation

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Regulatory Requirements

- FDA – Current Good Manufacturing Practices (21 *CFR* 117)
- FSIS – Sanitation Performance Standards for Meat and Poultry (9 *CFR* 416.1-416.6)
- SSOPs

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Sanitation Standard Operating Procedures

(SSOPs)

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SSOPs in FDA HACCP Regulations 21 *CFR* Parts 120 and 123

1) Water safety
2) Cleanliness of equipment, tools, product contact surfaces
3) Prevention of cross-contamination
4) Hand washing & sanitizing, toilet facilities
5) Protection from chemical, biological and physical contaminants
6) Control of toxic compounds
7) Employee hygiene
8) Pest control

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21 CFR 117 Subpart B

- If you are subject to FDA jurisdiction or perhaps your State has a cooperative arrangement with the FDA you will base all your sanitation on the Current Good Manufacturing Practice Regulation

21 CFR 117 Subpart B

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SSOPs in FDA HACCP Regulations
21 *CFR* Parts 120 and 123

- Implementation
  - Monitoring sanitation activities in the key areas.
- Record-keeping
  - Records must be kept to show the monitoring of activities and any corrections taken.

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SSOPs for Meat and Poultry
(9 *CFR* 416.11 - .17)

- Written SSOPs are required for meat and poultry products
- SSOPs must identify procedures to prevent direct product contamination

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The SSOPs for Meat and Poultry shall include:

- Procedures to be performed
- Individuals responsible
- Frequency of each task

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SSOPs for Meat and Poultry

- Must identify daily pre-op procedures
- Must identify daily operational procedures
- Must be signed and dated
- Establishment must initiate corrective and preventative actions
- Daily records must be maintained

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Proper implementation of prerequisite programs simplifies the development of a HACCP Plan.

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Prerequisite Programs Should Be:

- Well-documented with written SOPs
- Adhered to by all employees
- Reviewed and revised as needed
- Effective in accomplishing objectives

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Establishing Prerequisite Programs

Documentation

- What procedures should be performed?
- At what frequency?
- Who has responsibility?
- What actions should be taken if:
  - a procedure is not performed as required?
  - there is an unexpected outcome?

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Establishing Prerequisite Programs

Employee training

- Continuing education
- Important to understand and follow assigned tasks
- Provide time and materials for training
- Verify by reviewing performance

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Verification of Prerequisite Programs

Periodic review of the SOPs and audit reports to ensure that the programs are operating in a manner that should not require a change in the hazard analysis or HACCP plan.

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Establishing Prerequisite Programs

Verification

- Is the SOP performed in the manner intended?
- Is the procedure monitored?
- Are appropriate records kept?
- Is there an independent audit?
- Are programs revised as necessary?

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Establishing Prerequisite Programs

Resources

- Are the proper tools/equipment available?
- Are appropriate personnel available to perform the task effectively?
- Are systems adequate for monitoring and storing data?

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Prerequisite Program or HACCP?

Prerequisite Programs	HACCP Plans
Deal **indirectly** with food safety issues	Deal **solely** with food safety issues
Cross multiple product lines	Specific to product & line
Failures seldom result in food safety hazards	Deviations must be considered potential food safety hazards

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Prerequisite Program or HACCP?

Depending upon the results of the hazard analysis and identification of control measures, some activities normally addressed in prerequisite programs may be included in the HACCP plan.

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HACCP is a Food Safety Management System

It is NOT "stand-alone"

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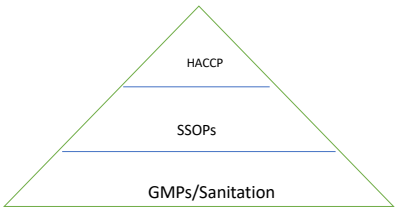

A HACCP System is built on a solid foundation of GMPs & Sanitation

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Questions?

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Biological Hazards and Controls

Presented by
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Chapter 3

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Pathogens vs Spoilage Organisms

Biological hazards = Pathogens

Pathos is Greek for suffering
Genes is Greek for maker of
Pathogens are illness causing microorganisms

Spoilage organisms (yeast, mold, fungi and bacteria) are not biological hazards

- May affect quality but not safety
- Rarely cause illness there are a few exceptions

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Foodborne Illness in the US

- 48 million cases/year
- 128,000 hospitalizations
- 3,000 fatalities

CDC Scallan et al. 2011)

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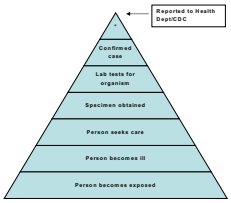
Actual vs Reported Foodborne Disease Outbreaks



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Foods Involved in Outbreaks

- Most frequently – foods of animal origin
- Increasingly – contaminated fruits and vegetables

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Steps Necessary to Cause Illness

- Pathogen or toxin present in food
- In some cases, pathogen must grow in food to high enough numbers to produce infection or toxin.
  - Some pathogens, e.g., *E. coli* O157:H7, have low infectious dose
  - Parasites and viruses do not grow in foods
- Food must be ingested and survive digestive tract barriers
- Some pathogens must establish and multiply in body

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Place Where Illness Acquired

- Most commonly, foodservice establishments and group-feeding situations

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Etiologic Agents of Foodborne Diseases 2011 (CDC)

Table 2. Top five pathogens contributing to domestically acquired foodborne illnesses

Pathogen	Estimated number of illnesses	90% Credible Interval	%
Norovirus	5,461,731	3,227,078–8,309,480	58
Salmonella, nontyphoidal	1,027,561	644,786–1,679,667	11
Clostridium perfringens	965,958	192,316–2,483,309	10
Campylobacter spp.	845,024	337,031–1,611,083	9
Staphylococcus aureus	241,148	72,341–529,417	3
Subtotal			91

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Bacterial Foodborne Pathogens

- *Salmonella* spp.
- *Clostridium botulinum*
- *Staphylococcus aureus*
- *Yersinia enterocolitica*
- *Listeria monocytogenes*
- *Vibrio* spp.
- Shiga toxin producing *Escherichia coli*
- *Clostridium perfringens*
- *Bacillus cereus*
- *Campylobacter* spp.
- *Shigella* spp.

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Pathogenic Viruses

- Hepatitis A and E viruses
- Norovirus

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Pathogenic Parasites

- Worms
  - *Trichinella spiralis*
  - *Anisakis simplex*
- Protozoa
  - *Cyclospora cayetanensis*
  - *Cryptosporidium parvum*
  - *Toxoplasma gondii*
  - *Giardia lamblia*

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Types of Foodborne Disease

- Intoxication
- Infection

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Types of Foodborne Disease

- **Infections** – ingest live organisms
  - Viable pathogens infect and multiply in body (e.g., *Salmonella*, *L. monocytogenes)*
  - Viable pathogens multiply and produce toxins in body (e.g., *C. perfringens, V. cholerae*)

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Types of Foodborne Disease

- **Intoxications -** ingest toxins
  - Metabolic products of certain bacteria (e.g., *C. botulinum*, *S. aureus*)
  - Note – naturally occurring toxins (e.g., shellfish) – chemical hazards

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Factors Contributing to Foodborne Disease Outbreaks

- Improper storage/holding temperature
- Inadequate cooking
- Poor personal hygiene
- Cross-contamination
- Improper reheating
- Poor storage practices

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Bacterial Forms

- Sporeformers
  - *C. botulinum*, *B. cereus*
- Non-sporeformers (vegetative cells)
  - *Salmonella*, *L. monocytogenes, E. coli* O157:H7

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Pertinent Microorganism(s)

- Any association of a pathogen with (isolation from) a product?
- Any outbreaks associated with the product?
- Any outbreaks associated with the ingredients?

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Biological Hazards - Sources

Beef	*Salmonella, STEC, C. perfringens*
Poultry	*Salmonella, Campylobacter, C. perfringens*
Vegetables	*L. monocytogenes, C. botulinum, Salmonella*
Fruits	*Cyclospora, STEC, Salmonella*
Fish	*Vibrio, C. botulinum,* parasites, viruses
Eggs	*Salmonella*
Juice	*STEC, Salmonella, Cryptosporidium*
Peanuts	*Salmonella*

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Control Measures for Biological Hazards

- Prevent contamination of foods (keep them out)
- Inactivate of foodborne disease agents (kill them)
- Prevent multiplication of pathogens (control them)

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Factors Contributing to Foodborne Disease Outbreaks

- Improper storage/holding temperature
- Inadequate cooking
- Poor personal hygiene
- Cross-contamination
- Improper reheating
- Poor storage practices

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Clostridium botulinum
sporeforming, toxigenic

- Soil, marine sediment, vegetables, seafood
- Anaerobic
- No growth below pH 4.6
- Spores are extremely heat resistant

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Clostridium botulinum
Control

- Retort process to destroy spores
- Control growth (germination) by means of pH, a_w, temperature, inhibitor

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Clostridium perfringens
sporeforming

- Soil, intestinal tract of animals, meat, vegetables, spices
- Anaerobic
- Optimum growth 43-45°C (109-113°F)
- Very rapid growth in food at optimum temperatures

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Clostridium perfringens
Control

- Vegetative cells but not spores killed by normal cooking
- Proper hot-holding and/or cooling of cooked foods prevents growth

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Salmonella
non-sporeforming, infectious

- Intestinal tract of animals
- Over 2,000 serovars known
- Survives freezing and dehydration
- Killed by mild heat
- Special concern in low moisture foods
- Environmental monitoring in RTE areas

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Salmonella
Control

- Killed by thorough cooking of food
- Avoid recontamination
- Proper hygiene by food handlers
- Low pH prevents growth
- Note: Prevention of growth not enough to assure safety

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Pathogenic *Escherichia coli* non-sporeforming, infectious

- Intestinal tract of animals
- Low pH prevents growth (but may survive)
- Killed by mild heat

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Escherichia coli Control

- Good sanitation and personal hygiene
- Killed by proper cooking and reheating
- Prevent cross-contamination
- Proper refrigeration, low pH, low a_w prevent growth

Some pathogenic *E. coli* strains have very low infectious dose

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Staphylococcus aureus non-sporeforming, toxigenic

- Human skin or nasal passages
- Resistant to high salt
- Cells killed by mild heat
- Enterotoxin very heat stable

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Staphylococcus aureus
Control

- Prevent contamination through proper hygiene, exclusion of food handlers with boils, abscesses
- Cells destroyed by normal cooking
  but enterotoxin is not
- Proper refrigeration /hot holding prevent growth

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Listeria monocytogenes
non-sporeforming, infectious

- Animals, humans, environment (ubiquitous)
- Low pH prevents growth
- Survives dehydration and freezing
- Grows at refrigeration temperatures

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Listeria monocytogenes
Control

- Proper heat treatment
- Proper temperature control (cold slows growth)
- Add growth inhibitors, reduce a_w
- Avoid recontamination of RTE foods
- Environmental monitoring in RTE areas

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Campylobacter
non-sporeforming, infectious

- Animals, poultry, raw milk, water (via animal contamination)
- Microaerophilic
- Growth range 32-45°C, dies in refrigeration
- Grows at pH 4.9-9; rapid death below pH 4.0
- Sensitive to heat and to drying

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Campylobacter
Control

- Proper cooking
- Milk pasteurization
- Water chlorination
- Prevent cross-contamination, especially from raw poultry

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Vibrio parahaemolyticus
non-sporeforming, infectious

- Seawater - oysters, clams
- Grows between 5 and 43°C (optimum 37°C)
- Grows in 0.5-10% NaCl

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Vibrio parahaemolyticus Control

- Proper harvest practices
- Prevent growth of organism after harvesting by chilling product to <5°C
- Prevent cross-contamination
- Proper cooking, cooling, and storage

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Viruses, Parasites infectious

- e.g., hepatitis A, *Cyclospora*, *Cryptosporidium,* seafood parasites
- Only some are pathogenic for humans (most don't cross species)
- Primarily from food handlers, fecal (raw sewage) contamination
- Don't grow in food

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Viruses, Parasites Control

- Prevent contamination through proper food handler hygiene
- Appropriate source of raw materials
- Use heat treatment to kill
- Some parasites killed by freezing

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Viruses, Parasites
Control

- Prevent contamination through proper food handler hygiene
- Appropriate source of raw materials
- Use heat treatment to kill
- Some parasites killed by freezing

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Control Measures for Biological Hazards

- Time/temperature applications
  - Cooking, Freezing, Refrigeration
- Use of acids or preservatives
- High pressure
- Irradiation
- UV light

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General measures for control

- Microbiological specifications
- Food handling practices
- Sanitation
- Prevention of cross-contamination
- Packaging integrity
- Storage, distribution practices
- Consumer directions for use (to prevent abuse)

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Pathogen Inactivation

- Thermal inactivation
  - Cooking used to kill *Salmonella* in roast beef
  - Pasteurization to kill vegetative pathogens in juice
  - Retort to destroy *C. botulinum* spores in canned foods
- Freezing used to destroy parasites in fish

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Prevent Multiplication of Pathogens

- Store and prepare products under appropriate conditions
- Prevent or minimize growth
  - Freezing or refrigeration
  - Hot holding
  - Water activity, pH, etc.
  - Rapid cooling

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Refrigeration as a Control Measure

Minimum growth temperatures (in ºC) for foodborne pathogens

Clostridium botulinum	3.3 or 10
Listeria monocytogenes	-0.4
Yersinia enterocolitica	-1.3
Escherichia coli O157:H7	7-8
Vibrio vulnificus	8

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Refrigeration as a Control Measure

Minimum growth temperatures (in ^{o}F)
for foodborne pathogens

Clostridium botulinum	38 or 50
Listeria monocytogenes	31.3
Yersinia enterocolitica	29.7
Escherichia coli O157:H7	44.6 - 46.4
Vibrio vulnificus	46.4

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Influence of Temperature on *L. monocytogenes* Growth

Temperature (^{o}C)	Generation Time (hour)
21	1.7 - 1.9
13	5.8 - 6.0
8	10.6 - 13.1
4	33.3 - 36.3

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Prevention of Recontamination

- RTE foods exposed to environment must be protected from recontamination
  - e.g., potential *L. monocytogenes* recontamination of ready-to-eat meat
- Need effective prerequisite programs to ensure pathogens due to recontamination are unlikely to occur.
- Environmental monitoring key.

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Questions?

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Chemical Hazards and Controls

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Chapter 4

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Chemicals Used in Food Processing

Point of Use	Types of Chemicals
• Raising livestock	• Growth hormones, antibiotics
• Growing crops	• Pesticides, herbicides, defoliants
• Production	• Food additives, processing aids
	• Lubricants, paints
• Plant maintenance	• Cleaners, sanitizers, pesticides
• Plant sanitation	

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Chemical Hazards

- Hazard may depend on exposure
  - Long and short term effects
- Based on toxicological studies, safe levels have been set
- Laws and regulations are designed to ensure exposure levels are safe when chemicals are properly used.

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Laws and Regulations

- Require that foods are safe and free of adulterants.
- The FDA, EPA and USDA enforce provisions of pertinent laws and regulations.

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Federal Food, Drug and Cosmetic Act

A food is adulterated:

- if it bears or contains any poisonous or deleterious substance which may render it injurious to health, or
- if it bears or contains added poisonous or deleterious substance.

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Naturally Occurring Substances

- Some toxic chemicals occur naturally in a variety of
  - Plants, e.g., mushrooms
  - Animals, e.g., shellfish
  - Microorganisms, e.g., certain molds and bacteria

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Unavoidable Poisonous or Deleterious Substances

- Substances that are necessary in the production of food, or cannot be avoided with cGMP
- FDA establishes tolerances or action levels for specific commodities
  - e.g., aflatoxin, action level in foods 20 ppb

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Toxins of Microbial Origin

- Histamine or scombrotoxin
  - Growth of bacteria in certain fish due to temperature abuse
  - Bacterial enzyme reacts with free histidine in fish
- Other seafood toxins, e.g. ciguatoxin
- Mycotoxins
  - Aflatoxin from mold growth in grains, nuts, and other products
  - Patulin

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Patulin in Apple Juice

- Produced by mold growth on apples
- CPG 510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin
  - 50 μg/kg (ppb) as determined in single strength apple juice (includes single strength juice component of food or from concentrate)

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Allergens

- Proteins that induce an allergic reaction.
- Symptoms range from mild rashes to anaphylaxis and, rarely, death.
- 1-2% of adults have a food allergy.
- 5-6% of children have a food allergy.

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Top 9 Food Allergens

- Peanut
- Tree nuts
- Soybeans
- Wheat
- Milk
- Egg
- Fish
- Crustaceans
- Sesame

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Allergens and Food Safety

- Major concern is product containing an undeclared allergen
  - Peanuts in peanut butter vs. undeclared peanut in chili
- Control of allergenic ingredients and prevention of cross-contact are essential for food safety

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Chemical Sensitivities

- A small percentage of the population is sensitive to certain chemicals, e.g., sulfites and FD&C Yellow #5, in foods.
- Control is similar to allergen control.

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Intentionally Added Chemicals

- Safe when used appropriately, but can be hazardous if improperly used.
  - Pesticides, fertilizers, antibiotics, preservatives
- Regulations control the level of use and maximum allowable residues of certain chemicals in foods.

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Antibiotics and Hormones

- Use controlled by FDA and USDA
  - Approval of veterinary drugs by FDA
  - Assurance of correct use by USDA APHIS and FSIS
- If used appropriately, antibiotics and hormones pose no health hazard
  - Residues in milk

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Pesticide Chemicals

- Regulated by the Environmental Protection Agency (EPA).
- If used appropriately, pesticide chemicals pose no health hazard.
- Consider potential for pesticide residues in globally sourced ingredients.

137

Lubricants and sanitizers

- Pose no hazard when used in accordance with GMPs
- Food grade lubricants used where possible contact with food, food-contact surfaces
- SSOPs ensure residues of sanitizers pose no hazard

138

Control of Chemical Hazards

139

Control of Patulin in Apple Juice

Action level: 50 μg/kg (ppb) in apple juice

Consider:

- No drops used
- Trimming
- Removal of rotten/damaged fruit

140

Allergen Control – Appropriate Labeling

- Ensure labels reflect all allergens
  - Careful control of product labeling
  - Formulation control
  - Ingredient specifications and supplier control

141

Allergen Control – Recognize Inadvertent Introduction due to Cross-Contact

- Results of environmental exposure
- During processing or handling
  - Ineffective cleaning
  - Dust or aerosols containing allergen
- Multiple foods produced in same facility
  - Use of same processing line
  - Misuse of rework

142

Control Measures for Inadvertent Allergens

Minimize cross-contact by:

- Separate storage
- Appropriate scheduling of production
- Careful and thorough cleaning
- Controlling traffic patterns
- Design of equipment and systems
- Adequate training of employees

143

Chemical Control Program Prior to Receipt

- Suppliers can help reduce occurrence of potential chemical hazards.
  - Pesticide residues on products (e.g., fruits, vegetables)
  - Mycotoxins in foods (e.g., aflatoxin in milk, patulin in apples)
  - Toxic chemicals in packaging materials

144

Chemical Control Program Prior to Receipt

- Develop specifications for ingredients, packaging materials and chemicals.
- Qualify suppliers and audit operations
- Obtain letters of guarantee

145

Upon receipt

- Inspect vehicles prior to unloading
- Inspect materials during unloading
- Periodic sampling and testing
- Verify presence of COA, where applicable

146

Establishment Operations

- Ensure that only approved chemicals are used at the facility.
- Designate responsibility for chemical receipt, storage and use.
- Establish programs for controlling chemicals at point of use.
- Audit to ensure adequate control of chemicals.

147

Chemical Use in Processing

- Use only approved chemicals.
- Control chemicals at point of use.
- Cleaning and sanitizing procedures must prevent harmful levels of residues on food contact surfaces.

148

Storage of chemicals

- Store in tightly sealed containers.
- Store hazardous/toxic chemicals in physically separated, locked enclosures.
- Store allergens to prevent cross-contact.
- Cover packaging materials.

149

Pesticide Usage

- Labels of pesticides used should be kept on file.
- Keep pesticide usage records.
- Limit poison baits to outside plant.
- Control storage.

150

Questions?

151

Physical Hazards and Controls

Presented by
David LA Rosson
International HACCP Alliance

Chapter 5

152

Physical Hazards

- Foodborne injuries caused by physical hazards usually involve relatively few consumers.
- Typically - result in personal injuries such as a broken tooth, lacerations of mouth or choking.

153

Food Safety vs. Aesthetics

- Potential physical hazards are foreign objects or extraneous matter capable of causing injury, e.g. glass, metal, rocks.
- Aesthetic contaminants such as insect fragments, hair and sand typically do not cause injury to consumers.

154

Regulatory Guidance

- FDA Compliance Policy Guide 555.425 "Foods - Adulteration Involving Hard or Sharp Objects"
- Ready-to-eat foods containing hard or sharp foreign objects
  - 7-25 mm in length considered a hazard for general public
  - Objects less than 7 may present a hazard if product intended for special risk-group, e.g., infants, elderly

155

Regulatory Guidance

- USDA/FSIS guideline
  - FSIS Directive 7310.5 provides guidance to inspectors on foreign materials; no specific size guidance for physical hazards

156

Physical Hazard

A contaminant in a product represents a physical hazard if it will result in injury to the consumer.

(Usually hard, sharp objects between 7-25 mm.)

157

Sources of Physical Hazards

- Contaminated raw materials
- Poorly designed or maintained facilities and equipment
- Faulty procedures during production
- Improper employee practices
- Certain processes/operations
  - Metal-to-metal contact, e.g., grinding
  - Glass filling operations

158

Minimizing Physical Hazards - Raw Material Receipt

- Material specifications
- Letters of guarantee
- Vendor inspection and certification
- Periodic product inspection

159

Minimizing Physical Hazards - Facility

- Attention to GMPs will insure that the facility is not a source of physical hazards
  - Properly protected light fixtures
  - Appropriately designed equipment
  - Adequate maintenance programs

160

Minimizing Physical Hazards - Employee Practices

- Adherence to cGMPs
  - Proper outer attire, no jewelry, no pens in outer pockets.
- Employee training
- Control maintenance work
  - Inspect work areas for loose hardware and tools.
  - Clean/inspect lines prior to restarting operations.
  - Reconcile tool and parts inventory.

161

Minimizing Physical Hazards During Processing

- Control measures for glass
  - Glass breakage program (bottle invert, shrouding glass handling line, etc.)
- Control measures for metal
  - Magnets, metal detectors, x-ray
- Control measures for hard/sharp objects
  - Screens, filters

162

Equipment Used to Detect or Remove Foreign Materials

- Magnets / metal detectors
- Screens / sifters
- Aspirators
- Flumes
- Bottle / can cleaner
- X-ray equipment

163

HAZARD	CONTROL
Glass from light fixtures	Shatter-proof bulbs shields
Metal fragments from equipment	Preventive maintenance, magnets, metal detector

164

Physical Hazards and Controls

This concludes Chapter 5
Please complete the Chapter quiz and review all attachments

165

Initial Tasks in Developing HACCP Plans

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International HACCP Alliance

Chapter 6

166

Gain Management Support

Upper management must make a commitment to support HACCP – both financially and in spirit.

167

Implement Well-Designed Prerequisite Programs First

168

Prerequisite Programs

- Prerequisite programs provide the foundation for the HACCP system.
- Identify and evaluate existing programs to determine the efficiency of these programs.

169

Five Initial Tasks

170

1. Assemble HACCP Team

- HACCP coordinator
- Multi-disciplinary unit
- Consultants (if necessary)
- Ad hoc groups

171

2. Describe the Food and Its Distribution

- Common name and ingredients
- Nature of the product and shelf life
- General description of the process
- Type of storage and distribution
- Parameters related to food safety: pH, a_w, packaging, preservatives, etc.

172

Collect Detailed Information on Formulation and Ingredients

- Processing aids
  - Sulfites, soy lecithin
- Ingredients known to be source of potential pathogens
  - *Salmonella* in poultry, eggs
  - Staphylococcal growth and enterotoxin formation in cured meats, pasta
- Ingredients with associated potential chemical hazards
  - Antibiotics in milk
  - Nitrite in cured meats

173

3. Describe the Intended Use and Consumers

- Intended use, e.g., retail, foodservice, further manufacturing
- Potential for mishandling
- Preparation procedures, e.g., heat-and-serve, RTE, reconstitute
- Intended for at-risk individuals, e.g., infants, immunocompromised, elderly

174

3. Describe the Intended Use and Consumers

- Intended use, e.g., retail, foodservice, further manufacturing
- Potential for mishandling
- Preparation procedures, e.g., heat-and-serve, RTE, reconstitute
- Intended for at-risk individuals, e.g., infants, immunocompromised, elderly

175

4. Develop a Flow Diagram

- A simple (block) flow diagram showing the locations where specific ingredients are added, and where storage, preparation and processing steps occur.

176

Description of Product and Process

The block flow diagram should be supplemented with a description of the product and process flow

May include information associated with ingredient storage, preparation, equipment, processing, packaging, storage and distribution, etc.

177

Regulatory Requirement

- FSIS requires a flow chart as part of the hazard analysis for meat and poultry products
  - Include designation of CCP(s) on the flow chart

178

5. Verify the Flow Diagram

The flow diagram should be verified for accuracy and completeness by an on-site inspection of the facility, equipment and operations.

179

Summary – Initial Tasks

1. Assemble HACCP Team
2. Describe the Food and Its Distribution
3. Identify Intended Use and Consumers
4. Develop a Flow Diagram
5. Verify the Flow Diagram

180

Questions?

181

Hazard Analysis

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Chapter 7

182

HACCP PRINCIPLE 1

Conduct a Hazard Analysis

183

Hazard

A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

(NACMCF, 1997)

184

Hazard Analysis

The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

(NACMCF, 1997)

185

What is a Hazard Analysis?

- Hazard Analysis- Food processors must determine if there are any significant hazards associated with your products (ingredients, raw materials) or process.

An Analysis involves estimating the likelihood of an occurrence, and possible severity of particular kinds of hazards

What can go wrong? How likely is it? What are the consequences? How certain is this (your) knowledge?

186

Hazard Analysis

Two Stages:

1. Hazard identification
   - List of potential hazards
   - Consider each ingredient
   - Consider the Process
2. Hazard evaluation
   - Based on severity and likelihood of occurrence (three steps)

187

Stage 1: Hazard Identification

Review for potential hazards:

- Raw materials and/or ingredients used in product.
- Activities conducted at/around each process step.
- Equipment used to make product.
- Method of storage and distribution.
- Intended use and consumers of product.

188

Evaluation for Hazards to Include:

1. Microbiological contamination
2. Parasites
3. Chemical contamination
4. Unlawful pesticide residues
5. Decomposition (if a food hazard exists)

189

Hazards (continued)

6. Natural Toxins
7. Unapproved use of food or color additives
8. Presence of undeclared ingredients that may be allergens
9. Physical hazards

190

Stage 2: Hazard Evaluation

Step 1: Assess Severity

- Severity is the seriousness of the effect(s) of a hazard.
- Consider:
  - Susceptibility of intended consumers.
  - Impact of secondary problems.
  - Magnitude and duration of illness and injury.

191

Stage 2: Hazard Evaluation

Step 2: Determine Likelihood of Occurrence

Consider:

- Likely occurrence of potential hazard under existing prerequisite programs.
- Association of hazard with ingredient/product.
- Method of preparation in facility.
- Conditions during transportation.
- Expected storage conditions.
- Likely preparation steps before consumption.

192

Stage 2: Hazard Evaluation

Step 3: Determine if Hazard Needs to be Addressed in HACCP Plan

- Eliminate hazards of low severity and/or likelihood of occurrence
- Include all significant hazards – based on severity and "reasonably likely to occur"
- Justify decisions
- Difficult, often subjective process
- Keep a record!

193

Hazard reasonably likely to occur:

- One for which a prudent processor would establish controls
  - experience
  - illness data
  - scientific reports
- Reasonable possibility hazard will occur in the absence of the controls

194

Potential Hazard

Hazard

195

Potential Hazard is Significant?

What can go wrong? How likely is it? What are the consequences? How certain is this (your) knowledge?

196

Potential Hazard

C. botulinum

197

Understand the Hazard

UNDERSTAND THE POTENTIAL HAZARD.

- *Clostridium botulinum* (*C. botulinum*) toxin formation can result in consumer illness and death. It is the toxin responsible for botulism. About 10 outbreaks of foodborne botulism occur annually in the United States, from all sources.
- Symptoms include: weakness, vertigo, double vision, difficulty in speaking, swallowing and breathing, abdominal swelling, constipation, paralysis, and death.
- When *C. botulinum* grows, it can produce a potent toxin, one of the most poisonous naturally occurring substances known.

198

Is the Potential Hazard Significant?

pH ?
Water Activity (aw)?
Oxygen?
Temperature? cooking
Time? Holding
Process? Pressure/Heat

C. Botulinum

199

Use Archival Data TOO

200

NATIONAL OUTBREAK REPORTING SYSTEM NORS

- https://wwwn.cdc.gov/norsdashboard/

201

OUTBREAK DATABASE

- http://outbreakdatabase.com

202

Example - analysis for egg containing product

Stage 1: hazard identification

Determine potential hazards associated with product

B - *Salmonella* in finished product

203

Stage 2: Hazard evaluation

Step (1): Assess severity of health consequences if potential hazard is not properly controlled

Salmonella in finished product may result in salmonellosis, an infection with moderate to severe consequences.

204

Stage 2: Hazard evaluation

Step (2): Determine likely occurrence of potential hazard.

Product is made with liquid eggs, which have been known to contain *Salmonella*; if not controlled, some consumers are likely to be exposed to *Salmonella* from this product.

205

Stage 2: Hazard evaluation

Step (3): Decide if this potential hazard is to be addressed in the HACCP plan.

Yes;

If *Salmonella* from liquid eggs is not properly controlled, consuming this product presents a significant risk.

206

Example – Blending step

Stage 1: hazard identification

Determine potential hazards associated with product

C- Residual sanitizers in the blend tank

207

Stage 2: Hazard evaluation

Step (1): Assess severity of health consequences if potential hazard is not properly controlled

Sanitizer residues would be diluted with product, therefore unlikely to have severe public health impact

208

Stage 2: Hazard evaluation

Step (2): Determine likely occurrence of potential hazard.

Residual sanitizers are NRLTO due to SSOP XXX.1, which includes a pH check of the final rinse.

209

Stage 2: Hazard evaluation

Step (3): Decide if this potential hazard is to be addressed in the HACCP plan.

No;

Occurrence of residual sanitizers not likely to occur and levels unlikely to pose health risk.

210

Example – Grinding step

Stage 1: hazard identification

Determine potential hazards associated with product

P- Metal from grinder

211

Stage 2: Hazard evaluation

Step (1): Assess severity of health consequences if potential hazard is not properly controlled

Metal fragments generated from grinding are < 7 mm, and are therefore unlikely to cause severe injury.

212

Stage 2: Hazard evaluation

Step (2): Determine likely occurrence of potential hazard.

NRLTO; evaluation of metal detector kick-out records for last two years shows only 5 metal findings over XX million pounds of product produced.

213

Stage 2: Hazard evaluation

Step (3): Decide if this potential hazard is to be addressed in the HACCP plan.

No;

Occurrence of metal fragments not likely to occur and size/shape unlikely to pose health risk.

214

Justifications for Not Including Potential Hazard in HACCP Plan

Not Reasonably Likely to Occur…

- Even in absence of control
- At levels likely to cause illness or injury
- In finished product due to system design
- Because of a specific SSOP or prerequisite program

215

After identifying the hazards to be controlled by the HACCP plan, identify control measures to prevent occurrence.

216

Control Measure

Any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard

(NACMCF, 1997)

217

Control Measure

- Examples of control measures: pasteurization, roasting, metal detection, filters, acidification
- Control does not need to occur at the point the hazard first appears

218

Examples:

Point of Occurrence	Identified Hazard	Control Measure
Raw juice	Vegetative pathogens	Pasteurization
Puree	Sulfites	Labeling
Equipment	Metal fragments	Metal detectors

219

Regulatory Considerations

- Hazard analysis required component
  - USDA/FDA Juice HACCP regulations require written hazard analysis
  - FDA Seafood HACCP regulation does not
- Specific hazards have been identified by the agencies
  - Fish and Fishery Products Hazards Guide
  - Meat and Poultry Products Hazards Guide
  - Juice Products Hazards Guide
  - Hazard Analysis & Risk Based Preventive Controls Human Food Guide
- The agencies require scientific justifications for evaluating hazards

220

Summary

- Thorough hazard analysis vital to effective HACCP Plan.
- Identify hazards using two-stage process (hazard identification and hazard evaluation).
- Evaluation of hazards based on likelihood of occurrence and severity.
- Identify control measures for hazards to be addressed in the HACCP plan.

221

Questions?

222

Critical Control Points

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Chapter 8

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HACCP PRINCIPLE 2

Determine Critical Control Points (CCPs)

224

Introduction

- CCPs are based on the results of hazard analysis.
  - Significant hazards
  - Control measures
- Identify one or more CCPs to control each significant hazard.

225

Control Point (CP)

Any step at which biological, chemical, or physical factors can be controlled.

(NACMCF, 1997)

226

Critical Control Point (CCP)

A step at which a control measure can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

(NACMCF, 1997)

227

Critical Control Point (CCP)

A step at which a control measure can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

(NACMCF, 1997)

228

Remember:

There are many CPs in a process but only those points essential for the production of safe food are CCPs.

229

Example

Hazard	Controls
Salmonella on raw vegetables	• Supplier guarantee • Refrigerated storage • Sanitary environment • Heat treatment

230

Example (cont.)

Hazard	Controls
Salmonella on raw vegetables	• Supplier guarantee • Refrigerated storage • Sanitary environment • Heat treatment (CCP)

231

Determine the CCPs for all identified hazards

- Each identified hazard has at least one CCP.
- More than one control measure may be needed to address a hazard.
- More than one hazard may be controlled with a control measure.

232

Important Considerations

- Use the output of the hazard analysis – do not base CCPs on where there are controls!
- A subsequent step in the process may be more effective for controlling a hazard.

233

CCP Decision Tree

- Tool to help determine appropriate CCPs
- NACMCF and Codex documents have examples
- Do not apply to all potential hazards
- Use only with caution, common sense

234

Question 1

Does this step involve a hazard of sufficient likelihood of occurrence and severity to warrant its control?

235

Question 2

Does a control measure for the hazard exist at this step?

236

Question 3

Is control at this step necessary to prevent, eliminate, or reduce the risk of the hazard to consumers?

237

"Modes of Failure" Concept to Production of Foods

Developed by US Army

By knowing ever detail about everything you do all the time it is possible to predict what might go wrong (hazard) but not only that but how and where it will occur.

238

Designating CCPs

- CCP1, CCP2…
- CCP P1, CCP B1, CCP C1…
- CCP oven, CCP packaging…

239

How many CCPs should we have?

240

It depends on…

- Hazard analysis
  - type of product
  - ingredients
  - processing methods
  - existing prerequisite programs
- Regulatory concerns or issues

241

It depends on…

- More and more buyers are requiring HACCP and specific controls as well

242

Government Regulations

- Required to set CCP(s) for each identified food safety hazard.
- USDA/FSIS expects to see at least one CCP.
- CCPs not required for biological hazards that are controlled under canning regulations or in producing shelf stable juice

243

Questions?

244

Critical Limits

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HACCP PRINCIPLE 3

Establish
Critical Limits (CLs)

246

For each CCP:

Parameters are established to signify whether a CCP is “in” or “out” of control.

247

Critical Limit

A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard.

(NACMCF, 1997)

248

Critical Limit

Codex Definition

A criterion which separates acceptability from unacceptability.

249

Examples of parameters
that may be CLs

- Temperature
- pH
- Moisture level
- Line speed
- Time
- Water activity
- Weight
- Physical dimensions
- Sanitizer conc.
- Viscosity

250

Examples of parameters
that may be CLs

- "on and functioning" (metal detector)
- "in place and intact" (screen)
- "presence of supplier guarantee"

251

Critical limit
is a
maximum or minimum value,
not an average value.

252

Not meeting a CL may indicate:

- Existence of direct health hazard
- Direct health hazard could develop
- Product not produced under conditions assuring safety

253

Setting Critical Limits

- HACCP team determines standard/ benchmark to be met
- Criteria may be established by regulatory standards and guidelines – e.g., action levels, performance standards

254

Example-regulatory standards or guidelines

- FDA maximum allowable concentration of 50 ug patulin per liter of apple juice
- FSIS 7-log reduction of *Salmonella* in cooked poultry
- FDA 5-log reduction of pathogens in juice

255

Setting Critical Limits

- Scientific publications
- Government guidelines
- Consultation with experts
- Research

256

Develop CLs Best Suited for the Type of Operation

Achieving an Internal Temperature of 151ºF for 41s in Meat Patties

- Product related - Internal temperature of product ≥151ºF for ≥41 seconds.

or

- Process parameter related - Oven temperature ≥300ºF, belt speed <8.0 ft/min, initial temperature ≥32ºF, and patty thickness <15 mm.

257

Experiments Used To Establish CLs

- Heat penetration
- Temperature distribution
- Thermal death time (TDT) studies
- Inoculated pack or microbial challenge studies
- Metal detector sensitivity studies

258

Critical Limit
vs.
Operating limit

259

Operating Limits

- May be set for quality or non-safety purposes
- Exceed limits for safety
- Allow a process adjustment before critical limit is exceeded
- Avoid CL deviations and need for corrective actions

260

Operating limits

- May be set for quality (non-safety) purposes
- Exceed limits for safety
- Compensate for expected variations
- Allow process adjustment before CL is violated
- Avoid need for corrective action, holding product

261

Critical Limits

Regulatory Considerations

- Both FDA and USDA/FSIS HACCP regulations require establishments to list the CLs to be met at each CCP.
- FSIS stipulates that the CLs be designed to ensure that applicable targets, performance standards or other agency requirements are met.

262

Questions?

263

Monitoring Critical Control Points

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HACCP PRINCIPLE 4

Establish
Monitoring Procedures

265

Monitor

- To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

(NACMCF, 1997)

266

Monitoring

- What
- How
- When (Frequency)
- Who

267

What Will Be Monitored?

- The critical limit parameter
  - e.g., oven temperature, time (belt speed), product pH
- The critical limit and monitoring activity must be suited to each other.
  - e.g., chicken temperature vs. oven temperature and belt speed

268

How Will It Be Monitored?

- Measurements, e.g. pH, time, temperature, water activity, etc.
- Observations, e.g. screen is intact and in place, ingredient is added, etc.

Note: Monitoring activities must provide a real-time assessment of the status of the CCP.

269

When Will It Be Monitored?

- Continuous
  - preferred
- Discontinuous
  - periodically, specified frequency

270

Considerations for Periodic Monitoring

- Interval must be short enough to detect possible deviations
- Frequency should not be overly burdensome
- Consider the amount of variability in the parameter
- Consider how close the operating parameter is to the CL
- Consider how much product you are willing to sacrifice

271

When Will It Be Monitored?

- It is important to conduct the monitoring activities at least as frequently as specified in the HACCP plan.
- Missing a monitoring activity can have the same consequence as not meeting a CL.

272

Who Will Perform Monitoring?

- Designate in the HACCP plan who will be responsible for monitoring the CL(s) for each CCP.
- Adequately train personnel to perform monitoring procedures and to prepare appropriate records.
- Provide "backup."

273

Example: Screen

- What is monitored?
  - screen intact
- How is it monitored?
  - visually
- When is it monitored?
  - at start up, at end of operation
- Who monitors it?
  - production employee

274

Regulatory Requirements

- Require HACCP plans to list the monitoring procedures and frequencies for each CCP to ensure compliance with the critical limits.
- Monitoring records must be prepared when monitoring activity occurs
  - Records subjected to record-keeping requirements

275

Questions?

276

Corrective Actions

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Chapter 11

277

HACCP PRINCIPLE 5

Establish
Corrective Actions

278

Corrective Actions

- Procedures followed when a deviation occurs.
- Corrective actions must be taken whenever a CL is violated and the CCP is out of control.

279

Corrective Actions - General

- In a well designed HACCP program, whenever a deviation occurs, specific corrective action is already assigned, the CCP will be brought back into control, and no potentially violative product will leave the facility.

280

The corrective actions procedures outlined in the HACCP plan should:

A) Determine and correct the cause of non-compliance;
B) Determine disposition of non-compliant product;
C) Record the corrective actions that have been taken.

(NACMCF, 1997)

281

Adjusting the Process

- Some potential deviations can be prevented by automatic controls
  - e.g., flow diversion valve
- Operators can adjust process manually
  - e.g., increase cook time
- Can prevent the need to hold product

282

Process adjustments

- Actions taken in response to deviations from an operating limit are not corrective actions if CL is not violated.

283

Product Held for Deviations

- What tests can evaluate safety?
- Is safety in question?
- Can product be diverted to another use?
- Can product be reprocessed or reworked?
- How can product be safety discarded?
- What records are needed?

284

Responsibility for Decision-Making

- It is essential to describe clearly the responsibility for making decisions about taking corrective actions.
- A responsible individual should have the authority to make decisions on the production floor in order to maintain appropriate control of the operations.

285

Corrective Action Records

- Actual production records or a reference to the production records related to any products involved in the deviation.
- Names and recommendations of authorities regarding final disposition of product.
- A record describing the actions
  - Corrective action log

286

Corrective Action Log

- # units and code (product identification)
- Action taken (by whom)
- Rationale for decision
- Disposition

287

Regulatory Requirements

- Corrective actions must be taken in response to a deviation.
  - Records required
- For meat and poultry products
  - HACCP plan must describe corrective actions.
- For juice or seafood products
  - Written corrective action procedures may be included in HACCP plan, but predetermined procedures are not required.

288

Regulatory Requirements

9 CFR 417.3 Corrective Actions.

- The HACCP plan shall describe the corrective actions to be taken, and assign responsibility for taking corrective action, to ensure:

1) The cause of the deviation is identified and eliminated;

289

Regulatory Requirements
9 CFR 417.3 (cont.)

2) The CCP will be in control after the corrective action is taken;
3) Measures to prevent recurrence are established; and
4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

290

Where No Corrective Action Has Been Established

- Hold product
- Review acceptability
- Correct cause of deviation
- Reassess HACCP plan

291

Questions?

292

Verification Procedures

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International HACCP Alliance

Chapter 12

293

Principle No. 6

Establish Verification
[and Validation] Procedures

294

Verification - Definition

Those activities, other than monitoring, that determine the validity of the HACCP plan and that the HACCP system is operating according to the plan.

(NACMCF, 1997)

295

Validation - Definition

The element of verification that focuses on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the identified hazards.

(NACMCF, 1997)

296

Initial Validation

- Includes documenting scientific basis for control
  - Scientific publications
  - Regulatory documents
  - Models
  - Expert advice
  - In-plant measurements, observations

297

Initial Validation

- Assure that the plan is adequate for controlling food safety hazards
- Determine control parameters can be adhered to
- Confirm plan is being implemented properly
- Adjust plan if deficiencies found

298

Validation Example - Cooking Process for Shrimp Egg Rolls

- Scientific justification for heating time and temperature
  - Destroy pathogens of concern
- Study to confirm conditions of cooking step
  - Delivers required time and temperature to each egg roll

299

Validation Example - Pasteurization for Orange Juice

- Scientific justification for critical limit of minimum 160 °F/ 3 sec
  - Delivers 5-log reduction of vegetative pathogens (Mazzotta, 2001)
- Confirm conditions of pasteurization can be met in the facility
  - Pasteurizer delivers minimum 160 °F
  - Flow rate assures minimum 3 sec

300

Verification

- Ensures HACCP plan properly implemented
- Involves reviews, audits, tests

301

Types of Verification

- "Routine" verification that the CCPs are in control and effective
- Verification that the HACCP system is operating according to the HACCP plan
- Regulatory verification

302

Verification of CCPs

- Evaluation of the day-to-day compliance of the activities at each CCP with the HACCP Plan.
- Procedures conducted less frequently than the monitoring activities.
- Usually conducted by management or other specially trained personnel.

303

CCP Verification Activities

- Calibration of all instruments used in monitoring, corrective actions and verification
- Review of records (monitoring, corrective actions and verification)
- Independent check on the adequacy of the CCP to control the identified hazard

304

Calibration

- Goal – ensure accuracy
- Out of tolerance – recalibrate, replace, review measurements taken with the device

305

Record review

- Necessary to ensure that all HACCP plan requirements have been met and are accurately documented
- Conducted by a designated, qualified individual
- Documented by signing and dating the record
- Useful to detect deficiencies

306

Record review

- FDA – within one week of day record was made
- FSIS – prior to shipment of product

307

Types of Independent Checks

- Direct observation of monitoring activities and corrective actions
- Performance of monitoring activity by second individual
- Alternative method to verify adequacy of the hazard control, e.g., sample and test

308

HACCP System Verification

The overall objective is to verify that the HACCP plan is being effectively implemented and followed.

309

HACCP System Verification

Compliance Audit of HACCP System
- Records review
- On-site observations

310

HACCP System Verification

On-site observations
- Observe monitoring activities
- Confirm operator's knowledge of CCP's operation
- Confirm operator's knowledge of actions to take if there is a deviation
- Examine in-process monitoring records

311

HACCP System Verification

Records review
- HACCP plan
- Product/process description and flow diagrams
- Audit reports of prerequisite programs
- Selected monitoring, corrective action, verification records
- Previous HACCP audit reports

312

Regulatory Considerations

- Current US HACCP regulations relegate responsibility for verification to industry
- FSIS will verify adequacy of HACCP plan for meat and poultry products

313

Verification by FSIS

- Reviewing the HACCP plan
- Reviewing CCP and other HACCP records
- Reviewing and determining the adequacy of corrective actions taken
- Reviewing the critical limits
- Direct observation or measurement at a CCP
- Sample collection and analysis to determine the product meets all safety standards
- On-site observations and record review

314

Regulatory Considerations

- FDA also will verify compliance with and adequacy of HACCP plan for seafood and juice products

315

Revalidation = Reassessment

U.S. regulations require reassessment at least annually or whenever any changes occur that could affect accuracy of the hazard analysis or effectiveness of the HACCP plan.

316

Changes Warrant Reassessment

- Raw materials or source of raw materials;
- Product formulation;
- Processing methods or systems, including computers and their software;
- Packaging;
- Finished product distribution systems; or
- The intended use or consumers of the finished product.

317

Other Reasons for Reassessment

- HACCP plan is found inadequate
- Compliance to plan is difficult (deviations)
- New pathogen linked to product type
- Recalls on similar foods, ingredients
- Consumer complaints
- New information on safety of product
- Foodborne illness due to product category

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Questions?

319

Record-Keeping

Presented by
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Chapter 13

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HACCP Principle 7

Establish Record-keeping and Documentation Procedures

321

HACCP Records

- Provide evidence that the HACCP plan is being followed (Required for products under regulatory HACCP)
- Document safety of product
- Provide a mechanism to learn of potential problems

322

Types of HACCP Records

1) Summary of the hazard analysis
2) The HACCP plan
3) Support documentation
4) Daily operational records

323

1) Summary of the Hazard Analysis

- Records of the discussions and decisions of the HACCP team
- Complete hazard analysis
  - potential hazards identified
  - hazards evaluated as significant
  - justifications for decisions
  - selection of control measures

324

2) HACCP Plan Records

- The NACMCF recommends that HACCP plan records include:
  - list of the HACCP team and assigned responsibilities
  - description of the food, its distribution, intended use and consumers
  - verified flow diagram with CCPs
  - HACCP Plan Summary Table

325

3) Support Documentation
(The rationale behind the HACCP plan)

- Written hazard analysis
- Establishment of CCPs
- Establishment of critical limits
- Establishment of monitoring procedures
- Establishment of corrective actions
- Establishment of verification procedures
- Summary of prerequisite programs that support the HACCP system

326

4) Daily Operational Records

- Three basic types:
  - Monitoring records
  - Corrective action records
  - Verification records
- Purpose: document implementation
- Tool for management
- Provide information regarding trends

327

All records should include:

- Name and location of processor
- Date and time of activity
- Signature or initials of responsible individual
- Identity of product and production code, where appropriate
- Actual observations or data values obtained during monitoring
- Reviewer's signature and date of review

328

Record-keeping System

- Document control is important
- HACCP plan, charts, forms, SOPs and other instructions must be kept current
  - Outdated materials should be discarded immediately to avoid confusion
- Computerized records must ensure the integrity of the data and electronic signatures

329

Record Review

- Conducted by a designated, qualified individual
  - Necessary to ensure that all HACCP plan requirements have been met and are accurately documented
- Documented by signing and dating the record
- Used to detect deficiencies in record-keeping and other procedures

330

Documentation

Written hazard analysis and HACCP plan

… should be signed and dated by the most responsible person on site or higher authority.

... should be signed and dated upon initial acceptance, any modifications, upon verification and validation.

331

Record Retention

- Regulatory requirements for HACCP record retention
  - At least 1 year - slaughter activities, perishable or refrigerated products.
  - At least 2 years - frozen, preserved or shelf-stable products.
- Products not covered by a HACCP regulation
  - Consider shelf-life of products and other regulatory requirements.

332

Other Requirements for Record Retention

- Low-acid canned food and acidified foods regulations
  - 3 years
- Adhere to longest time that applies to product

333

Record Requirements in HACCP Regulations

Required Records	USDA/FSIS Meat & Poultry	FDA Juice	FDA Seafood
Written Hazard Analysis	X	X	
Flow chart	X		
Documentation of intended use	X		
Written HACCP plan	X	X	X
Decision-making documents	X		
CCP monitoring records	X	X	X
Calibration records	X	X	X
Corrective action records	X	X	X
Verification records	X	X	X
Product codes and other info	X		
Records relating to adequacy of processes		X	X

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Regulatory Access to Records

- Required HACCP records must be made available to an inspector upon request.
- HACCP records copied by a government inspector have the potential to be released to the public through the Freedom of Information Act (FOIA).
- Companies should develop SOPs for records access protocols.

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Questions?

336

Organizing and Managing HACCP Programs

Presented by
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International HACCP Alliance

Chapter 14

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Making HACCP Work

- Must become an integral part of the operation
- Must be organized and managed to assure that it is operating correctly and maintained appropriately

338

Organize to Avoid Problems

- Management must provide proper support:
  - Statement presenting corporate policy
  - Resources ($, time, people, equipment, training)
  - Provide for assessment

339

Costs

- Training HACCP team, managers, and other employees
- Time for HACCP team to develop HACCP plan
- Upgrade equipment (e.g. monitoring equipment)
- Time and personnel needed for monitoring, recordkeeping, and CA

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Costs

- Training HACCP team, managers, and other employees
- Time for HACCP team to develop HACCP plan
- Upgrade equipment (e.g. monitoring equipment)
- Time and personnel needed for monitoring, recordkeeping, and CA

341

Benefits

- Greater employee awareness of food safety and needed control measures
- Continuous monitoring reveals problems quickly and enables prompt correction which results in less waste and down time
- Recordkeeping and record review make employees more accountable
- More efficient handling of deviations

342

HACCP Coordinator

- Provides leadership and guidance for the development and implementation of the HACCP plan
- Special skills:
  - Technical skills to develop science-based plan
  - Interpersonal skills to facilitate teamwork

343

HACCP Team

- Multidisciplinary
  - Operations
  - Engineering
  - Maintenance and sanitation
  - QA/QC
  - Management
  - Outside assistance

344

HACCP Team

- Primary duties
  - Develop and maintain HACCP plan and system
  - Develop SOPs to facilitate HACCP implementation

345

Strategy for Developing a HACCP Plan

- Careful planning, avoid being overwhelmed
  - Assignment of small tasks
  - Delegate
- Review all operations, identify the approach first

346

Strategy for Developing a HACCP Plan

- Careful planning, avoid being overwhelmed
  - Assignment of small tasks
  - Delegate
- Review all operations, identify the approach first

347

Strategy (continued)

- Develop a model plan for one product and one line
- Ad hoc teams assembled for new products to work with HACCP team
- Expand to entire plant covering all products/production lines

348

Strategy (continued)

- Multiple products may be grouped under a single HACCP plan
  - Hazards, CCPs, critical limits, and procedures must be essentially the same
    - any features unique to a specific product or method must be clearly delineated
- Some HACCP plans may be based on a unit operations approach
  - e.g., HACCP in the foodservice sectors

349

Implementing a HACCP Plan

- Train and retrain
  - Line workers/key operators
  - Assess training and expertise
- Trial period
  - Expect problems
  - Initial validation
- Evaluate and review progress

350

Managing a HACCP Program

- HACCP programs need appropriate support and management.
- All responsibilities must be clearly defined.
  - Develop appropriate SOPs
- Define reporting lines and interaction of various groups.
- Have a system for evaluating new products or changes related to ingredients and processing operations.

351

Systems for Evaluating New Products

- Develop structure evaluating new products and processes.
- Develop HACCP plan for new product/process before production begins.

352

Systems for Evaluating Product/Process Changes

- Essential the HACCP team evaluates for impact on safety of the food
- Should develop a policy that prohibits changes from being made without the evaluation

353

Systems for Evaluating Evolving Hazards

- Pay attention to food safety issues for similar products/processes.
- Reassess HACCP plan if needed.

354

Day-to-Day Management

- Daily review of records makes it easier to manage the plan
- Management can receive daily reports related to food safety
- Spot trends that may trigger adjustments to a process or operation

355

Periodic Evaluation and Revision

- In addition to day-to-day reviews, have periodic review of the entire plan to assure that it is working properly.
- Internal and external audits help determine if changes are needed.
- Team reviews audit report and forwards to management with recommendations.

356

Summary

- HACCP provides a systematic, structured approach to assuring safety of food products
- Success depends on:
  - Management commitment
  - HACCP team's managing and continually improving HACCP system

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Questions?

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HACCP Regulations
9 CFR 417
21 CFR 123
21 CFR 120
Intro to
21 CFR 117 Subpart C

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Chapter 15

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HACCP and the Regulatory Agencies

Chapter 15

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Regulatory HACCP

- Relatively recent
- Two primary agencies:
  - USDA/FSIS
  - US Dept. of HHS/FDA

361

USDA/FSIS Jurisdiction

- Meat and poultry containing products
- Liquid, frozen, and dried egg products

362

FDA Jurisdiction

- All foods other than meat, poultry and egg products
  - Includes processed fruits and vegetables, grain products, juice, dairy, seafood and shell eggs

363

US HACCP Regulations
USDA/FSIS

"Hazard Analysis and Critical Control Point (HACCP) Systems" for meat and poultry products

9 CFR Part 417

364

Format/Table of Contents

- **PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

§ = Section

§ 417.1 Definitions.
§ 417.2 Hazard Analysis and HACCP plan.
§ 417.3 Corrective actions.
§ 417.4 Validation, Verification, Reassessment.
§ 417.5 Records.
§ 417.6 Inadequate HACCP Systems.
§ 417.7 Training.
§ 417.8 Agency verification.

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US HACCP Regulations
USDA/FSIS

"Hazard Analysis and Critical Control Point (HACCP) Systems" for meat and poultry products

9 CFR Part 417

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US HACCP Regulations
FDA

"Hazard Analysis and Critical Control Point (HACCP) Systems" for juice

21 CFR Part 120

"Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products"
21 CFR Part 123

367

Other Relevant U.S. Regulations

FDA

"Hazard Analysis and Preventive Controls for Human Food"

21 CFR 117 Subpart C

- This regulation includes requirements beyond basic HACCP principles

368

Hazard Analysis

- FDA, FSIS: Every processor shall conduct, or have conducted for it, a hazard analysis.
- FSIS, FDA-Juice: Written hazard analysis required.

369

Hazards To Be Considered

- Natural toxins
- Microbiological contamination
- Chemical contamination
- Pesticides
- Drug residues
- Decomposition
- Parasites
- Unapproved use of additives
- Physical hazards
- Zoonotic diseases (FSIS)
- Allergens (FDA-Juice)

370

Hazards To Be Considered

- FDA
  - Fish & Fishery Products Hazards & Controls Guide
  - Juice Products Hazards & Controls Guide
  - Hazard Analysis and Risk-Based Preventive Controls Guide
- FSIS
  - Hazard Identification Guide
  - *E. coli* O157:H7 in raw ground beef
  - *Listeria monocytogenes* in RTE products
  - Control the use and declaration of the ingredients identified by FALCPA

371

HACCP Plan

FDA, FSIS - Every processor shall have and implement a written HACCP plan whenever

a hazard analysis reveals one or more food safety hazards that are reasonably likely to

occur…

Except ---

372

Exception

Thermally processed, shelf-stable foods (21 CFR 113, 114 or 9 CFR 318 subpart G, 381 subpart X) do not need to consider microbiological hazards (FDA-Seafood HACCP specifies *C. botulinum*) in HACCP Plan.

373

The HACCP Plan Shall Be Signed and Dated

- By the responsible establishment individual.
- Upon initial acceptance, upon modification, and at least annually upon reassessment of the plan.

374

HACCP Plan

- **Must contain components related to the application of HACCP principles, including:**
  - A list of hazards
  - A list of CCPs
  - A list of Critical Limits
  - A list of monitoring procedures
  - Corrective Actions to be used in response to deviations
  - A record-keeping system
  - A list of verification procedures

375

Corrective Actions

- Shall assign responsibility
- Shall ensure that no injurious (adulterated) product enters commerce, the cause of the deviation is corrected, the CCP will be under control after corrective action is taken, and measures to prevent recurrence are established
- Shall be documented

376

Verification and Validation

- **The meat and poultry HACCP regulation lists requirements for:**
  - Initial validation
  - On-going verification activities
    - calibration of process-monitoring instruments
    - direct observations of monitoring activities and Corrective Actions
    - the review of records
  - Reassessment of the HACCP plan

377

Verification and Validation

- **The FDA HACCP regulations specify requirements for:**
  - On-going verification activities
    - a review of consumer complaints
    - the calibration of process-monitoring instruments
    - end-product or in-process tests (optional for most products)
  - Records review
  - Reassessment of the HACCP plan or hazard analysis

378

Reassessment

- Required at least annually or whenever a change occurs that could affect the Hazard Analysis or alter the HACCP plan.
- At least every 3 years for a Food Safety Plan 21 CFR 117 Subpart C requirement

379

Record Retention

- The HACCP regulations require that HACCP records be kept for one year for raw or fresh products, and for two years for frozen, preserved or shelf-stable products.
- Records may be kept off-site after 6 months for meat and poultry and juice products, or upon seasonal closure for seafood and juice products.
  - Retrieve within 24 hours

380

Record Reviews

- Records must be reviewed prior to shipment for meat and poultry products to ensure that all Critical Limits were met and, if appropriate, Corrective Actions were taken.
- HACCP records (monitoring, Corrective Actions and calibration records) for seafood and juice products must be reviewed within one week of when the records were made.

381

Training

- **The current HACCP regulations require that a HACCP trained individual is involved in:**
  - developing the hazard analysis (Juice only)
  - developing the HACCP plan
  - verifying and modifying the HACCP plan
  - reviewing records (FDA)
- Need not be an employee of the firm (FSIS and FDA)
- FDA allows qualification through job experience.

382

Imported Foods

- Regulatory requirements apply to imported products
- FSIS has specific approvals for countries to export to US based on equivalency of inspection system
- FDA - defines responsibilities (verification) for importers, requires evidence of compliance

383

Preventive Control Rules

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 CFR Part 117 subpart C

384

Overview of Key Provisions

- Updated and revised GMPs- Subpart B
- Must have a Food Safety Plan- Subpart C- Hazard Analysis and Risk Based Preventive Controls (HARPC)

385

Requirements

- Training
- Qualified individuals
- Employee training
- Preventive control qualified individual
- Environmental monitoring & testing
- By product diversion from a human food facility to an animal food facility

386

GMPs (subpart B)

- GMPs updated for first time since 1986
- include elements to manage allergen cross-contact –(not just cross contamination)
- Definition of an environmental pathogen

387

The written food safety plan (FSP) MUST include the following elements

- Hazard analysis
- Preventative controls
- Recall Plan if you have a preventive control
- Monitoring
- Verification, including validation
- corrective actions
- recordkeeping

388

Hazard Analysis

- Identify & evaluate known/reasonably foreseeable hazards to determine whether there are any "hazards requiring a preventative control"

" known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing or holding of food would,

389

Hazard Analysis cont.

- based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventative controls) establish one or more preventive controls to significantly minimize or prevent the hazard in a food and

390

Hazard Analysis

Components to manage those controls (such as monitoring, corrections or corrective actions, verification and records) as appropriate to the food, the facility and the nature of the preventive control and its role in the facility's food safety system"

391

Hazard analysis- Economically motivated adulteration

- Facilities are required to consider economically motivated adulteration (EMA) as part of their hazard analysis
- Hazard identification must consider "Hazards that may be intentionally introduced for purposes of economic gain"
- FDA suggests it's practicable to determine whether EMA's

392

Hazard Analysis

Reasonably foreseeable by focusing on circumstances where there has been a pattern of adulteration in the past

393

Hazard analysis- environmental contaminants

- Hazard identification must include
- Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens
- The hazard evaluation must include an evaluation of environmental pathogens whenever a ready to eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure such as a formulation lethal to the pathogen that would significantly minimized the pathogen

394

Definitions

- Environmental pathogen

A pathogen capable of surviving and persisting within the manufacturing, processing, packing or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen

395

Definitions

- Ready to eat food (RTE food)

means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards

396

Preventive Controls

- Identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented (SMOP-ed)
- process controls
- food allergen controls
- sanitation controls
- supply chain controls
- recall plan
- other controls

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Preventive controls

- We may find that many of our PCs are what we used to call prerequisite programs
- These must now have all the management elements of a PC

Monitoring

Verification (records review)

Corrective actions

Records of the above including record review by a Preventive Controls Qualified Individual

Training

As appropriate taking into account both the nature of the preventive controls and their role in the facility's food safety system

398

Qualified Individuals and Employee Training

- The definition of "qualified individual" has changed

"Preventive controls qualified individual" now is used, where "qualified individual" previously was used

-Qualified individual" now is defined more broadly, essentially to means that employees must be qualified to do their jobs

All employees must be "Qualified individuals"

399

Preventive Controls Qualified Individual

- Must prepare or oversee certain preventive controls functions, such as preparing the food safety plan and conducting or overseeing validation and verification activities

400

Questions?

401

§ 117.7 Applicability of subparts C, D, and G of this part to a facility solely engaged in the storage of unexposed packaged food.

(a) *Applicability of subparts C and G.* Subparts C and G of this part do not apply to a facility solely engaged in the storage of unexposed packaged food.

(b) *Applicability of subpart D.* A facility solely engaged in the storage of unexposed packaged food, including unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 117.206 for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

§ 117.8 Applicability of subpart B of this part to the off-farm packing and holding of raw agricultural commodities.

Except as provided by § 117.5(k)(1), subpart B of this part applies to the off-farm packaging, packing, and holding of raw agricultural commodities. Compliance with this requirement for raw agricultural commodities that are produce as defined in part 112 of this chapter may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

[81 FR 3956, Jan. 25, 2016]

§ 117.9 Records required for this subpart.

(a) Records that document training required by § 117.4(b)(2) must be established and maintained.

(b) The records that must be established and maintained are subject to the requirements of subpart F of this part.

Subpart B—Current Good Manufacturing Practice

§ 117.10 Personnel.

The management of the establishment must take reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (*e.g.,* by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

(1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-

contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

§ 117.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

(5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (*i.e.,* manufacturing, processing, packing, and holding). The plant must:

(1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

(2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.

(3) Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food,

food-contact surfaces, or food-packaging materials with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 117.35 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.* (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(c) *Pest control.* Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

(1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation,

the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(e) *Sanitation of non-food-contact surfaces.* Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

(f) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

§ 117.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

(a) *Water supply.* The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.* Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

(e) *Hand-washing facilities.* Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) *Rubbish and offal disposal.* Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

§ 117.40 Equipment and utensils.

(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

§ 117.80 Processes and controls.

(a) *General.* (1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

(b) *Raw materials and other ingredients.* (1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

(2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

(5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(6) Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.

(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

(c) *Manufacturing operations.* (1) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

(6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

(8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.

(9) Food, raw materials, and other ingredients that are adulterated:

(i) Must be disposed of in a manner that protects against the contamination of other food; or

(ii) If the adulterated food is capable of being reconditioned, it must be:

(A) Reconditioned (if appropriate) using a method that has been proven to be effective; or

(B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

(11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

(12) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

(14) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.

(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with §117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§ 117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

§ 117.95 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in §507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

[80 FR 56337, Sept. 17, 2015]

§ 117.110 Defect action levels.

(a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at*http://www.fda.gov/pchfrule* and at*http://www.fda.gov*.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 117.126 Food safety plan.

(a) *Requirement for a food safety plan.* (1) You must prepare, or have prepared, and implement a written food safety plan.

(2) The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.

(b) *Contents of a food safety plan.* The written food safety plan must include:

(1) The written hazard analysis as required by § 117.130(a)(2);

(2) The written preventive controls as required by § 117.135(b);

(3) The written supply-chain program as required by subpart G of this part;

(4) The written recall plan as required by § 117.139(a); and

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a)(1);

(6) The written corrective action procedures as required by § 117.150(a)(1); and

(7) The written verification procedures as required by § 117.165(b).

(c) *Records.* The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 117.130 Hazard analysis.

(a) *Requirement for a hazard analysis.* (1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.

(2) The hazard analysis must be written regardless of its outcome.

(b) *Hazard identification.* The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) *Hazard evaluation.* (1)(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

Student Information Sheet

First Name

M.I.

Last Name

Address

City/State/Zip

Country

Phone Ext. Fax

Email

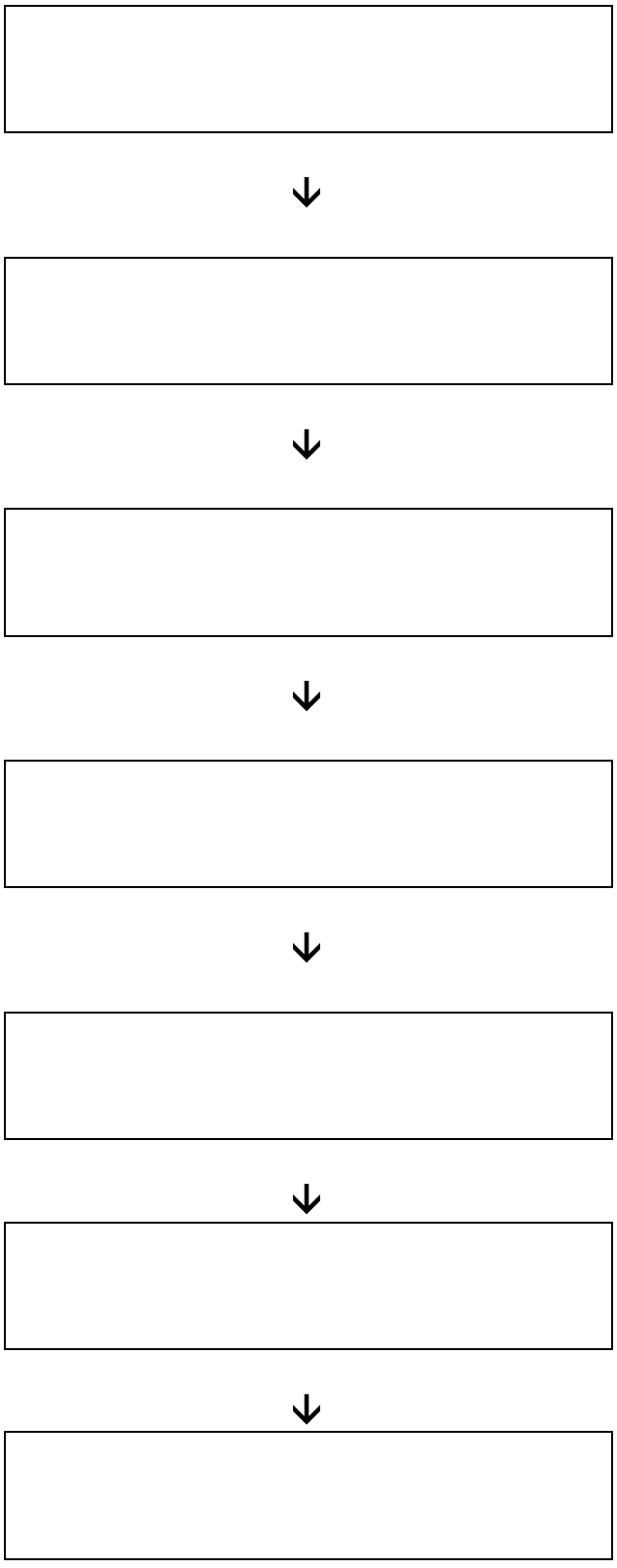
Training Location/City Training Location/State

Training Date

Company Name

Professional Affiliation (*please check one*)

❑ Industry ❑ Government/Regulatory ❑ Education ❑ Consultant ❑ Other



HAZARD-ANALYSIS WORKSHEET

Firm Name:	Product Description:
Firm Address:	Method of Storage and Distribution:
	Intended Use and Consumer:

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/processing step	Identify potential hazards introduced, controlled or enhanced at this step (1)	Are any potential food-safety hazards significant? (Yes/No)	Justify your decisions for column 3.	What preventative measures can be applied to prevent the significant hazards?	Is this step a critical control point? (Yes/No)
	Biological Chemical Physical				
	Biological Chemical Physical				
	Biological Chemical Physical				
	Biological Chemical Physical				

HAZARD-ANALYSIS WORKSHEET (continued)

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/processing step	Identify potential hazards introduced, controlled or enhanced at this step (1)	Are any potential food-safety hazards significant? (Yes/No)	Justify your decisions for column 3.	What preventative measures can be applied to prevent the significant hazards?	Is this step a critical control point? (Yes/No)
	Biological Chemical Physical				
	Biological Chemical Physical				
	Biological Chemical Physical				
	Biological Chemical Physical				
	Biological Chemical Physical				
	Biological Chemical Physical				

HACCP Plan Form

Firm Name: Firm Address:	Product Description: Method of Storage and Distribution: Intended Use and Consumer:

(1) Critical Control Point	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective Actions	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			

Signature of Company Official: Date:

HACCP Plan Form (continued)

(1) Critical Control Point	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective Actions	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			