

Introduction to HACCP

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- **H**azard
- **A**nalysis
- **C**ritical
- **C**ontrol
- **P**oints

A proven food safety management system applicable to the entire food chain

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What is HACCP?

- A system to eliminate, reduce or minimize hazards associated with foods
- A system that is required by the regulatory agencies for some products:
 - Seafood (FDA)
 - Meat and Poultry products (USDA)
 - Juices (FDA)
- Food Safety Modernization Act (FSMA)

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The US Regulatory Agencies

- USDA – jurisdiction over meat and poultry products, including slaughter and processing and liquid, frozen and dried egg products
 - FSIS – Food Safety and Inspection Services
- FDA – jurisdiction over all other foods, including seafood, juice, dairy and shelled eggs
 - CFSAN – Center for Food Safety and Applied Nutrition

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What is HACCP?

- A system based on scientific concepts
- The objective is to prevent problems
- A system separate and different from Quality Control
 - Color Biological hazards
 - Texture Chemical hazards
 - Taste Physical hazards

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A HACCP System...

- identifies food safety related problems associated with a product or facility
- determines specific factors which must be controlled to prevent (minimize) problems from occurring
- establishes programs that will measure and document that the factors are being controlled properly

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What are hazards?

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

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Biological hazards

Pathogens – can cause illnesses

- Infections - caused by swallowing living pathogens, which grow within the body and cause illness
- Intoxications - caused by swallowing toxin (poison) that has been formed in food as pathogens grow

Reactions usually occur within hours or days of consumption

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Biological hazards

- Bacteria
 - Salmonella spp.
 - *E. coli* 0157:H7
 - *Listeria monocytogenes*
- Viruses
 - Hepatitis A
 - Norwalk virus
- Parasites
 - Cryptosporidium
 - Cyclospora

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Characteristics of biological hazards

- What they need to grow?
 - Food, water
 - Environment (temperature, oxygen, etc.)
- How are they destroyed, controlled?
 - Heat
 - Cold
 - Acid, preservatives
 - Remove oxygen, water, etc.

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Potential Controls for Biological Hazards

- Heating time and temperature (blanching, pasteurizing, thermal process)
- Refrigeration/Freezing
- Label preparation instructions
- pH control (formulation, processing)
- Product formulation and size (thickness)
- Moisture content and water activity
- Residual sanitizer levels
- Cross contamination prevention

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Chemical Hazards...

- Naturally-occurring chemicals
- Intentionally added chemicals
- Unintentional/incidental chemicals

- Reactions may occur immediately or may accumulate in the body over time (acute vs chronic reactions)

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Naturally-occurring chemicals

- Allergens
- Mold toxins
 - Patulin, Aflatoxin, Ochratoxin
- Shellfish toxins (oysters)
- Fish toxins
 - Scombrototoxin (Histamine)

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Intentionally added chemicals

- Preservatives
 - Sodium nitrite, Sodium benzoate
 - Sulfites
- Colors
 - FD&C Yellow # 5
- Nutrients
 - Vitamin A
- Flavor enhancer
 - MSG

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Unintentional/Incidental additives

- Pesticides
- Sanitizers
- Packaging components
- Lead/tin (canned products)
- Cross contaminants
- Antibiotics
- Hormones

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Potential Controls for Chemical Hazards

- Ingredient and materials specifications
- Controlled raw material and ingredient sourcing
- Controlled storage of raw material
- Allergen control programs
- Employee training

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Physical hazards...

- Any potentially harmful extraneous matter not normally found in food
- Usually associated with 'injury' like cuts, broken teeth, choking
- Reaction is immediate

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Potential physical hazards in foods

- Metal
- Wood
- Glass
- Plastic
- Stones
- Bones

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Potential Controls for Physical Hazards

- Metal detectors
- Magnets
- X-ray equipment
- Screens/Sieves
- Raw material contract stipulations
- Manual removal of contaminants

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But ... before you start

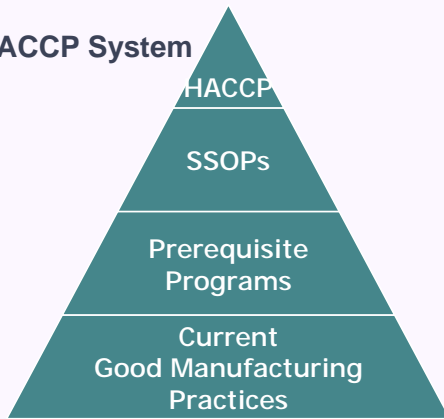
- Must have other programs established:
 - Good Manufacturing Practices (GMPs 21CFR110)
 - Sanitation Standard Operating Procedures (SSOPs)
 - Prerequisite Programs
 - Preventive maintenance
 - Pest control
 - Chemical control
 - Supplier controls
 - Education and training programs

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The HACCP System



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Preliminary Steps

1. Assemble the HACCP Team
2. Describe the food and its distribution
3. Describe the intended use and consumer (different sensitivities)
4. Develop flow diagram
5. Confirm flow diagram

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The HACCP Team

- Responsible for developing a plan, obtaining and giving training (education) and determining responsibilities
- Will meet, evaluate the facility, procedures, ingredients and apply the 7 principles of HACCP

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HACCP Principles

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Determine Critical Limits
4. Determine Monitoring Procedures
5. Determine Corrective Actions
6. Determine Verification and Validation Procedures
7. Establish Documentation and Recordkeeping Procedures

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1. Conduct a Hazard Analysis

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

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Potential hazards to consider ...

- Biological hazards
 - Pathogenic microorganisms
- Chemical hazards
 - Naturally occurring chemicals
 - Intentionally added chemicals
 - Unintentionally/Incidental chemicals
- Physical hazards
 - Metal, glass, wood, stones, etc.

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Hazard Analysis

- Evaluate each hazard listed for
 - Likelihood of occurrence
 - Severity of illness or injury
- Decide if the hazard needs to be controlled in the HACCP Plan or if it can be controlled 'adequately' in a Prerequisite Program

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Factors to consider:

- Prerequisite Programs
 - may minimize the likelihood of occurrence
- Frequency of occurrence of hazard
 - past experience
- Distribution
- Storage
- Consumer preparation

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2. Determine Critical Control Points

- Critical Control Point (CCP) = point, step or procedure in a food process at which a control measure can be applied and at which control is essential to **prevent** or **eliminate** a food safety hazard or **reduce** it to an acceptable level

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Critical Control Points

- Depend on:
 - Formulation
 - Process flow
 - Equipment
 - Ingredient selection
 - Sanitation and other support programs
- Are specific to:
 - Product
 - Process
 - Line

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3. Establish Critical Limits

- A criterion which separates acceptability from unacceptability
 - Process specifications (time/temp)
 - Numerical value or 'yes/no' decisions
- If appropriate limits are not well defined, need to generate data or change the process

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Sources of information on CL's

- Scientific publications
- Regulatory guidelines
- Competent experts
- Experimental studies

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Critical Limits vs. Operational Limits

- Critical Limits
 - Values or parameters necessary to make sure the hazard is being controlled
- Operational Limits
 - Usually set for quality or production purposes;
 - Usually more stringent than Critical Limits
 - If there's a 'deviation' usually make a 'process adjustment'

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4. Establish Monitoring Procedures

- Monitoring = a planned sequence of observations or measurements to assess whether the point, step or procedure is under control

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Monitoring Procedures

- What should be monitored
 - Time, temperature, pH, etc.
 - Make sure it matches the CL
- How it should be monitored
 - Thermometer, recording chart, pH meter, visual observation, etc.
- Frequency
 - Daily, hourly, continuously, etc.
 - As it happens, not after the fact!
 - Minimize hazards and product loss

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Monitoring Procedures

- By whom
 - Line operator, QC tech, etc.
 - Must be properly trained
 - Clearly defined responsibility and time available
 - Initial responsibility for Corrective Actions (Principle 5)
 - Responsible for documentation (accurate, verifiable)

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5. Establish Corrective Actions

- Procedures that must be taken when Critical Limits are not met, in order to eliminate an actual or potential hazard

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Corrective Actions

- Predetermined in HACCP Plan
- Procedures to be taken at each CCP
 - Get production back on track
 - Correct the problem
- Responsibility
 - One person should be assigned to make decisions and everyone else must respect

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Corrective Actions

- Disposition of affected product
 - Divert
 - Reprocess
 - Segregate until evaluated (Release/Destroy)
- Documentation
 - Records showing exactly what happened at every step, including product disposition
- Reassess the HACCP Plan
 - Minimize/Eliminate recurrence!

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A corrective action plan ensures...

- ...no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation
- ...the cause of the deviation is corrected

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6. Determine Verification and Validation Activities

- **Verify** that we are following the Plan we developed ('compliance')
- **Validate** that what we're doing is truly providing a safe food

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Verification vs. Monitoring

- **Monitoring**
 - what occurs during the process to assure the CL's are met
- **Verification**
 - check of the **system** to make sure that it is being followed as written

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Various Types of Verification

- Verification of the CCPs
 - Review of daily monitoring and CA records
 - Review of HACCP plan
 - Calibration of equipment
- Verification of the HACCP System
 - Are the programs that support the HACCP Plan still working as intended?
- Regulatory Verification
 - Is the HACCP Plan/System in compliance with the regulations?

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Validation

- **Validate** that what we're doing is truly providing a safe food
 - Did we consider all the potential hazards?
 - Are we controlling them properly?
 - Is there anything new we need to consider?

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Validation Frequency

1. Initially upon development of the HACCP Plan
2. Annually (at least)
3. Whenever any of the following occurs:
 - changes in raw material
 - changes in product or process
 - adverse review findings
 - recurring deviations
 - new information on hazards or control measures
 - on-line observations
 - new distribution or consumer handling practices

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7. Establish Documentation and Recordkeeping Procedures

- Documentation is the basis of the HACCP Plan
- It must be written down, otherwise ... it didn't happen!!
- Provides opportunity to review trends, and possibly prevent problems
- Difficult at first, but then becomes 'routine'

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Documentation and Records

- HACCP Plan and support documentation used in developing the plan, including hazard analysis
- Documentation of CCP monitoring
- CCP deviation and Corrective Action records
- Verification audits
- Validation documents
- Prerequisite program documentation

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Records

- Data entry
 - Accurate
 - No erasures, write-overs, etc.
 - Corrections are made with single line over incorrect entry, new entry, initials, date
- Review
 - Within prescribed period of time
 - Trained individual
 - Assure that procedures were followed, particularly CA's when deviations occurred

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