


**Risk Assessment  
and Validation**

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**Risk Analysis**

- Risk Assessment
- Risk Management
- Risk Communication



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**7 Principles of HACCP**

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



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## Hazard Analysis

- NACMCF (1998) Definition
  - Develop a list of hazards of such significance that they are reasonably likely to occur if not effectively controlled
- Food safety hazards only, no quality issues



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## Role of Hazard Analysis in HACCP

- Principles 2-7 depend on the Hazard Analysis
- If appropriate hazards not identified
  - Plan won't control hazards
  - Unsafe product produced



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## Who should evaluate?

- HACCP Team
  - Include members of team from different areas of the plant
  - Quality assurance
  - Maintenance
  - Engineering
  - Line workers
  - Purchasing



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### Hazard Analysis – 2 step process

1. Hazard Identification
  - List hazards for each step in flow diagram
2. Hazard Evaluation
  - Likelihood of occurrence
  - Severity



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### Cannot write “cookie cutter” Hazard Analysis

- Hazards can differ based on:
  - Facility
  - Formulation
  - Equipment
  - Pre-Requisite Program Effectiveness
  - Process



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### Hazard Identification

- Brainstorming
- Experts can be consulted but should not write the plan
- Subjective
  - Ask 10 experts = 10 different Hazard Analyses



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### Types of Hazards - Biological

- Viruses
  - Norovirus
  - Hepatitis A
- Parasites
  - *Giardia lamblia*
  - *Toxoplasma gondii*
  - *Trichinella spiralis*
  - *Anasakis simplex*,  
*Taenia solium* &  
*saginata*
- Bacteria
  - *Salmonella*
  - *E. coli* O157:H7
  - *Listeria monocytogenes*
  - *Campylobacter*
  - *Clostridium botulinum*
  - *Clostridium perfringens*
  - *Bacillus cereus*
  - *Staphylococcus aureus*



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### Types of Hazards - Chemical

- Allergens
  - Peanuts, Tree nuts,  
Soy, Eggs, Dairy,  
Wheat, Fish, Shellfish
- Restricted Ingredients
- Insecticides
- Pesticides
- Sanitizer Residues
- Mycotoxins
  - Aflatoxin, Patulin...
- Seafood toxins
  - Scombrototoxin,  
Ciguatoxin...
- Lead, Mercury
- Antibiotics
- Growth hormones



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### Types of Hazards - Physical

- Foreign Objects ranging from 7mm – 25mm
- Metal
  - Jewelry
- Plastic
  - Pens
- Glass
  - Paper clips
- Wood
  - Hair pins



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### Hazard Evaluation

- Remember HACCP addresses product specific hazards
- Pre-requisite programs address hazards to ensure plant environment is safe for food production



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### Hazard Evaluation

- Severity
  - Magnitude and Duration of Illness
  - Public Health Impact
- Likelihood to occur
  - Epidemiological data
  - Plant experience
  - Scientific literature



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### Definition

- Reasonably likely to occur
  - A prudent processor would establish controls because the hazard has occurred or because there is a reasonable possibility it will occur in the particular type of product being processed in the absence of controls



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### Step 1. Process Step

- Hazard identification and evaluation must be performed for each step in the flow diagram



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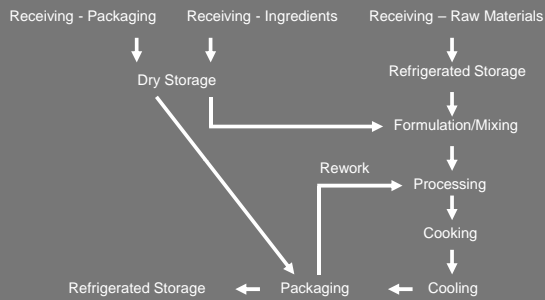
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### Flow Diagram



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### Step 2. Potential Hazard Introduced, Controlled or Enhanced at this step (Biological, Chemical, Physical)

- Identify hazards associated with each step in flow diagram
- Evaluate if hazard is introduced, controlled or enhanced



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**Step 3. Does the hazard need to be addressed in the HACCP plan?**

- Base decision on severity and likelihood of occurrence
- Provide supporting documentation for your decision



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**Step 4. Justification for decision made in previous column**

- Justify “Yes” or “No” whether the HACCP plan needs to address the hazard
- Support your decision based on severity and likelihood of occurrence
- Use supporting documentation



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**Step 4. Justification for decision made in previous column**

- Pre-Requisite Programs
- Letters of Guarantee
- Plant data
- Scientific Literature



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**Step 5. What control measures can be applied to prevent, eliminate or reduce the hazard being addressed?**

- Only answer this question if Step 3 Answer is “Yes”
- Can identify more than 1 control measure for each hazard if appropriate
- **DO NOT** try to identify critical control points



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**Frequency of Hazard Analysis Review**

- Need to evaluate on a regular basis
  - Minimum: annually
  - More frequently is recommended
- Consider changes that affect hazards
  - New equipment
  - Construction
  - Changes in process flow
  - New ingredients/formulation



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**6. Establish Verification Activities**

- Activities other than monitoring that assess plan validity and operation
- “Do we do what we say and do we say what we do”
- Equipment Calibration
- Independent Checks
- Record Review



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### Validation

- Collecting and evaluating scientific information to determine if the plan effectively controls hazards
- “Is it the right thing to do?”



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### Validation Steps

- Initial Validation
- Annual HACCP Plan Reassessment
  - Need to evaluate on a regular basis
  - Minimum: Annually
  - More frequently is recommended



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### Frequency of Reassessment

- Consider changes that affect hazards
  - New equipment
  - Construction
  - Changes in process flow
  - New ingredients/formulation/feeds



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### Resources

- Scientific experts
- Scientific literature
- In-plant data
- Plant records



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### Points for Validation

- Additional or changes to hazards
- Critical Control Points
- Critical Limits
- Monitoring
- Corrective Actions
- Recordkeeping



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### Scientific Literature

- Utilize peer-reviewed publications to support decisions
- Recognize strengths and limitations



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**Collecting In-Plant Data**

- Seek appropriate expertise to develop an appropriate study
- Ensure adequate sample sizes
- Utilize appropriate test organisms

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**Risk Assessment Summary**

- Involve operation employees
- Use your food safety management system
  - Hazard Analysis
  - Validation Activities
- Be actively engaged in your food safety programs

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**Go Cougs!**  
**Go Vandals!**

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