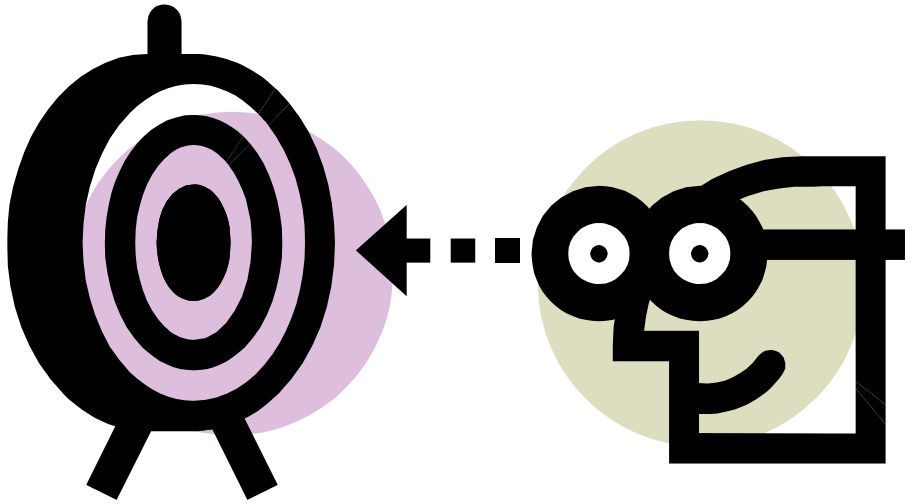
Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Fundamentals of HACCP II
Hazard Analysis

Objectives

- Describe the significance of the hazard analysis on an establishment's HACCP system.
- Describe when and how to verify the adequacy of an establishment's hazard analysis.
- Identify situations in which the establishment has clearly failed to adequately conduct and/or support its hazard analysis.
- Identify when further guidance may be necessary to reach a noncompliance decision.



Purpose of this Training

- A thorough hazard analysis is the key to development of an effective HACCP plan
- An inadequate hazard analysis results in an inadequate HACCP plan regardless of how well the plan is implemented
- Inspection personnel must be able to verify that an establishment's hazard analysis meets regulatory requirements

The Hazard Analysis

- Foundation of entire HACCP System
  - Must be thorough and well supported
  - Considers all potential biological, chemical, and physical food safety hazards
  - Determine the food safety hazards reasonably likely to occur in its process
  - Establish controls for those hazards

Inadequate HA = Insanitary Conditions?

- Insanitary Conditions
  - Filth, like rodent droppings
  - Failure to execute measures intended to ensure sanitary standards are maintained

Conducting a Hazard Analysis

- HA involves 3 general steps:
  - Hazard identification
  - Hazard evaluation
  - Determine control(s) for hazards RLTO

3 Steps

Conducting a Hazard Analysis (2)

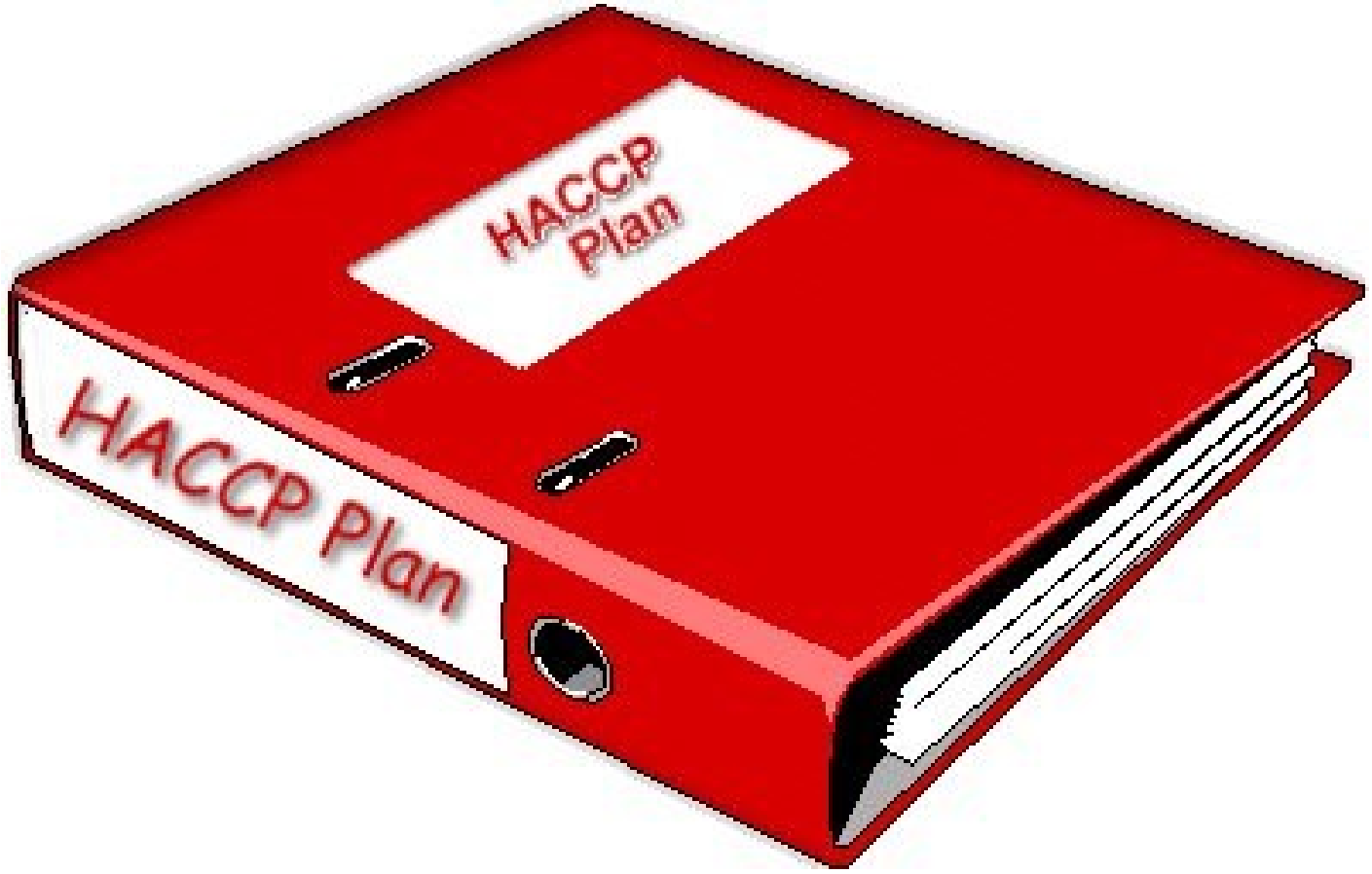
- Identification step
  - Identifies all potential hazards in its production process
  - Consider each step in the process
    - Raw materials, ingredients, activities, storage methods, distribution, intended use or consumer

Conducting a Hazard Analysis (3)

- Evaluation Step
  - Evaluates all hazards to determine likelihood of the risk in the process

Conducting a Hazard Analysis (4)

- Identifying Control Steps
  - For hazards RLTO establishment determines controls to prevent, eliminate, or reduce to acceptable levels
  - Foundation of CCPs in HACCP Plan

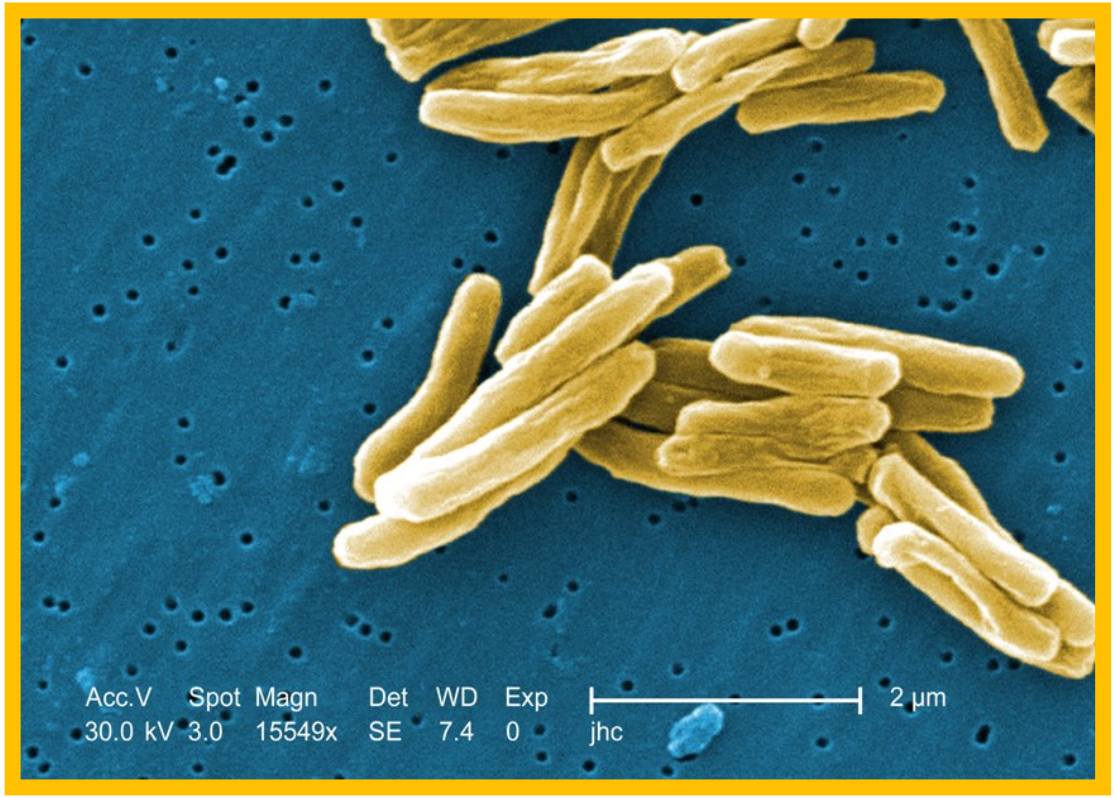


Hazard Analysis Thought Process

- What is your current understanding of the importance of the hazard analysis (HA)?
- What are the possible implications of doing a less than thorough HA?
- Describe the thought process a plant will use in the HA?

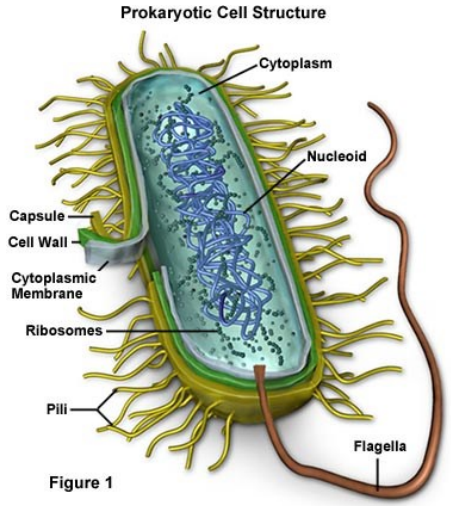
Common Hazards

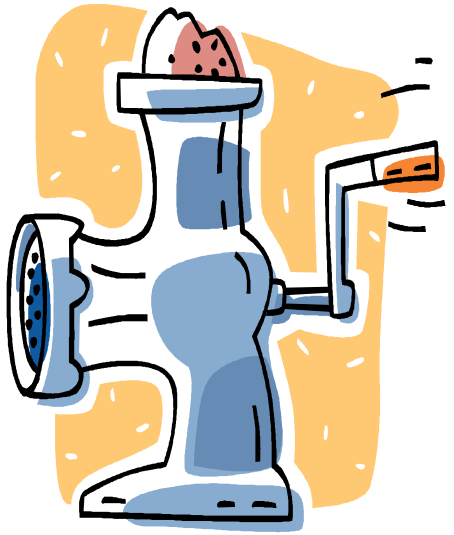
- In this section we will look at common hazards for the various processes.
- Refer to the Hazards Guide



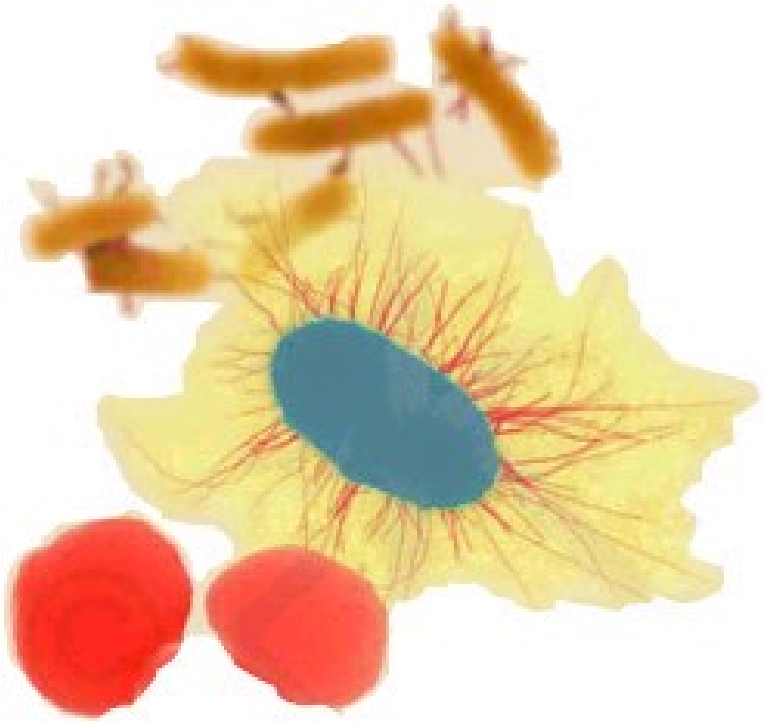
Definition

- Food safety hazard
  - A biological, chemical, or physical agent that is likely to cause illness or injury if not controlled





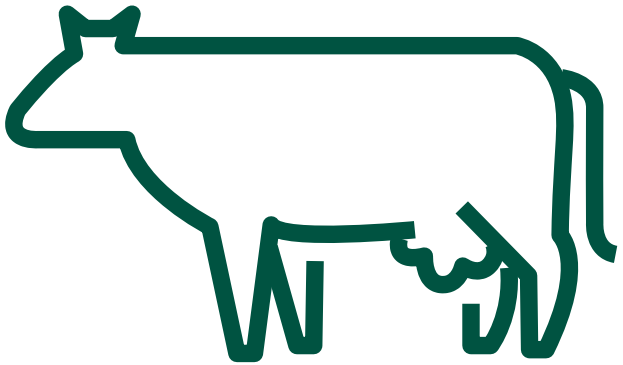
Biological Hazards

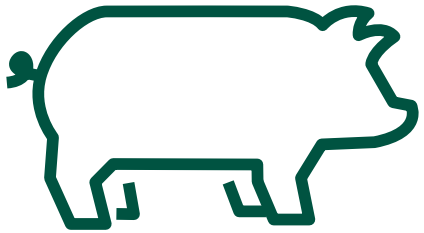


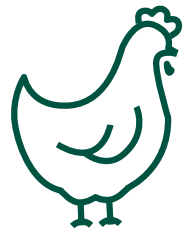
- Bacteria
- Toxins
- Parasites
- Viruses

Biological Hazards – Raw Product Pathogens

- Pathogens most commonly found in raw products as a result of slaughter
    - *Salmonella*
    - *Campylobacter*
    - *E. coli O157:H7*

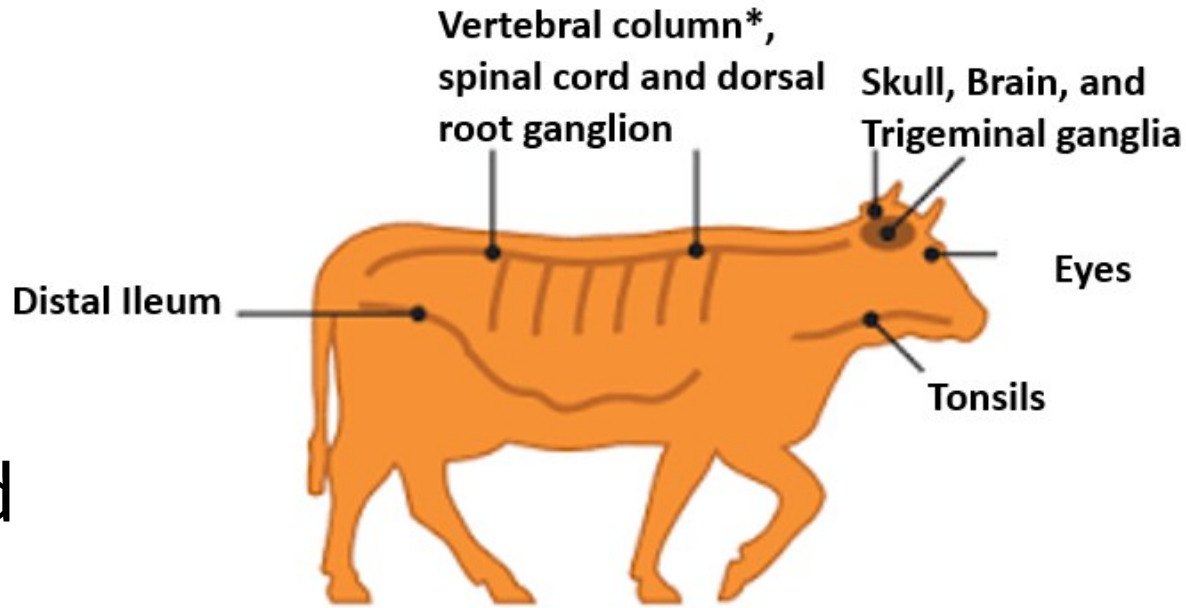






Biological Hazards – Raw Product SRM

- SRMs in beef designated as inedible
- Downers shown to be higher risk for BSE transmission
- Must be considered in hazard analysis of beef operations

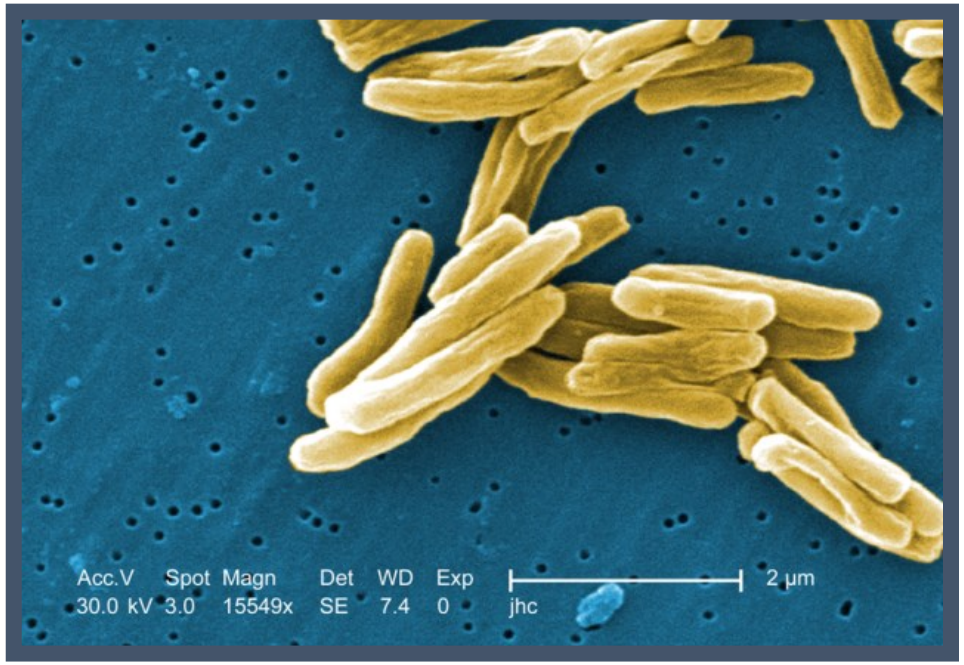


Biological Hazards – Raw Product Pathogen Outgrowth

- Pathogen outgrowth must be considered in the hazard analysis
  - Storage
  - Thawing
  - Any step where conditions may allow proliferation of pathogens

Biological Hazards – RTE/NRTE Products

- Pathogens of concern in RTE/NRTE products include:
  - *Salmonella*
  - *E. coli O157:H7*
  - *Listeria monocytogenes*



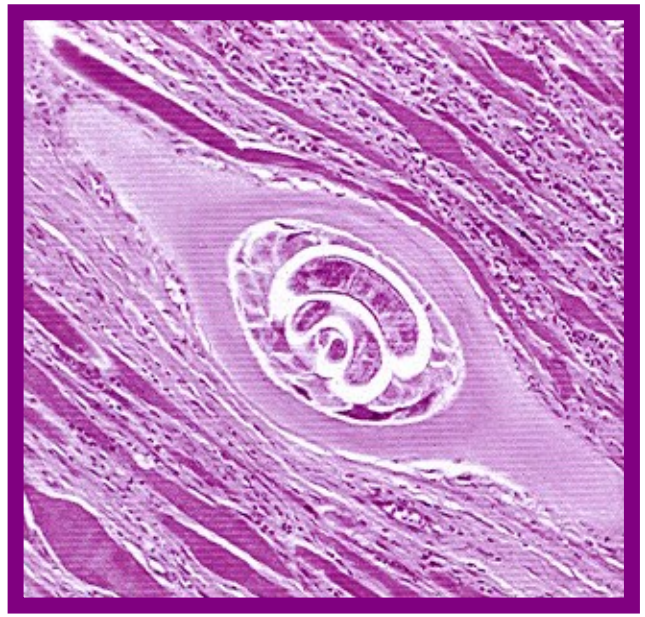
Biological Hazard Controls

- Control Methods
  - Temperature
  - Acidity
  - Salt and drying
  - Lethality
  - Stabilization

Biological Hazards – RTE/NRTE Product Parasites

- Parasitic hazard NRTE pork products
  - Trichinella spiralis

- Control of Parasites
  - Freezing
  - Cooking
  - Low Water Activity (Aw)

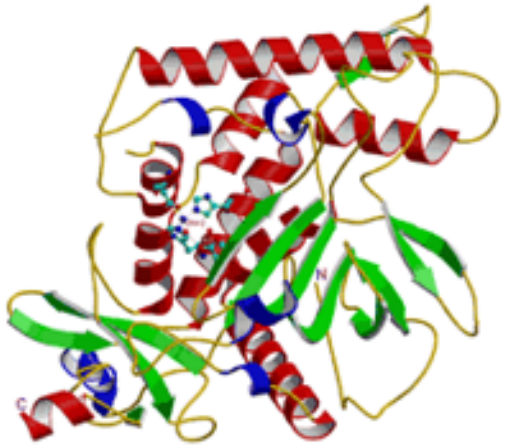


Biological Hazards – RTE/NRTE Product Toxins

- Toxins in RTE/NRTE products from outgrowth of:
  - *Clostridium botulinum*
  - *Clostridium perfringens*
  - *Staphylococcus aureus*

Controls for Biological Hazards – Toxins

- Control of Toxins
  - Prevention
    - Proper retorting/commercially sterile procedures
    - Stabilization
    - Fermentation



Botulinum Toxin

Biological Hazards – RTE/NRTE Product Pathogens

- Primary public health concern in RTE products is *Listeria monocytogenes*
  - Post-lethality contamination in the processing environment
  - Consumer not expected to cook product
  - Results in exposure to the pathogen
  - Highest mortality rate

Biological Hazards – RTE/NRTE Product Other Hazards

- Other public health concerns in NRTE products
  - NRTE products may still contain pathogenic bacteria

Biological Hazards – RTE/NRTE Product Cross Contamination

- Cross contamination potential from raw products is a major area of concern
- Should be considered in hazard analysis

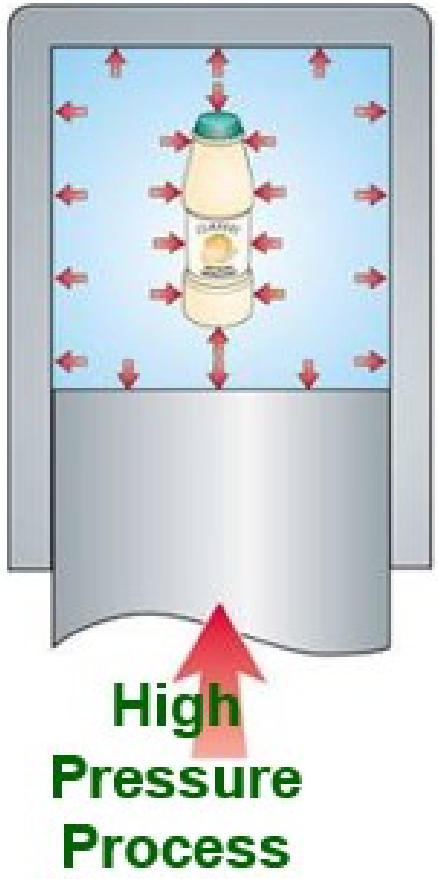
RTE

Biological Hazard Control Methods

- Control Methods
  - Good Manufacturing Practices (GMPs)
  - Sanitation procedures
  - Employee hygiene
  - Separation of not-ready-to-eat and ready-to-eat

Biological Hazards Pathogen Controls

- Control Methods for Pathogens
  - Post-lethality pasteurization
  - Antimicrobials



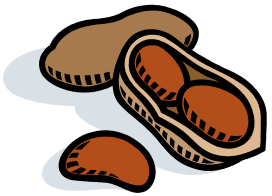
Chemical Hazards

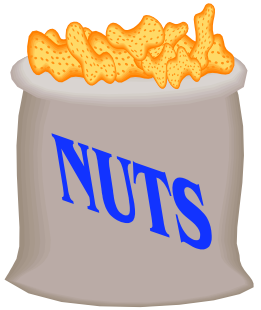
Chemical Hazards – Potential Sources

- Five sources of chemical hazards
  - Agriculture chemicals – animal drugs
  - Establishment chemicals
  - Naturally occurring toxicants
  - Food chemicals
  - Environmental contaminants

Chemical Hazards – Allergens

- Food Allergens
  - Peanuts
  - Soybeans
  - Milk
  - Eggs
  - Fish
  - Crustacea
  - Tree nuts
  - Wheat
  - Sesame





Chemical Hazards – Allergens (2)

- Food Allergens
  - Protein in these foods or food ingredients have been shown to result in an adverse immunological reaction in sensitive individuals.
    - Highly refined oils (e.g., peanut and soybean) may not be a concern because the protein is removed

Chemical Hazards – Food Intolerance

- Food Sensitivities or Intolerances
  - Potential sources of food intolerances which are caused by an adverse reaction in sensitive individuals to the ingredient itself or its chemical composition.
    - Examples, monosodium glutamate (MSG), sulfites, lactose, and Yellow 5 (tartrazine)

Controls for Chemical Hazards

- Controls for allergens/ingredients of public health concern
  - Ensure ingredients which may cause adverse reactions are controlled
  - Consider the potential hazard of cross-contamination and non-declaration of ingredients in the hazard analysis

Chemical Hazard Controls

- Possible controls for allergens/ingredients of public health concern
  - Develop Allergen Awareness and Control Plan (ACP) within the HACCP system
  - Evaluate SSOP and modify it to include procedures to prevent cross contamination between products.

Chemical Hazards Controls (2)

- Controls for other chemical hazards
  - Intended use
  - Appropriate concentrations
  - Proper storage
  - Labeling
  - Letters of guarantee

Physical Hazards

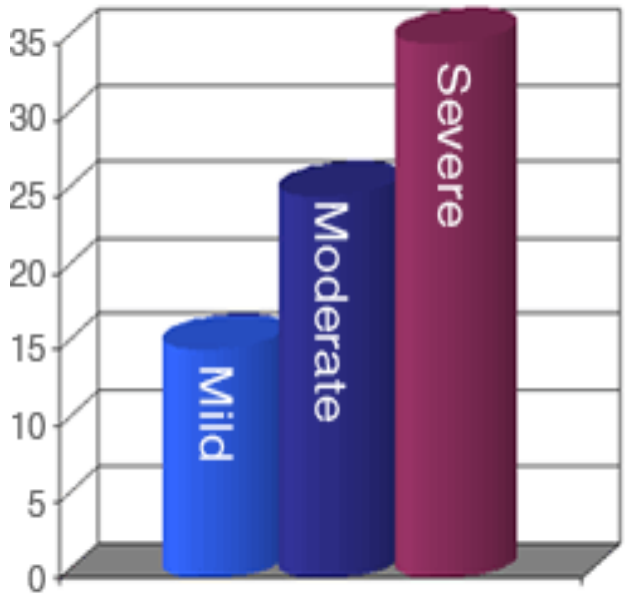
- May cause physical injury due to size or shape of the object(s)

Physical Hazards Controls

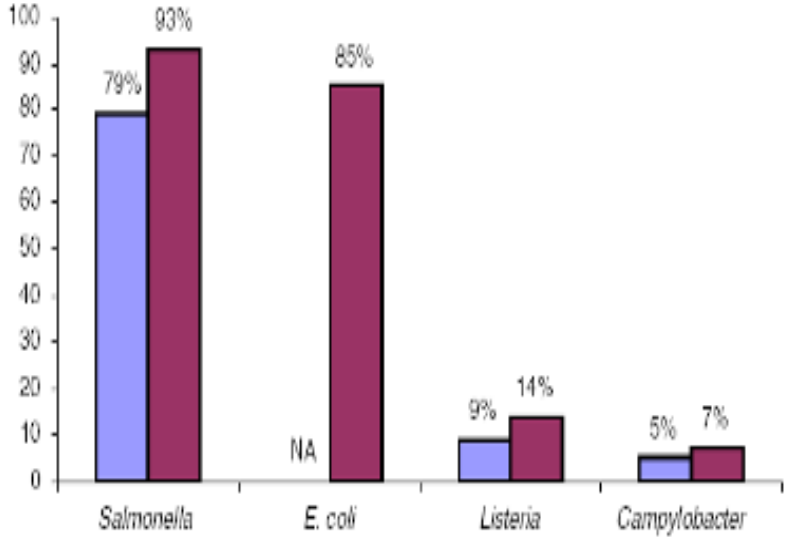
- Control Methods
  - Visual observations
  - Sanitation procedures
  - SOPs for product handling
  - GMPs for maintenance, inspection
  - Foreign materials detection

Evaluating Hazards

- **Based on:**
  - Severity
  - Likelihood



- **Arbitrary decisions can lead to:**
  - CCPs unrelated to product safety
  - No CCP for controlling a high-risk hazard



Hazard Analysis Decisions

Key Principle

- Reasonably Likely To Occur
  - CCP somewhere in the process
  - Support and validation for CCP
- Not Reasonably Likely To Occur
  - Nature of process or product prevents the hazard from occurring
  - Prerequisite programs to prevent the hazard from occurring

Pop Quiz

Which regulatory citations have to do with an establishment's hazard analysis?

Pop Quiz

Which regulatory citations have to do with an establishment's hazard analysis?

- ✓ **9 CFR 417.2(a)(1)**
- ✓ **9CFR 417.2(a)(2)**
- ✓ **9 CFR 417.5(a)(1)**

9 CFR 417.2(a)(1) Hazard Analysis

- Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards.

9 CFR 417.2(a)(1) Hazard Analysis (2)

- The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

Noncompliance with 417.2(a)(1)

- Failure to conduct a hazard analysis for a given product/process
- Failure to consider all hazards commonly associated with the particular product or process
- Failure to identify control measures the establishment can apply to the food safety hazards

Flow Chart

- 9 CFR 417.2(a)(2)
  - A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

Noncompliance with 417.2(a)(2)

- Failure to include a flow chart that describes (diagrams) the steps of each process and production flow in the establishment
- Failure to identify the intended use or consumers of the finished product

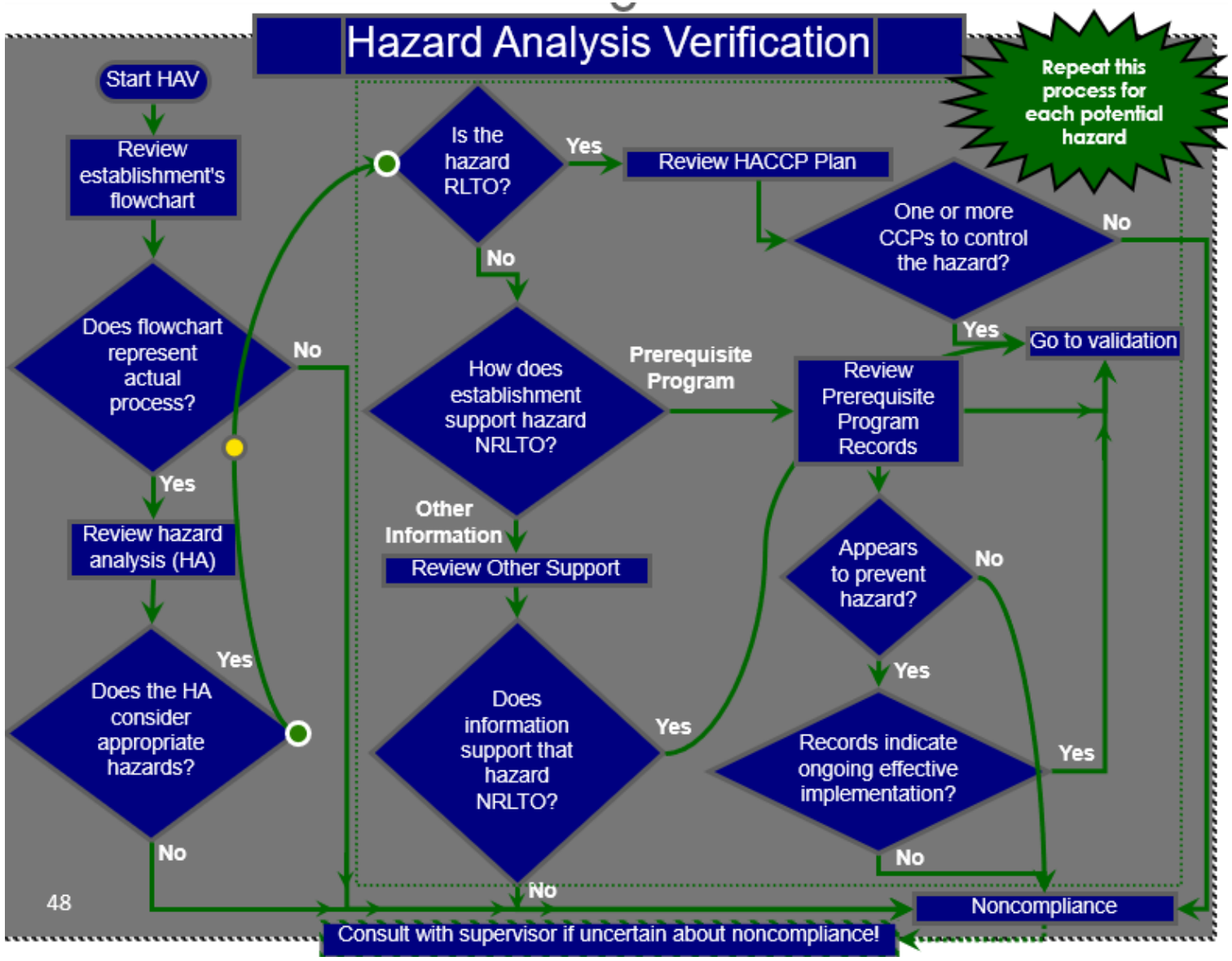
Hazard Analysis Records

- 9 CFR 417.5(a)(1)
  - The establishment shall maintain the following records documenting the establishment’s HACCP plan (1) The written hazard analysis prescribed in § 417.2(a) of this part , including all supporting documentation

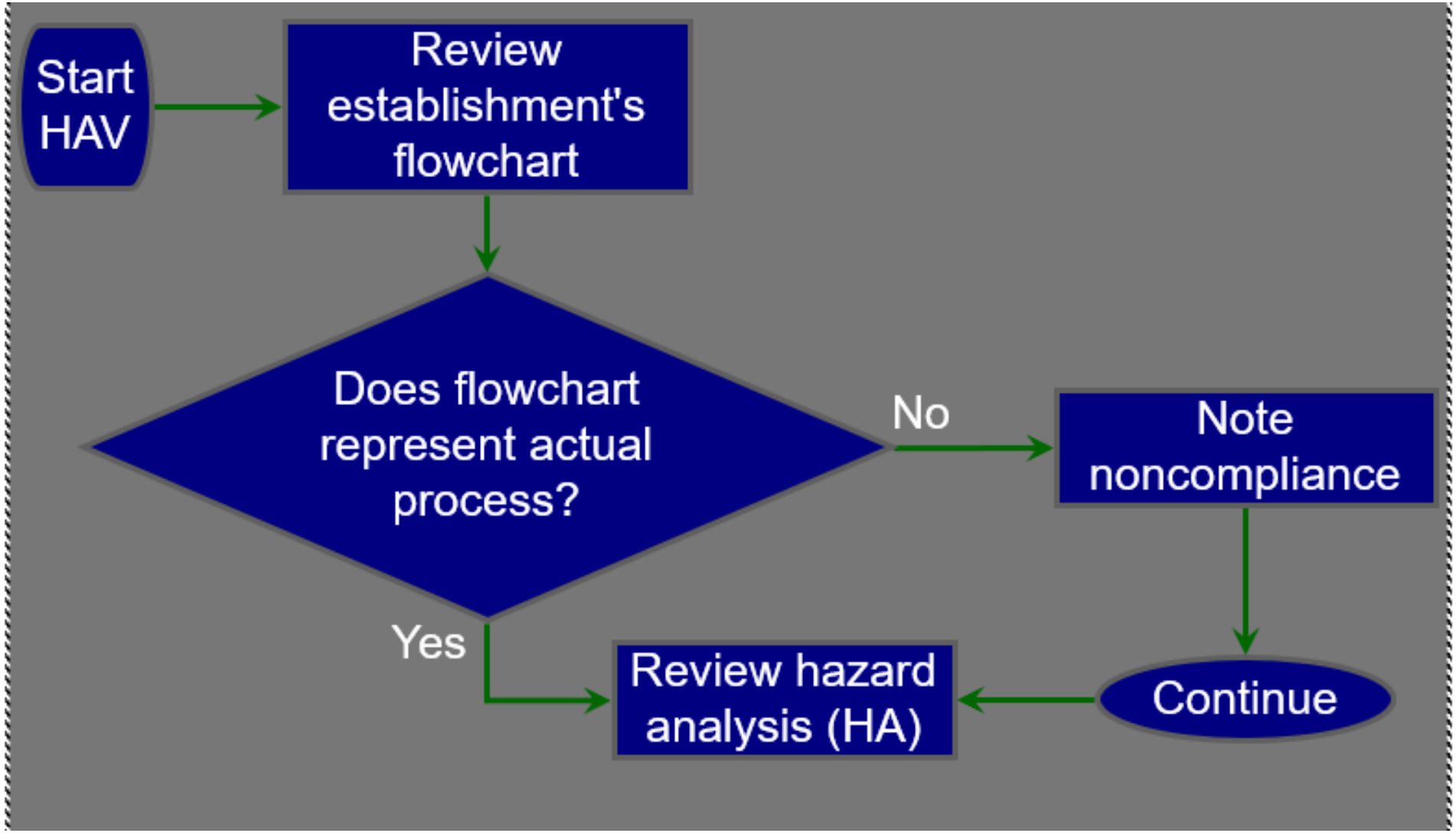
Noncompliance with 417.5(a)(1)

- No written hazard analysis
- No written description for intended use or consumer of the product
- No documentation adequately supporting one or more decisions in the hazard analysis

Hazard Analysis Verification



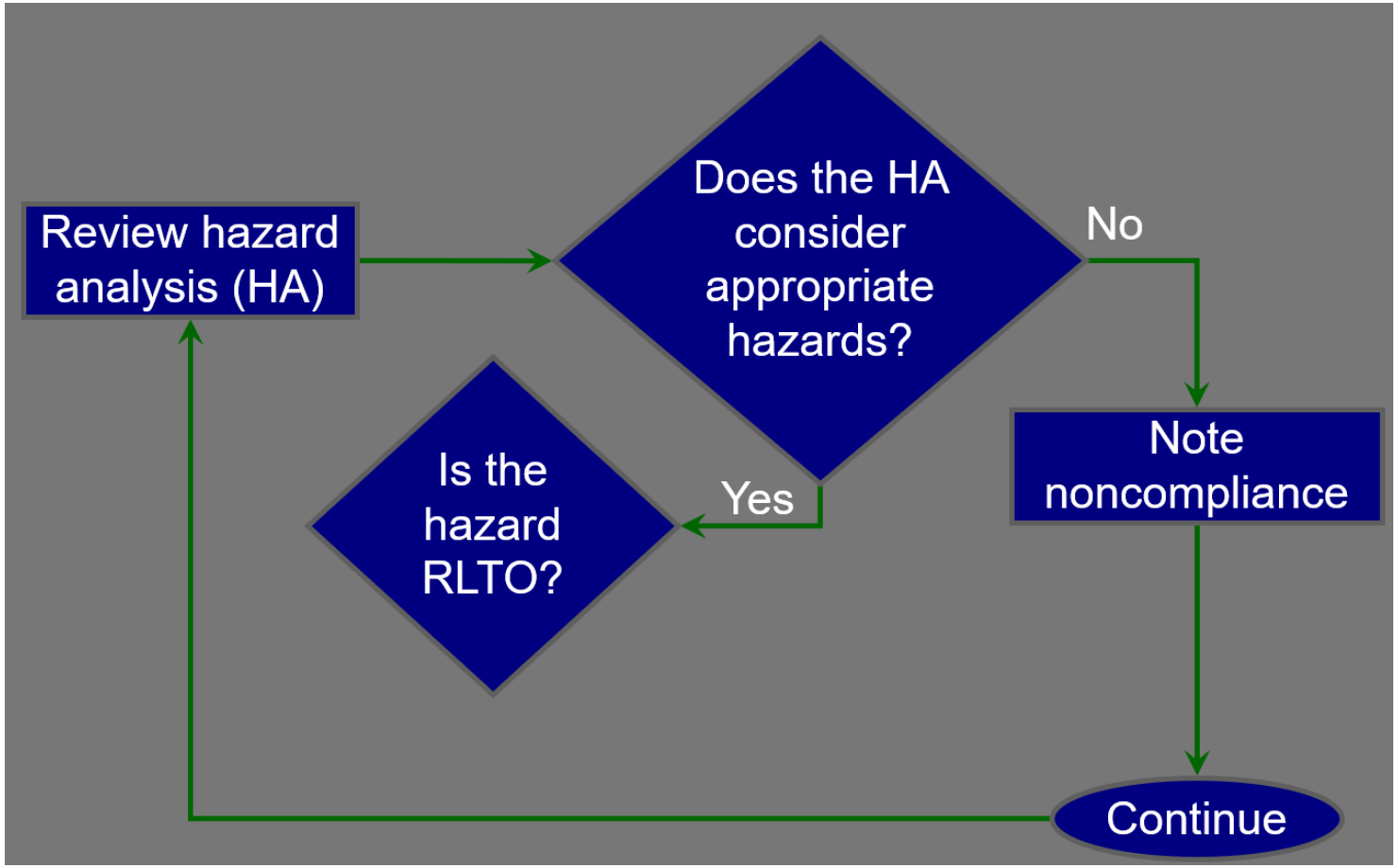
Flowchart


Start HAV
Review establishment's flowchart
Does flowchart represent actual process?
No
Note noncompliance
Yes
Review hazard analysis (HA)
Continue

Flowchart Noncompliance Example

The plant produces fully-cooked ham products. In the post-lethality product packaging area, you observe employees mixing and applying a honey glaze solution to hams just before sealing the package. You have not observed production of this glazed product before, and the plant supervisor explains the glazed hams are only produced seasonally. You review the plants fully cooked ham flowchart and HA. There are no steps identified for mixing or applying a glaze solution. The HACCP Coordinator explains that any potential hazards were considered in product formulation steps, but in the flowchart you note all steps associated with formulation occur prior to cooking.

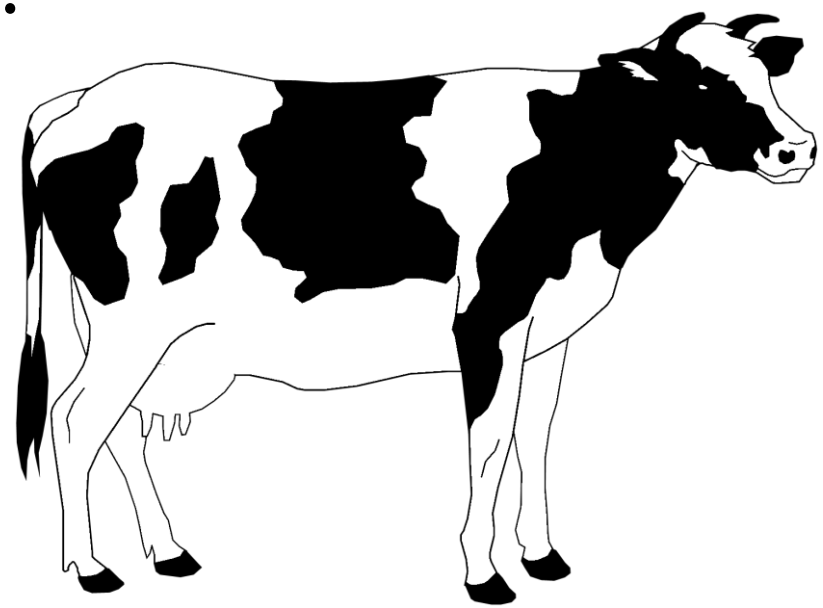
Hazard Analysis- Appropriate Hazards



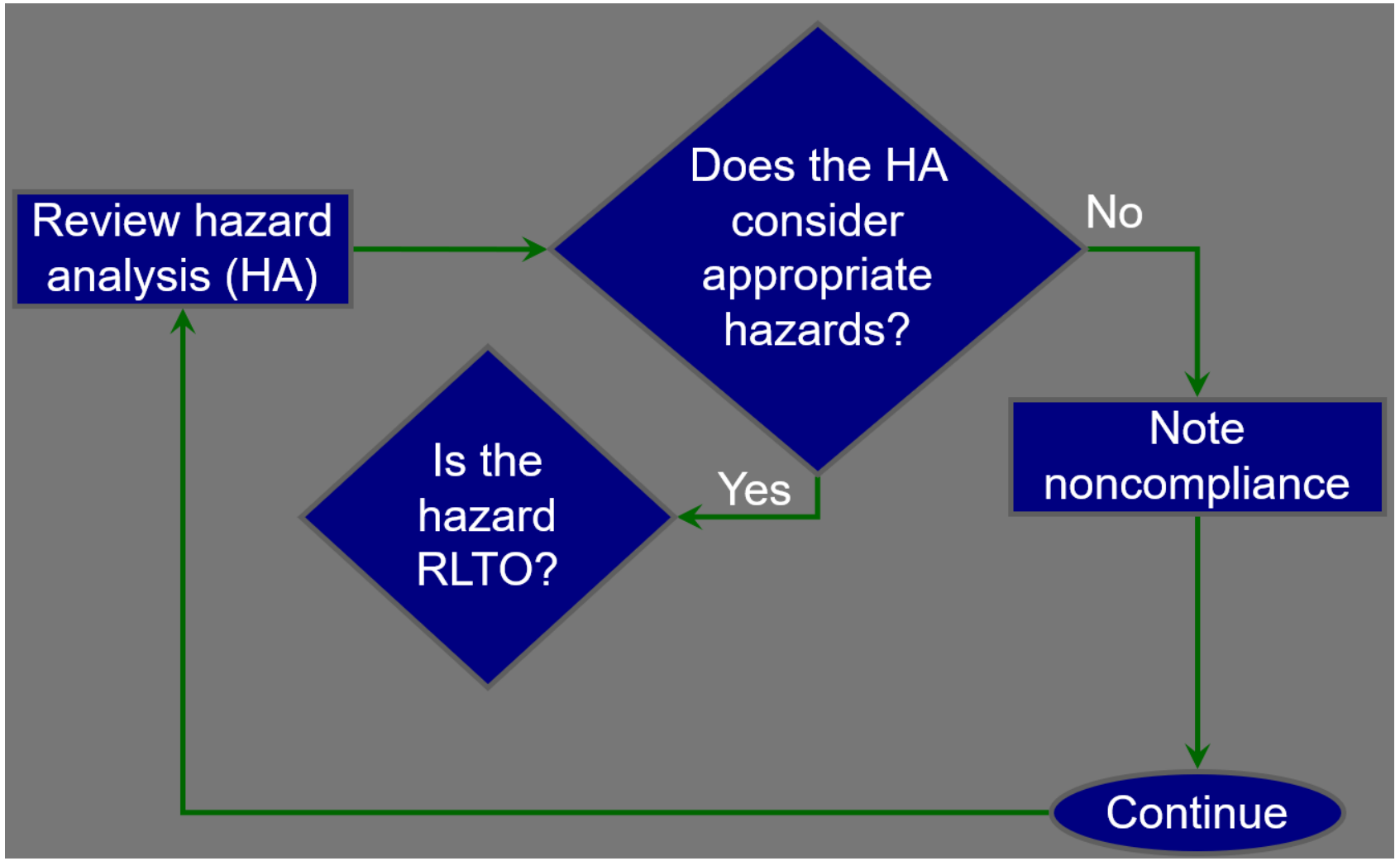
*** Repeat for Each Process Step**

Appropriate Hazards Noncompliance Example

- You review the slaughter hazard analysis at a plant that slaughters cull dairy cows.
- You observe that drug residues are not considered as a potential hazard.

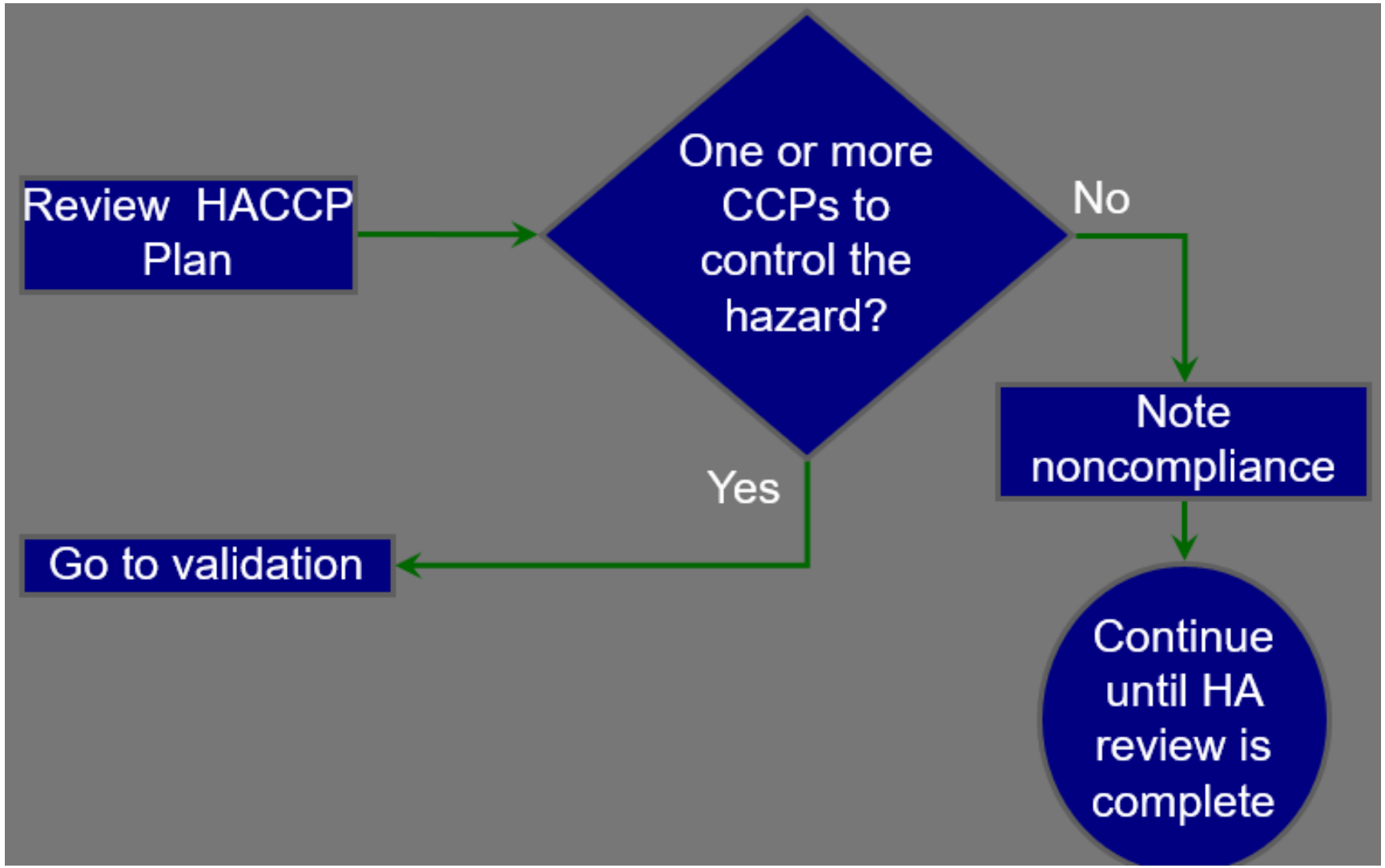


Hazard Analysis – RLTO Decisions

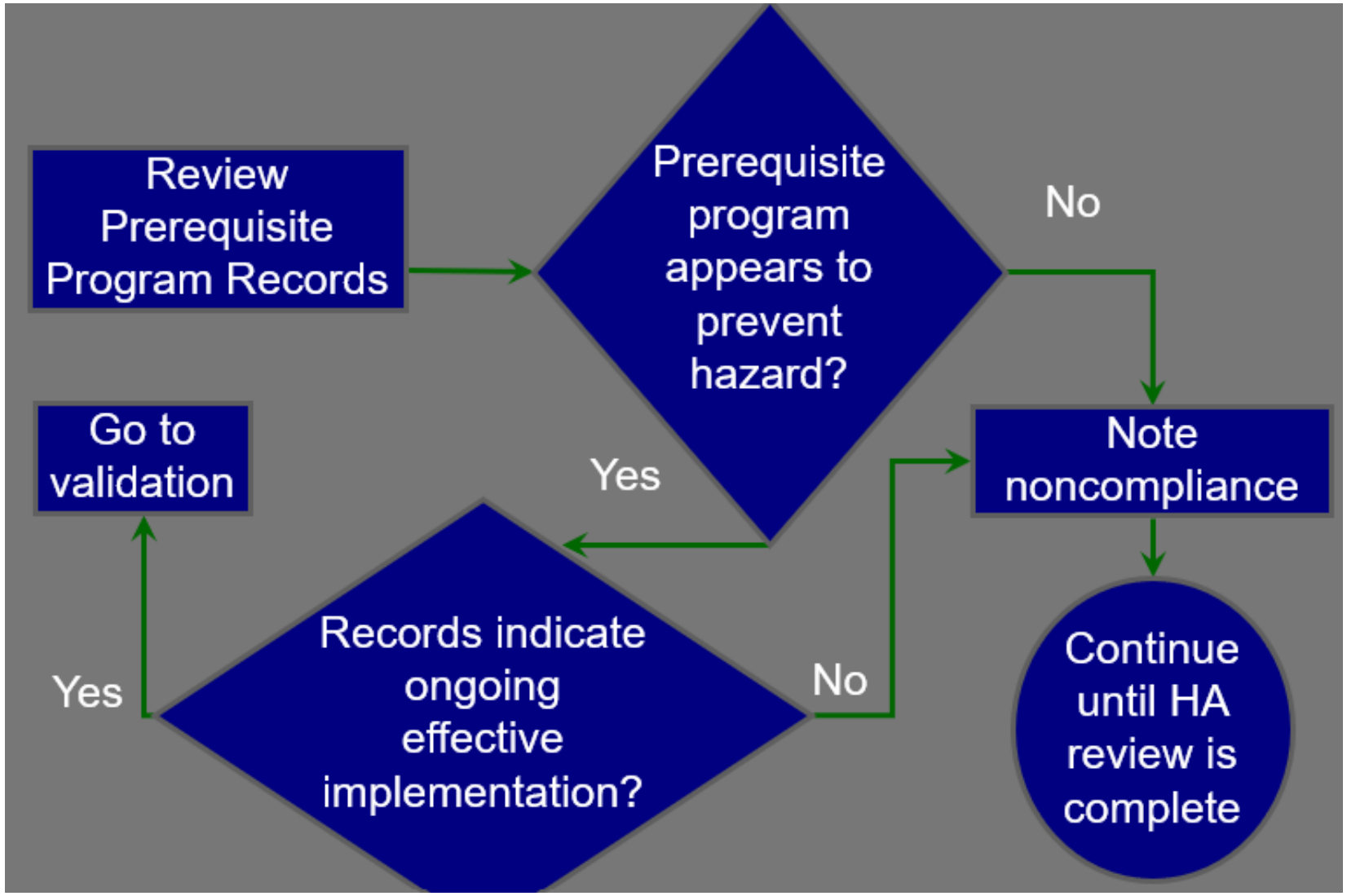


*** Repeat for Each Process Step**

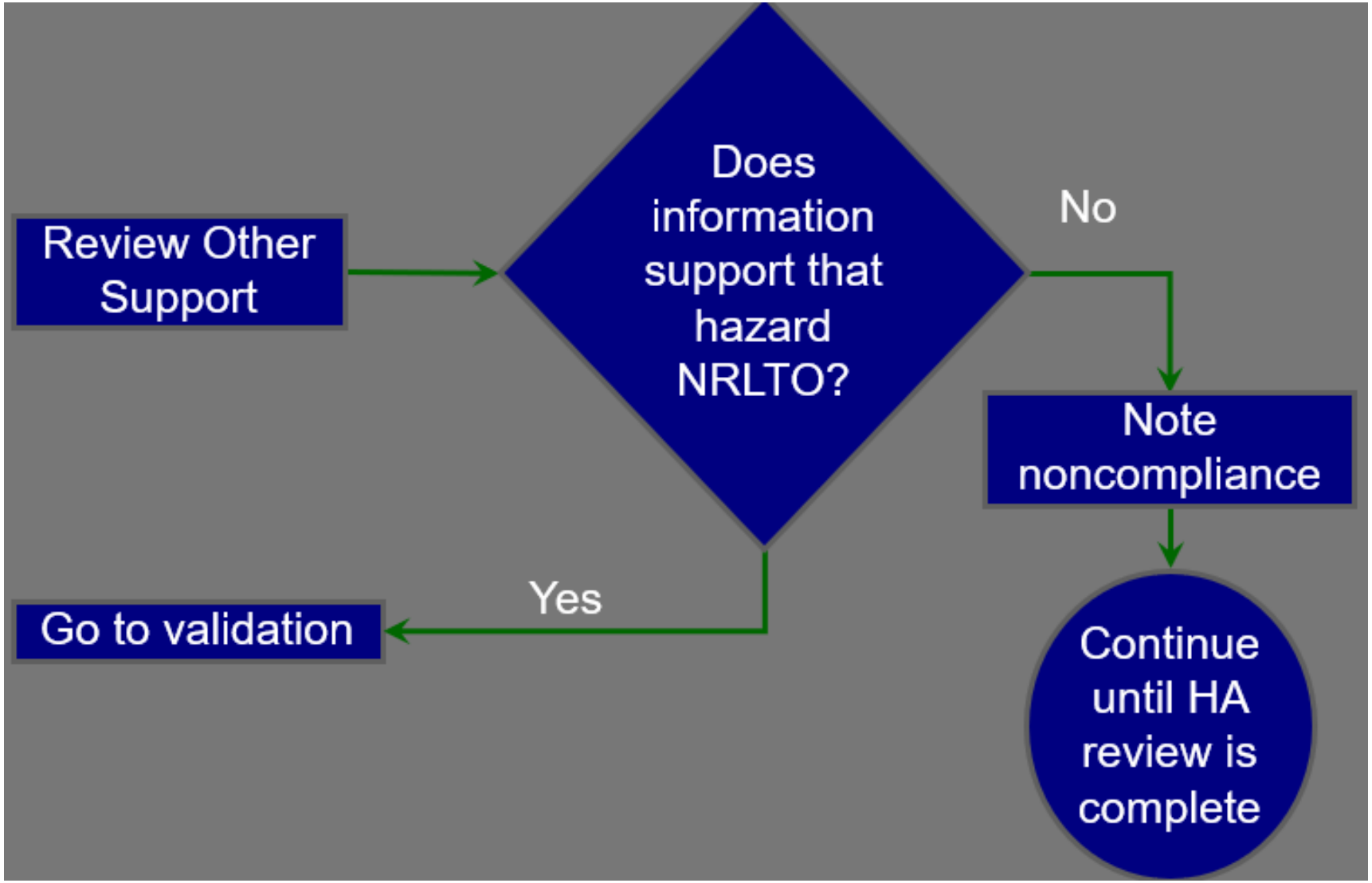
CCPs for RLTO Hazards



Prerequisite Programs



Other Support



Simple Support Example 1

Step	Food Safety Hazard	RLTO ?	Justification
Thawing Frozen Meat	**Biological:** Outgrowth of Pathogens	No	Thawing SOP
	Chemical: No Common Hazards	No	Meat and Poultry Hazards and Control Guide
	Physical: No Common Hazards	No	Meat and Poultry Hazards and Control Guide

Simple Support Example 2

A plant receives raw boneless beef cuts and processes them into steaks, roasts and non-intact products. In considering Specified Risk Materials (SRMs) as a potential hazard, the plant determines that since boneless cuts of beef do not contain SRMs, they are a hazard not reasonably likely to occur based on the nature of the raw materials.

The plant supports this decision with records of invoices for incoming products showing receipt of only boneless products.

Simple Support Example 3

A plant that receives only fully cooked poultry products for assembly of meal kits would easily be able to conclude that Salmonella is a hazard not reasonably likely to occur in their incoming poultry products because of their fully cooked nature.

Complex Support Example 1

E. coli O157:H7 is a food safety hazard known to be associated with raw ground beef and ground beef components. If a plant's hazard analysis determines that *E. coli* O157:H7 is not reasonably likely to occur in raw ground beef, FSIS would expect the establishment to have one or more written programs to support that decision, and documentation to support the ongoing effectiveness of those programs in preventing E. coli O157:H7.

Complex Support Noncompliance Example

You review the hazard analysis for a large beef slaughter and processing plant. You observe that the plant identified *E. coli* O157:H7 as a potential hazard at dehiding but judged it NRLTO.

You ask for documentation supporting the decision. The plant's HACCP manager presents you with 2-years of test results, and states, "We've never had a problem with it before."

You review the testing program and results. You note that sponge samples from 10 carcasses have been collected and tested quarterly.

Types of Supporting Documentation

- Historical data
- Scientific journal articles
- Plant generated data
- Other regulatory requirements
- Pathogen modeling program
- Processing authority

Historical Data as Support

- Verify records supporting a claim about historical conditions
- Consider whether the historical records are reflective of current plant operations
- Look for a recordkeeping system that would have recorded the event if it occurred

Historical Data Noncompliance Example

While reviewing a plants raw, not ground HA, you observe that a NRLTO decision was made for potential hazards at the returned product step.

Justification for the decision states, “All returned product is destroyed through inedible rendering.”

Further investigation reveals the plant has no records documenting the destruction of returned product; however, 3 months of receiving logs indicate the plant has had deliveries of returned product at least once a month.

Scientific Documents as Support

- Assess whether:
  - Conditions in document or study are representative of those in the plant's process
  - Document describes how and why the data support the conclusion

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Escherichia coli O157 Prevalence and Enumeration of Aerobic Bacteria, *Enterobacteriaceae*, and *Escherichia coli* O157 at Various Steps in Commercial Beef Processing Plants†

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ABSTRACT

The effectiveness of current antimicrobial interventions used in reducing the prevalence or load of *Escherichia coli* O157 and indicator organisms on cattle hides and carcasses at two commercial beef processing plants was evaluated. Sponge sampling of beef cattle was performed at five locations from the initial entry of the animals to the slaughter floor to the exit of carcasses from the "hotbox" cooler. For each sample, *E. coli* O157 prevalence was determined and total aerobic bacteria, *Enterobacteriaceae*, and *E. coli* O157 were enumerated. *E. coli* O157 was found on 76% of animal hides coming into the plants, but no carcasses leaving the cooler were identified as contaminated with *E. coli* O157. A positive relationship was seen between the incidence of *E. coli* O157 in hide samples and that in preevisceration samples. Aerobic plate counts and *Enterobacteriaceae* counts averaged 7.8 and 6.2 log CFU/100 cm^2, respectively, on hides, and 1.4 and 0.4 log CFU/100 cm^2, respectively, on chilled carcasses. Aerobic plate counts and *Enterobacteriaceae* counts on preevisceration carcasses were significantly related to the respective levels on the corresponding hides; the carcasses of animals whose hides carried higher numbers of bacteria were more likely to carry higher numbers of bacteria. Implementation of the sampling protocol described here would allow processors to evaluate the efficacy of on-line antimicrobial interventions and allow industrywide benchmarking of hygienic practices.

Escherichia coli O157:H7 has been a pathogen of concern to the meat processing industry for two decades. Cases of hemorrhagic colitis caused by *E. coli* O157:H7 were associated with consumption of undercooked ground beef in the early 1980s *(26)*. In the United States during 1992 and 1993, an outbreak of *E. coli* O157:H7 infection associated with consumption of ground beef caused hundreds of illnesses and four deaths *(31)*. These events led the Food Safety and Inspection Service (FSIS) to declare the *E. coli* O157:H7 organism an adulterant in ground beef and to require that meat processors establish hazard analysis and critical control point (HACCP) plans for their plants *(12)*. Since this time, numerous intervention strategies focusing on prevention of carcass contamination and decontamination of carcasses have been designed, tested, and put into practice at commercial processing plants.

Recent studies have demonstrated that combinations of antimicrobial interventions are more effective at reducing surface contamination on beef tissue than are individual interventions alone *(8, 20, 24)*. Many commercial beef processing plants presently employ several interventions (i.e., trimming, steam vacuuming, steam pasteurization, water washes, and organic acid washes) in combination to achieve large reductions in carcass contamination in accordance with their individual HACCP plans *(1)*.

In 2002, the FSIS required all raw beef processors to reassess their HACCP plans to ensure that their critical control points were adequately addressing *E. coli* O157:H7 contamination *(13)*. In verifying process control, testing for pathogens is generally not useful because of the low numbers of bacterial cells *(6, 17)*. Therefore, indicator organisms, present in sufficiently high numbers throughout the processing line, are monitored to ensure that intervention systems are functioning properly. To adequately interpret these data, the relationships between the indicator organisms and the pathogen(s) of interest must be established *(15)*.

In this study, counts of indicator organisms (aerobic bacteria and *Enterobacteriaceae*) and *E. coli* O157 and the prevalence of *E. coli* O157 were assessed at various steps in processing to identify relationships that may be exploited to monitor process control. The objectives of this study were twofold: (i) to determine the effectiveness of current interventions used in reducing the prevalence or level of *E.*

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† Names are necessary to report factually on available data; however, the U.S. Department of Agriculture neither guarantees nor warrants the standard of the product, and the use of the name by the U.S. Department of Agriculture implies no approval of the product to the exclusion of others that may also be suitable.
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Scientific Documents– Noncompliance Examples

- A plant is using a study regarding *E. coli* O157:H7 being used to support decisions regarding *Salmonella* in pork

- A plant presents a scientific document as support for a not reasonably likely to occur decision, but the information appears to be outdated based on more recent FSIS guidance

Plant Generated Data as Support

- Challenge studies
- Pathogen modeling programs
- Microbiological test results
  - Frequency of sampling
  - Sample selection
  - Sampling method
  - Sample handling
  - Analytical method

Plant Data- Noncompliance Examples

- A plant presents a spreadsheet of test results as the sole support for a decision, with no accompanying explanation or interpretation of how the test results support the NRLTO decision

- A plant's tests for *E. coli* O157:H7 was always negative during periods when FSIS or customer tests were positive

Other Regulations or FSIS Guidance Materials as Support

- Use regulations or other FSIS guidance to support a not reasonably likely to occur decision
- Must follow those regulatory requirements in their entirety or else have additional support
- Failure to do so will result in noncompliance

Summary

Key Points

- Inspection personnel must verify that establishments:
  - Conduct and maintain an adequate hazard analysis
  - Maintain documentation supporting decisions made in the hazard analysis
  - Demonstrate ongoing support for decisions made in the hazard analysis
  - Do not have results that contradict decisions made in the hazard analysis

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Questions?

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Hazard Analysis Workshop II

- Read the beef slaughter hazard analysis
- Discuss your observations and any concerns in your group

Be Ready to "Report Out"