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

HACCP
EIAO Training

Performing the Assessment – HACCP

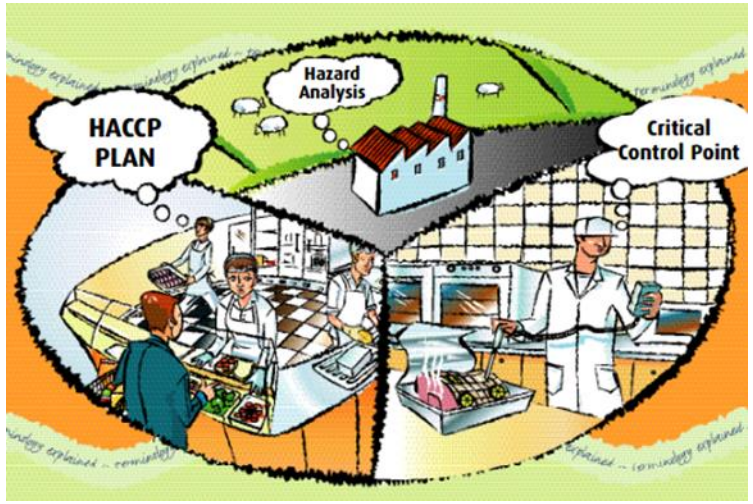
- Use Directive 5000.1 for policy guidance
- Answer the questions in the FSA Tool appropriate for the processing category
- Assess design and implementation

HACCP–Hazard Analysis

- 9 CFR 417.2(a)(1): Each establishment must have a hazard analysis conducted to determine the food safety hazards reasonably likely to occur in the production process and identify preventive measures the plant can apply to control those hazards.
- Consider all potential biological, chemical, and physical food safety hazards, and determine the food safety hazards reasonably likely to occur in its process.
- HA provides the basis for an establishment's food safety system.

Hazard Analysis – 417.2(a)(1)

- HA involves: Hazard identification & evaluation.
- An adequate HA ensures the level of risk to the consumer is acceptable.
- The HA must be supported according to 417.5(a)(1)



Hazard Identification

- Meat and Poultry Hazards and Controls Guide

  https://www.fsis.usda.gov/guidelines/2018-0005

- FSIS Microbiological Hazards Guide

  https://www.fsis.usda.gov/node/2253

- Appendices C & D of the HACCP Final Rule FR Notice

  https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/93-016F_0.pdf

- FSIS HACCP Guidance

  https://www.fsis.usda.gov/inspection/compliance-guidance/haccp

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
  - Supporting documentation
  - Prerequisite programs to prevent the hazard from occurring

Hazard Analysis

- If HA conducted incorrectly and does not identify significant hazards - HACCP plan will be ineffective.
- Noncompliance with 417.2(a) because of an inadequate hazard analysis can result in an inadequate system.
- Begin review of the HACCP system-Verify the design of the hazard analysis.
- Assess whether appropriate hazards have been addressed.
- Use the questions from the Hazard Analysis and HACCP system section of each tool.

Performing the Assessment – HACCP

- Let’s look at some of the questions from the FSA Tools in your notebook that deal with the hazard analysis and HACCP system

Performing the Assessment – HACCP

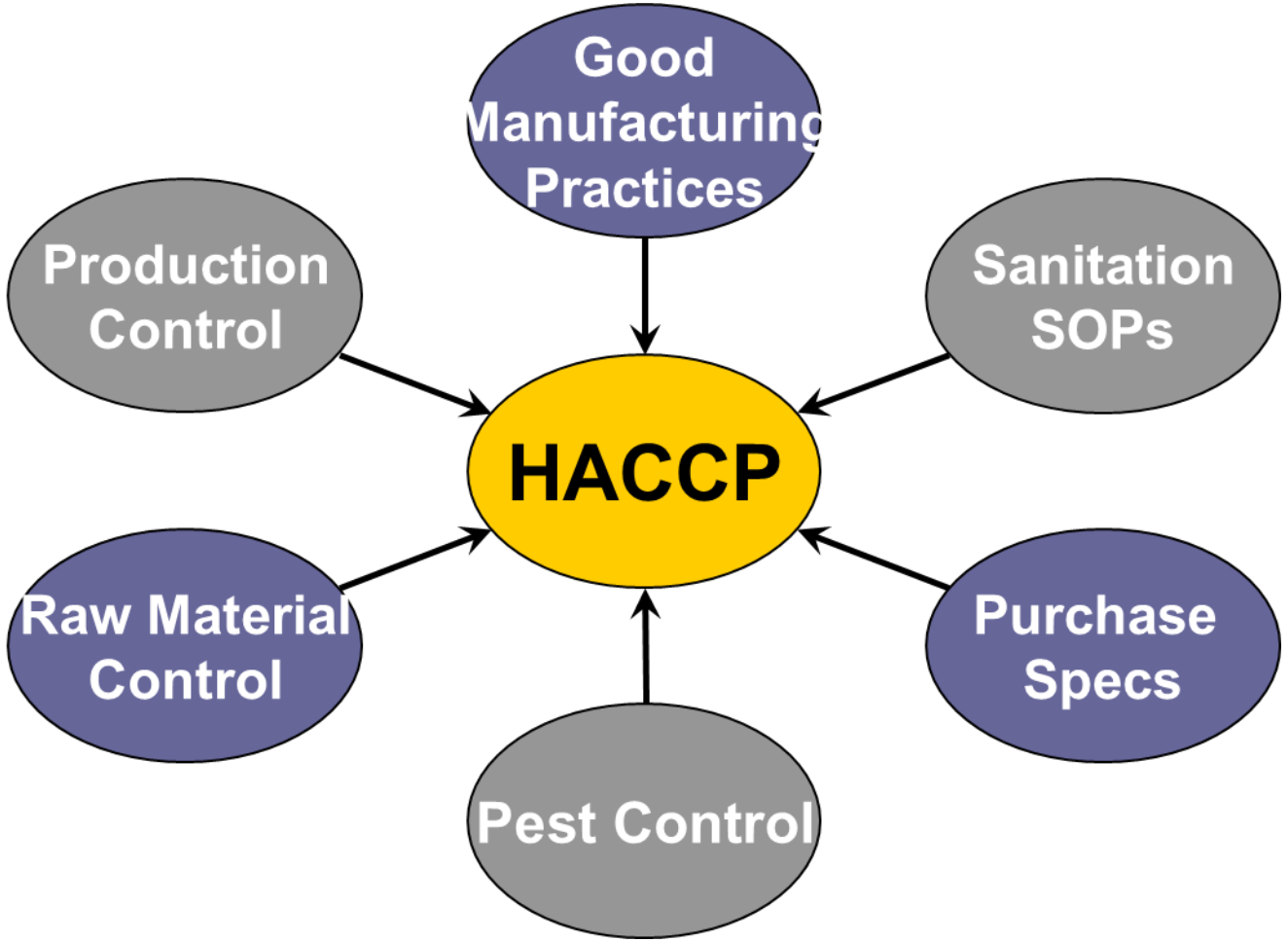
Performing the Assessment – Prerequisite Programs (PRP)

- PRPs are often used to support decisions in hazard analysis
- Decisions often involve these programs preventing a hazard from being reasonably likely to occur (RLTO) or significant.
  - Example: Purchase specifications for incoming materials.
- Provide basic environmental and operating conditions necessary for the production of safe & wholesome food.
- PRPs are the foundation for an effective HACCP system.
- PRPs frequently function facility wide.

Performing the Assessment – Prerequisite Programs (PRP)

- PRPs may have unique names that do not incorporate the actual term “prerequisite program”
- Examples
  - Purchase Specification Program
  - Allergen Control Program
  - Temperature Control Program

Prerequisite Program Examples



Performing the Assessment – PRPs

- Plant may determine a hazard is not significant because of ongoing execution of a PRP.
- The EIAO will look closely at programs used in hazard analysis decisions
- Determine if the design and implementation of the programs actually support the decision

Prerequisite Program Records

Performing the Assessment – Prerequisite Programs (PRP)

- PRPs cannot be used to directly control a hazard.
- Non-conformance with a PRP may not create a food safety concern or call for product action.
- Non-conformance with the PRP may call into question support for decisions in the HA.

Prerequisite vs. CCP?

Prerequisite Program	Critical Control Point
• Cannot be used to directly control a hazard. • May prevent a hazard from being likely to occur. • Deviations from program may not create direct food safety concerns; BUT may call into question hazard analysis decisions.	• Directly control specific hazards. • Prevents, eliminates, or reduces a likely to occur hazard. • Deviations from controls in a HACCP plan cause food safety concerns and generally require action on affected product.

Performing the Assessment: Inappropriate Use of PRPs

The EIAO will seek info such as:

- If criteria of the PRP are not met, are there questions about the safety of the food?
- If criteria of the PRP are not met, does the establishment implement corrective actions that meet 417.3?
- Is the only support for the PRP use historical info showing that the program is the primary means of control? Performing the Assessment:
  Inappropriate Use of PRPs

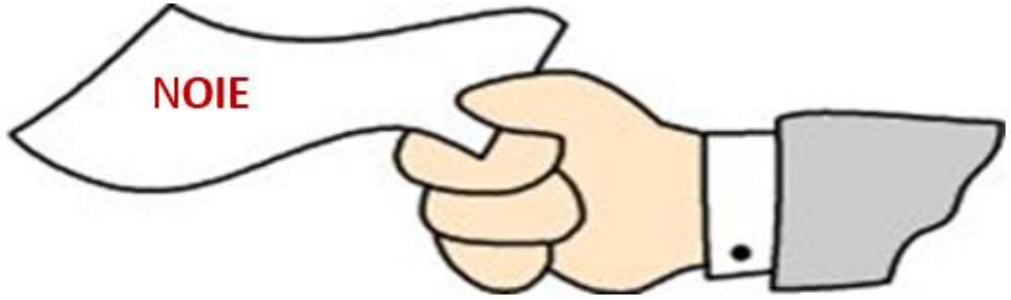
If the answers is “yes” to such questions, then it is probable that the program is being used to directly control the hazard

Performing the Assessment: Inappropriate Use of PRPs

The EIAO will discuss such finding with the establishment and inform them that they need to:

- Reassess its HACCP plan to reconsider use of the programs and properly address the hazard.

Failure to reassess and properly use the programs may result in the issuance of a NOIE



Performing the Assessment Prerequisite Programs

The EIAO will review:

- Features of the written PRP
- Supporting documents
- Program data over a period of time
- Observe employees implementing the PRP

The standard of performance for prerequisite programs records are different from the expectations of HACCP records

Performing the Assessment
Prerequisite Programs

- A single instance of nonconformance may not represent noncompliance, if decisions in the HA are still supported.
- PRP Records must continue to support the not reasonably likely to occur hazard analysis decision.
- If EIAO determines the prerequisite program is ineffective or not being executed as designed and there are no food safety concerns.
- The establishment will need to reassess the hazard analysis to determine whether there is continued support for the decisions.

Evaluating Sampling that is part of a Prerequisite Program

- FSIS website resources to help EIAOs evaluate sampling and testing done by an establishment:
  - Foodborne Pathogen Test Kits Validated by Independent Organizations

    https://www.fsis.usda.gov/guidelines/2019-0008
  - FSIS Guidance for Evaluating Test Kit Performance

    https://www.fsis.usda.gov/guidelines/2010-0004
  - Establishment Guidance for Selecting a Lab

    https://www.fsis.usda.gov/guidelines/2013-0009
  - AskFSIS

Prerequisite Programs – Example

- Raw ground beef operation has a PR program based on purchase specifications
- The EIAO will review the records from the program to verify that it supports the decision made in the hazard analysis that E. coli O157:H7 is not likely to occur.

Prerequisite Programs – Example

- Establishment producing post-lethality exposed RTE products has product or environmental testing in a PR program
  - The EIAO will review the program, results, and decision documents to verify it is science based.
  - Assess the total system to verify design of the testing and implementation effectively addresses Listeria.

Prerequisite Programs

- Example of Regulatory Thought Process:
  - Ineffective PR Program
  - Hazard likely to occur(?)
  - No support for NRLTO decision in HA: 417.5(a)(1) noncompliance
  - HA Inadequate (hazard unaccounted for): 417.2(a)(1)
  - HACCP system not valid (lack of support): 417.4
  - Inadequate HACCP system: 417.6
- The EIAO should analyze the information and document a supportable agency position related to the plants' use of prerequisite programs.

Performing the Assessment – HACCP

- Monitoring: Assess the design and frequency of monitoring procedures.
- Review the HACCP plan, supporting documentation and at least 60 days of records

Performing the Assessment – HACCP

- Verification: Review the HACCP plan and at least 60 days of verification records
  - Determine whether verification procedures comply with requirements
  - Look at the design and implementation of the procedures
- Let’s look at some questions dealing with monitoring and verification.

Performing the Assessment – HACCP

M17 Does the establishment conduct the monitoring and verification (procedure and frequency) as written in its HACCP program (i.e., HACCP plan, prerequisite program, or another program), including chilling/cooling procedures if the establishment slaughters? Noncompliances and vulnerabilities are to be described in M19.

☐Yes
☐No, the establishment does not conduct monitoring and verification as written
☐No, the monitoring and verification are not written in its HACCP program

M18 Does the establishment maintain support for the selected monitoring and verification procedures and frequencies? Noncompliances and vulnerabilities are to be described in M19.

☐Yes
☐No

M19 Briefly describe any vulnerability and noncompliance finding with the establishment's monitoring and verification procedures and frequencies, including the support for its monitoring and verification procedures and frequencies in its program (i.e., HACCP plan, prerequisite program, or another program) (limit 20,000 characters).

Click here to enter text.

Performing the Assessment – HACCP

- Recordkeeping: From the 60 days of records, summarize what happened related to safe and wholesome product production.
- Review supporting documentation
  - Randomly select 13 production days from the 60 days
  - Assess whether the HACCP System design is implemented and whether it meets regulatory requirements.
  - If an establishment has operated less than 13 days in last 60 days, review minimum 13 days.

Note: Only review more records if larger food safety issue is observed.

Recordkeeping

M22 Do the records include the actual times, temperatures, or other quantifiable values, and include the product code(s), product name or identity, or slaughter production lot?
Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).
☐Yes – Click here to enter text.
☐No – Click here to enter text.

Corrective Actions

Corrective Actions (CA): Review the HACCP plan and at least 60 days of records.

- Assess design of CA and determine if they meet 417.3 requirements.
- If no CA taken in that timeframe attempt to find the last instance where CA was taken.
- Answer questions in the tools

Corrective Actions

M21 Has the establishment taken corrective actions as appropriate in response to deficiencies as required by 9 CFR 417.3 over the last 60 days? *If yes, note whether all applicable parts of 9 CFR 417.3 were met. If no, note why the establishment did not take appropriate corrective actions(limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

☐N/A, the establishment has not had any deficiencies over the last 60 days.

Performing the Assessment – HACCP

Reassessment:

- Review at least 60 days of records
- Determine if reassessment should have occurred
- Review reassessment decisions and any actions taken as a result
- Verify annual requirement is met
- Verify reassessment documentation

Performing the Assessment – HACCP

- Requires documentation of all reassessments
- Requires documentation of reasons for changes or no changes
- Reassessment: 417.4(a)(3)(ii)
    - For annual reassessment if there are no changes a reason is not required

Reassessment

M5 Did a significant development occur in the last 60 days that affects the hazard analysis such as major process or product
change, categorization change, or unforeseen hazard? NOTE: Answer this question based on your review of the selected records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1.
☐Yes – If selected, answer the following question(s)
☐No

M5a Briefly describe how the hazard analysis and/or HACCP plan was reassessed in response to the change. Briefly describe any vulnerability and noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 5,000 characters).
Click here to enter text.

Performing the Assessment

Analyze, formulate and document a supportable Agency position about whether regulatory requirements have been met for:

- Monitoring
- Verification
- Corrective Action
- Reassessment
- Recordkeeping

Performing the Assessment – Validation

Now let’s review the validation requirements and key points to look for in the assessment.

Performing the Assessment – Validation 417.4(a)(1)

When a HACCP plan is implemented, the establishment must:

- Conduct activities designed to determine that the HACCP plan is functioning as intended
- Repeatedly test CCPs, CLs, monitoring, recordkeeping, corrective action
- Review records to ensure proper functioning of the HACCP system

Performing the Assessment – Validation

Initial validation = first 90 days

- 9CFR 304.3(b) and 381.22(b)

Validation has **2 parts**:

- Scientific or technical support for the HACCP system
- In-plant demonstration proving the HACCP system can perform as expected

Part 1 Scientific or Technical Support

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

Historical Data as Support

- Records must be available
- Verify historical records reflect current establishment operations

Scientific Documents as Support

- Conditions in the study are representative of those in the establishment's process.
- Document describes how and why the data support the conclusion.
- Scientific Support Characteristics:
  - Identify hazard and pathogen
  - Level of reduction
  - Identify critical parameters
  - Sufficient relationship to hazard
  - Implemented in the establishment as documented
  - Otherwise additional research data needed

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

Plant Generated Data as Support

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

Other Regulations as Support

- May use regulations or other agency issuances to support a NRLTO decision
- Must follow **or** have additional support

Part 2 Initial In-Plant Validation

- In-plant observations
- Measurements
- Microbiological test results
- Other information demonstrating control measures can be implemented to achieve the intended food safety objective

Initial In-Plant Validation Characteristics

- Based on critical parameters identified in scientific support
- Intensified data collection during first 90 days “repeatedly testing” NOT recreating entire scientific support.
- EIAO may see microbial before/after testing used to demonstrate log reductions documented in scientific support
    - Indicators and pathogen of concern
    - Not required by regulation
    - No deliberate introduction of pathogens allowed

In-plant Validation Data Uses

- “Repeatedly testing” data often used as supporting documentation for frequencies.
- Establish a baseline of performance.
- Data can show which critical parameters are most important and give the first signs the system is “out of control”.
- Scientific support documentation and 90-day initial validation data become records under 9 CFR 417.5(a)(1) supporting documentation

Validation & Validation Updates

- 9 CFR 417.4(a)(1): Includes review of HACCP system records.
- 9 CFR 417.1 HACCP System Defined: The HACCP plan in operation including the HACCP plan itself.
- Entire system must be validated- Including any interventions or processes used to support decisions in the hazard analysis.
- FR Docket No. FSIS–2009–0019
- Clarification of Requirements for Validation
- Compliance Guideline updated April 2015

Validation

M11 Does the establishment maintain adequate scientific or technical support that relates to the establishment's actual process, product, and hazard identified in the hazard analysis, including chilling/cooling if the establishment slaughters (1st part of validation – design)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No, support does not relate – Click here to enter text.

☐No, establishment does not have support – Click here to enter text.

M12 Does the establishment's scientific support demonstrate the process meets the performance standards or targets(i.e., pathogen reduction level)identified in the hazard analysis for each food safety system (limit 4,000 characters)?

☐Yes – Click here to enter text.

☐No, the support does not demonstrate that it meets the performance standards or targets –Click here to enter text.

☐No ,the establishment does not identify performance standards or targets – Click here to enter text.

Validation

M13 Does the establishment use multiple interventions, including antimicrobial interventions, to meet the overall performance standard or target (i.e., multi-hurdle approach)?

☐Yes – If selected, answer the following question(s)

☐No

M13a In the event of a worst-case scenario when not all antimicrobial interventions are operational, does the establishment have support that the remaining antimicrobial interventions will adequately reduce the pathogen to an acceptable level?

☐Yes

☐No

☐Each antimicrobial intervention is required during production

Validation

M14 Does the establishment incorporate the critical operating parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits? Briefly describe any vulnerabilities or noncompliances(limit 4,000 characters).
☐Yes – Click here to enter text.
☐No – Click here to enter text.

M15 Does the establishment maintain in-plant validation data demonstrating the control measures, as written in the HACCP system, achieve the intended food safety outcome (2nd part of validation –execution)?Briefly describe any vulnerabilities or noncompliances(limit 4,000 characters).
☐Yes – Click here to enter text.
☐No – Click here to enter text.

M16 Briefly describe any vulnerability or noncompliance finding with the establishment's HACCP system (i.e., HACCP plan, prerequisite program, or another program) validation that affect the establishment's ability to produce safe, wholesome, and unadulterated food not described above (limit 20,000 characters).
Click here to enter text.

Questions?