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

Fundamentals of HACCP III
Prerequisite Programs

Objectives

- Identify and define prerequisite programs (PRPs).
- Describe the importance of prerequisite programs to the effectiveness of a food safety system.
- Verify that prerequisite programs used to support hazard analysis decisions are in compliance.
- Identify findings that clearly indicate noncompliance related to prerequisite programs.
- Recognize situations in which PRP design or execution are flawed – NOIE recommendation

Purpose of this Training

- Establishments often use prerequisite programs to prevent food safety hazards.
- Investigations after recalls and illness outbreaks revealed poor design and/or execution of prerequisite programs.
- EIAOs must consider how prerequisite programs impact an establishment's hazard analysis and food safety system.

Prerequisite Programs

The EIAO is to:

- Gather information on prerequisite programs
- Assess whether the prerequisite programs support decisions made in the hazard analysis
- Determine whether there is compliance with 9 CFR 417.5(a)(1) and 9 CFR 417.2(a)

What are Prerequisite Programs?

- Practices and conditions needed prior to and during implementation of the HACCP plan that are essential for food safety

- Provide basic environmental and operating conditions necessary for production of safe, wholesome food

- Prerequisite programs provide conditions necessary to prevent hazards from becoming likely to occur in the process

Prerequisite Program Examples

- GMPs – employee hygiene, traffic flow patterns, and general product handling practices
- SSOPs – a prerequisite program required by regulation. Cleaning schedules for non-PCS of facilities/equipment
- Purchase Specifications – temperature control, COA and specifications geared toward residue avoidance.
- Pest Control – also related to ensuring SPS compliance.
- Raw Material Control – temp controls during holding, processing, and storage; controlling rework; and incoming raw material inspection procedures
- Production Control – controls for foreign material, metal, and allergens

How are Prerequisite Programs Used?

- Basic prerequisite programs
  - Reduce likelihood of food safety issues
  - Apply to all products and processes
  - Not necessarily associated with decision in HA

- Process or product specific prerequisite programs
  - Prevent one or more food safety hazards from occurring in a specific process
  - Support decisions in the hazard analysis

Knowledge Check

Which prerequisite programs are we concerned with as regulators?

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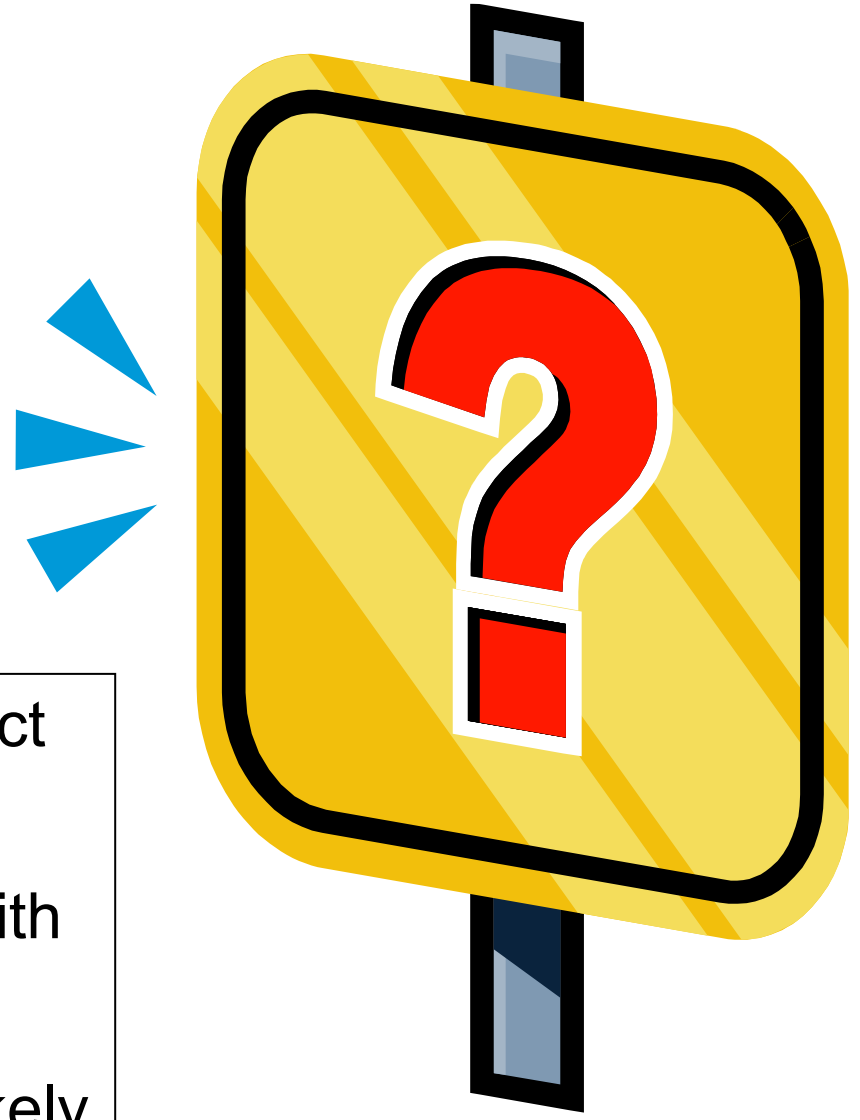


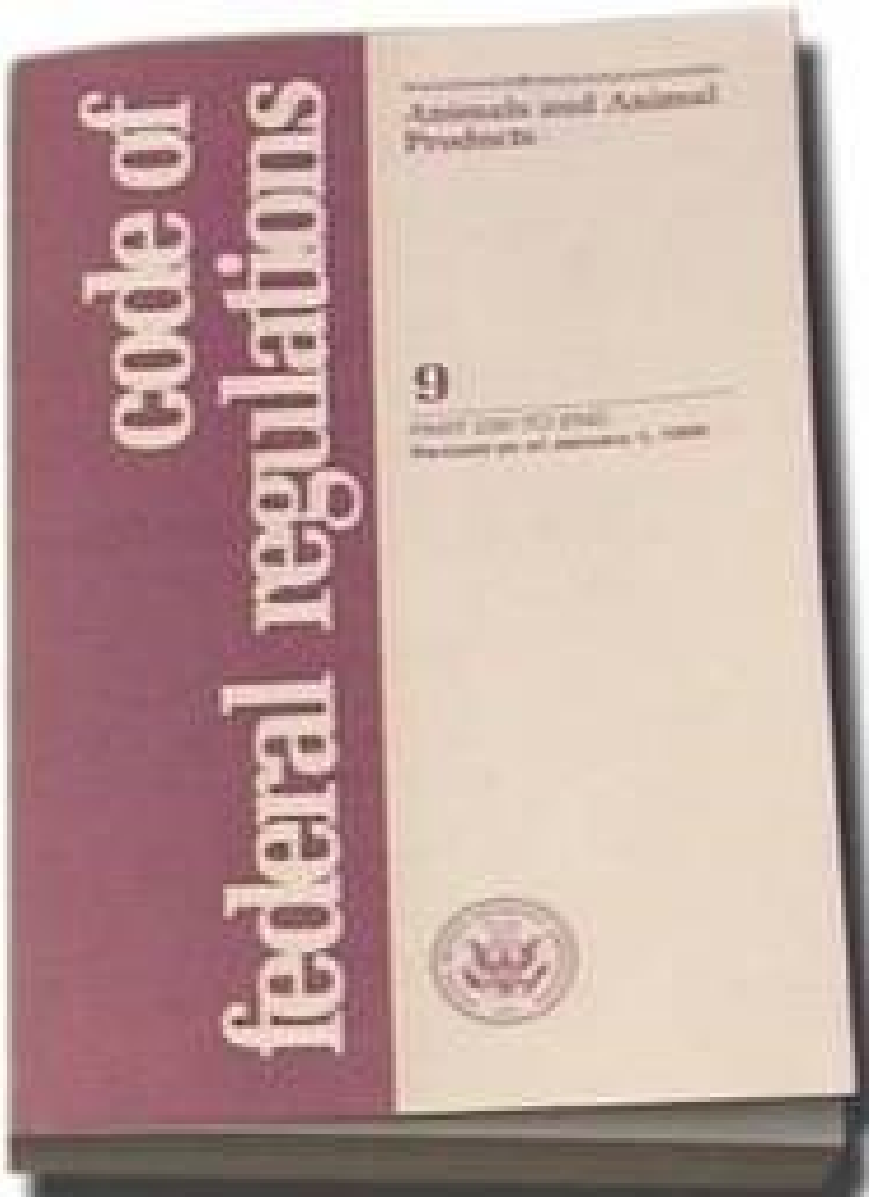
Key Principle

All of them, because they all have an impact on the food safety system.

- PRPs designed to ensure compliance with SPS and Sanitation SOPs regulations
- Any PRP supporting a not reasonably likely to occur decision in the hazard analysis.

Regulatory Expectation

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



Written Program Characteristics

- The written prerequisite program describes:
  - Procedures to prevent the hazard
  - Records to demonstrate the program is implemented and effectively prevents the hazard
  - Actions taken when the establishment fails to implement the program or finds that the program has failed to prevent the hazard

Sanitation SOP = Prerequisite Program

- The Sanitation SOP is a PRP with regulations that prescribe what must be addressed, including recordkeeping requirements.

- During an assessment, analyze how issues in complying with Sanitation SOP requirements can affect support for hazard analysis decisions.
  - How does failed implementation affect the food safety system?

Sanitation SOP = Prerequisite Program

- An establishment must routinely evaluate the Sanitation SOPs and make changes, if necessary.

- There is no recordkeeping requirement to document this evaluation.

Sanitation SOP Example

- A slaughter establishment has positive pathogen sampling results or failed zero tolerance checks.
    - Determine whether the Sanitation SOPs are designed to prevent product contamination or adulteration, and whether the decisions in the hazard analysis are fully supported.

****Think SYSTEM…Impact on the SYSTEM****

Knowledge Check

Can an establishment remove operational sanitation procedures from their written SSOP and use separate GMP, SOP, or PRPs?

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Key Principle

No.

The regulation requires the Sanitation SOP to contain procedures conducted daily during operations to prevent product contamination or adulteration (9 CFR 416.12)

Knowledge Check

Can an establishment add reconditioning procedures to their Sanitation SOP?

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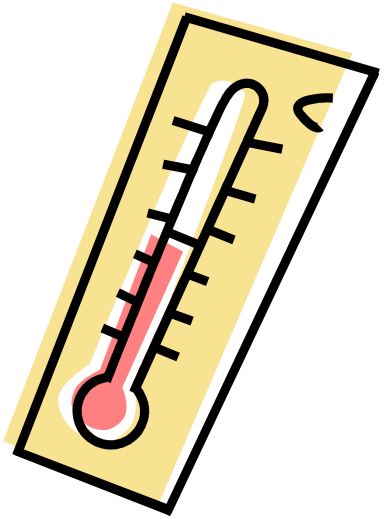
Key Principle

Yes.

These procedures may prevent additional product contamination by ensuring the product is properly reconditioned before it is put back into production.

Common Types of Programs

- Microbial Testing Programs
- Supplier Purchase Specifications
- Temperature Controls



Microbial Testing Programs – What to Consider in your Assessment

- Specific hazard of concern is tested for
- Sampling method is well designed
- Sampling frequency sufficient
- Lab testing method valid for the hazard
- Results consistently demonstrate the hazard is not occurring

Testing Program Example

A cull cow slaughter and beef grinding plant is using its generic *E. coli* testing program to support a decision that *E. coli* O157:H7 is not reasonably likely to occur in its raw ground beef.

Is testing carcasses for generic *E. coli* adequate to support this decision?

Testing Program Example

No

- Testing carcasses for generic E. coli is not adequate to support this decision.
- A microbial testing program must test for the specific hazard of concern.
- There is noncompliance with 9 CFR 417.5(a)(1).

Purchase Specifications

- Must specify:
  - Requirements supplier must meet
  - Methods and documentation demonstrating suppliers are meeting specifications
  - How plant ensures effective prevention on an ongoing basis
  - Actions to determine product disposition if no records that product met specifications

Purchase Specification Example

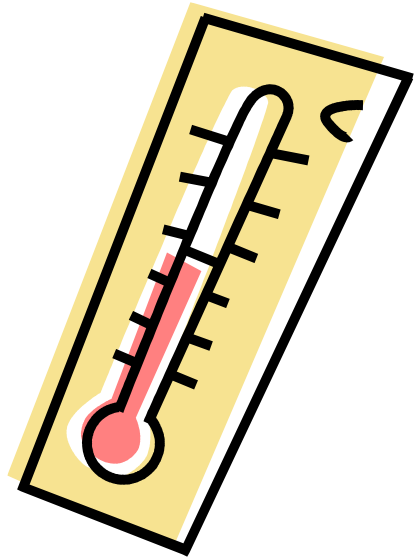
A plant implements a prerequisite program of purchase specifications to support E. coli O157:H7 is not reasonably likely to occur in received beef trim. The program states the plant will receive a certificate of analysis (COA) for each lot of trim to demonstrate that the program is preventing the hazard. You observe that the establishment does not appear to have a COA for the lot of trim they are currently grinding.

What is your conclusion?

Purchase Specification Example

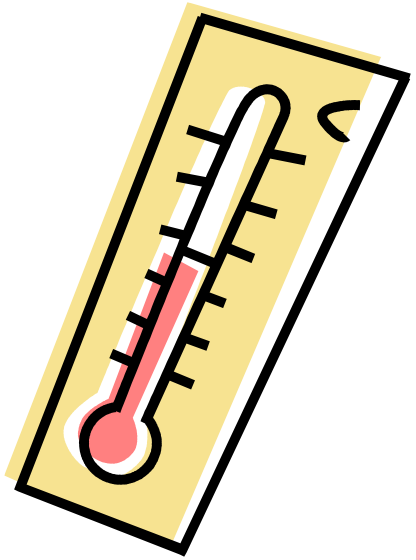
- What additional questions do you have?
- What other observations might you make?
- If the COA is missing or does not exist, there is noncompliance with 9 CFR 417.5(a)(1).
- Evaluate observations and determine the impact to the food safety system.

Temperature Controls



- Program should:
  - Include supporting documentation to demonstrate specified temperature is sufficient to prevent the hazard
  - Generate records to demonstrate temperatures consistently maintained at specified levels

Temperature Control Example

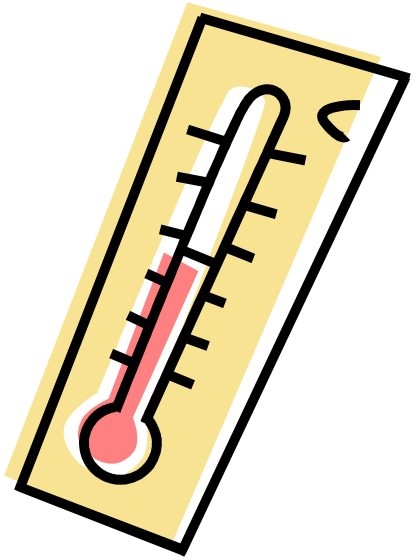


An establishment implements a PRP to maintain raw product coolers below 35°F to prevent pathogen growth from being reasonably likely to occur.

On 3 days last week, the employee recording the cooler temperature records did not record his initials as specified in the written program.

How does this finding impact the design and execution of the program?

Temperature Control Example



- This nonconformance:
  - would not result in failure to support the decision made in the hazard analysis.
  - is a vulnerability
  - should be discussed with the establishment and documented in the FSA.
  - should prompt additional questions
  - may require additional observations to evaluate the impact to the overall food safety system.

Knowledge Check

Do EIAOs have access to the establishment's written procedure, and the results generated by these prerequisite programs?

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Yes.

EIAOs have access to this information, including sample collection procedures, testing or analysis protocols, and results.

Knowledge Check

Does the establishment have to share microbiological testing performed on finished product with the EIAO?

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Does the establishment have to share microbiological testing performed on finished product with the EIAO?

Yes.

The establishment must provide any records needed by the EIAO for their review. The EIAO should request any records that could have a bearing on the hazard analysis.

FSIS Directive 5100.1 EIAO Comprehensive Food Safety Assessment Methodology

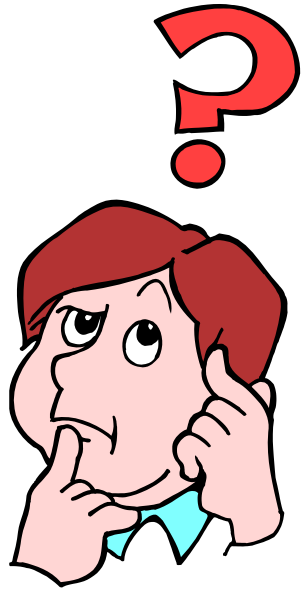
- Use communication techniques from the course and in FSIS Directive 5100.1 to obtain information needed for the FSA .

- Be able to explain FSIS's statutory authority under the FMIA, PPIA, and EPIA to examine facilities and to copy records.

PR Program Thinking Exercise

Come up with an example of a specific prerequisite program and explain how it may be used to support a decision in the hazard analysis .

What would you look for to see if it supports the decision?



Knowledge Check

Should the EIAO request records for establishment procedures such as quality checks, bone checks, paw dumping system checks, and preventive maintenance programs?

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Should the EIAO request records for establishment procedures such as quality checks, bone checks, paw dumping system checks, and preventive maintenance programs?

The EIAO should request any records that may relate to the effectiveness of the hazard analysis and HACCP system. In some cases, these may include the types of records described above.

Knowledge Check

What should an EIAO do if the establishment refuses to provide access to records that do impact the food safety system?

Knowledge Check

What should an EIAO do if the establishment refuses to provide access to records that do impact the food safety system?

The EIAO should advise his or her SEIAO of the situation immediately.
SEIAO will advise the DM/DDM who will determine enforcement strategy

Thawing as a Prerequisite Program

Step	Food Safety Hazard	RLTO?	Justification
Thawing frozen raw meat	**Biological:** Outgrowth of pathogens	No	Thawing SOP

Thawing as a Prerequisite Program

Step	Food Safety Hazard	RLTO?	Justification
Thawing frozen raw meat	**Biological:** Outgrowth of pathogens	No	Thawing SOP

1. **What does the Thawing SOP prescribe?**
2. **Will the Thawing SOP prevent the hazard?**
3. **What records are generated?**
4. **Is the Thawing SOP being effectively executed?**
5. **Has the plant validated the Thawing SOP?**

Thawing SOP

Written Program

- Frozen product thaws in a room at 50°F or less.
- Continuous monitoring chart and alarm if the temperature >50°F.
- The surface temperature checked ≥3 times per shift
- Surface temperature of thawed product ≤ 41°F ≤8 hours before processing.

Thawing SOP

Written Program

- The establishment has several references which specify that growth of pathogens, such as *Salmonella*, on this product would be minimal at temperatures less than 44.6°F.
- A challenge study demonstrated it would take holding product at 50°F for greater than 48 hours to achieve a 1-log increase in pathogens of concern.
- Product held at 41°F for 5 days will spoil.

Knowledge Check–Thawing SOP

Will this Thawing SOP, be adequate for supporting the NRLTO decision in the hazard analysis?

Knowledge Check–Thawing SOP

Will this Thawing SOP, be adequate for supporting the NRLTO decision in the hazard analysis?

Yes.

Based on the design, if properly implemented, this prerequisite program will control potential pathogen outgrowth at the thawing step.

Knowledge Check–Thawing SOP

Has the Thawing SOP been validated to demonstrate its effectiveness?

Knowledge Check–Thawing SOP

Has the Thawing SOP been validated to demonstrate its effectiveness?

It appears the establishment used scientific information to theoretically support the program and had a challenge study performed to demonstrate it would be effective in limiting the outgrowth of pathogens.

Knowledge Check

Why is it important to observe the implementation of the prerequisite programs?

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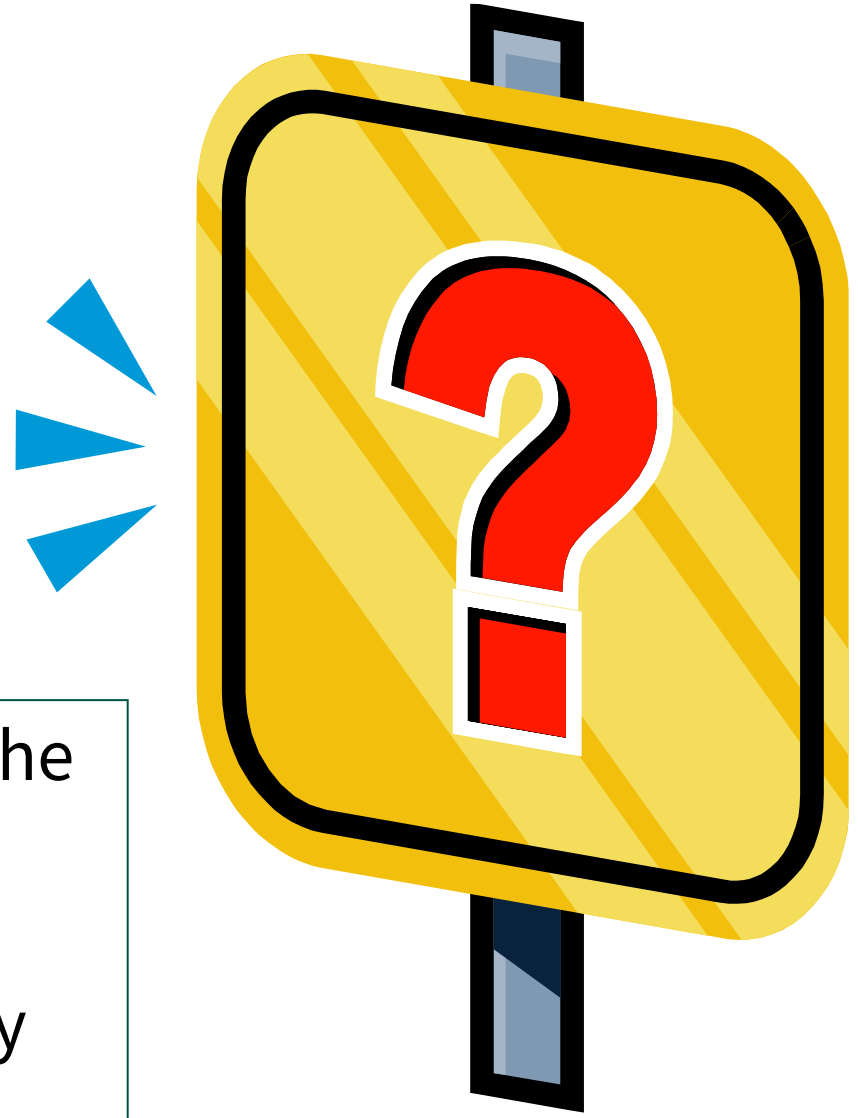

Key Principle

By observing the implementation of the prerequisite program an EIAO can support decisions made about the execution and support as well as any recommendations for NOIE.

Knowledge Check

What if you do not have the scientific or technical expertise to reach a conclusion about the design of a prerequisite program?

Knowledge Check

What if you do not have the scientific or technical expertise to reach a conclusion about the design of a prerequisite program?

1. Contact your SEIAO for guidance.
2. After consulting SEIAO if still need assistance submit detailed information through askFSIS.

Prerequisite Program Noncompliance

- Noncompliance examples:
  - Prerequisite program is not being executed as designed to prevent the relevant hazard.
  - Prerequisite records indicate repeated failures to implement the procedures to prevent the hazard.
  - Prerequisite records do not demonstrate the program is effectively preventing the hazard.

Recommendations

- Document 417.5(a)(1) noncompliance if the establishment does not have support for decisions in the hazard analysis.
- If you are unsure whether the findings support a decision in the hazard analysis, talk to the SEIAO and then use askFSIS
- Document 417.5(f) noncompliance if the establishment does not make prerequisite program records available for review.

Scenario #1

An establishment produces a ready-to-eat dried fermented beef sausage.

The hazard analysis states that *Lm* is not reasonably likely to occur and supports the decision by stating that the water activity and pH of the finished product will prevent growth of Lm during the shelf life (Alternative 2b from 9 CFR 430.4).

You investigate and find the establishment has no written program for monitoring water activity or pH and is not able to produce records to show the product meets a particular water activity or pH.

What Action(s), if any, would you take?

Scenario #1

Actions to take:

- Document noncompliance with 417.5(a)(1)
  - The establishment clearly does not have support for the decisions in the hazard analysis

- Perform additional investigation to determine if the findings could lead to an NOIE if the establishment has no records and isn't achieving the a_w or pH.

Scenario #2

A plant produces cured pork products. In the hazard analysis pathogen growth is not reasonably likely to occur at product receiving because products are received ≤40°F.

The hazard analysis refers to a PRP that checks product temperatures and condition at receiving.

You review product receiving records and find that 10 of the last 20 loads of incoming product were ≥40°F and several were as high as 60°F. The log indicates that the products were all accepted with no mention of any actions to ensure product safety.

Action: Recommend IIC document noncompliance with 417.5(a)(1) when the prerequisite program is ineffective

Prerequisite Program – Key points

- An ineffective PRP results in a hazard being reasonably likely to occur because the hazard is no longer prevented.
  - noncompliance with 417.5(a)(1) and 417.2(a)
- The establishment must reassess its hazard analysis to determine whether any changes to the hazard analysis are needed and make those changes. (417.4)
- The HACCP system may also be inadequate and result in the EIAO recommending an NOIE be issued by the DO. (417.6)

Prerequisite Program – Key points

When a PRP is found to be ineffective:

- The establishment must reassess its hazard analysis to determine whether any changes to the hazard analysis are needed and make those changes. (417.4)

- The HACCP system may also be inadequate and result in the EIAO recommending an NOIE be issued by the DO. (417.6)

Summary

- Establishments often use PRPs as justification for hazard being NRLTO
- The PRP must be effectively implemented and maintained to continue to support a hazard analysis
- EIAOs evaluate the design and execution of PRPs.
- There is a lot of information to consider in making an enforcement decision:
  - hazard analysis and supporting documentation
  - HACCP plan, Sanitation SOP, and SPS
  - PRP and GMP
- Send questions to askFSIS using the EIAO Methodology category

Summary

- There is a lot of information to consider in making an enforcement decision:
  - hazard analysis and supporting documentation
  - HACCP plan, Sanitation SOP, and SPS
  - PRP and GMP
- Send questions to askFSIS using the EIAO Methodology category.

Summary

- Determinations need to be based on the support for hazard analysis decisions and impact on the food safety system.
- An isolated failure of PRP implementation is generally not a noncompliance
- Poorly implemented or maintained PRPs can result in noncompliance
- Noncompliance must be documented with the proper regulatory citation

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Questions?

fsis.usda.gov

Prerequisite Program Workshop

An establishment is using a PRP to support a hazard analysis decision, but the program documentation does not support it.

What would the regulatory-statutory thought process be if an NOIE were issued?

Prerequisite Program Workshop

417.5(a)(1) - for lack of support for the decision in the hazard analysis (HA) that the hazard is NRLTO.

417.2(a)(1) – for failure to conduct an adequate hazard analysis. There may be a hazard that is reasonably likely to occur and they have not identified it as required.

417.6(a) – there may be an inadequate system because of failure to meet the 417 regulations – failure to conduct an adequate HA and there may be a hazard in the process for which there is no control.

417.2(e) – failure to meet the 417 requirements may render those products adulterated under 21 USC 601(m)(4) and 453(g)(4).

500.4(a) – FSIS may suspend inspection with prior notice (NOIE) if HACCP system is inadequate according to 417.6.

21 USC 601(m)(4) or 453(g)(4) product may be adulterated because of the insanitary conditions because of the failure of the establishment to conduct an adequate hazard analysis.

21 USC 608 or 21 USC 456 require that sanitary conditions be maintained and if not, the Secretary may refuse to render inspection services.