



Preventive Controls for Human Foods Inspections

AFDO Bootcamp
January 15, 2025

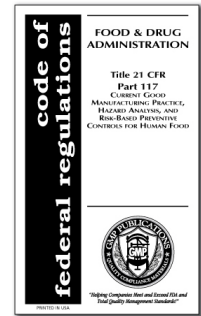
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Agenda

- Qualified Facility inspections
- Full scope PCHF inspections
 - Documenting observations
- Remaining questions



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Qualified facility – definition

- A *very small business*
 - < \$1 million annually (including subsidiaries and affiliates)
 - Sales of human food
 - Average from previous 3-year period
 - Adjusted for inflation since 2011 (FSMA)
 - Plus market value of human food manufactured, processed, packed, or held without sale (e.g. held for a fee)

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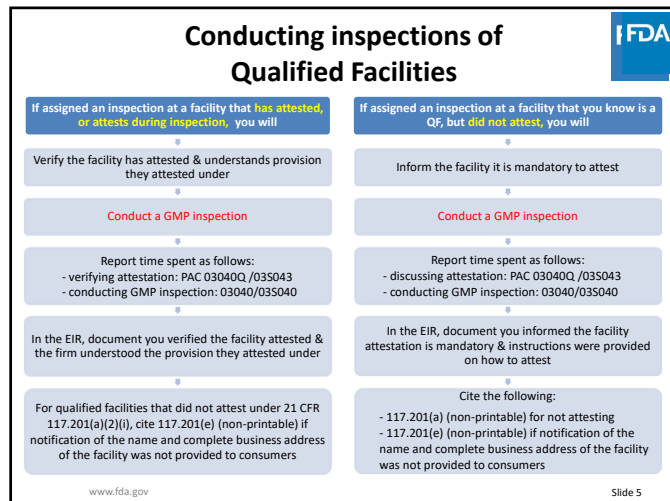
Qualified facility – consequence

- Must attest as qualified facility
- Exempt from PCHF requirements regardless of whether it attests
- Subject to CGMP (foundation)

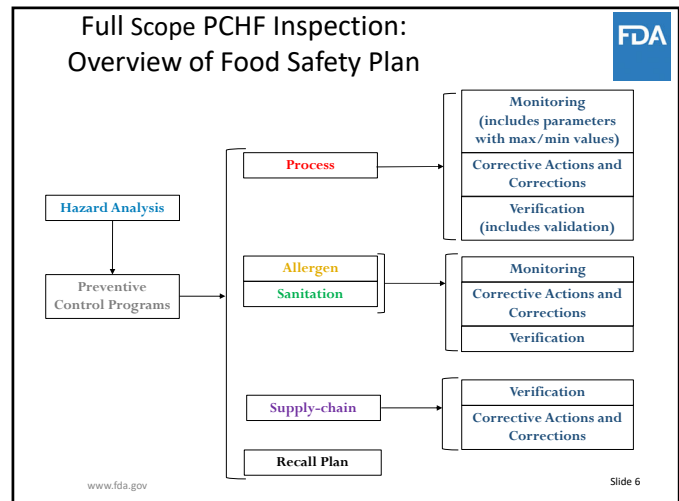
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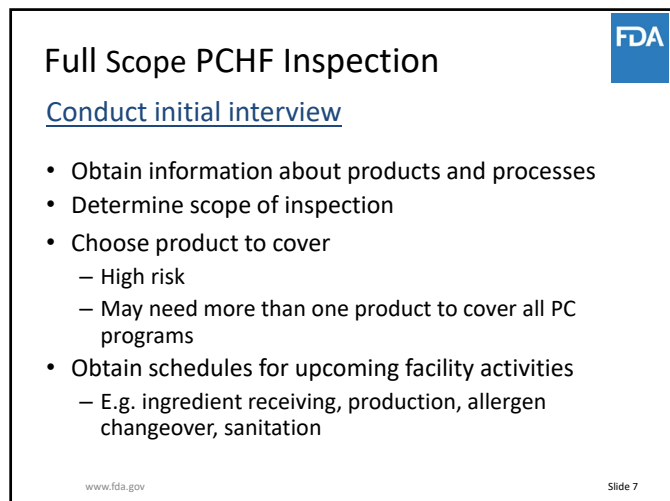
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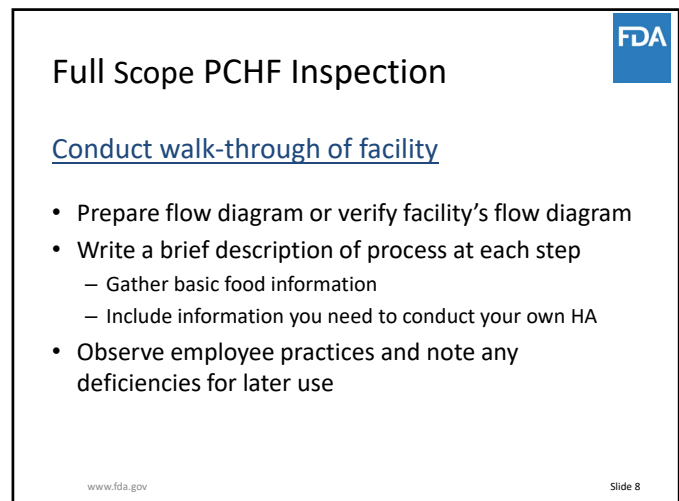
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Full Scope PCHF Inspection



Conduct your own hazard analysis

- Conduct finished product HA (process-related hazards) to determine which hazards require a preventive control at facility
 - Chapter 3 and Appendix 1 of [Food Hazards Guide](#)
- Conduct ingredient HA to determine which hazards associated with incoming ingredients require a preventive control
 - Obtain label and confirm ingredients
 - Chapter 3 and Appendix 1 of Food Hazards Guide

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Full Scope PCHF Inspection



A **process** preventive control is necessary when: the facility applies a process to control significant hazards, typically to the food itself

- Think “Critical Control Point” in a HACCP plan
- Process PCs typically have parameters with minimum/maximum values
 - Think “critical limit” in a HACCP plan
- Examples of process controls include:
 - Heating, cooling, refrigerated storage for safety, and metal detection

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Full Scope PCHF Inspection



An **allergen** preventive control is necessary when:

- The firm receives, stores, and uses allergenic ingredients
 - If product is or contains an allergen, a preventive control is generally needed for undeclared allergens
 - If unlike allergens are present in facility, a preventive control may be needed to control allergen cross-contact (unintended allergen presence)

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Full Scope PCHF Inspection



A **sanitation** preventive control is necessary when:

- The facility processes a finished product that is ready-to-eat and is exposed to the environment prior to packaging and there is an opportunity for pathogen recontamination.
 - A sanitation preventive control will generally be required in the area where RTE food is exposed and there is a risk of pathogen cross-contamination through poor employee practices or inadequate equipment cleaning
 - If a sanitation preventive control is necessary, environmental monitoring (sampling) is required

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A **supply-chain** program is necessary when:

- The ingredient hazard analysis finds the supplier or another entity in the supply-chain (e.g. supplier's supplier) is responsible for controlling the hazard.
 - Hazard controlled prior to receiving at the facility being inspected

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Summary of Hazards Requiring a Preventive Control

Process Controls (Step(s)/Hazard(s))

Allergen Controls (Step(s)/Hazard(s))

Sanitation Controls (Step(s)/Hazard(s))

Supply-chain Controls – Receiving (Ingredient/Hazard(s))

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Cream Filling



- Silky Sensations Corp. manufactures cream fillings. They are distributed to restaurants who fill them into pastries.
- All fillings contain milk, eggs, and wheat flour. Some fillings contain tree nuts such as almonds and pine nuts; others do not. Equipment is shared for processing the various fillings with and without nuts, on the same day.
- Filling ingredients are mixed and cooked in a kettle.



POLL

- Which hazards would require a PC? **Poll 1**
 - Undeclared allergens due to incorrect label
 - Allergen cross-contact
 - Both

Poll 2

- Does the hazard of vegetative pathogens require a PC?
 - Yes
 - No

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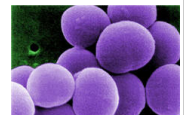
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Poll 3: Cream Filling (cont'd)



- Once cooled enough for handling, the fillings are removed from the kettles (including manual transfer using large handheld utensils).
- The facility determines that the finished product fillings require refrigeration to control *Staph aureus* growth and toxin formation, and it establishes the critical limit as $\leq 40^{\circ}\text{F}$ (Process PC).
- Must the facility independently validate this critical limit?
 - Yes, the PCHF Rule requires every facility to perform its own validation studies
 - Yes, critical limits in all PCs must be validated
 - No, the critical limit is already scientifically established



POLL

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Full Scope PCHF Inspection



Evaluate the facility's hazard analysis

- Compare your HA summary to the facility's HA
 - Resolve differences if necessary
- Note if facility did not identify a hazard that requires a preventive control
 - Decision to write or discuss observation made later during inspection

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Evaluate the adequacy of the facility's preventive control programs

- Review written preventive control procedures as determined during the HA
 - Adequacy of control measures, monitoring, corrective actions, verification

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Full Scope PCHF Inspection



Evaluate implementation of written preventive control procedures

- Interview employees at each point where controls are applied
 - Tell me what you do
 - What would you do if something went wrong
 - Show me how you fill out your record
- Observe employee practices
- Review records
 - Monitoring, corrective action, verification

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Full Scope PCHF Inspection



Document observations

- PCHF written observations written according to Structure OF Observations job aid for PCHF



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Full Scope PCHF Inspection

Document observations

- Determine regulatory significance
 - Significant (major) written
 - E.g. food safety impact, loss of control, repeat
 - Not significant (minor) is discussed
- Significant observations grouped by topic

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Poll 4: Hand Hygiene

- At pre-op, a supervisor observes an employee walk past the handwashing station and enter the RTE production room without washing and sanitizing her hands.
- This is the third time this month the employee did not wash or sanitize her hands.
- Is this a significant deficiency?
 - Likely yes
 - Likely no



POLL



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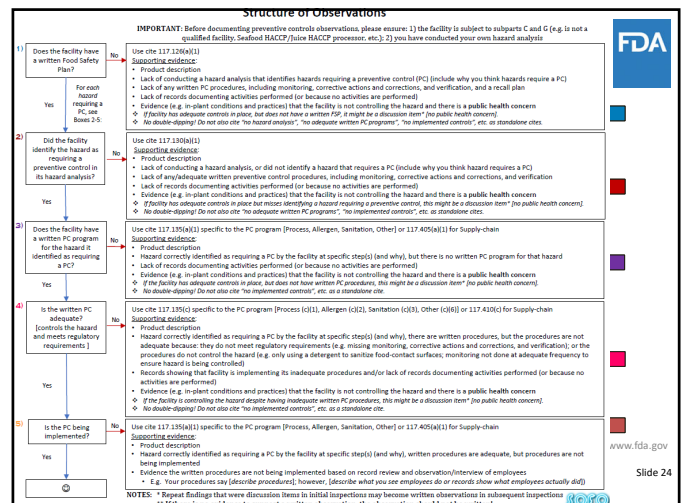
Basics of Writing Observations

- Observations must include evidence
 - Written as if they are a stand-alone document
- Start with the most significant observation at the highest level and build the evidence under it
- Minor observations that are discussion items also need to be documented

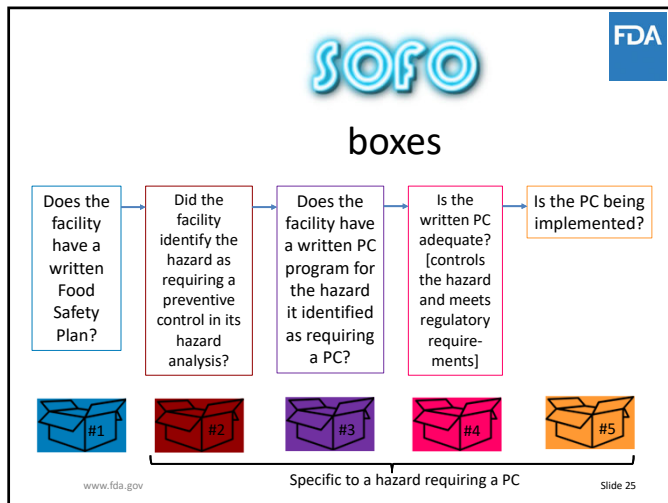
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Documenting Observations - PCHF
No Food Safety Plan – 117.126 (a)(1)

Does the facility have a written Food Safety Plan? **No**

Supporting evidence should include as applicable:

- Product description
- Lack of conducting a hazard analysis that identifies hazards requiring a preventive control (PC) (include why you think hazards require a PC)
- Lack of any written PC procedures, including monitoring, corrective actions/corrections, and verification, and a recall plan
- Lack of records documenting activities performed (or because no activities are performed)
- Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a **public health concern**
 - ❖ If facility has adequate controls in place, but does not have a written FSP, it might be a discussion item* [no public health concern].
 - ❖ No double-dipping! Do not also cite "no hazard analysis", "no adequate written PC programs", "no implemented controls", etc. as standalone cites.

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You did not have a written food safety plan. Specifically,

Documenting Observations: 117.126(a)(1) – No Food Safety Plan

- You manufacture two ready-to-eat snack foods, Almond, Cashew, Cherry Bites and Peanut, Raisin, Oat Bars which are exposed to the environment and are processed on shared equipment on the same day.
 - product
 - no hazard analysis
 - why hazard requires a PC
- You did not perform a hazard analysis of your RTE snack foods to identify and evaluate hazard(s) including recontamination with environmental pathogens, allergen cross-contact, undeclared allergens, and metal to determine if any require a preventive control.
 - no written PC procedures
- You do not have written preventive control program procedures including monitoring, corrective actions, and verification and you do not have records documenting activities performed.
 - no records of activities performed

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You did not have a written food safety plan. Specifically, (cont'd)

Documenting Observations: 117.126(a)(1) – No Food Safety Plan

in-plant observations/evidence

- Furthermore, you do not have controls in place for any of these hazards as evidenced by:
 - recontamination with environmental pathogens:
 - On [date], employees were observed to enter the snack packaging room from outside and did not wash and sanitize their hands prior to starting work and directly handling ready-to-eat Almond, Cashew, Cherry Bites.
 - allergen cross-contact:
 - On [date], employees did not wash the mixer that had been used to make Peanut, Raisin, Oat bars before using to mix ingredients for Almond, Cashew, Cherry Bites, lot [xxxx]. Food residue was visible on the mixer paddle and interior of the mixing bowls.
 - undeclared allergens:
 - On [date], during a production run of Almond, Cashew, Cherry Bites, lot [xxxx], an employee brought a new roll of foil pouches to replenish the line. However, the pouches were for your Peanut, Raisin, Oat Bar which does not declare almonds and cashews. The error was not noticed, and production continued.
 - metal:
 - There is metal-on-metal contact during the grinding of almonds and cashews used for your Almond, Cashew, Cherry Bites. You do not have a metal detector or any other control measure in place to ensure the hazard of metal inclusions is controlled.
 - why this hazard requires a PC

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Documenting Observations - PCHF

Hazard analysis – 117.130(a)(1)

Did the facility identify the hazard as requiring a preventive control in its hazard analysis?

No

Supporting evidence:

- Product description
- Lack of conducting a hazard analysis, or did not identify a hazard that requires a PC (include why you think hazard requires a PC)
- Lack of any/adequate written preventive control procedures, including monitoring, corrective actions and corrections, and verification
- Lack of records documenting activities performed (or because no activities are performed)
- Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a **public health concern**

❖ *If facility has adequate controls in place but misses identifying a hazard requiring a preventive control, this might be a discussion item* [no public health concern].*

❖ *No double-dipping! Do not also cite "no adequate written PC programs", "no implemented controls", etc. as standalone cites.*

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Documenting Observations - PCHF

Your hazard analysis did not identify a hazard that required a preventive control. Specifically,

Documenting Observations: 117.130(a)(1) – Hazard analysis

- Your hazard analysis did not identify the hazard of recontamination with environmental pathogens as requiring a preventive control for your Almond, Cashew, Cherry Bites. The in-process ingredients and finished product are RTE and are exposed to the environment from the grinder through to packaging.
 - hazard analysis missed a hazard
 - product
 - why hazard requires a PC
 - no written PC procedures
- You did not have written sanitation control procedures including monitoring, corrective actions, and verification, and you do not have records documenting activities performed.
 - no records of activities performed
- Furthermore, you did not have controls in place, as evidenced by the following observations regarding employee practices and equipment cleaning:
 - On [date], employees were observed to enter the snack packaging room from outside and did not wash and sanitize their hands prior to starting work and directly handling ready-to-eat Almond, Cashew, Cherry Bites.
 - You wash and sanitize your mini muffin tins at the end of each day. At the start of production on [date], these tins had visible product residue and were not cleaned and sanitized again before you used them to make RTE Almond Cashew Cherry Bites, lot [xxxx].

in-plant observations/evidence

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Documenting Observations - PCHF

No Written PC program for significant hazard – 117.135(a)(1) specific to Process/Allergen/Sanitation/Other PC program – 117.405(a)(1) for Supply-chain

Does the facility have a written PC program for the hazard it identified as requiring a PC?

No

Supporting evidence:

- Product description
- Hazard correctly identified as requiring a PC by the facility at specific step(s) (and why), but there is no written PC program for that hazard
- Lack of records documenting activities performed (or because no activities are performed)
- Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a **public health concern**

❖ *If the facility has adequate controls in place, but does not have written PC procedures, this might be a discussion item* [no public health concern].*

❖ *No double-dipping! Do not also cite "no implemented controls", etc. as a standalone cite.*

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Documenting Observations - PCHF

You did not identify a sanitation preventive control for a hazard when one was needed. Specifically,

Documenting Observations: 117.135(a)(1) – No written PC program for hazard identified as requiring a PC

- Your hazard analysis for your RTE Almond, Cashew, Cherry Bites appropriately identifies recontamination with environmental pathogens as a hazard requiring a preventive control at the grinding, mixing, depositing, and packaging/labeling steps. The in-process ingredients and finished product are exposed to the environment at these steps.
 - why hazard requires a PC
 - product
 - hazard analysis identified the hazard as significant
 - no written PC procedures
- However, you do not have written preventive control program procedures including monitoring, corrective actions, and verification and you do not have records documenting activities performed.
- Furthermore, you are not implementing controls, as follows:
 - On [date], employees were observed to enter the snack packaging room from outside and did not wash and sanitize their hands prior to starting work and directly handling ready-to-eat Almond, Cashew, Cherry Bites.
 - You wash and sanitize your mini muffin tins at the end of each day. At the start of production on [date], these tins had visible product residue and were not cleaned and sanitized again before you used them to make RTE Almond Cashew Cherry Bites, lot [xxxx].

in-plant observations/evidence

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Documenting Observations – PCHF

Written PC program not adequate – 117.135(c) cites specific to PC; 117.410(c) for supply-chain adequacy

Is the written PC adequate? [controls the hazard and meets regulatory requirements]

No

Supporting evidence:

- Product description
- Hazard correctly identified as requiring a PC by the facility at specific step(s) (and why), there are written procedures, but the procedures are not adequate because: they do not meet regulatory requirements (e.g. missing monitoring, corrective actions and corrections, and verification); or the procedures do not control the hazard (e.g. only using a detergent to sanitize food-contact surfaces; or monitoring not done at adequate frequency to ensure hazard is being controlled)
- Records showing that facility is implementing its inadequate procedures and/or lack of records documenting activities performed (or because no activities are performed)
- Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a **public health concern**
 - ❖ If the facility is controlling the hazard despite having inadequate written PC procedures, this might be a discussion item* [no public health concern].
 - ❖ No double-dipping! Do not also cite "no implemented controls", etc. as a standalone cite.

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Your written sanitation monitoring procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control. Specifically,

product

why hazard requires a PC

Documenting Observations: Written PC program not adequate 117.135(c)(3) example

what procedures say

hazard analysis identified the hazard as significant

how the procedure is inadequate

records show implementation of inadequate procedures

in-plant observations/evidence

- Your hazard analysis for your RTE Almond, Cashew, Cherry Bites appropriately identifies recontamination with environmental pathogens as a hazard requiring a preventive control at the grinding, mixing, depositing, and packaging/labeling step.
- Your written Sanitation Control Plan states that employees must wash and sanitize their hands before starting work, returning from breaks, and at any time when hands may have become contaminated. However, the procedure states that employee practices are only monitored at pre-op and not during production.
- A review of Employee Hygiene records from [dates] indicate that employee practices are only monitored at pre-op.
- Furthermore, you do not have controls in place as evidenced by:
 - On [Date], employees returning from lunch were observed to enter the snack packaging room from outside and did not wash and sanitize their hands prior to starting work and directly handling ready-to-eat Almond, Cashew, Cherry Bites.

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Documenting Observations - PCHF

Written PC program not implemented
– 117.135(a)(1) specific to Process/Allergen/Sanitation/Other PC program
– 117.405(a)(1) for Supply-chain

Is the PC being implemented?

No

Supporting evidence:

- Product description
- Hazard correctly identified as requiring a PC by the facility at specific step(s) (and why), written procedures are adequate, but procedures are not being implemented
- Evidence the written procedures are not being implemented based on record review and observation/interview of employees
- E.g. Your procedures say [describe procedures]; however, [describe what you see employees do or records show what employees actually did]

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You did not implement your sanitation monitoring procedures. Specifically,

product

why hazard requires a PC

Documenting Observations: Written PC program not implemented 117.135(a)(1) example

What procedures say

hazard analysis identified the hazard as significant

Lack of implementation as evidenced by records

In-plant observations/evidence

- Your hazard analysis for your RTE Almond, Cashew, Cherry Bites appropriately identifies recontamination with environmental pathogens as a hazard requiring a preventive control at the grinding, mixing, depositing, and packaging/labeling step.
- Your Sanitation Preventive Control program states that employee practices are monitored at the beginning of operations, at breaks, every 2 hours during production, and product changeovers.
- However, a review of records dated [dates] revealed the following observations:
 - There are no records for monitoring employee practices at breaks and product changeovers. Further, on [dates], I observed employee practices that can contribute to recontamination with environmental pathogens as follows:
 - Several employees returned from break, did not wash and sanitize their hands, and then proceeded to touch in-process RTE product.
 - The employee who is responsible for monitoring employee practices did not notice this deviation and production resumed.

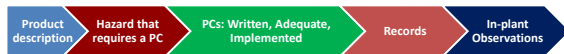
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Documenting Observations – Summary



- Written observations must be significant
 - Public health concern
- Organize written observations by significance of observation
- Add evidence to tie in public health concern with each observation following



- **Tell a food safety story:** don't be guided by individual citations unless necessary

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Macaroni Coleslaw



- Feather-in-Cap Deli Foods Inc. manufactures Macaroni Coleslaw which is packaged in a clear plastic deli container.
- The facility's hazard analysis did not identify the hazard of recontamination with environmental pathogens as requiring a PC after the macaroni is cooked and until the RTE salad is sealed in its finished product container. Instead, the facility relies on its prerequisite program (including an SSOP and recordkeeping) to control the hazard.



Poll 5

- Do you agree that the hazard does not require a PC?
 - a) Yes, the hazard does not require a PC
 - b) No, the hazard requires a PC



Poll 6

- Should the inspector evaluate the adequacy and implementation of the SSOP?
 - a) Yes, the inspector should evaluate any and all procedures maintained by the facility (no matter what)
 - b) Yes, the inspector should evaluate the prerequisite program as if it were a Sanitation PC
 - c) No, the facility does not consider it a PC

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Compliance Actions



- Examples of when to recommend:
 - Breakdown of a PC that results in a reasonable probability of causing SAHCODHA
 - Likely to pose an imminent public health threat
 - Recidivism
- What to do
 - *Contact State Liaison* as soon as compliance action recommendation is seriously being considered
 - State Liaison can coordinate with FDA compliance personnel
 - Consider applicable state and federal options

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Questions?



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