Preventive Controls for Human Foods Inspections

AFDO Bootcamp

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Agenda

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

Building PAC Codes
21 CFR 117 Inspection types

Type of Inspection	21 CFR Subparts	PAC
GMP	A, B and F	FDA: 03040 STATE: 03S040
Qualified Facility	A, B, D and F	FDA: 03040 + 03040Q State: 03S040 + 03S043
Limited Scope PCHF	A, B, C* and F (*117.135(a)(1) implementation cite)	FDA:03040 + 03040L State: 03S040 + 03S041
Full Scope PCHF	A, B, C, F, and G	FDA: 03040 + 03040F State: 03S040 + 03S042

Qualified facilities

- A *very small business* is a qualified facility
- All qualified facilities are exempt from PCHF requirements in Subparts C & G regardless of whether they attest
- A qualified facility must submit an attestation and is subject to Subpart D 117.201

Conducting inspections of Qualified Facilities

If assigned an inspection at a facility that has attested, or attests during inspection, you will

Verify the facility has attested & understands provision they attested under

Conduct a GMP inspection

Report time spent as follows:
- verifying attestation: PAC 03040Q /03S043
- conducting GMP inspection: 03040/03S040

In the EIR, document you verified the facility attested & the firm understood the provision they attested under

For qualified facilities that did not attest under 21 CFR 117.201(a)(2)(i), cite 117.201(e) (non-printable) if notification of the name and complete business address of the facility was not provided to consumers

If assigned an inspection at a facility that you know is a QF, but did not attest, you will

Inform the facility it is mandatory to attest

Conduct a GMP inspection

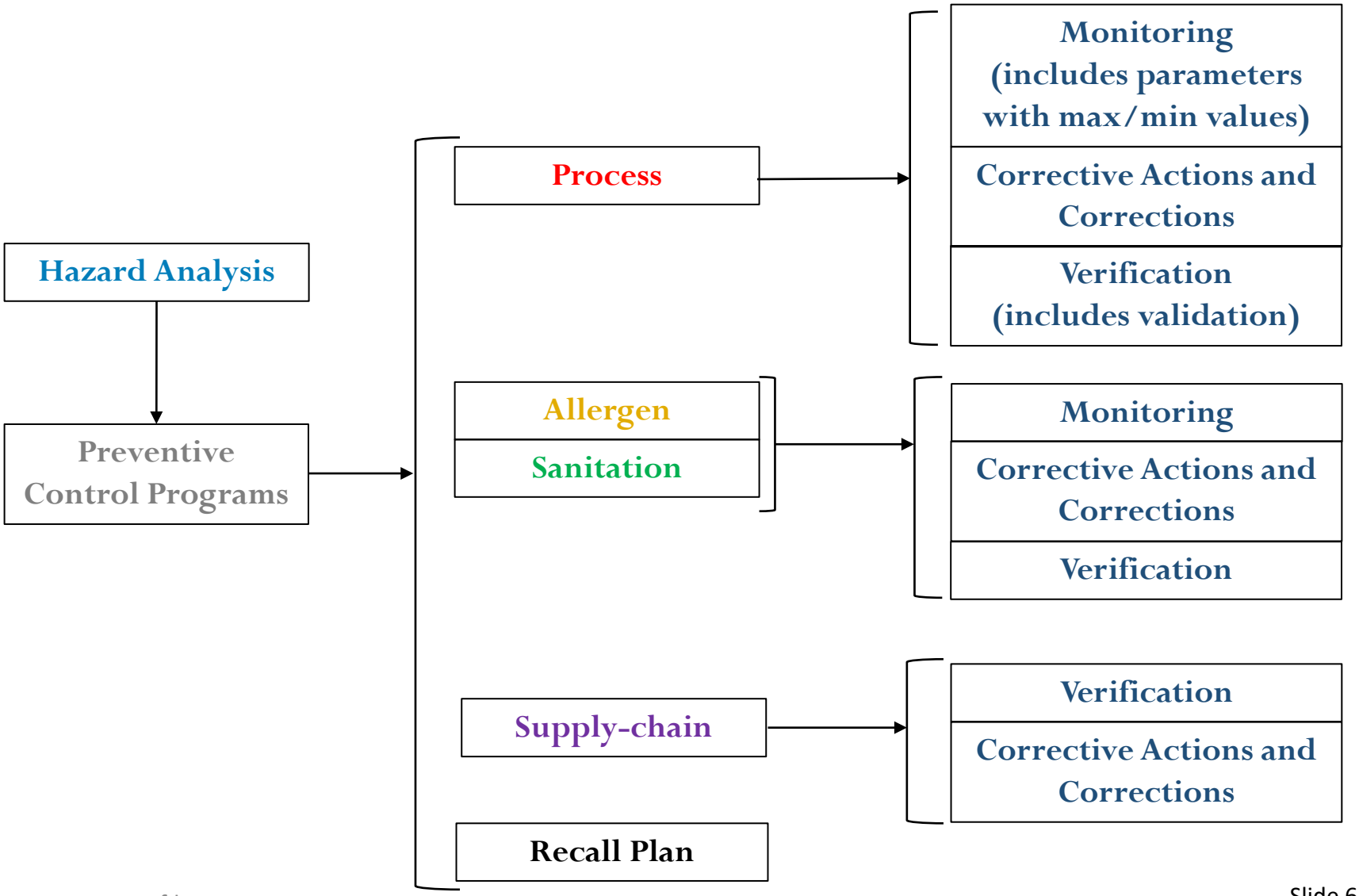
Report time spent as follows:
- discussing attestation: PAC 03040Q /03S043
- conducting GMP inspection: 03040/03S040

In the EIR, document you informed the facility attestation is mandatory & instructions were provided on how to attest

Cite the following:

- 117.201(a) (non-printable) for not attesting
- 117.201(e) (non-printable) if notification of the name and complete business address of the facility was not provided to consumers

Full Scope PCHF Inspection: Overview of Food Safety Plan



Full Scope PCHF Inspection

Conduct initial interview

- Obtain information about products and processes
- Determine scope of inspection
- Choose product to cover
  - High risk
  - May need more than one product to cover all PC programs
- Obtain schedules for upcoming facility activities
  - E.g. ingredient receiving, production, allergen changeover, sanitation

Full Scope PCHF Inspection

Conduct walk-through of facility

- Prepare flow diagram or verify facility's flow diagram
- Write a brief description of process at each step
  - Gather basic food information
  - Include information you need to conduct your own HA
- Observe employee practices and note any deficiencies for later use

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

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

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)

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

Full Scope PCHF Inspection

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

Full Scope PCHF Inspection

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)*)

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.

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

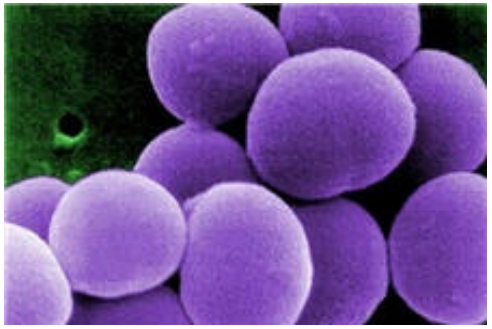
POLL

Poll 2

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

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 ≤ 40˚F (Process PC).
- Must the facility independently validate this critical limit?
  a) Yes, the PC Rule requires every facility to perform its own validation studies
  b) Yes, critical limits in all PCs must be validated
  c) No, the critical limit is already scientifically established



POLL

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

Full Scope PCHF Inspection

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

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

Full Scope PCHF Inspection

Document observations

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

Full Scope PCHF Inspection

Document observations

- Determine regulatory significance
  - Significant (major) written
    - E.g. egregious filth, issue with PC
  - Not significant (minor) is discussed
    - E.g. training or routine filth issue
- Significant observations grouped by topic

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?
  a) Likely yes
  b) Likely no

POLL

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

Structure of Observations

IMPORTANT: Before documenting preventive controls observations, please ensure: 1) the facility is subject to subparts C and G (e.g. is not a qualified facility, Seafood HACCP/Juice HACCP processor, etc.); 2) you have conducted your own hazard analysis

1) Does the facility have a written Food Safety Plan?

No → Use cite 117.126(a)(1)

Supporting evidence:
- 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 and 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.*

Yes → For *each hazard* requiring a PC, see Boxes 2-5:

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

No → Use cite 117.130(a)(1)

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.*

Yes →

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

No → Use cite 117.135(a)(1) specific to the PC program [Process, Allergen, Sanitation, Other] or 117.405(a)(1) for Supply-chain

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.*

Yes →

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

No → Use cite 117.135(c) specific to the PC program [Process (c)(1), Allergen (c)(2), Sanitation (c)(3), Other (c)(6)] or 117.410(c) for Supply-chain

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; 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.*

Yes →

5) Is the PC being implemented?

No → Use cite 117.135(a)(1) specific to the PC program [Process, Allergen, Sanitation, Other] or 117.405(a)(1) for Supply-chain

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*])

Yes → ☺

NOTES: * Repeat findings that were discussion items in initial inspections may become written observations in subsequent inspections

** **If there is no evidence to support a written observation, the observation should not be written!**

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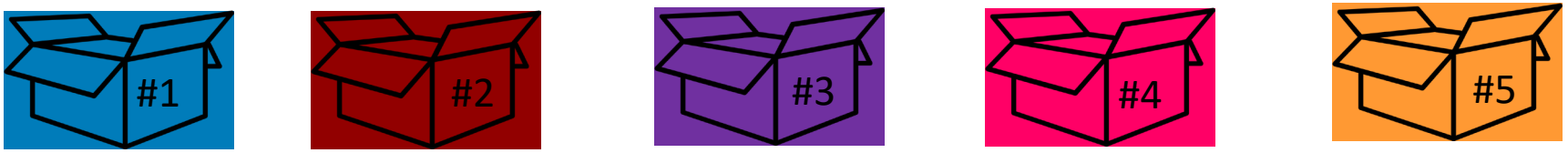
boxes

#1	#2	#3	#4	#5
Does the facility have a written Food Safety Plan?	Did the facility identify the hazard as requiring a preventive control in its hazard analysis?	Does the facility have a written PC program for the hazard it identified as requiring a PC?	Is the written PC adequate? [controls the hazard and meets regulatory require-ments]	Is the PC being implemented?



Specific to a hazard requiring a PC

Documenting Observations - PCHF

No Food Safety Plan – 117.126 (a)(1)

Does the facility have a written Food Safety Plan?

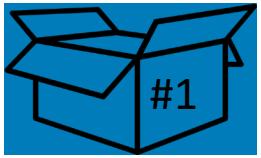
No →

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.*



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

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 hazard analysis

- 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 written PC procedures

no records of activities performed

(*cont'd on next slide*)

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

in-plant observations/ evidence

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

- Furthermore, you do not have controls in place for any of these hazards as evidenced by:

a) <u>recontamination with environmental pathogens:</u>

- 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].

b) <u>allergen cross-contact</u>:

- 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.

c) <u>undeclared allergens</u>

- 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.

why this hazard requires a PC

d) <u>metal</u>

- 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.

Documenting Observations - PCHF

Hazard analysis – 117.130(a)(1)

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

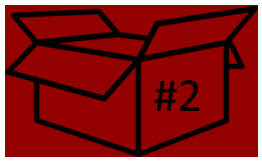
No →

<u>Supporting evidence</u>:

- 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.*



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

- You did not have written sanitation control procedures including monitoring, corrective actions, and verification, and you do not have records documenting activities performed.

no written PC procedures

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].

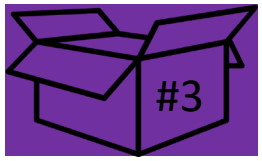
in-plant observations/evidence

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.*

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

product

why hazard requires a PC

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 where RTE ingredients and finished product are exposed to the environment at these steps.

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

Documenting Observations – PCHF

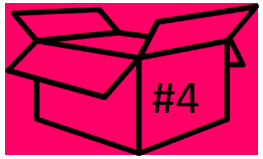
Written PC program not adequate – 117.135(c) cites specific to PC; 117.410(c) for supply-chain adequacy

Is the written PC adequate? [controls the hazard and meets regulatory require-ments]

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.*



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

- 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 ste

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

what procedures say

hazard analysis identified the hazard as significant

- 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.

how the procedure is inadequate

- A review of Employee Hygiene records from [dates] indicate that employee ractices are only monitored at pre-op.

records show implementation of inadequate procedures

- 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.

in-plant observations/evidence

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*])

You did not implement your sanitation monitoring procedures. Specifically,

product

why hazard requires 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 st

What procedures say

hazard analysis identified the hazard as significant

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

- 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.

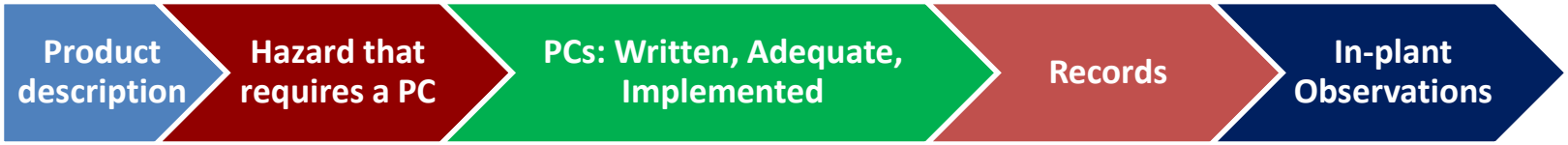
Lack of implementation as evidenced by records

- 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.

In-plant observations/evidence

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 SOFO



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

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

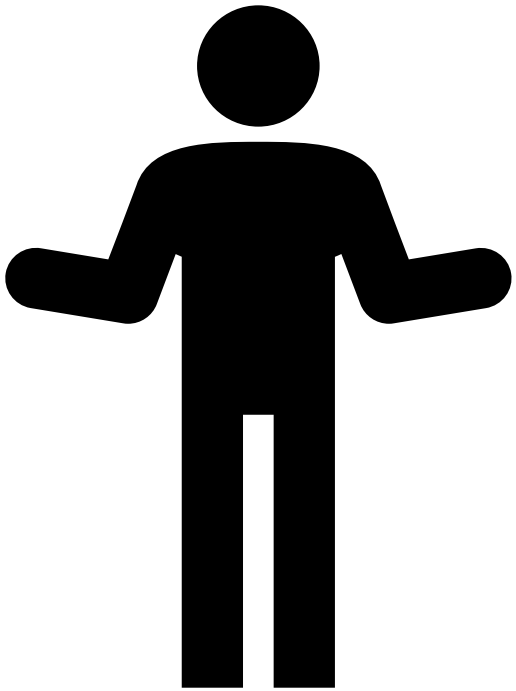
POLL

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

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



Questions?