Preventive Controls for Human Foods Inspections

AFDO Bootcamp

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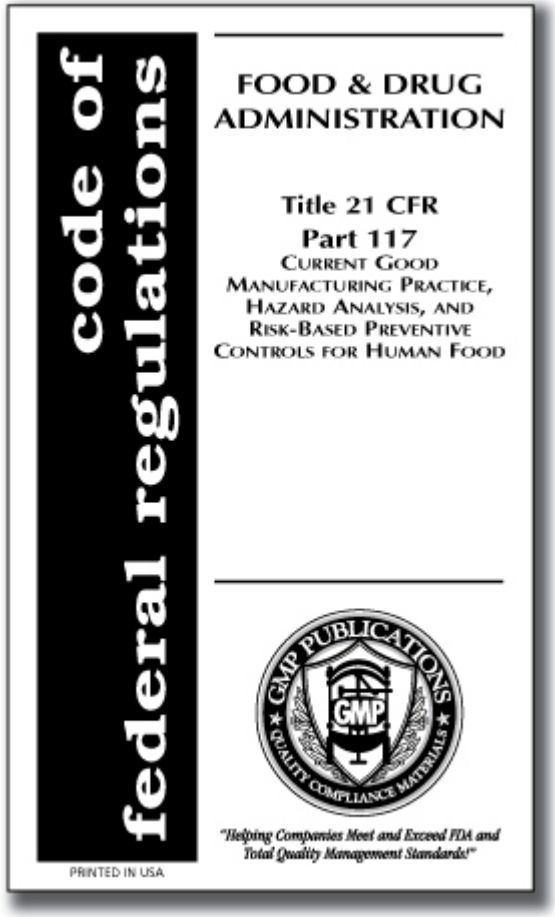
Objectives

- Understand the types of preventive controls inspections
- Understand basic components of a risk-based preventive controls inspection
- Learn how to assess adequacy and implementation of food safety plans
- Understand how to evaluate significance of observations



Types of PCHF inspections

Inspection type	Coverage	PAC (FDA/State)
Food CGMP (GMP)	GMPs (subpart B)	03040/03S040
Limited scope PCHF	GMPs and PC implementation	03040L/03S041 (PC implementation) + 03040/03S040 (GMPs)
Full scope PCHF	GMPs and Adequacy and implementation of the food safety plan (subparts C and G)	03040F/03S042 (PCHF) + 03040/03S040 (GMPs)
Qualified facility	GMPs and attestation requirements in 117.201	03040Q/03S043 (attestation requirements) + 03040/03S040 (GMPs)
Warehouses solely engaged in the storage of unexposed packaged food requiring time/ temperature controls for safety	GMPs and time/temperature controls in 117.206	03040R/03S044 (time/temp controls) + 03040/03S040 (GMPs)
Focused PCHF	GMPs and specific PCs as directed	03040U/03S045 (specific PC coverage) + 03040/03S040 (GMPs)

Limited scope PCHF inspection

- Can only be performed at facilities that are subject to the full PCHF requirements
  - Cannot be performed at a qualified facility or any facility exempt from subparts C and G
- Assessment of implementation of process, allergen, and sanitation PCs
  - No review of written procedures or records
  - Information is obtained through observation of employee practices and interviewing employees
- If issues with implemented controls pose a significant food safety concern, convert inspection to full scope PCHF
  - **No written PC observations** (e.g. no FDA 483 PC observations)
  - Significant GMP issues can be written observations

Qualified facility inspections

- Can only be performed at facilities that meet the definition of a qualified facility:
  - V*ery small business*
    - < $1 million annually (including subsidiaries and affiliates) adjusted for inflation (current threshold: $1,331,894)
      - Sales of human food
        - Average from previous 3-year period
      - Plus market value of human food manufactured, processed, packed, or held without sale (e.g. held for a fee)

Conducting inspections of Qualified Facilities

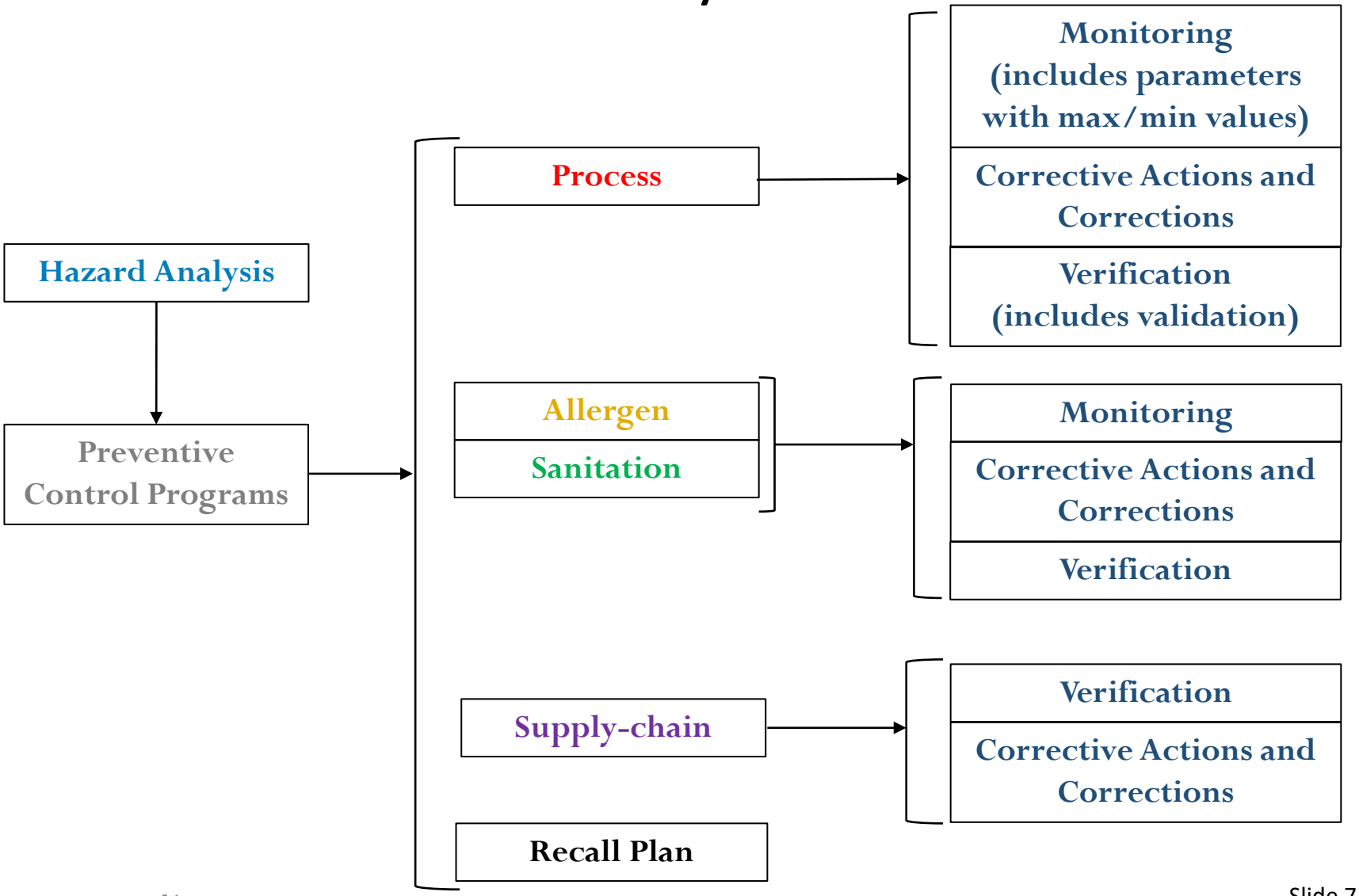
If assigned an inspection at a facility that has attested, or attests during inspection, you will

- 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)*)

Polls 1-2: 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

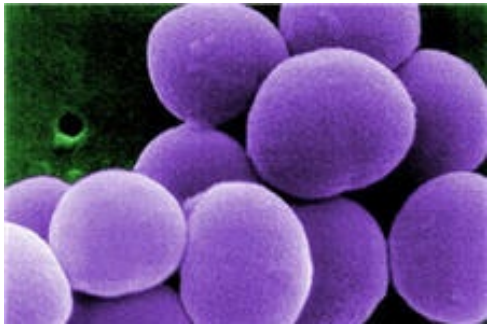
POLL

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 PCHF 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 for PCHF (discussed later)

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

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

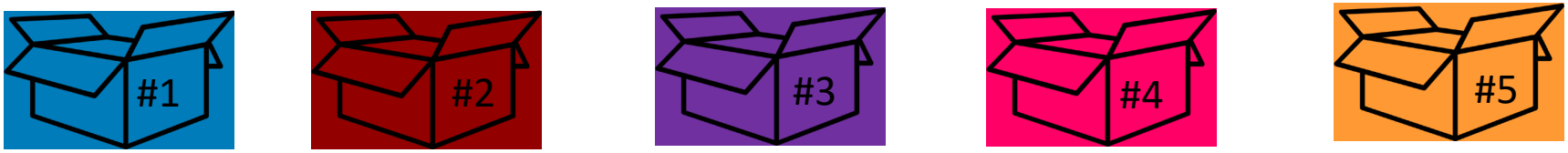
POLL

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

SOFO 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

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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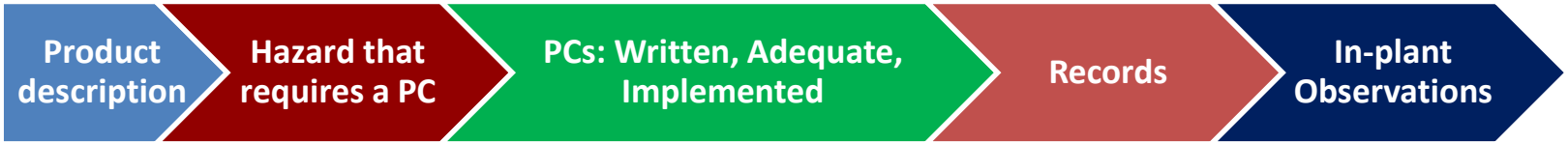
Documenting Observations – Summary

- 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

Polls 5-6: 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

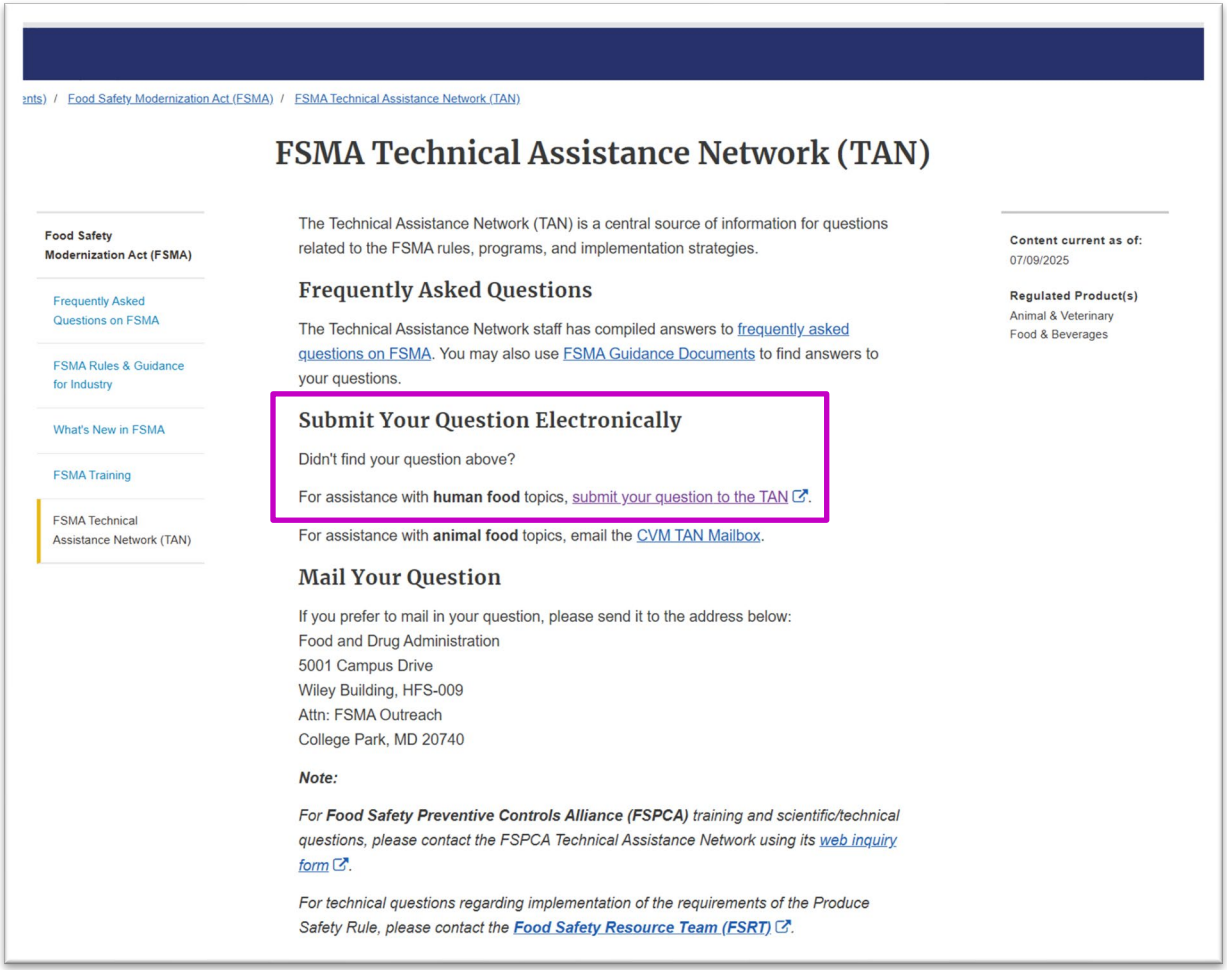
- Examples of when to recommend:
  - Breakdown of a PC that results in a reasonable probability of causing SAHCODHA
  - Likely to pose an imminent public health threat
  - Recidivism
- What to do
  - *Contact State Liaison* as soon as compliance action recommendation is seriously being considered
  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

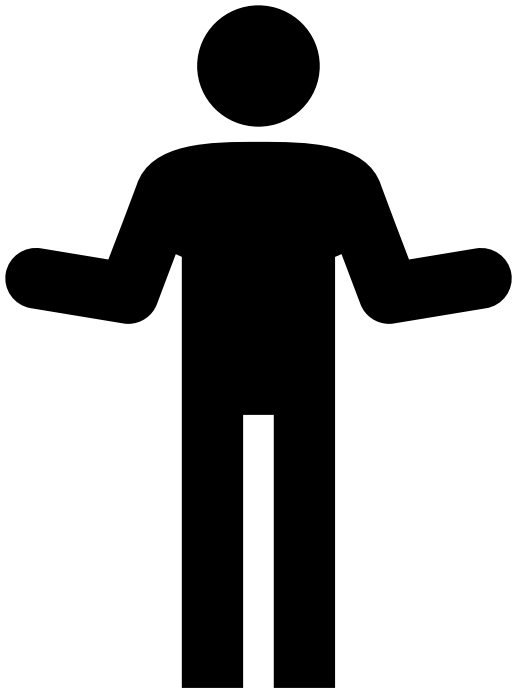
Facilitating an FDA inspection

- Be prepared to:
  - provide the written procedures and records to support compliance with the PCHF rule promptly
  - explain the rationale behind the determination of why a hazard is or is not significant
  - provide the scientific support behind the adequacy of preventive controls
- Be open to:
  - answering questions from the inspector
  - making thorough and lasting corrections to address findings
- Remember: We are on the same team – safe food is a win for industry, regulators, and the American people

FSMA TAN

- Industry questions on FSMA-related regulations and guidance, reach out to FDA via the FSMA Technical Assistance Network





Questions?