

HAVING “THE TALK”: PREPARING FOR NEW CONVERSATION-BASED INSPECTIONS

What types of FDA inspections have you personally been involved in? If you have been involved in multiple, select the first option that fits your involvement).

- A. A food safety investigation
- B. Subpart B inspection
- C. FSMA readiness (sub B and readiness are probably the same thing)
- D. Other - medicated feed, BSE, etc.
- E. I've never been part of an FDA inspection



Scenario One

FSMA READINESS



DOES THE COMPANY HAVE THE RIGHT TO REQUEST THAT AN FDA INVESTIGATOR RETURN TO PERFORM A ROUTINE INSPECTION AT A MORE CONVENIENT TIME?

- A. Yes
- B. No
- C. Maybe/I don't know

DOES THE PCQI NEED TO COMPLETE DOCUMENTED FOOD SAFETY TRAINING?

- A. Yes
- B. No
- C. Maybe/I don't know

IS THE COMPANY OBLIGATED TO PROVIDE A COPY OF ITS WRITTEN FOOD SAFETY PLAN TO THE INSPECTOR?

- A. Yes
- B. No
- C. Maybe/I don't know

IS THE COMPANY OBLIGATED TO PROVIDE
INFORMATION ABOUT ENVIRONMENTAL MONITORING
AND THE RECALL PLAN TO THE INSPECTOR?

- A. Yes
- B. No
- C. Maybe/I don't know

Take-Aways

1. Develop a plan on how to respond to FSMA readiness questions. Depending on your compliance date and your company's food safety plan, you may not have an obligation to provide the requested information.
2. The PCQI is not required to complete FSPCA training, but they still need to be a *Qualified Individual*.
3. Importers of foreign food, human and/or animal, are to comply with FDA's rule for Foreign Supplier Verification Programs. The rule applies to importers only. Using a foreign food does not make you subject to the FSVP rule.

Scenario Two

INSPECTION PRELIMINARY QUESTIONS



DOES FDA HAVE THE AUTHORITY TO HAVE ACCESS TO ANNUAL SALES VOLUMES — DOLLARS, TONS, ETC.?

- A. Yes
- B. No
- C. Maybe/I don't know



WHEN DOES FDA HAVE THE RIGHT TO ACCESS RECORDS RELATED TO FULL-TIME EMPLOYEES?

- A. Always
- B. Never
- C. Only in specific circumstances

DOES FDA HAVE THE RIGHT TO KNOW WHO ARE YOUR 'TOP' CUSTOMERS OR SUPPLIERS?

- A. Yes
- B. No
- C. Maybe/I don't know

Take-Aways

1. It may be appropriate to ask an investigator why information is being requested. FDA may ask questions in a roundabout way.
2. Develop a policy on how to handle FDA requests for customer and supplier information. FDA does have authority to access records associated with movement of food in interstate commerce.
3. Unless the company is an “other” business (large), companies will need to provide FDA with business size information to substantiate their compliance dates. Also, Very Small Businesses will need to share sales data.

Scenario Three

INSPECTION PRELIMINARY QUESTIONS - CONTINUED



CAN QUALIFIED INDIVIDUAL RECORDS BE STORED ELECTRONICALLY?

- A. Yes
- B. No
- C. Maybe/I don't know

WAS THE DESCRIBED LEVEL OF PERSONAL HYGIENE PRACTICES GENERALLY APPROPRIATE FOR ALL TYPES OF ANIMAL FOOD FACILITIES?

- A. Yes
- B. No
- C. Maybe/I don't know

ARE ALL PLANT EMPLOYEES (INCLUDING MAINTENANCE WORKERS AND DRIVERS) REQUIRED TO RECEIVE QUALIFIED INDIVIDUAL TRAINING?

- A. Yes
- B. No
- C. Maybe/I don't know

ARE OUTSIDE PEST CONTROL PERSONNEL OR
MAINTENANCE/REPAIR PERSONNEL REQUIRED TO
RECEIVE QUALIFIED INDIVIDUAL TRAINING?

- A. Yes
- B. No
- C. Maybe/I don't know

DOES THE PERSON CONDUCTING THE QI TRAINING
NEED TO HAVE RECEIVED DOCUMENTED TRAINING TO
BE QUALIFIED TO DELIVER THE TRAINING?

- A. Yes
- B. No
- C. Maybe/I don't know

DOES THE DOCUMENTED QI TRAINING NEED TO COVER THE FACILITY'S SOP FOR THE JOB(S) THE INDIVIDUAL PERFORMS?

- A. Yes
- B. No
- C. Maybe/I don't know

SIDEBAR – FREE QI TRAINING RESOURCE

<https://www.youtube.com/watch?v=O6kflfOqxYs&feature=youtu.be>



The image shows a YouTube video player interface. At the top left is the YouTube logo. To its right is a search bar with the text "Search". Below the search bar is a video player. The video title is "Animal Food Hygiene and Animal Food Safety". Below the title is a description: "A module developed to help animal food facilities meet the personnel training requirements of the Preventive Controls for Animal Food rule of the Food Safety Modernization Act". The video player has a progress bar at the bottom showing "0:01 / 20:06". There are also icons for play, volume, and settings. In the bottom right corner of the video player, there is a Creative Commons license icon and the Kansas State University logo.

Animal Food Qualified Individual Training

HOW LONG DO THE REQUIRED QUALIFIED INDIVIDUAL TRAINING RECORDS NEED TO BE KEPT?

- A. 1 year after the training occurs
- B. 2 years after the training occurs
- C. 1 year after the individual's affiliation with the facility ends
- D. 2 years after the individual's affiliation with the facility ends
- E. None of the above



IS INCLUDING A PROCESS FLOW DIAGRAM WITHIN YOUR FOOD SAFETY PLAN A GOOD IDEA?

- A. Yes
- B. No
- C. Maybe/I don't know

DURING A ROUTINE INSPECTION (NOT FOR INVESTIGATING A FOOD SAFETY INCIDENT), CAN FDA ACCESS CUSTOMER COMPLAINT FILES?

- A. Yes
- B. No
- C. Maybe/I don't know

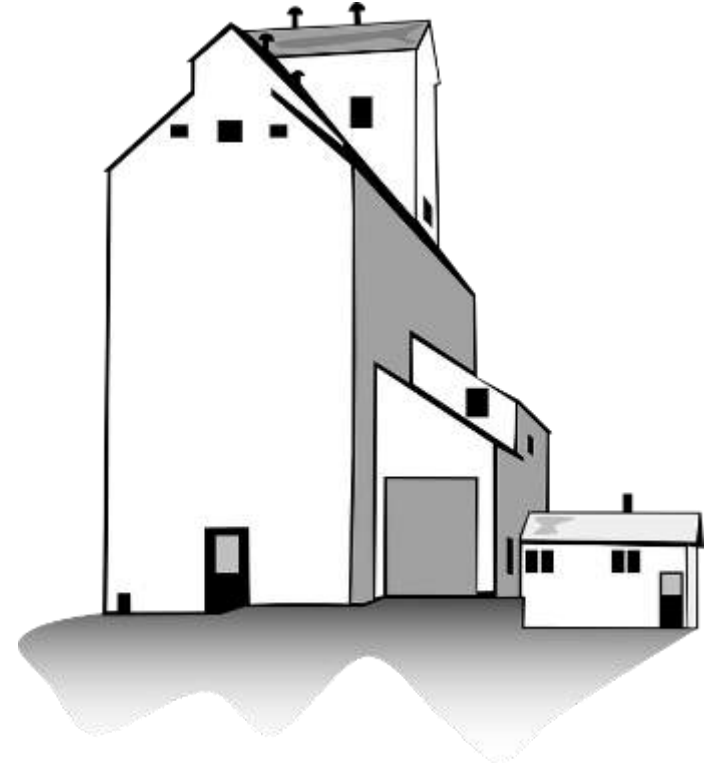


Take-Aways

1. Records required by the rule may be established and maintained electronically, so long as the integrity of the records can be assured.
2. Think through how to complete appropriate Qualified Individual training and who needs to receive documented training. The importance of personnel health and personal hygiene to animal food safety may differ between facilities.
3. The use of a process flow diagram during hazard evaluation is not required, but may be useful. The investigator during the inspection likely will want to evaluate process flow.
4. Develop a policy for how to handle FDA requests for complaint files during routine inspections

Scenario Four

CGMP INSPECTION – PLANT AND GROUNDS





IS IT NECESSARY TO DRAIN PUDDLES IN THE DRIVEWAY
TO PROTECT AGAINST CONTRIBUTING TO THE
CONTAMINATION OF ANIMAL FOOD?

- A. Yes
- B. No
- C. Maybe/I don't know



DO YOU THINK THE ABSENCE OF VISIBLE PEST ACTIVITY AND CONTAMINATION WITHIN A FACILITY SATISFIES THE CGMP REQUIREMENT RELATED TO GRASS, WEEDS, AND DRAINAGE?

- A. Yes
- B. No
- C. Maybe/I don't know

IS IT NECESSARY TO CONTROL WEEDS, GRASS AND LITTER WITHIN 100 FEET OF THE FACILITY TO PROTECT AGAINST CONTAMINATION OF ANIMAL FOOD?

- A. Yes
- B. No
- C. Maybe/I don't know





IS ANIMAL FOOD STORED OUTDOORS IN BULK REQUIRED TO HAVE PROTECTIVE COVERING?

- A. Yes
- B. No
- C. Maybe/I don't know

DO YOUR INSPECTION POLICIES ALLOW FOR INVESTIGATORS TO TAKE PHOTOGRAPHS?

- A. Yes
- B. No
- C. Maybe/I don't know

Take-Aways

1. Although not specifically required by the CGMPs, FDA generally expects a written pest control plan that includes monitoring records.
2. Identify the grounds around the plant that need to be maintained for pest control and establish a plan. Be able to justify your decisions.
3. If standing water has the potential to contaminate animal food, take steps to eliminate it.
4. If you store bulk animal food outdoors without a cover, routinely monitor for pests and product condition.
5. Develop a policy for photos and communicate it to the investigator.

Scenario Five

CGMP INSPECTION – RECEIVING





IS AN INSPECTION CHECKLIST REQUIRED TO DOCUMENT THE EXAMINATION OF CONVEYANCES THAT DELIVER RAW MATERIALS AND INGREDIENTS TO THE FACILITY?

- A. Yes
- B. No
- C. Maybe/I don't know

DO YOU (OR DO YOU PLAN TO) USE A CHECKLIST FOR THE PURPOSES OF EXAMINING CONVEYANCES WHEN THEY ARRIVE AT YOUR FACILITY?

- A. Yes
- B. No
- C. Maybe/I don't know



HOW WOULD YOU CLASSIFY AFLATOXIN IN THIS FACILITY'S FOOD SAFETY PLAN?

- A. Not a hazard
- B. Hazard, but not known or reasonably foreseeable
- C. Known or reasonably foreseeable, but does not require a preventive control
- D. Hazard requiring a preventive control – control via supply-chain-applied control
- E. Hazard requiring a preventive control – control via process control/other control
- F. Hazard requiring a preventive control – control via 21 CFR 507.36



Discussion: How robust should a prerequisite program be to use it as justification for a hazard not requiring a preventive control?

From FSPCA Preventive Controls
for Animal Food Course Training
Manual v1.1



A facility should consider whether an effective prerequisite program (such as CGMP) reduces the probability that a *known or reasonably foreseeable hazard* may occur. This consideration may result in the facility determining that, based on the overall hazard analysis:

- the hazard does not require a preventive control;
- the hazard requires a preventive control and the prerequisite program is the preventive control; or
- the hazard requires a preventive control beyond the prerequisite program.

This prerequisite program must be effectively implemented to reduce the probability, thus having procedures and routine recordkeeping in place are a good industry practice.



IF COMPRESSED AIR IS USED TO CLEAN ANIMAL FOOD CONTACT SURFACES, BUT NOT INTRODUCED INTO ANIMAL FOOD, DO PRECAUTIONS NEED TO BE TAKEN TO PROTECT AGAINST THE CONTAMINATION OF ANIMAL FOOD?

- A. Yes
- B. No
- C. Maybe/I don't know

Take-Aways

1. Implement procedures to evaluate shipping containers (e.g., trucks, etc.) associated with in bound ingredients.
2. If you use ingredients susceptible to mycotoxins, implement procedures to protect against unsafe contamination. Routinely review the plan.
3. Use procedures to protect against contamination of animal food when using compressed air for cleaning. As necessary, visit with your air compressor supplier about the potential for oil residues and take appropriate actions.

Scenario Six

CGMP INSPECTION – HAZARD DISCLOSURES, WRITTEN ASSURANCES





SHOULD THIS FACILITY'S HAZARD ANALYSIS ADDRESS ENVIRONMENTAL PATHOGENS?

- A. Yes
- B. No
- C. Maybe/I don't know

SHOULD TIS FACILITY CHARACTERIZE A PATHOGEN (E.G. *SALMONELLA* SPP.) AS A HAZARD REQUIRING A PREVENTIVE CONTROL?

- A. Yes
- B. No
- C. Maybe/I don't know

Discussion: How should this hazard be disclosed, since the facility is not disclosing the hazard?

§ 507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

(a) If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:

Take-Aways

1. Your hazard analysis is to consider the effect of the intended or reasonably foreseeable use on the safety of the finished animal food for the intended animal.
2. FDA has issued draft guidance on how to make written disclosures.
3. FDA has extended the compliance date for obtaining written assurances by two years



Scenario Seven

CGMP AND SANITARY TRANSPORT RULE INSPECTION – OUTBOUND
PRODUCT SHIPMENTS



IS THE ANIMAL FOOD FACILITY RESPONSIBLE FOR
EVALUATING THE CONDITION OF THE VEHICLE PRIOR TO
LOADING BULK ANIMAL FOOD AS DESCRIBED?

- A. Yes
- B. No
- C. Maybe/I don't know

DOES THE EXAMINATION OF THE VEHICLE REQUIRE DOCUMENTATION?

- A. Yes
- B. No
- C. Maybe/I don't know

DOES THE ANIMAL FOOD FACILITY NEED TO IDENTIFY PRIOR LOAD(S) HAULED BY THE VEHICLE?

- A. Yes
- B. No
- C. Maybe/I don't know

Discussion: What are some effective means by which vehicles could be examined to ensure they are suitable and not a potential source of contamination?



Take-Aways

1. The animal food rule requires facilities to examine outbound shipping containers for suitability if the facility transports the product or arranges for transport.
2. The sanitary transportation rule requires loaders of bulk food to determine if the shipping container is suitable regardless of who arranged for the transportation.
3. You may evaluate/examine shipping containers by any effective means. The rules' do not establish specific obligations for knowing prior loads or clean-out methods.

Summary

- CGMP requirements are flexible due to the breadth of facility types.
- It is the responsibility of management of a facility to make appropriate decisions for CGMP compliance.
- CGMP requirements are observable and typically do not require documentation.
 - Supporting documentation may be valuable to help defend and justify your determinations, particularly if used to evaluate probability in hazard analysis.