INSPECTION GUIDANCE

Guidelines for Managing FDA Facility Inspections

ASTA developed the following guidelines for its members to address how to handle regulatory inspections by the Food and Drug Administration (FDA) or state regulatory agencies conducting inspections on FDA's behalf. This manual is specific to inspections conducted by FDA or a state regulatory agency on FDA's behalf and does not cover inspections by the agencies such as the U.S. Department of Agriculture (USDA) or the Occupational Safety and Health Administration (OSHA).

The information ASTA provides in this document is accurate and factual to the best of our knowledge, but ASTA does not provide any warranties of any kind regarding the content of this document. The information in this document is guidance and does not constitute legal advice. Because inspections are inherently tied to enforcement of legal obligations, it is generally advisable to engage with legal counsel regarding any questions, concerns, or other issues that may arise in connection with FDA inspections. ASTA reminds its members that they each bear an independent responsibility to comply with all applicable laws and regulations.

Background

General FDA Authority. U.S. FDA inspectors (called "investigators" by the agency) are lawfully authorized to enter and inspect any facility, warehouse, establishment in which foods are manufactured, processed, packed or held for shipment into interstate commerce or any vehicle used to transport or hold such food. The term "food" includes seeds destined for animal consumption. An inspection may include an examination of the building, equipment, raw ingredients and materials, in-process or finished products, containers, labeling, and certain records.

Purpose. FDA conducts inspections to determine compliance with legal requirements. During an inspection, FDA collects evidence (including records and samples) to potentially use if an enforcement action is deemed necessary. Inspectors are particularly looking for compliance with the Preventive Controls for Animal Food (PCAF) rule, 21 CFR Part 507, (both the current Good Manufacturing Practice (cGMP) and preventive control requirements) and violations of the adulteration provisions in Section 402 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

FSMA-Related Talking Points

When FDA conducts inspections of seed production facilities for compliance with the FDA Food Safety Modernization Act (FSMA) regulations, you may encounter questions relating to your facility's compliance obligations. ASTA has prepared the following Q&As to help you during the inspection. Note, however, that these discussion points need to be tailored to each facility's operation and FSMA compliance strategy.

- Why is your establishment registered with FDA?
  - > Materials such as cracked, damaged, culled, or excess seeds from our facility are sent for animal consumption. Historically, FDA has advised through guidance that an establishment that conditions seed for planting purposes must be registered with FDA if the owner, operator, or agent in charge of the establishment reasonably believes that the seed is reasonably expected to be directed to a food use, including animal food use or as an ingredient in animal food.
- Is your facility subject to the PCAF regulation?
  - > No, because FDA is exercising enforcement discretion for seed conditioning facilities that send discarded seed materials for consumption by either animals or humans. The enforcement discretion applies to both the Preventive Controls and cGMP regulations.
  - > The enforcement discretion was announced by FDA on January 4, 2018 in the

document: *Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs*. The enforcement discretion applies to our operation because it is dedicated to harvesting, packing, and/or holding raw agricultural commodities. FDA specifically provided in its Guidance that "facilities engaged in conditioning seed for cultivation that solely pack and hold seed for use in animal food" are intended to fall within the scope of this enforcement discretion.

    - Note: If the inspector disagrees and is pushy on this point, contact ASTA. The Association may be able to intervene with FDA on your behalf.

- Are your silage operations "manufacturing" activities that trigger application of the Preventive Controls regulation? [Note, other operations could be inserted here in place of silage.]

  > Through the American Seed Trade Association, we have shared a detailed description of our activities with FDA's Center for Veterinary Medicine and received confirmation that none of the activities constitutes "manufacturing." For example, chopping cobs and husks is a "harvesting" activity because they are activities traditionally performed on farms for the purpose of removing raw agricultural commodities from the place where they were grown.

- What is your compliance date for the PCAF regulation? *Choose the applicable statement:*

  > Because we have more than 500 full-time equivalent employees company wide, we are classified as a "large business." Our compliance dates were September 19, 2016 for cGMPs and September 18, 2017 for Preventive Controls.

  > Because we have fewer than 500 full-time equivalent employees company wide, we are classified as a "small business." Our compliance dates were September 18, 2017 for cGMPs and September 17, 2018 for Preventive Controls.

> Because we average less than $2,500,000 (adjusted for inflation) in average annual in sales of animal food, plus the market value of animal food manufactured, processed, packed, or held without sale, we are classified as a "very small business." Our compliance dates were September 17, 2018 for cGMPs and September 17, 2019 for Preventive Controls.

- Can we see your Food Safety Plan?

> Because FDA is exercising enforcement discretion for seed conditioning facilities, we are not required to have a Food Safety Plan.

Actual Inspection

1. **Inspector Arrival**

When an FDA inspector arrives at a facility, security or the receptionist should welcome the inspector as any other business visitor and treat the inspector with courtesy. Security or the receptionist should immediately notify the plant manager and the most senior person on-site.

2. **Pre-Inspection Meeting**

Greet the inspector promptly. This should be done by the site manager or the most senior person on-site. Try not to keep the inspector waiting for more than 20 minutes.
Review and record the inspector's credentials and Notice of Inspection. An FDA inspector will present Form FDA 482. A state inspector will have their own form. If an FDA inspector presents credentials with the designation "200-D" (these are criminal investigators) or if he/she presents a Form FDA 482c (Notice of Inspection and Request for Records), consider contacting legal counsel.

Request a pre-inspection conference. Ask the inspector to explain the purpose of the inspection. It could be a routine inspection, a follow-up to complaint, or an inspection conducted for some other reason. Probe as to whether this inspection is being conducted to assess compliance with FSMA, the Bovine Spongiform Encephalopathy (BSE) regulations, or

for some other specific purpose. An inspector may mention FSMA (and provide you with FSMA-related fact sheets) even if they are not conducting a FSMA inspection.

Explain the company's policies and procedures regarding visitors/inspections. For example, inspectors often are expected to follow company policy regarding GMPs and obey all safety signs and precautions.

- Communicate the company's policy regarding the use of photographic equipment. Each company should decide on their policy on this issue in advance of the inspection and communicate it to the site. There is no express legal authority for FDA to take photographs during facility inspections, but investigators will push hard on this point and cite case law that they believe provides them with authority. Some state laws do permit inspectors to take photographs, so you should know the applicable rules before you push back on a state inspector.
    - > If company policy prohibits the use of photographic equipment—
        - Be prepared for the inspector to insist that he/she has the authority to take photographs. Ask what the inspector wishes to photograph and if issues escalate consider elevating the request to legal counsel.
        - Make it clear the company is not denying the inspection, only the ability to
          take photographs.
    - > If company policy authorizes the use of photographic equipment—
        - Ask the inspector to mark all photos as "confidential commercial information" and take both a similar photograph to the one the inspector takes, as well as a broader photograph depicting the surrounding area.

Ask the inspector to direct any questions during the inspection to the facility's designated representatives accompanying the inspector. The facility manager or the most senior person on site should accompany the investigator throughout the inspection of the facility.

3. The Facility Inspection

General.

- Knowledgeable, trained, and previously designated employees should accompany the inspector at all times. The inspector should never be unaccompanied. If there is more than one inspector, each should be accompanied by a designated facility employee. Questions and requests for information should be directed to the designated employees.
- If the inspector identifies an issue of concern and it can be readily fixed or addressed, implement the remedial action and ask that the inspector note the corrective action in his/her report.
- Take copious notes of the inspection including questions asked and answered, observations and comments made, corrections implemented, samples taken, and records requested.

Samples.

- FDA inspectors have the authority to take sample of products and labels, as well as to conduct swabs of the environment to test for environmental pathogens. It is unlikely that inspectors will conduct any environmental swabbing during seed facility inspections.
- The inspector will leave a receipt for the samples, Form FDA 484. This is the ONLY form that any employee should sign.
- If the investigator collects samples of products, consider taking duplicate samples from the same lot/location and label the samples.

Records.

- The regulations implementing FSMA provide FDA with broad records access. Even if FDA is not inspecting for compliance with the PCAF regulation, the regulation's records access provisions remain effective after your applicable compliance date.
- If FDA requests access to records and you have any questions about whether records should be provided to the inspector, consult with legal counsel.
  - FDA may ask to see records that they lack the legal authority to access. The company must decide whether it will voluntarily disclose these records.

- The company has 24 hours to provide FDA with the requested records. It is appropriate to tell the investigator you must first consult with legal counsel before you can determine whether the records will be made available.
- Any copies of records that are provided should be marked "Confidential Commercial Information."
- Under the Bioterrorism Act (the Public Health Security and Bioterrorism Preparedness and Response Act of 2002), FDA has expanded access to records in certain "emergency" situations. These situations can include FDA investigations into Class I recalls or reports to the Reportable Food Registry. Specifically, if FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death to humans or animals, any records and other information regarding the manufacturing, processing, packing, holding, distribution, receipt, or importing for either that article of food or any other article likely to be affected in a similar manner, must be made readily available for inspection and photocopying within 24 hours of the request. **FDA must provide written notice on a Form FDA 482c when invoking the records access provisions under the Bioterrorism Act.**

4. Exit Interview

The plant manager and other appropriate facility employees should conduct an exit interview or "close out meeting" with the inspector.

- Ask the inspector to describe the findings and observations, one by one. Ask questions about any findings that are not understood and politely voice any disagreements.
- Discuss any corrective actions taken and ask that they be noted appropriately. Inform the inspector of any planned additional corrective actions and when they are expected to be completed.

If the inspector observed any objectionable conditions or practices, he/she will issue a Form FDA 483—Inspectional Observations. State personnel will have their own version of this document, which has the same import. Make sure you understand the observations on the Form FDA 483, as these are considered deficiencies that need to be corrected.

- **If the inspector left a Form FDA 483, a written response must be submitted to FDA within 15 business days in order for FDA to consider the information when**

deciding whether to take enforcement action. You may want to consult with legal counsel regarding preparation of this response.

Do not sign or initial any affidavits. If the inspector insists, forward the unsigned affidavit to legal counsel or review and advice. Ask the inspector whether he/she anticipates coming back to conduct a follow-up inspection in the near future.

5. Post-Inspection

After the inspector leaves, prepare a detailed report of the inspection for internal purposes. This report should contain:

- Date and time of inspection
- Inspector's name and credentials
- Copies of any documents provided by FDA (e.g., Form FDA 482)
- Company personnel accompanying the inspector(s)
- Whether photographs were taken, areas photographed, and duplicate photos
- Areas of the plant inspected
- A list of all forms, labels, samples, documents, or records provided (and preferably copies of these documents).
- Questions asked by the inspector and answers provided
- Observations and comments by the inspector
- Corrective actions taken during the inspection
- Details on samples taken and testing to be performed
- Records requested, reviewed and copied

Following the inspection, the inspector must prepare an Establishment Inspection Report (EIR) (a much more detailed report than a Form FDA 483). If the facility does not receive a copy within 2 months of the inspection, contact the inspector and ask for a copy.

After the EIR is received, review with the plant manager and the head of food safety. Consider submitting a blinded Freedom of Information Act (FOIA) request (not on company letterhead) requesting a copy of the EIR to make certain FDA has deleted all proprietary information. If proprietary information has not been deleted, you should follow-up with FDA.