ASTA Food Safety Guidance

September 2018

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EXECUTIVE SUMMARY

The FDA Food Safety Modernization Act (FSMA) was signed into federal law on January 4, 2011. Its objective is to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

The American Seed Trade Association (ASTA) prepared this document to help its members understand how the regulations implemented under FSMA affect the seed industry. In particular, this document addresses the responsibilities of seed facilities that send discarded materials into the food or feed chain. It does not address seeds used for sprouting. As discussed in more detail below, if seed facilities are registered with the Food and Drug Administration (FDA), they may be required to comply with the FSMA current Good Manufacturing Practices (cGMP) and Hazard Analysis and Risk-Based Preventive Controls regulations under the Preventive Controls for Animal Food (PCAF) rule or the Preventive Controls for Human Food (PCHF) rule (collectively, the "Preventive Controls rules").

A facility is required to register with FDA if it manufactures, processes, packs, or holds food for human or animal consumption in the United States.[1] FDA has long taken the position that an establishment conditioning seed is required to register with FDA if it 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.[2]

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 requirements under the PCAF and PCHF rules. 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*

[1] 21 C.F.R. § 1.225.
[2] 81 Fed. Reg. 45912, 45919 (July 14, 2016).

Verification Programs.[3] The enforcement discretion applies because seed facilities are dedicated to harvesting, packing, and/or holding raw agricultural commodities and do not engage in any manufacturing activities. 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.

In this document, the American Seed Trade Association (ASTA) addresses the legal requirements for facility registration, cGMPs, and preventive controls, as well as FDA's plans to exercise enforcement discretion. This document also contains an overview of the exemptions from cGMPs and preventive controls for "holding" Raw Agricultural Commodities (RACs). For companies that do not qualify for this exemption, additional guidance is enclosed within this document in the cGMPs and preventive controls section. This document also contains guidance for companies when FDA conducts an inspection of a seed facility. Lastly, there also are new regulations regarding sanitary transportation of human and animal food, which are discussed in this document.

ASTA is providing this Guidance as a service to its members in order to memorialize the work that ASTA has undertaken on FSMA. The information we are providing is accurate and factual to the best of our knowledge as of September 2018, but ASTA does not provide any warranties of any kind regarding this information. This information also does not constitute legal advice. ASTA members are advised to consult with their own legal counsel regarding enforcement issues, FSMA compliance, and FDA regulations. ASTA reminds its members that they each bear an independent responsibility to comply with all applicable laws and regulations.

[3] *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*, January 2018, *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM590661.pdf.

I. FACILITY REGISTRATION

FDA has long maintained that seed facilities that send byproducts into the human or animal food supply chains are expected to register with the agency. Over several years, ASTA has sought an exemption from registration for seed facilities, but FDA has declined to change its position. Below is a summary of FDA's position on registration for seed facilities.

FDA's Registration Requirement

FDA's regulations require registration by either a domestic or foreign facility that is engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the United States, unless an exemption applies.[4] There is no express exemption from registration for seed facilities.[5] However, an entity that meets the definition of "farm" rather than "facility" would be exempt from registration.[6]

FDA has long taken the position that an establishment conditioning seed is required to register with FDA if it 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.[7] The agency most recently articulated this position as follows:

> **Is an establishment that conditions seed and sells seed to farmers for cultivation a facility that is required to register if some of the seed sold is intended to be used as animal food?**
>
> A facility that manufactures/processes, packs, or holds food for consumption in the United States is required to register. "Food" is defined in section 201(f) of the Federal Food, Drug & Cosmetic Act (FD&C) (21 U.S.C. 321(f)) to include articles used for food or drink for man or other animals. An establishment that conditions and sells seed to farmers for planting purposes is typically excluded

[4] 21 CFR § 1.225(a).
[5] *Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry*; August 2018; *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332460.pdf.
[6] 21 CFR § 1.328.
[7] *See, e.g.*, 81 Fed. Reg. 45912, 45919 (July 14, 2016).

from the requirements for registration. However, an establishment that conditions seed for planting purposes is a facility that must be registered if the owner, operator, or agent in charge of the establishment reasonably believes that the seed is reasonably expected of be directed to a food use, introducing animal food use or as an ingredient in animal food. Whether a particular establishment is required to register will depend on the specific nature of the establishment. This would include situations where seeds are sent for use as animal food because they become cracked, damaged, culled, or are otherwise not suitable for cultivation. However, some establishments may direct such cracked, damaged, culled, or excess seeds for incineration and landfilling. If the seed is reasonably expected only to be cultivated or destroyed (e.g., by incineration or landfill), the establishment is expected only to be cultivated or destroyed (e.g., by incineration or landfill), the establishment is not required to register.[8]

How to Register

Please visit FDA's registration website:

http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm

Note: You need to create a login account if you don't have one already.

Who Can Register?

The owner, operator, or agent in charge of the facility, or any individual authorized by one of these people can register. Foreign facilities must designate a U.S. agent as part of their registration; this U.S. agent may also register the facility. Be sure to choose the correct type of registration (e.g., "Food Facility Registration").

[8] *Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry*; Draft Guidance; December 2016 at B.1.2 (emphasis added); *available in archived form at* https://web.archive.org/web/20180425153835/https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332460.pdf. FDA did not include this question and answer in its finalized version of the seventh edition of this guidance, which was issued in August 2018. However, ASTA has been told by FDA that this omission does not signal a change in the agency's longstanding position.

Types of information needed for registration:

- Facility name and address
- Parent company name and address
- Facility emergency contact information
- Trade name
- General product categories and type of activity conducted at facility
- Owner, operator, or agent in charge information

Recommendation: Clearly explain the scope of your operations that relate to food/feed. For example, *"We condition and package seed to sell to farmers. Any unused grain, husks, or cobs may be directed to local grain elevators or animal feed lots."* See example below of how this is put into the FDA system.

To be completed by all animal food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 33.	Animal food manufacturer / Processor	Animal Food Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Acidified Food Processor	Low Acid Food Processor	Contract Sterilizer	Packer / Repacker	Labeler / Relabeler	Salvage Operator (Reconditioner)	Farm Mixed-Type Facility	Other Activity (Please Specify)
1. GRAIN OR GRAIN PRODUCTS (I.E., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE, WHEAT, OTHER GRAINS OR GRAIN PRODUCTS)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑
2. OILSEED OR OILSEED PRODUCTS (I.E., COTTONSEED, SOYBEANS, OTHER OILSEEDS OR OILSEED PRODUCTS)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑
Other Activity Conducted										
We condition and package seed to sell to farmers. Any unused grain, husks or cobs may be directed to local grain elevators or animal feed lots.										

Significance of Facility Registration

Registration triggers the requirement to comply with the FSMA PCAF and PCHF regulations, as applicable, unless an exemption applies.

II. CURRENT GOOD MANUFACTURING PRACTICES AND PREVENTIVE CONTROLS

A. Overview/Summary

Registered facilities must comply with the PCAF and PCHF regulations, as applicable, unless an exemption applies. The Preventive Controls for Animal Food rule is codified in 21 C.F.R. Part 507.[9] The Preventive Controls for Human Food rule is codified in 21 C.F.R. Part 117.[10]

The PCAF and PCHF rules are very similar to each other, with the difference being that one is focused on protecting animal health and the other is focused on protecting human health. The rules each have two components: 1) cGMPs and 2) Preventive Controls. The cGMP regulations require foundational food safety programs, such as setting standards for sanitary facilities and controls. The preventive control regulations require facilities to develop and implement a "Food Safety Plan" based on a hazard analysis that identifies hazards requiring preventive controls.

There are several exemptions from the PCAF and PCHF regulations, which are explained in more detail below. Guidance regarding compliance with the cGMP and preventive controls regulations is provided in the following section.

B. "Solely Engaged" Exemptions from Current Good Manufacturing Practices and Preventive Controls

Regulatory Exemption

The PCAF rule exempts facilities from preventive controls (and supplier verification) if they are "**solely engaged** in the storage of Raw Agricultural Commodities [RACs] (other than fruits and vegetables) intended for further distribution and processing." The PCAF rule exempts facilities from GMPs if they are "**solely engaged** in the holding and/or transportation of one or more [RAC's]. "Storage" and "holding" are synonyms here.

[9] The rule was published at 80 Fed. Reg. 56170 (Sept. 17, 2015), *available at* https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21921.pdf.

[10] The rule was published at 80 Fed. Reg. 55908 (Sept. 17, 2015), *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332460.pdf.

"Holding" is defined to include:

- Storage and activities incidental to storage of food (e.g., activities performed for safe/effective storage, such as fumigating; drying/dehydrating RACs when doing so does not create a distinct commodity);
- Activities performed as practical necessity for distribution of food (e.g., blending of same RAC; breaking down pallets)

FDA's regulations explain that holding facilities could include warehouses, storage silos, and grain elevators. Holding does not include activities that transform RAC into processed food.[11] FDA has issued draft guidance further clarifying the definition of "holding," and also explaining the meaning of terms such as "harvesting," "packing," and "manufacturing/processing."[12]

Accordingly, to determine whether a facility falls with the "holding" exemption, each seed facility needs to assess whether **all** of its activities fall within the exemption. The exemption is activity-specific, not end-user specific, assuming that the end user is a human or animal.

Enforcement Discretion

In January 2018, FDA issued guidance announcing enforcement discretion for several components of FSMA.[13] Enforcement discretion means rules will not be enforced. As explained below, FDA will exercise enforcement discretion for seed conditioning facilities that send discarded seed materials for consumption by either animals or humans. This means that seed

[11] 21 CFR § 1.328.
[12] *Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Guidance for Industry*, Draft Guidance (August 2016), *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM517575.pdf.
[13] *Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry* (January 2018), *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM590661.pdf; *see also* FDA's Fact Sheet, *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM591242.pdf.

conditioning facilities do not need to comply with the preventive controls or cGMP requirements under either the PCAF or PCHF rules, unless they manufacture human or animal food.

FDA explains in the guidance that it intends to exercise enforcement discretion from both the PCAF and PCHF rules for any operation that is "dedicated to harvesting, packing, and/or holding" raw agricultural commodities (RACs). This enforcement discretion applies both to "facilities" required to register with FDA and to "farms" that are not required to register with FDA. Essentially, the agency's position is that because a farm would be exempt from the Preventive Controls rules when it performs these activities, a registered facility also should not have to comply with the Preventive Controls rules when these are the only activities performed. The Guidance explains 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.

In the process of preparing the seeds for planting, seed conditioning facilities typically perform a finite set of activities. ASTA has shared a list of these activities with FDA and engaged in discussions with the agency about how these activities are classified for regulatory purposes (e.g., as manufacturing, packing, or holding). Based on discussions with FDA in 2018, ASTA understands that FDA considers all of the activities typically performed by seed conditioning facilities, as summarized below, to fall within the definitions of "harvesting, packing, and/or holding." Accordingly, ASTA's current understanding is that facilities that only engage in the following activities are subject to enforcement discretion from the cGMP and preventive controls requirements in the Preventive Controls rules:

- Drying
- Blending
- Weighing
- Sampling
- Grading
- Fumigating to control pest infestation during storage
- Cleaning (e.g. sifting, sieving, and screening)

- Conveying
- Sorting
- Removing materials (e.g., stems, leaves, and husks)
- Removing seeds from the cob
- Removing soybeans from the pod
- Chopping husks (to decrease their size and bulk for shipping)
- Hulling
- Moisturizing (i.e. using warm, moist air to increase the moisture of the seed in order to prepare the seed for optimum performance)
- Drying (i.e., using ambient or conditioned air to dry the seed if the moisture content is too high so it can be prepared for planting.)
- Shelling corn (i.e. removing it from the cob)
- Chopping husks to facilitate more efficient transportation

It is important to note the following additional points regarding this enforcement discretion:

- This is an interim solution. FDA plans to exercise this enforcement discretion until it has sufficient time to pursue rulemaking related to the farm definition, which will address various issues that have been raised by the broader agriculture industry. However, through that rulemaking FDA plans to continue taking the position that seed conditioning facilities are not required to comply with the Preventive Controls rules.
- The Guidance does not change the facility registration requirements. If a seed conditioning facility previously concluded that it is required to register with FDA, that registration should remain in place.
- Despite the enforcement discretion, seed facilities are still subject to enforcement under the Federal Food, Drug, & Cosmetic Act (FFDCA) for actions that fall outside of the scope of the enforcement discretion, such as introducing adulterated food into interstate commerce.

Finally, ASTA encourages its members to review the requirements under the Preventive Controls rules with their own legal counsel to assess whether they are comfortable concluding that they do not need to comply in light of FDA's enforcement discretion. ASTA is not providing legal advice through this document.

C. Compliance Requirements if "Manufacturing" Food

Precision Agricultural Services, Inc. (PAS) was retained by ASTA to develop a toolkit that ASTA members can use to support their implementation programs for the PCAF regulations. The section below provides information and resources that are intended to support development of Food Safety Plans and cGMP programs by ASTA members. The toolkit was prepared by Alan Phillips and Jason Breitenstein of PAS, who have both been trained as Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls Qualified Individuals (PCQIs) under the PCAF rule.[14] The documents supporting PAS's evaluation are available to ASTA members through the Association's website.

Every company has an independent responsibility to comply with the PCAF regulation, should they determine that the rule is applicable to their operations. The information provided in this toolkit may be helpful to assist with required activities under the PCAF regulation, such as performing a hazard analysis. It is not adequate for a facility to simply put this toolkit in their files, but rather the information developed by PAS will need to be assessed and tailored for each facility based on the nature of its operations and individual experience. PAS is available for individual consultations that will provide assistance to ASTA members as they work to adapt this information to their operations.

The toolkit focuses only on operations engaged in corn seed production. Other products and manufacturing processes will require further assessment to develop an appropriate hazard analysis.

[14] A PCQI is "a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system." 21 CFR § 507.3.

Contents

1. Executive Summary

PAS evaluated three products (outputs) from corn processing as potential inputs into animal feed: corn kernels, corn husks, and shelled corn cobs. Through PAS's research into the various hazards associated with corn seed production facilities and this type of animal food, PAS has concluded that there are no hazards requiring preventive controls for such operations. Accordingly, PAS concluded that no preventive controls are needed. While PAS's evaluation resulted in the conclusion that there are no preventive controls needed, the evaluation of whether or not a preventive control is needed must be individually conducted by each company and for each facility. The reason for this is that for each potential hazard, an evaluation of severity and probability must be evaluated and these measures can vary between operations.

2. Hazard Analysis

Under 21 CFR § 507.33, facilities must conduct a hazard analysis to identify known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility and determine whether any of the hazards requires a preventive control. The hazard analysis must be written, regardless of its outcome, and must consider biological, chemical, and physical hazards. The determination of whether or not a hazard requires a preventive control must consider the severity of the illness or injury if the hazard were to occur, as well as the probability that the hazard will occur in the absence of controls. The hazard

analysis should be based on experience, illness data, scientific reports, and any other relevant information.

PAS evaluated the severity and probability for potential hazards using a rubric, which is displayed below. Companies may have their own risk rubric that they use instead of this format, as this format and approach is not mandated by FDA.

Critical		Moderate		Negligible	
	Severity	**High (I)**	**Medium (II)**	**Low (III)**	**Very Low (VI)**
Probability		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals	Danger and Illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
High (A)	Immediate danger that the hazard will occur.	**I-A**	**II-A**	**III-A**	**VI-A**
Medium (B)	Probably will occur in time if not corrected.	**I-B**	**II-B**	**III-B**	**VI-B**
Low (C)	Possible to occur in time if not corrected.	**I-C**	**II-C**	**III-C**	**VI-C**
Very Low (D)	Unlikely to occur; may assume hazard will not occur.	**I-D**	**II-D**	**III-D**	**VI-D**

Based on the above, anything determined to be in the "Critical" area should be considered a "hazard requiring a preventive control" and addressed by a preventive control. Anything in the "Moderate" section should be examined more closely to assess whether it is a "hazard requiring a preventive control." Anything falling in the "Negligible" category can be fully managed with cGMPs.

Below are the known or reasonably foreseeable hazards PAS identified for a corn production facility and how PAS determined they should be classified based on their severity and probability. Each facility should do their own review in terms of severity and probability to determine whether each of these hazards is a "hazard requiring a preventive control." Facilities also should consider whether there are any other hazards that need to be considered for their operations. The conclusions are explained in the documents available to ASTA members on the Association's website.

- **Mycotoxins:** Determined (I-D) Negligible, hazard does not require a preventive control.
- **Salmonella:** Determined (II-D) Negligible, hazard does not require a preventive control.
- **Escherichia Coli:** Determined (VI-A) Negligible, hazard does not require a preventive control.
- **Listeria Monocytogenes:** Determined (VI-B) Negligible, hazard does not require a preventive control.
- **Foreign Materials (metal, glass, stones):** Determined (VI-D) Negligible, hazard does not require a preventive control.
- **Pesticides:** Determined (I-D) Negligible, hazard does not require a preventive control.
- **Bovine Spongiform Encephalopathy (BSE):** Determined (I-D) Negligible – Hazard Does not require a Preventive Control
- **Seed Treatment:** Determined (I-D) Negligible – Hazard does not require a preventive control.

- **Weed Seeds:** Determined (I-D Negligible – Hazard does not require a preventive control.

- **Other Hazards:** The hazards above include all that PAS considered as being known or reasonably foreseeable. If facilities have experience with any other hazards, these hazards also should be assessed for severity and probability.

Each facility has an independent obligation to have a PCQI conduct and document a hazard analysis for their operations and products based on previous experience, history, and research.

3. Current Good Manufacturing Practices

There also are requirements under the PCAF regulation to implement cGMPs. The hazard analysis considers the role of cGMPs that PAS expects are put in place at seed production facilities. These cGMPs are the standard operating procedures to ensure the facility maintains an adequate sanitary condition so that the personnel, transport vehicles, holding areas, processing equipment, and the environment do not adulterate the feed product.

Included in the materials available on ASTA's website, PAS has developed a *Gap Analysis Worksheet* in Excel. This tool steps through the regulation. PAS has included some guidance on the right hand side of the worksheet. PAS suggests each site review their operations against the cGMPs and make notes of how each regulation is covered, whether it be with a written SOP or a generally accepted practice in the facility. FDA's *Guidance for Industry: Current Good Manufacturing Practice Guidance Requirements for Food for Animals* includes a similar exercise.[15] This guidance document also is an excellent resource for companies working to understand the requirements under the cGMPs. PAS believes that most of what is set forth in the cGMPs are activities that seed facilities are already performing, but each company should conduct an assessment to determine whether there are any gaps to close.

The types of activities included as part of cGMP requirements include but are not limited to the following:

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[15] *Current Good Manufacturing Practice Guidance Requirements for Food for Animals, Guidance for Industry* (October 2017), *available at* https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499200.pdf.

- Personnel hygienic practices such as handwashing, jewelry, clothing, etc.
- Maintaining grounds such as:
    - Proper waste storage, weed and grass cutting, adequate drainage, etc.
    - Plant construction and design such as space around equipment, ventilation, lighting, etc.
    - Protection of bulk food stored outdoors using tarps or other coverings
- Sanitation such as cleaning, pest and trash management
- Water and plumbing such as water sources, plumbing design, sewage system, toilet and hand washing facilities.
- Equipment and utensils including designated tools with appropriate design, construction, design and maintenance for holding, conveying, manufacturing, and processing systems
- Plant operations
- Holding and distribution

The cGMPs do not require any recordkeeping. Rather, these are visually observable practices.

PAS recommends from a management perspective that there be Standard Operating Procedures (SOPs) in place to address the pertinent cGMPs for the facility. This recommendation is also included in the recent cGMP Guidance document from the FDA where they state, "Animal food safety is best achieved by developing and implementing a system of procedures, practices, and checkpoints that are designed to produce safe animal food."

4. Training

There are two training requirements under the PCAF regulation: (1) qualified individuals, and (2) PCQIs.

Qualified Individuals

The PCAF regulation provides that all individuals who manufacture, process, pack, or hold animal food (including temporary and seasonable personnel) must be qualified to perform their assigned duties and meet the definition of a "qualified individual."[16] A "qualified individual" must have the education, training, or experience necessary to perform their assigned duties and must receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene as appropriate to the animal food, the facility, and the individual's assigned duties.[17] All training needs to be documented.

Accordingly, employee training is extremely important. Training frequency is not stated in the regulation other than "before performing their assigned duties." PAS recommends that there be an annual training on cGMP requirements yearly. PAS also recommend that the scope of individuals trained be as broad as possible. This includes truck drivers who should be trained on the cGMPs applicable to them. They should be aware of the type of material they are loading, as well as provide information of their previous loads and applicable cleaning records if they hauled material that would adulterate the feed product subsequently loaded. Also, their training should cover the limitations of their actions and movement upon entering the facility to keep them out of unauthorized areas. These types of trainings can be handled by giving the drivers an iPad with the training loaded and obtaining a sign-in sheet. (See discussion in Section V. of this document regarding compliance with FDA's regulations on safely transporting animal food.)

Every facility should already have a system in place for conducting and documenting trainings. PAS suggests these trainings be conducted with everyone annually and included with new hire training before starting work. FDA may assess training as part of its inspections, for example by

[16] 21 CFR § 507.4.
[17] 21 CFR § 507.3.

identifying an individual in the facility and requesting their cGMP training records. PAS's take home message here is "train everyone and record it."

Management should also be active in the oversight the training and observe individuals performing their assigned duties with respect to food safety. If there are consistent employee breakdowns, management may need to re-train or re-assign employees in order to maintain food safety.

Precision Agricultural Services, Inc. has provided a PowerPoint presentation for ASTA members with training for the cGMPs, which utilizes some input from the PCQI training. If you choose to utilize this program PAS suggests you incorporate your own processes to supplement this training to make it appropriate to your organization and to ensure you meet the regulatory requirements. PAS is available to support a customized training program for your organization.

For a more in-depth training, the American Feed Industry Association has an online training program available for purchase.[18]

Preventive Controls Qualified Individuals

The PCAF rule also requires that certain activities must be performed by a PCQI. Specifically, one or more PCQIs must do or oversee specified activities, including the following:

- Preparation of the Food Safety Plan,
- Validation of the preventive controls,
- Records reviews, and
- Reanalysis of the Food Safety Plan.[19]

To be a PCQI, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job

[18] The online training is *available at* http://www.afia.org/store_product.asp?prodid=122.
[19] 21 CFR § 507.53(a).

experience to develop and apply a food safety system.[20] Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility. The standardized training curriculum is available through the FSPCA. A current list of training courses is maintained on the FSPCA's website.[21]

5. Developing a Food Safety Plan

When a facility is covered by the PCAF rule, it must develop and implement a Food Safety Plan. The following is a high-level overview of the components of a Food Safety Plan:

1. Background information, which is optional, but suggested. Useful information to include in this section are the members of the food safety team and their role within the facility, a description of the facility, and a flow diagram showing equipment within the facility.

2. Hazard analysis, including written justifications regarding your determination of whether there are any hazards requiring a preventive control.

3. Preventive controls to significantly minimize or prevent the hazards requiring a preventive control (but these are not needed if there are no hazards requiring a preventive control identified through the hazard analysis)

4. Management components for the preventive controls – Specifically, procedures for monitoring, verification (including validation, as appropriate), and corrective actions. (These procedures are not needed if there are no preventive controls.)

4. Recall plan – Technically this is optional if no preventive controls are necessary, but PAS recommends including it regardless.

5. Implementation records –A list of all the records that are required to document implementation of the Food Safety Plan can be found in 21 CFR § 507.55.

[20] 21 CFR § 507.3.
[21] The list of training courses is *available at* https://fspca.force.com/FSPCA/s/courselist?language=en_US.

The Food Safety Plan must be prepared and implementation overseen by a PCQI. The owner, operator, or agent in charge of the facility must sign and date the Food Safety Plan upon initial completion and upon any modification. The facility has the option to store records offsite, as long as they are able to be retrieved within 24 hours. However, the Food Safety Plan must be located on site at the facility at all times.

To assist ASTA members with the development of their Food Safety Plans, PAS has developed a template Food Safety Plan based on its hazard analysis, discussed above. The plan was developed utilizing the Food Safety Plan Builder tool provided by the FDA.[22]

PAS recommends use of this tool to expedite the writing process. PAS has provided a .fsp file for ASTA members which includes the template plan that should be customized for each individual facility. This file is compatible with the Food Safety Plan Builder. This will need to be further customized by each site. A .pdf copy of the plan template is available as well. For a copy of the .fsp file and additional support for tailoring the information in this file to create a Food Safety Plan utilizing the Food Safety Plan builder, please contact Precision Agricultural Services (pas@precisionags.com) or 859-873-6138.

6. Summary and Ongoing Support

PAS appreciates the opportunity to support the American Seed Trade Association's aid in member compliance with FSMA. PAS's task was to assemble an implementation guide/toolkit, provide template materials including training materials, and establish a set of cGMP guidelines. PAS's focus was on corn seed production facilities.

PAS is available for ongoing review and support of member questions. PAS tried to apply a practical approach for the templates, training and examples, and intended to keep it flexible to a range of facilities. PAS is available to review Food Safety Plans and SOPs for cGMP requirements as well as research specific situations that PAS may not have addressed.

[22] Further information is *available at* https://www.accessdata.fda.gov/scripts/foodSafetyPlanBuilder/.

A significant portion of PAS's time on this project was on researching and finding scientific backing for the potential hazards to determine whether there are any hazards requiring preventive controls. With these types of products, and for corn cobs and corn husks specifically, it was a challenge finding the research needed to support the hazard analysis. ASTA's members should supplement PAS's research with their own experience as part of the justifications for their own hazard analyses.

Please let PAS know if you have any questions, comments or concerns regarding what has been assembled.

- PAS's main office phone number is 859-873-6138
- Alan Phillips can be reached at alan.phillips@precisionags.com
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III. LARGE, SMALL, & VERY SMALL BUSINESS REQUIREMENTS

Scope

Large and small businesses have the same compliance obligations under FSMA; however, the compliance timelines are longer for small and very small businesses. The compliance dates are as follows:[23]

Compliance Dates

Size of Business	cGMP Compliance Date	Preventive Controls Compliance Date
500+ full-time equivalent (FTE) employees	September 19, 2016	September 18, 2017
Under 500 FTE employees (small businesses)	September 18, 2017	September 17, 2018
Less than $2.5 million in annual sales/holding value of animal food (very small business)	September 17, 2018	September 17, 2019

A "small business" is defined as a company with fewer than 500 full-time equivalent employees.

A "very small business" is a business (including any subsidiaries and affiliates) averaging less than $2.5 million adjusted for inflation, per year, during the three year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g. held for a fee or supplied to a farm without sale).[24] Importantly, when considering whether a company meets this definition, you should be aware:

- Animal food distributed but not "sold" or supplied to a farm without sale must be included,
- Must consider global sales (i.e., not just U.S. sales) of the entire entity, including affiliates or subsidiaries, and

[23] A graphic summary of all of the compliance dates is *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM568798.pdf.
[24] 21 CFR § 507.3.

- The dollar value limit does not consider sales of seed for planting.

A very small business is sometimes referred to as a "qualified facility."

For the purposes of whether a very large company that only sells/holds a very small amount of food for animal consumption would be considered a "very small business," FDA provides in the preamble the following discussion:

> The qualified facility exemption of § 507.7 applicable to very small businesses is intended to enable these businesses to comply with modified requirements because they have fewer resources to direct to full compliance with subpart Cs and E of the rule and they provide a small volume of animal food for consumption. Many of the businesses that have feed mills that provide animal food under contract farming agreements are extensive and sophisticated businesses, such as some large-scale meat and poultry operations. Such businesses are not the intended beneficiaries of the qualified facility exemption because they should have adequate resources, such as personnel, equipment, and expertise, to implement the requirements of subparts C and E at their feed mills... These were some of the factors we considered when we revised the proposed definition of a very small business to include the market value of the animal food that is manufactured, processed, packed, or held without sales or supplied to a farm without sales. 80 Fed. Reg. 56203 (Sept. 17, 2015) (emphasis added).
>
> The purpose of the definition of "very small business" is principally to enable such businesses to comply with modified requirements, because they have fewer resources to direct to full compliance with the rule. A foreign business that sells more than the threshold dollar amount of animal food has more resources than the businesses being excluded, even if less than that threshold dollar amount reflects sales to the United States. Likewise, a domestic business that sells more than the threshold dollar amount of food has more resources than the businesses being excluded, even if that domestic business exports some of its food and, as a result, less than that threshold dollar amount reflects sales within the United States. *Id*.

FDA's intent is that the definition of "very small business" is for the benefit of companies that do not have the resources, personnel, equipment, etc. to contribute to compliance with all aspects of the rule, rather than for the benefit of larger companies that only participate in the relevant industry on a small scale. Any ASTA member that is considering classifying itself as a "very small business" should take account of this discussion when deciding whether it meets the definition.

Very Small Business Requirements

Very small businesses are subject to different substantive requirements than other businesses. They must submit attestation to FDA regarding their status as a qualified facility and affirming that either: (1) they have: Identified the potential hazards associated with the animal food being produced, and are implementing Preventive Control's to address the hazards, or (2) they are in compliance with State, local, county, tribal, or other applicable non-federal safety laws. The attestation can be submitted electronically at http://www.fda.gov/furls . FDA has issued guidance to help very small businesses understand whether the meet the definition of the term and how to submit this attestation.[25]

[25] *Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Guidance for Industry* (Draft Guidance); May 2016, *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM499509.pdf.

IV. 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 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).

1. 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 PCAF rule (both the cGMP and preventive control requirements) and violations of the adulteration provisions in Section 402 of the FFDCA.

2. FSMA-Related Talking Points

As FDA begins conducting inspections of seed production facilities for compliance with the new regulations under FSMA, 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 Preventive Controls for Animal Food 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 Preventive Controls for Animal Food 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 are 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 are 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

3. 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.

4. 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 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.

5. 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 the FDA Food Safety Modernization Act (FSMA) provide FDA with broad records access. Even if FDA is not inspecting for compliance with the

Preventive Controls for Animal Food 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.**

6. 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.

7. 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.

V. SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD

FDA has established a new regulation addressing requirements for Sanitary Transportation of Human and Animal Food (the "STF" rule). The regulations are codified in 21 CFR Part 1, Subpart O (§ 1.900 et seq.). The regulation establishes requirements for shippers, loaders, carriers, and receivers engaged in transportation of food by motor or rail vehicle that focus on ensuring the safety of food being transported.

PAS and Hogan Lovells have developed an educational presentation for ASTA members regarding the STF rule, which is attached as Appendix 1. It is not complete or exhaustive. ASTA members should not solely rely on the information in the presentation without reviewing the text of the actual regulations. Moreover, every ASTA member should carefully review the regulation to consider whether they need to modify any of their practices or enter into/amend written agreements with their transportation partners in light of the rule.

The regulation puts the primary responsibility on the "shipper," which is the party that arranges for transportation. The shipper takes on the significant portion of the responsibilities unless those responsibilities are transferred by contract to the carrier. We expect that in most situations seed facilities will be utilizing a 3rd party carrier for outbound shipments. In these situations there could be any number of truck drivers arriving at the facility to haul the seed materials that will be sent to the food supply chain. We suggest having agreements in place with the 3rd party carrier that address who bears responsibility for cleaning, acceptable cleaning standards, prior load cleaning documentation, and communication of the prior load's content.

Note that transportation carriers also require training. FDA has developed free training for use by carriers: https://collaboration.fda.gov/sanitary_transportation_carrier_training/

Additionally, it is important to be aware that there are cGMP requirements for shipping containers and bulk vehicles used for animal food distribution. These include provisions that:

- *Bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle.*
- *Facility personnel should be aware of the condition of the shipping container or vehicle, and consider what steps may be required to protect against contamination of the animal food.*
- *The cGMP requirements do not require the facility to examine the shipping container or bulk vehicle when the customer arranges for the transportation of the animal food, including when the customer arranges for a third-party carrier to pick up the animal food.*

VI. GLOSSARY OF SELECT TERMS

Facility- Any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities (21 CFR §1.227).

Farm- (i) Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood) or any combination of these activities. The term "farm" includes operations that, in addition to these activities: (A) Pack or hold raw agricultural commodities; (B) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in (i)(C)(2)(i) of this definition; and (C) Manufacture/process food, provided that: (1) All food used in such activities is consumed on that farm or another farm under the same management; or (2) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of: (i) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing); and (ii) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and (iii) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation);

(ii) Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm in (i)(B) and (C) of this definition. 21 CFR § 1.328.

FSMA- FDA Food Safety Modernization Act.

Good Manufacturing Practice (cGMP)- The principles, programs and practices of sanitary food production that industry must follow to provide the basic environment and operating conditions that are necessary for the production of safe, wholesome food.

Harvesting- Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm. 21 CFR § 1.328.

Holding- The storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the

drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity into a processed food. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. 21 CFR § 1.328.

Manufacturing/Processing- Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding. 21 CFR § 1.328.

Preventive Controls- Risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with current scientific understanding of safe food manufacturing, processing, packaging, or holding at the time of the analysis. 21 CFR § 117.3.

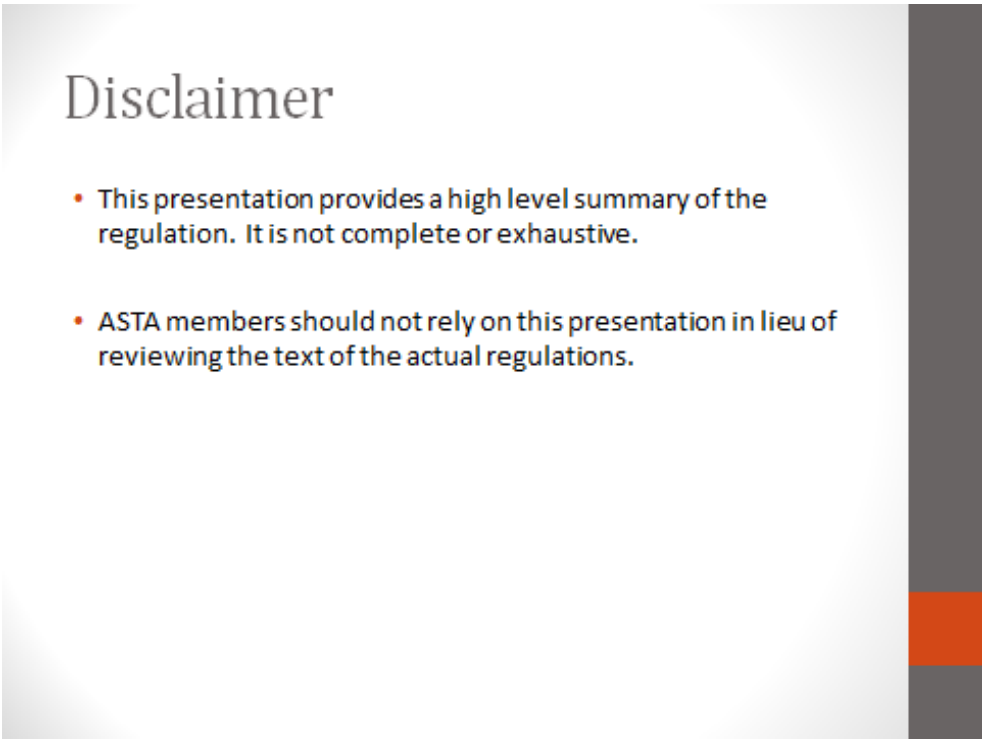
Raw Agricultural Commodity- Any food in its raw or natural state, including, but not limited to, all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing 21 USC § 321 (FFDCA § 201(r)).

VII. APPENDICES

1. FSMA Rule on Sanitary Transportation of Human and Animal Food – Key Takeaways for ASTA Members – PowerPoint Presentation – Prepared by Precision Agricultural Services, Inc. & Hogan Lovells US LLP, April 2018

2. PAS Hazard Analysis and other Supporting Documents – Available to ASTA members through the members-only section of the Association's website

Appendix 1: FSMA Rule on Sanitary Transportation of Human and Animal Food – Key Takeaways for ASTA Members



Who is Covered?

- The final rule applies to **shippers, receivers, loaders, and carriers** who transport food in the United States by **motor or rail vehicle** within the United States.
  - "Food" does not include seeds for planting, but does include seed discards that are being sent into the human or animal food supply
- The final rule also applies to persons, e.g., shippers, who ship food into the U.S.:
  - Directly by motor or rail vehicle (Canada or Mexico) that will then be transported within the U.S.; and
  - By ship or air, and arrange for the transfer of the intact container onto a motor or rail vehicle for transportation within the U.S., if that food will be consumed or distributed in the U.S. (only the motor or rail portion).

Who is Not Covered?

- Shippers, receivers, or carriers with transportation operations with less than $500,000 in average annual revenue
- Transportation of human food byproducts for use as animal food without further processing
  - E.g., byproducts moving directly from a human food manufacturing facility to a farm where they are fed directly to livestock
  - (NOTE: Transportation of byproducts from a human food manufacturing facility to a business where they will be used as an ingredient in manufactured animal food are covered by the rule.)
- Transportation of food fully enclosed by a container (except if requiring temperature control for food safety)
- Trans-shipments of food through the U.S. (Mexico → Canada)
- Food not consumed in the U.S. (import for export)
- Transportation activities performed by a farm

Examples of Food Subject to Rule

- Foods transported in bulk, e.g., seed discards destined for further processing
- Raw agricultural commodities transported in bulk that are not being transported by a farm, e.g., seed processor or third-party provides transportation

Prohibition on Adulteration

- Even if the rule does not apply, there is still a statutory prohibition on adulteration
- The Federal Food, Drug, and Cosmetic Act (§ 402) provides that food is adulterated if (among other reasons):
  - It bears or contains any poisonous or deleterious substance that may render it injurious to health;
  - It consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food;
  - It has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health

Role Definitions

- You must understand the role(s) you play in order so that you know what you need to do to comply with the rule
- You may be subject to the rule in multiple capacities (e.g., shipper may also be loader and carrier)
  - Shippers are persons who arrange for the transportation of food in the United States by a carrier or multiple carrier.
  - Carriers are persons who physically move food by rail or motor vehicle in commerce within the United States, regardless of ownership of the vehicles.
  - Loaders are defined as persons who load food onto a motor or rail vehicle during transportation operations.
  - Receivers are defined as persons who receive food at a point in the United States after transportation, regardless of whether that person is at the food's ultimate destination.

Vehicle & Transportation Equipment Requirements

- Vehicles and transportation equipment must be:
  - Designed and of appropriate material and workmanship to be suitable and adequately cleanable
  - Maintained in appropriate sanitary condition for their intended use
  - Stored in a manner that prevents them from harboring pests or becoming contaminated

Transportation Operations – General Responsibilities for All Roles

- These are general responsibilities applicable to all roles
- Designated responsibilities may be reassigned, in a written agreement, to another party subject to the rule

- Responsibility for ensuring transportation operations are carried out in compliance with the rule must be assigned to competent supervisory personnel
- Transportation operations must be conducted under such conditions to prevent food from becoming unsafe during transport, including:
  - Preventing contamination of food by contact with raw food or non-food items in the same load
  - Protection from contamination and cross-contact (e.g., food allergens if food will be for human consumption)
  - Protection of food transported in bulk

Transportation Operations – General Responsibilities for All Roles

- If a shipper, loader, receiver or carrier becomes aware of conditions that may render the food unsafe during transportation:
  - The food shall not be sold or otherwise distributed; and
  - These persons must take appropriate action including, as necessary, communication with other parties, to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the condition did not render the food unsafe.

Shipper Responsibilities

- The shipper must specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier's vehicle and transportation equipment, including any specific design specifications and cleaning procedures.
- The shipper must develop and implement written procedures adequate to ensure that:
  - Vehicles and equipment are in appropriate sanitary condition
  - A previous cargo does not make the food unsafe if food is transported in bulk

Loader Responsibilities

- Before loading food not completely enclosed by a container, the loader must determine (considering, as appropriate, the specifications provided by the shipper) that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food
  - For example, the loader must confirm that the equipment is in adequate physical condition, free of visible evidence of pest infestation, and free of previous cargo that could cause the food to become unsafe during transportation.

Carrier Responsibilities

- When the carrier and the shipper have a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during transportation operations, the carrier is responsible for the following as applicable per the agreement:
  1) Ensuring that vehicles and transportation equipment meet the shipper's specifications and are appropriate to prevent the food from becoming unsafe during transportation
  2) If requested by the shipper for food transported in a bulk vehicle, providing information to the shipper that identifies the previous cargo transported in the vehicle and/or the most recent cleaning of the bulk vehicle
  3) Develop and implement written procedures that:
     - Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides for use in food transportation to maintain appropriate sanitary condition; and
     - Describe how the carrier will comply with the provisions for identifying previous cargo and the most recent cleaning for bulk vehicles

Carrier Responsibilities – Training

- When the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, carrier personnel must be provided with training that covers:
  - Awareness of potential food safety problems that may occur;
  - Basic sanitary practices to address those problems
  - The responsibilities of the carrier under the rule
- Training must be documented
- FDA has developed a free one-hour training module to help carriers meet these requirements
  - https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm576097.htm

Receiver Responsibilities

- Receivers do not have any specific responsibilities if the food does not require temperature control for safety
- Note that the general responsibilities (on previous slides) still apply

Records

- Shippers must maintain:
  - Records that demonstrate that the shipper provides information to carriers about the necessary sanitary requirements for a vehicle, as appropriate
- Carriers must maintain:
  - Training records
  - Records of written standard operating procedures (SOPs) for cleaning and inspection of vehicles and that describe how it will meet requirements to provide information to shippers about bulk cargo protection, as appropriate
- Maintain written agreements assigning responsibilities to other parties
- Records generally must be retained for 12 months beyond their use (e.g., after termination of a written agreement)

Compliance Dates

- April 6, 2017 – All businesses that are not a "small business"
- April 6, 2018 – "Small businesses"
  - Businesses employing fewer than 500 full-time equivalent employees, except carriers by motor vehicle that are not also shippers and/or receivers
  - Motor vehicle carriers that are not also shippers and/or receivers having less than $27.5 million in annual receipts

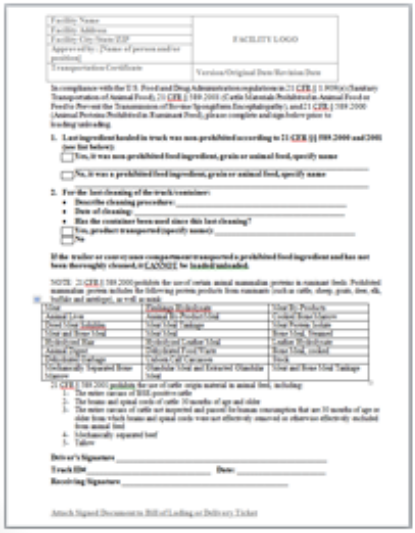
Practical Considerations for the Seed Industry

- The Sanitary Food Transportation applies more broadly than the Preventive Controls rule – covers all transportation of "food"
- Requirements apply to both transporting "finished" animal feed to the receiver and incoming trucks hauling harvested raw agricultural commodities from the field to the plant
  - Exemption applies for transportation from the farm if it is performed by the farm/farmer
- Start by determining:
  - The scope of transportation operations covered by the rule (e.g., are incoming RACs transported by a farm or a third-party?; are seeds/discards transported in bulk or fully enclosed by a container?)
  - Whether you function as a shipper, loader, carrier or receiver (or in multiple roles)
- Assess whether you need written agreements with the carrier and loader to assign responsibilities
  - Existing contracts may need to be updated to address the regulation and assign responsibilities

Practical Considerations for the Seed Industry

- Assign competent supervisory personnel to oversee transportation operations
- Ensure vehicles and transportation equipment are suitable, cleanable, and appropriately maintained
- Shipper must determine whether the carrier needs to provide them with documentation of the previous load and records of cleaning
  - If needed, shipper must have an agreement regarding these issues with the carrier
  - *See Transportation Certificate example on next slide for an example of how to share this information*
- Ensure that food is loaded into a clean and safe container or vehicle
  - Focus on protection of food from contamination by non-food items in the same load or previous load, and protection of food from cross-contamination or cross-contact, i.e., the unintentional incorporation of a food allergen if the food could be for human consumption
- Ensure carrier has procedures in place to address issues like cleaning/inspecting equipment and ensuring the food remains safe during transportation
- Ensure carrier personnel are appropriately trained on sanitary transportation

Sample Transportation Cert.



- *Sample adapted from AFIA BSE Transportation Certification Example G3.*
- Allows carrier to declare the previous cargo and cleaning
- Identifies the type of material previously transported
- States cleaning method
- Includes:
  - Signature from driver
  - Signature from receiver prior to loading
  - Truck Identifier
  - Date
- Though not required, it is a good practice to keep copy and send copy with driver to receiver.
- Note that the carrier only has to provide this information if they agree to do so by contract


Available Resources
• Sanitary Transportation of Human and Animal Food Regulation – 21 CFR Part 1, Subpart O (§ 1.900 et seq.)
• https://www.ecfr.gov/cgi-bin/text-idx?SID=3d4ff6549d8ad46a1aadf8e562db2b66&mc=true&node=sp21.1.1.o&rgn=div6
• FDA website with resources such as webinar, fact sheet, and final rule preamble
• https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm
• FDA training for carriers:
• https://collaboration.fda.gov/sanitary_transportation_carrier_training/