Hogan Lovells

FDA Food Safety Modernization Act (FSMA): Impacts for the Seed Industry

Presentation for American Seed Trade Association

February 6, 2017

Maile Gradison Hermida, Partner

Agenda

- Legal framework
- Engagement with FDA
- Compliance dates
- Sanitary Food Transportation rule
- Next steps
- Questions and answers

Legal Framework

- Key elements of FSMA framework for seed industry
  - Facility registration

    → Triggers compliance with
    - Good Manufacturing Practices (GMPs)
    - Preventive Controls (PCs)

    → Unless you fall within an exemption as "solely engaged" in "holding" raw agricultural commodities (RACs)

Facility Registration

- Registration required for facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States
- Establishment that conditions seed is required to register if owner/operator/agent in charge reasonably believes the seed is reasonably expected to be directed to a food use
  - Includes animal food use or an ingredient in animal food
  - Does not include seeds sent for incineration or landfilling
- FDA recently updated its guidance on facility registration, but takes the same position as previously

Facility Registration

- **FDA expects the seed industry to register!**

B.1.2 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?

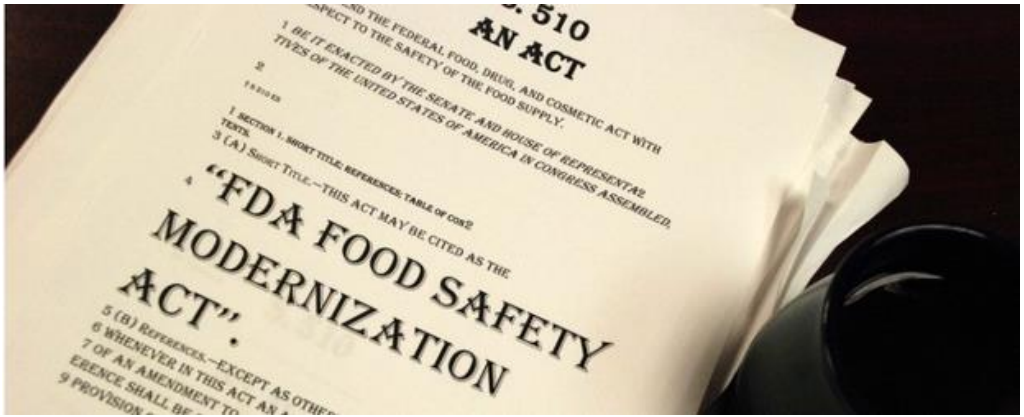
A facility that manufactures/processes, packs, or holds food for consumption in the United States is required to register. "Food" is defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)) to include articles used for food or drink for man or other animals. An establishment that conditions and sells seed to farmers for planting purposes is typically excluded 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 to be directed to a food use, including 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 not required to register. (See Comment 3 in the Registration Final Rule; 81 FR 45912 at 45919).

How to Register

- Visit FDA's registration website: http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm
  - Note: You'll 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 an individual authorized by one of these people
  - Foreign facilities must designate a U.S. agent; this U.S. agent may also register the facility.
- Be sure to choose the correct type of registration (e.g., "Food Facility Registration")
- Types of information needed:
  - 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

Significance of Facility Registration

- Facility registration did not used to have particular regulatory significance, but this changed with FSMA
- Registration now triggers the requirement to comply with FSMA regulations addressing Preventive Controls for Human Food (PCHF) and/or Preventive Controls for Animal Food (PCAF), as applicable, unless an exemption applies



FDA's Preventive Controls Regulations

- Final Rules:
  - Preventive Controls for Animal Food, 80 Fed. Reg. 56170 (Sept. 17, 2015)
    - 21 C.F.R. Part 507
  - Preventive Controls for Human Food, 80 Fed. Reg. 55908 (Sept. 17, 2015)
    - 21 C.F.R. Part 117

- The rules each have two components:
  - Good Manufacturing Practices
  - Preventive Controls
- There are exemptions from the GMP and PC requirements for certain types of foods

Exemptions for “Holding” Food

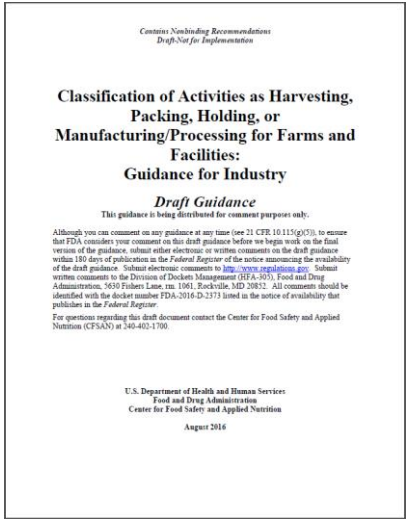
- PCAF rule exempts facilities from PCs (and supplier verification) if they are **“solely engaged in the storage of [RACs] (other than fruits and vegetables) intended for further distribution and processing”**
- PCAF rule exempts facilities from GMPs if they are **“solely engaged in the holding and/or transportation of one or more RACs”**
  - “Storage” and “holding” are synonyms
- To determine whether a facility falls with the “holding” exemption, it’s necessary to assess whether all of its activities fall under the definition

Definition of “Holding”

- “Holding” is defined to include:
  - Storage and activities incidental to storage of animal food (e.g., activities for safe/effective storage, such as fumigating, drying/dehydrating raw agricultural commodities (RACs)
  - Activities performed as practical necessity for distribution of animal food (e.g., blending of same RAC; breaking down pallets)
- Holding facilities could include warehouses, storage silos, and grain elevators
- Holding does not include activities that transform RAC into processed food

Definition of “Holding,” cont’d

- FDA has issued draft guidance intended in part to help facilities determine whether they fall under the two “solely engaged” in holding exemptions
- Draft guidance clarifies an activity can be classified as “holding” because it is performed:
  - For the safe or effective storage of food; or
  - As a practical necessity for distribution of food (limited to only those activities that are truly necessary)



Contains Nonbinding Recommendations
Draft-Not for Implementation

Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2016-D-2373 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

August 2016

Definition of “Holding,” cont’d

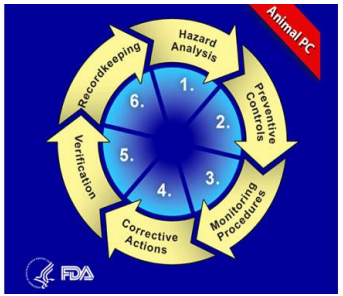
- “Holding” expressly does not include:
  - **Shelling**
  - **Removing or trimming parts of RACs**
- If a facility is not “solely engaged” in “holding,” it must comply with GMPs and PCs

Animal Food GMPs

- FSMA is first application of GMPs to animal food industry
- Focused on foundational food safety programs
  - Personnel
  - Plant and grounds
  - Sanitation
  - Water supply and plumbing
  - Equipment and utensils
  - Plant operations
  - Holding and distribution
- General performance standards applied flexibly and depending on type of food and facility
  - "Building, structures, fixtures, and other facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated"
  - "Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests."
  - "All plant equipment and utensils, including equipment and utensils that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained."

Preventive Controls

- Much more expansive than GMPs
- Requires every facility to conduct hazard analysis to identify and evaluate "known or reasonably foreseeable" biological, chemical, and physical hazards for each type of food manufactured, processed, packed, or held at the facility
- If any hazard identified is a "hazard requiring a preventive control," facility must implement PCs under a **Food Safety Plan** to significantly minimize or prevent the hazard
- PCs include:
  - Process controls (e.g., heat processing)
  - Sanitation controls (e.g., to prevent cross-contamination)



Preventive Controls, cont'd

- PCs are subject to "management components" that must be applied to ensure PCs are effective:
  - Monitoring
  - Corrective actions
  - Verification
- Facilities also must:
  - Validate certain PCs
  - Implement Supplier Verification program for any hazard controlled upstream
  - Reanalyze food safety plan at least every 3 years
  - Develop a recall plan
- All required activities must be documented in records available for FDA inspection

Training Requirements

- Qualified Individual:
  - All individuals who manufacture, process, pack, or hold animal food subject to GMPs and/or PCs must be qualified to perform their assigned duties
  - All individuals engaged in manufacturing, processing, packing or holding animal food must:
    - Be a "qualified individual" – i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assign duties; and
    - Receive training in the principals 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 assign duties
- Preventive Controls Qualified Individual (PCQI):
  - The Food Safety Plan must be prepared or overseen by a PCQI and certain activities under the plan must be conducted by a PCQI
  - PCQI is defined as "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"

ASTA Engagement with FDA

- ASTA has been focused on establishing that seed facilities are exempt from PCAF on the basis that all activities constitute "holding"
- In a February 2016 Meeting with FDA's Center for Veterinary Medicine (CVM), FDA expressed a clear intent to exempt seed facilities on basis that activities all constitute "holding"
  - Pointed to excerpt from PCAF supplemental proposed rule:

> Other facilities that conduct operations similar to those conducted at grain elevators and silos, such as facilities that package and sell seed for crops, but sell the leftover seed for animal food, also may satisfy these criteria for exemption.

ASTA Engagement, cont'd

- In mid-2016, ASTA submitted questions to FDA's Technical Assistance Network (TAN) to confirm seed facilities are classified as "holding"
  - Received generally positive feedback recognizing majority of activities fall within "holding" definition
  - **However, FDA took position removing seeds from cob (shelling) and removing soybeans from pod (threshing) are manufacturing/processing activities** (position later repeated in draft guidance)
- In November 2016 meeting with CVM and Center for Food Safety and Applied Nutrition (CFSAN), FDA continued to take hardline position on classification of shelling and threshing
- Agency also said **husk chopping** could be a manufacturing activity

ASTA Engagement, cont'd

- Agency not persuaded by arguments regarding risk-based approach
- FDA felt constrained by interpretation of legal framework
  - i.e., shelling, threshing, chopping are not necessary: (1) for safe or effective storage of food; or (2) as a practical necessity for distribution of food
- FDA not targeting seed facilities for inspection in FY 2017
  - But seed facilities could be inspected by state regulators
  - Some ASTA members have reported inspections in 2017

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

Very Small Businesses

- There are modified PC compliance requirements for “very small businesses” (a.k.a., “qualified facilities”)
  - **Must still comply with GMPs**
- A “very small business” is a business averaging less than $2.5 million adjusted for inflation, per year, during the 3-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)
  - Includes any subsidiaries and affiliates
  - 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)
  - Does not consider sales of seed for planting

Very Small Businesses, cont'd

- Very small businesses must submit attestation to FDA regarding status as qualified facility and affirming that either:
  - (1) they have:
    - identified the potential hazards associated with the animal food being produced,
    - are implementing PCs to address the hazards, and
    - are monitoring the performance of the PCs; **or**
  - (2) they are in compliance with State, local, county, tribal, or other applicable non-Federal food safety laws
- If attestation is under category (2) above, must provide consumers with name and complete address of the facility where the animal food was manufactured or processed
  - If an animal food packaging label is required, this information must appear prominently on the label
  - If no label is required, this information must appear prominently at the point of purchase, on a label, poster, sign, placard ,or documents delivered with the food, or in an electronic notice (for Internet sales)

Very Small Businesses, cont'd

- Qualified facilities must determine and document status on an annual basis, no later than July 1 of each calendar year
  - Facilities must maintain records relied upon to support attestations
- Initial attestation must be submitted by:
  - December 16, 2019 for facility that begins manufacturing, processing, packing, or holding animal food before September 17, 2019
  - Before beginning operations, for facilities that begin manufacturing, processing, packing, or holding animal food after September 17, 2019; or
  - By July 31 of the applicable calendar year, when the status of a facility changes from "not a qualified facility" to "qualified facility"
- Beginning in 2020, subsequent attestations must be made every 2 years between October 1 and December 31
- FDA also must be notified by July 31 of the applicable calendar year when a facility's status changes from "qualified facility" to "not a qualified facility"
  - Facility then must begin complying with preventive controls and supply chain program requirements by December 31 of the applicable calendar year (unless otherwise agreed to by FDA and the facility)

Current Status of Seed Operations

- Based on FDA's current position, seed facilities could be regulated differently based on the type of seed being produced
  - Corn facilities and soybean research facilities typically remove seeds from the cob/pod and would be considered engaging in manufacturing
  - Facilities that chop husks before sending them for animal consumption also would be considered manufacturing
- FDA's approach in draft guidance is non-binding
  - Companies could take position that their activities fall inside the scope of "holding" and therefore are exempt, but there is a risk that FDA will disagree

Current Status of Seed Operations

- Seed facilities are not an inspection priority for FDA
- State regulators are reportedly conducting inspections of seed facilities and asking about FSMA
- Current inspections focused on GMPs (earliest compliance date for PCs is September 2017)

Additional FDA Requirements

- Prior Notice
- Foreign Supplier Verification Program
- Sanitary Food Transportation

Sanitary Transportation Rule

- Establishes sanitary transportation requirements for parties involved in transporting human and animal food by motor or rail vehicle
- Rule supplements general prohibition in the statute on adulteration
- Exemptions include:
  - Transportation of food that is completely enclosed by a container (unless it needs temperature control)
  - Transportation activities performed by a farm

Sanitary Transportation Rule, cont'd

- Who is subject to the rule?
  - **Shipper**: the person who arranges for the transportation of food in the U.S. by a carrier or multiple carriers sequentially
  - **Loader**: a person that loads food onto a motor or rail vehicle during transportation operations
  - **Carrier**: a person who physically moves food by rail or motor vehicle in commerce in the U.S.
  - **Receiver**: any person who receives food at a point in the U.S. after transportation
- Rule generally codifies current industry practices, with specific obligations for each of these parties
- Contracts are essential for compliance, as many regulatory requirements only attach when provided by contract

Prior Notice

- The Bioterrorism Act of 2002 requires that FDA receive prior notification of food (including animal feed) that is imported or offered for import into the United States.
- FDA has addressed seeds in guidance:

Are seeds subject to prior notice requirements?

The answer depends on whether the seeds meet the definition of food. FDA considers a seed to be food if it is reasonably likely to be directed to a food use (73 FR 66294 at 66301; November 7, 2008). For example, if the seed is for use in animal feed, the seed is food and prior notice is required (21 CFR 1.276(b)(5); 21 CFR 1.277(a)). Similarly, if the seed is to be used for human food, such as sesame seeds to be used in baking or oilseeds for processing into edible oil, then prior notice must be submitted to FDA before the seed is imported or offered for import into the U.S. …

FDA has an enforcement discretion policy regarding seeds for planting. Under the policy, FDA and CBP would typically consider not taking any regulatory action regarding seeds that will be used for cultivation. The policy applies when no more than a small portion of that seed is diverted from cultivation to animal feed or other food use. …

Foreign Supplier Verification Program

- The Foreign Supplier Verification Program (FSVP) is a FSMA regulation that requires the FSVP "importer" of food to engage in supplier verification for any imported "food" with a hazard being controlled upstream
- FDA has not specifically addressed how FSVP intersects with imported seeds, but we should expect them to take a position aligned with their guidance on Prior Notice:
  - FDA considers a seed to be food if it is reasonably likely to be directed to a food use
  - It seems unlikely that FDA would consider FSVP to apply to seeds that will be used for cultivation, even if a small portion of that seed is then diverted from cultivation to animal feed
  - No substantive FSVP requirements if no hazards are controlled upstream

Next Steps

- Two public comment periods open, and ASTA plans to submit comments
  - Classification of activities draft guidance (due February 21, 2017)
  - Facility registration draft guidance (due March 27, 2017)
- It will take FDA time (perhaps more than a year) to finalize guidance
- In the meantime, FDA and state investigators likely will be trained on current interpretations in draft guidance (i.e., shelling, threshing, chopping is not "holding" and would trigger compliance with PCs and GMPs)
- Agency's current position was set under Obama administration
  - May be opportunity under Trump administration to affect agency's approach
  - ASTA also considering legislative options under new Congress

Conclusion

- Regulation of seed facilities will vary depending on activities the facility conducts
- ASTA disappointed with FDA's current position
- We will continue to advocate for industry position that all seed facilities should be exempt


Q & A

Contact Information

Maile Hermida, Partner
(202) 637-5428
Maile.Hermida@hoganlovells.com