2018 | THE ALMOND CONFERENCE

FSMA SCORECARD: HOW DOES YOUR OPERATION STACK UP?

ROOM 306-307 | DECEMBER 4, 2018

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Almond Board of California

growing ADVANTAGE
The Almond Conference

Continuing Education Units (CEU's)

- **What type of CEU's are offered at conference?**
  - Tuesday – Certified Crop Advisor (CCA)
  - Wednesday – Certified Crop Advisor (CCA)
  - Thursday – Certified Crop Advisor (CCA) and Department of Pesticide Regulations (DPR)

- **Where are the CEU sign in sheets?**
  - CEU sign in sheets will be in the back of each session
  - There are separate forms on Thursday for the CCA and DPR credits

- **Special instructions for Thursday**
  - PCA's will need to pick up their scantrons in the morning before the first session of the day. They will also need to return the scantron at the end of the day to the CEU booth. This is in addition to signing in and out of each session.

AGENDA

- **Brian Dunning,** ShoEi Foods Inc, USA, moderator
- **Maile Hermida**, Hogan Lovells

FSMA Scorecard: How Does Your Operation Stack Up?

Almond Conference

December 4, 2018

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Agenda

- FSMA Roadmap
  - Which rules apply to me?
    - Understanding how FDA defines and classifies certain activities
  - Exemptions
    - Written Assurances/commercial processing
  - Compliance Dates
    - Enforcement Discretion
      - Water
      - Farm like facilities
      - Written assurances
- Inspections

FSMA Roadmap

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FSMA Rules Applicable to the Almond Industry

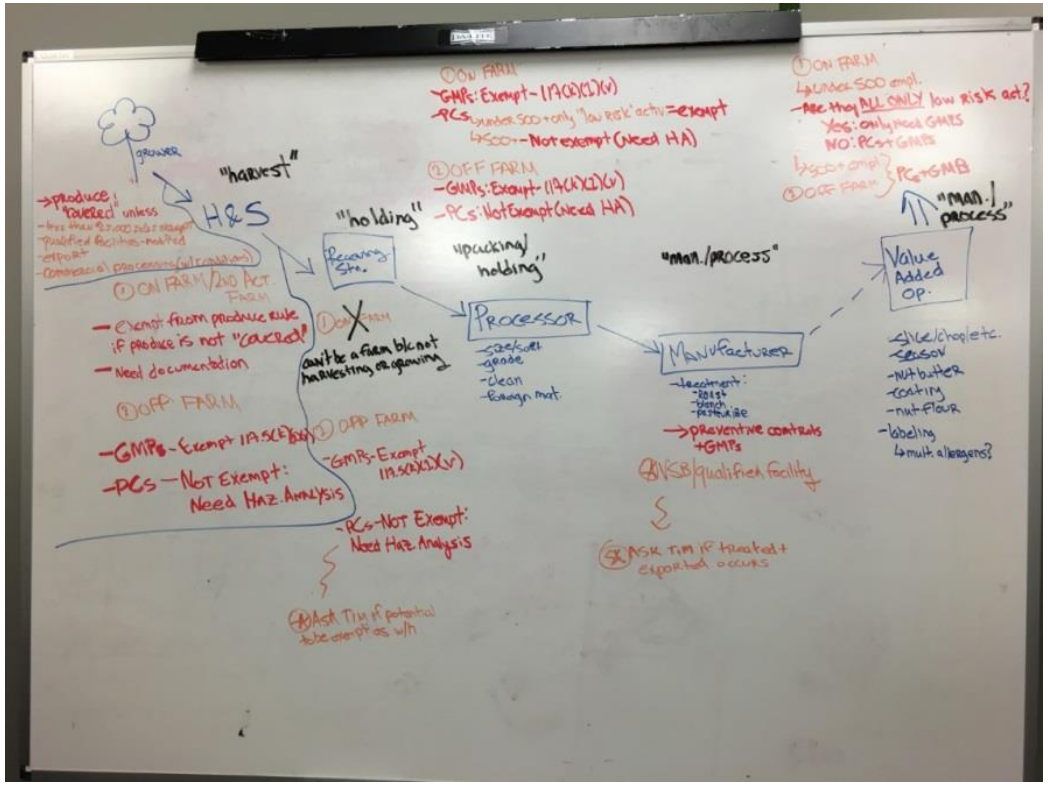
- Produce Safety
- Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food
- Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Animal Food
- Foreign Supplier Verification Programs
- Sanitary Transportation of Human and Animal Food
- Mitigation Strategies to Protect Food Against Intentional Adulteration

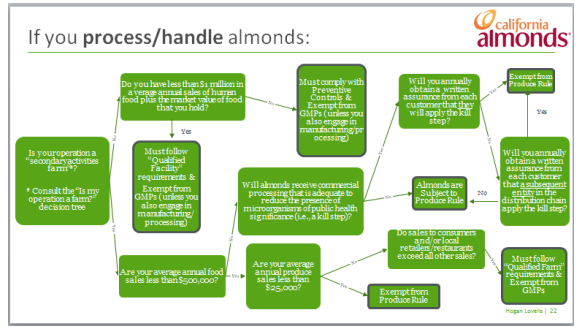
Types of Almond Operations

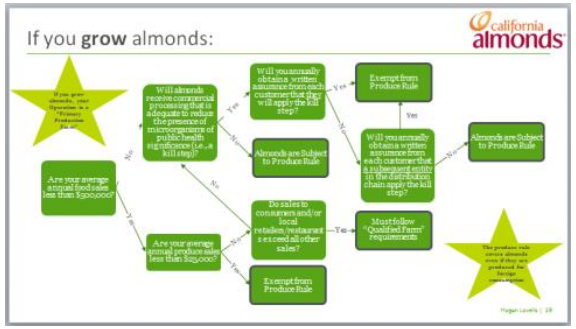
- Growers
- Hullers and Shellers
- Processors / Handlers
  - Sizing, sorting, grading
  - Cleaning (separating out foreign material)
  - Bulk packing
- Manufacturers
  - Treat almonds through pasteurization, roasting, and/or blanching
- Value Added Operations
  - Slicing, chopping
  - Seasoning, coating
  - Making nut butters, nut flour
  - Labeling
  - Packaging

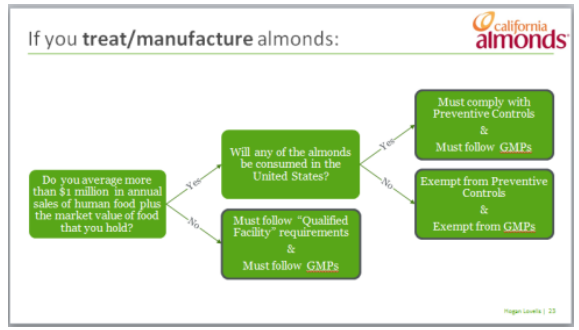
→ Many operations fall into more than one category

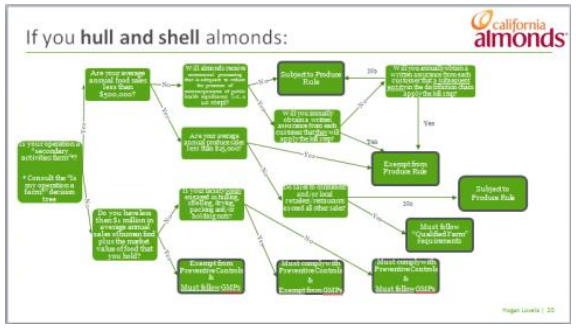
It’s Complicated!

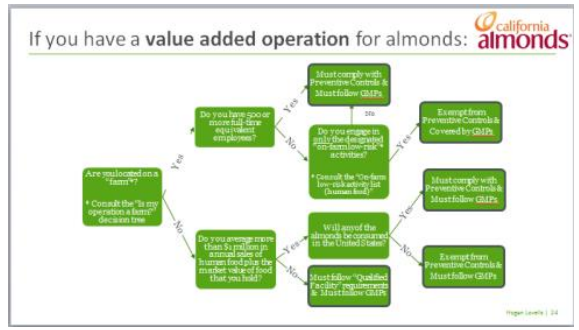












** This just an illustration, not advice!

Which Rules Apply to Me? - Overview

- Step 1: Understand which entities are covered by which rules
  - Facilities: Preventive Controls for Human Food, Preventive Controls for Animal Food, Intentional Adulteration
  - Farms: Produce Safety
  - Importers: Foreign Supplier Verification Programs (FSVP)
  - Shippers, Carriers, Receivers, Loaders: Sanitary Transportation
- Step 2: Determine how the activities you conduct are classified by FDA
  - Are you a farm or a facility?
  - Are you an importer?
  - Are you a shipper?
- Step 3: Look at each rule and determine whether any exemptions apply
  - For example: Do you meet the definition of a very small business? Can you obtain written assurances of commercial processing?
- Step 4: If you are covered by the rule, determine your compliance date
  - Look both at business size and any extensions granted

Step 1: Understand which entities are covered by which rules

Different FSMA Rules Apply to Different Entities

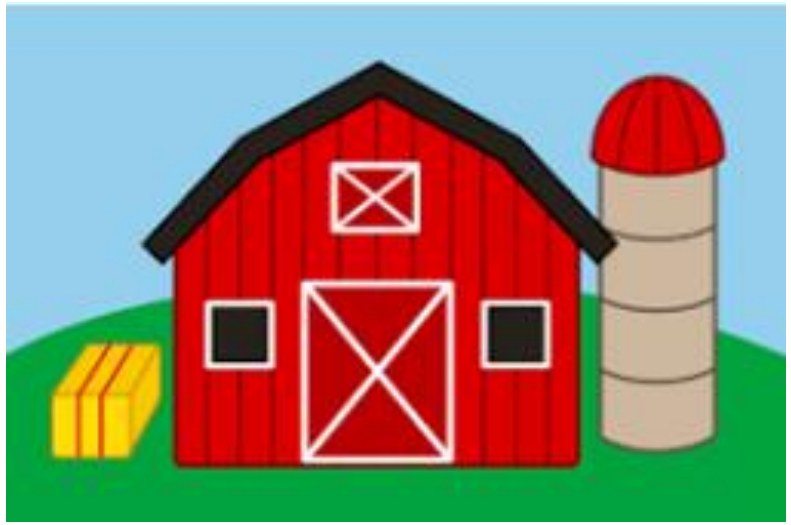
- Facilities:
  - Preventive Controls for Human Food
  - Preventive Controls for Animal Food
  - Intentional Adulteration
- Farms:
  - Produce Safety
- Importers:
  - Foreign Supplier Verification Programs (FSVP)
- Shippers, Carriers, Receivers, Loaders:
  - Sanitary Transportation of Human and Animal Food

→ Remember: Your operations may meet multiple definitions (e.g., you may be a facility, importer, and shipper)

Step 2: Determine How Your Activities are Classified

Understanding FDA's Definitions

- To determine your FSMA obligations, you need to start by determining how the activities you conduct are classified by FDA
- Hardest part is determining whether your operation is a "farm" or a "facility" (or a "farm mixed type facility")



Key Definitions

- A **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:
  - (i) Pack or hold raw agricultural commodities;
  - (ii) 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
- A **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.

→ Note: Farm definition is under review

Key Definitions Continued…

- **Facility** means any establishment, structure, or structures under one ownership at one general physical location . . . that manufactures/processes, packs, or holds food for consumption in the United States. 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.
- A **mixed-type facility** means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered (e.g., a “farm mixed-type facility” which is an establishment that is a farm, but that also conducts activities that require it to be registered).

Digging into the Definitions

- FDA has published a draft guidance document intended to help operations determine whether or not the activities they perform fall within the “farm” definition
  - Remember, for “farm mixed type facilities” some activities will be “farm” activities and others “facility” activities
- Importantly, activities may be classified in different ways, depending on the circumstances
- Start with determining whether your activities fall within the definition of a farm:
  - Start with whether the activity is “growing”
  - Then consider whether the activity meets the definition of “harvesting”
  - If not, consider whether the activity falls within the definition of “packing”
  - Then consider whether it is classified as “holding”
  - If the activities cannot be classified into any of the above categories, consider whether they are “manufacturing/processing”

Harvesting

- 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
  - Includes hulling and shelling, sorting/culling/grading
  - Importantly, harvesting relates to a place where RACs were grown or raised – it requires a connection to such a place; either:
    - By location (same general physical location where RACs are grown (though the RACs grown don't have to be the same RACs or same type of RACs harvested)) OR
    - By Ownership (see definition of a secondary activities farm)
- Hulling and shelling where almonds (or other RACs!) are grown (same general physical location) = within the primary production farm definition
  - Hullers and shellers that are primary production farms can hull/shell any amount of almonds from other farms
- Open questions:
  - Are all hullers/shellers farms because they harvest in the same region where almonds are grown? What does "same general physical location" entail?
  - How does FDA determine whether an operation is growing RACs?

Packing

- Placing food into a container other than packaging the food (i.e., placing food into containers that are not consumer containers)
- Includes re-packing and activities performed incidental to packing or re-packing a food
  - *e.g.,* activities performed for the safe or effective packing or re-packing of that food such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing
  - But also can include hulling/shelling when done for the safe and effective packing (such as to pack only the desired portion of the nut)
- Does not include activities that transform a raw agricultural commodity into a processed food
- Note that “packaging” and labeling are manufacturing/processing activities (e.g., putting almonds into bags that the consumer receives)

Holding

- 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)
  - Other activities within the definition of holding include aeration and turning for safe and effective storage
- 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 or activities optionally performed to add value
  - Blending must take place on foods that are the same (e.g., almonds with almonds)
  - Also includes sorting, culling, grading, weighing, conveying, and sampling when they are a practical necessity for the distribution of the food
- Holding facilities could include warehouses and storage silos
- Note: hulling, shelling, packaging, re-packing are NOT holding activities

Manufacturing/Processing

- Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients
  - Examples include: Baking, boiling, cooking, cooling, cutting, formulating, grinding, homogenizing, labeling, milling, mixing, packaging, pasteurizing, peeling, washing, chopping, slicing, hulling, shelling, crushing, sorting, culling, grading, weighing, conveying
- <u>For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding</u>

Examples of Activities Classified Multiple Ways

Activity	Classification	Details
Hulling/Shelling	• Harvesting • Packing • Manufacturing/ Processing	• Hulling/shelling RACs on a farm is a harvesting activity • Hulling/shelling for safe/effective packing (such as hulling almonds to pack just the desired part of the RAC) is a packing activity • Hulling/shelling almonds at a facility that chops the almonds is a manufacturing/processing activity

Examples of Activities Classified Multiple Ways

Activity	Classification	Details
Sorting Culling Grading	• Harvesting • Packing • Holding • Manufacturing/ Processing	• Sorting, culling, and grading RACs on a farm are harvesting activities • Sorting, culling, and grading performed for the safe or effective packing of the food incidental to packing are packing activities • Sorting, culling, and grading performed as a practical necessity for distribution of the food are holding activities • Sorting, culling and grading that does not fall into harvesting, packing, or holding (e.g., when performed as an initial step in a processing facility before pasteurization) are manufacturing/ processing activities

Implications of Activity Classification

- If your business is a “primary production farm” or a “secondary activities farm”, but you also perform at least one activity that falls outside the “farm” definition, your business is a “farm mixed-type facility” and you may be required to register as a food facility
  - The activities that trigger the registration requirement (those that are not within the farm definition) may be subject to GMPs and Preventive Controls, as applicable

- If your operation is not a “primary production farm” or a “secondary activities farm,” you may be required to register as a food facility
  - All of your operations may be subject to GMPs and Preventive Controls

Examples – Handlers

- Handlers size, sort, grade, and pack almonds

- Handler that grows almonds = primary production farm
- Handler that does not grow almonds and is not owned by growers = facility
- Handler owned by two growers that supply the majority of almonds sized, sorted, graded, and packed = secondary activities farm
  - If this handler also chops some of the almonds = farm mixed-type facility
- Handler owned by two growers that do not supply the majority of almonds packed = facility
- Handler who pasteurizes the almonds = facility

Examples – Hullers/Shellers

- Huller/sheller that grows almonds = primary production farm
- Huller/sheller that grows walnuts = primary production farm
- Huller/sheller that does not grow almonds and is not owned by growers, but is in the same general physical location where almonds are grown = primary production farm (but need FDA concurrence to be certain)
- Huller/sheller that does not grow almonds and is not owned by growers, but is in the same general physical location where other RACs are grown = primary production farm (but need FDA concurrence to be certain)
- Huller/sheller owned by two growers that supply the majority of almonds hulled and shelled = secondary activities farm
- Huller/sheller that does not grow almonds, is not owned by growers, and is not in the same general physical location where almonds are grown = facility

Still Confused? Use the ABC Decision Trees!

Other Almond Growers

Business A
Grows, Harvests, and Holds Almonds

Business B
Majority Owned by A; Majority of Almonds from A
Hulls, Shells, and Holds Almonds

Business C
Majority Owned by A; Majority of Almonds Not from A
Hulls, Shells, and Holds Almonds

Business D
- Grow Almonds
- Hulls, Shells, and Holds Almonds

Business G
(Brown Skin Facility)
- Handles Almonds (sizes, sorts, and grades)

Business H
Majority Owned by A; Majority of Almonds from A
(Brown Skin Facility)
- Handles Almonds (sizes, sorts, and grades)

Business I
Majority Owned by A; Majority of Almonds from A
- Pasteurizes Almonds
- Chops Almonds
- Packs and Holds Pasteurized Almonds and Chopped Almonds

Other Almond Growers

Business E
- Hulls, Shells, and Holds Almonds
- Handles Almonds
- Pasteurizes Almonds

Business F
Majority Owned by A; Majority of Almonds from A
– Hulls, Shells, and Holds Almonds
- Handles Almonds
- Pasteurizes Almonds

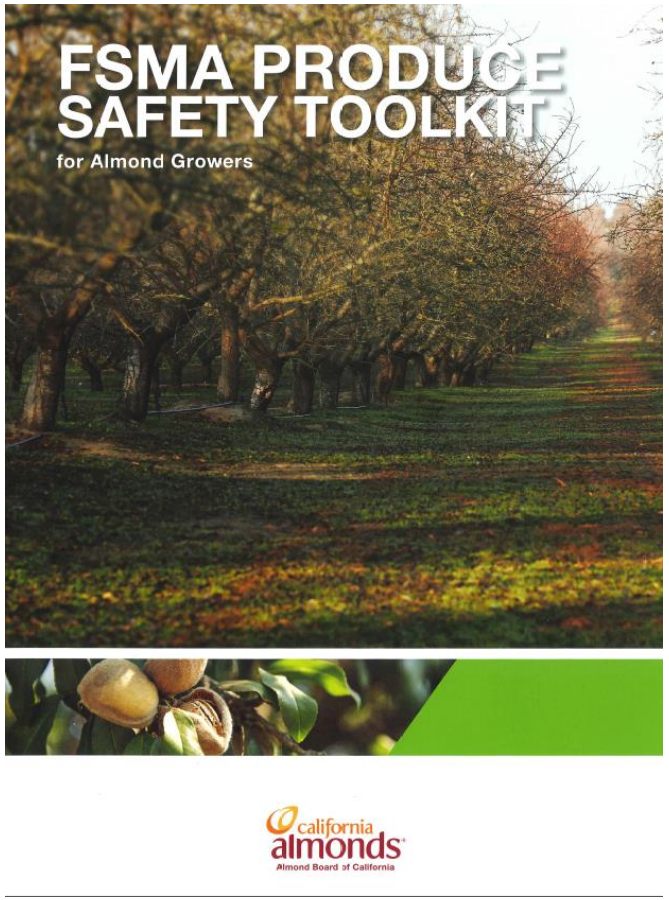
Other Definitions

- For the FSVP rule:
  - The “Importer” is the U.S. owner or consignee of the food
  - The U.S. owner or consignee means the person who, at the time of entry, owns the food, has purchased the food, or has a written agreement to purchase the food
  - This is NOT the same as the Importer of Record
- For the Sanitary Transportation rule:
  - “Shipper” means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially
  - “Carrier” means a person who physically moves food by rail or motor vehicle in commerce within the United States
  - “Loader” means a person that loads food onto a motor or rail vehicle during transportation operations
  - "Receiver” means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food

Steps 3 and 4: Determine Exemptions and Compliance Dates

Produce Rule Overview

- Covers domestic and imported produce, including produce for export
- Personnel qualifications and training
- Focus on conditions and practices identified as potential contributing factors for microbial contamination:
  - Worker health and hygiene
  - Agricultural water
  - Biological soil amendments of animal origin
  - Domesticated and wild animals
  - Growing, harvesting, packing and holding activities
  - Equipment, tools, buildings and sanitation
- Exemptions:
  - Commercial Processing
  - Rarely Consumed Raw



Produce Safety Rule Coverage

- Applies to farms
- Determine whether you qualify for any exemptions/modified requirements
  - Are average annual produce sales less than $25,000?
  - Are average annual food sales than $500,000 and do sales to consumers and local restaurants/retailers exceed all other sales?
  - Can you provide written disclosures/obtain written assurances of commercial processing?
    - NOTE that the requirement to obtain a written assurance has been delayed while FDA engages in rulemaking on this issue

***NOTE that FDA has proposed to delay the compliance date for compliance with the agricultural water requirements in the produce safety rule

Personnel Qualifications and Training

- Farm workers who handle covered produce and/or food-contact surfaces, and their supervisors, must be trained on certain topics, including the importance of health and hygiene, and the produce safety standards relevant to the worker's job.
- Farm workers who handle covered produce and/or food contact surfaces, and their supervisors, are also required to have a combination of training, education and experience necessary to perform their assigned responsibilities. This could include training (such as training provided on the job), in combination with education, or experience (e.g., work experience related to current assigned duties).
- Training must be done:
  - Upon hiring, periodically thereafter, and at least annually
  - As necessary if personnel aren't meeting produce safety standards

Personnel Qualifications and Training

- Workers engaged in harvesting must receive training that addresses:
  - Recognizing produce that must not be harvested
  - Inspecting harvest containers and equipment
  - Correcting problems with harvest containers and equipment
- At least one supervisor or responsible party for your farm must have successfully completed Produce Safety Alliance training or an equivalent
- Assign or identify personnel to supervise (or otherwise be responsible for) compliance with the produce safety standards
- Training must be documented (date, topic, person(s) trained)

Worker Health and Hygiene

- Take measures to prevent contamination of produce and food-contact surfaces by ill or infected persons, for example, instructing personnel to notify their supervisors if they may have a health condition that may result in contamination of covered produce or food contact surfaces and excluding persons from working.
- Use hygienic practices when handling (contacting) covered produce or food-contact surfaces
  - Personal cleanliness
  - Avoiding contact with animals
  - Washing hands at certain times
  - Maintaining gloves in an intact and sanitary condition
  - Removing or covering jewelry
  - Not eating, chewing gum, or using tobacco products
- Take measures to prevent visitors from contaminating covered produce and/or food-contact surfaces and making toilet and hand-washing facilities accessible to visitors.

Agricultural Water

- Purpose: Safe and adequate sanitary quality of water
- Requirements address:
  - Safe and adequate sanitary quality of water
  - Inspection of water system under farm's control
  - Water treatment, if a farm chooses to treat water
  - Specific microbial criteria for water used for certain purposes
  - Tiered approach to water testing
  - Corrective measures
  - Records requirements

- Complex regulations are under reconsideration by FDA based on industry concerns
  - FDA has proposed to extend the compliance dates for the agricultural water requirements and is reconsidering how to reduce the regulatory burdens posed by this part of the rule

Biological Soil Amendments of Animal Origin

- A soil amendment is a material, including manure, that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.
- Rule includes standards for “treated” and “untreated” BSAs
- General requirements for handling, conveying, and storing
- Prohibition on application of human waste
- Restrictions on application method depending on treatment status
- Establishes processes for meeting “treated” standard

Domesticated and Wild Animals

- Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated by grazing, working, and wild animals:
  - Assess, as needed, relevant areas during growing for potential animal contamination (regardless of harvest method);
  - If significant evidence of potential contamination is found (e.g., animal excreta, animal observation or destruction):
    - Evaluate whether covered produce can be harvested
    - If significant evidence of potential contamination by animals is found, to take steps throughout the growing season to ensure the produce that could be contaminated will not be harvested (e.g., placing flags outlining the affected area).
- Farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas.

Growing, Harvesting, Packing, and Holding Activities

- Requirements include:
  - Separate covered produce and produce not grown in accordance with the rule
    - Adequately clean and sanitize food contact surfaces between use for covered/excluded produce
  - Identify and do not harvest covered produce that is reasonably likely to be contaminated
  - Food-packing material must be appropriate for use

Equipment, Tools, Buildings and Sanitation

- The rule establishes standards related to equipment, tools and buildings to prevent these sourc sanitation, from contaminating produce.
- Required measures to prevent contamination of covered produce and food contact surfaces inc
  - Equipment/tools: designed and constructed to allow adequate cleaning and maintenance.
  - Food contact surfaces of equipment and tools must be inspected, maintained, cleaned, and sanitized as necessary.
  - Buildings: size, design and construction must facilitate maintenance and sanitary operations.
  - Toilet and hand-washing facilities must be adequate, and readily accessible during covered activities.

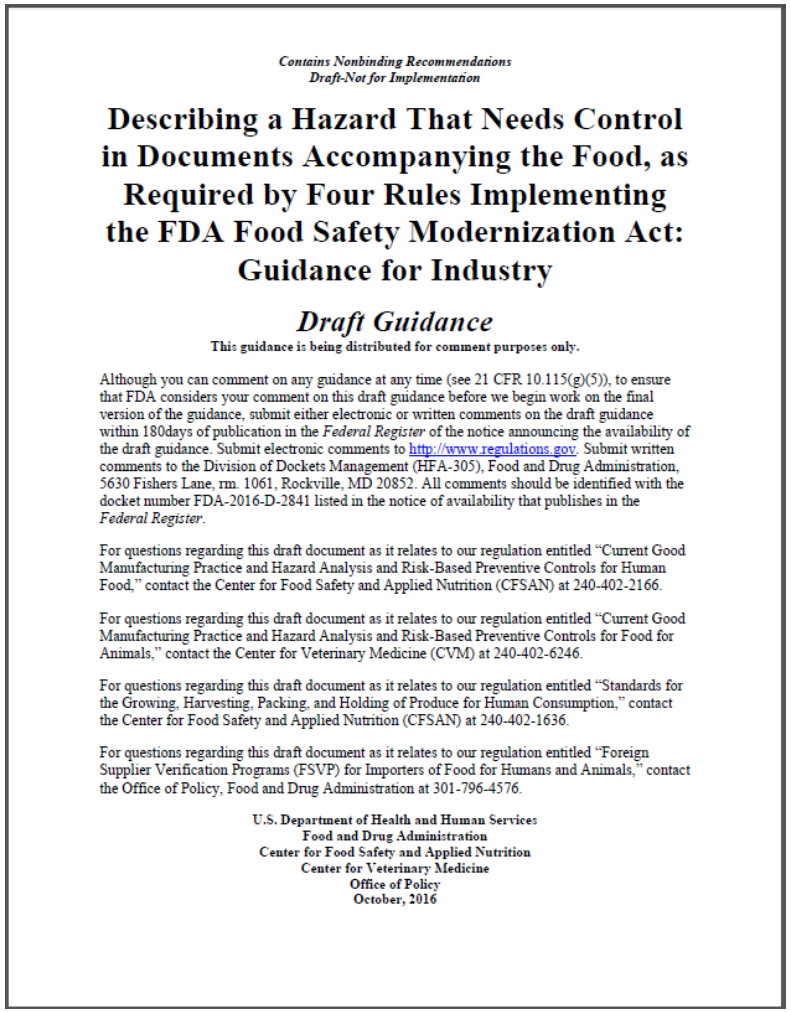
In Focus: Commercial Processing Exemption

- The Produce Safety Rule provides that farms are exempt from the rule if the produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the farm
  - (1) Provides documentation to its direct customer that the food is “not processed to adequately reduce the presence of microorganisms of public health significance” (the disclosure statement requirement); and
  - (2) Receives written assurance from its customer that the customer or an entity further down the supply chain performs commercial processing that adequately reduces the presence c microorganisms (customer assurance requirement)
- Under the regulations, there are two components:
  - Disclosure Statement
  - Written Assurance
- Currently, only the disclosure statement requirement is in effect
  - FDA is exercising enforcement discretion for written assurances while it engages in rulemaking regarding this provision in multiple FSMA rules

In Focus: Commercial Processing Exemption

- FDA has issued draft guidance on the disclosure statement requirements
- The guidance provides recommendations on:
  - How to describe the identified hazards; and
  - What constitutes "documents accompanying the food, in accordance with the practice of trade"

1. How to Describe the Hazard
   - The Produce Safety rule requires a disclosure that the food "is not processed to adequately reduce the presence of microorganisms of public health significance."
   - FDA will consider a farm to be in compliance if it discloses that its produce is "not processed to adequately reduce the presence of microbial pathogens," or uses a similar phrase



Contains Nonbinding Recommendations
Draft-Not for Implementation

Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: 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 180days 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-2841 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document as it relates to our regulation entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2166.

For questions regarding this draft document as it relates to our regulation entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals," contact the Center for Veterinary Medicine (CVM) at 240-402-6246.

For questions regarding this draft document as it relates to our regulation entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1636.

For questions regarding this draft document as it relates to our regulation entitled "Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals," contact the Office of Policy, Food and Drug Administration at 301-796-4576.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Policy
October, 2016

In Focus: Commercial Processing Exemption

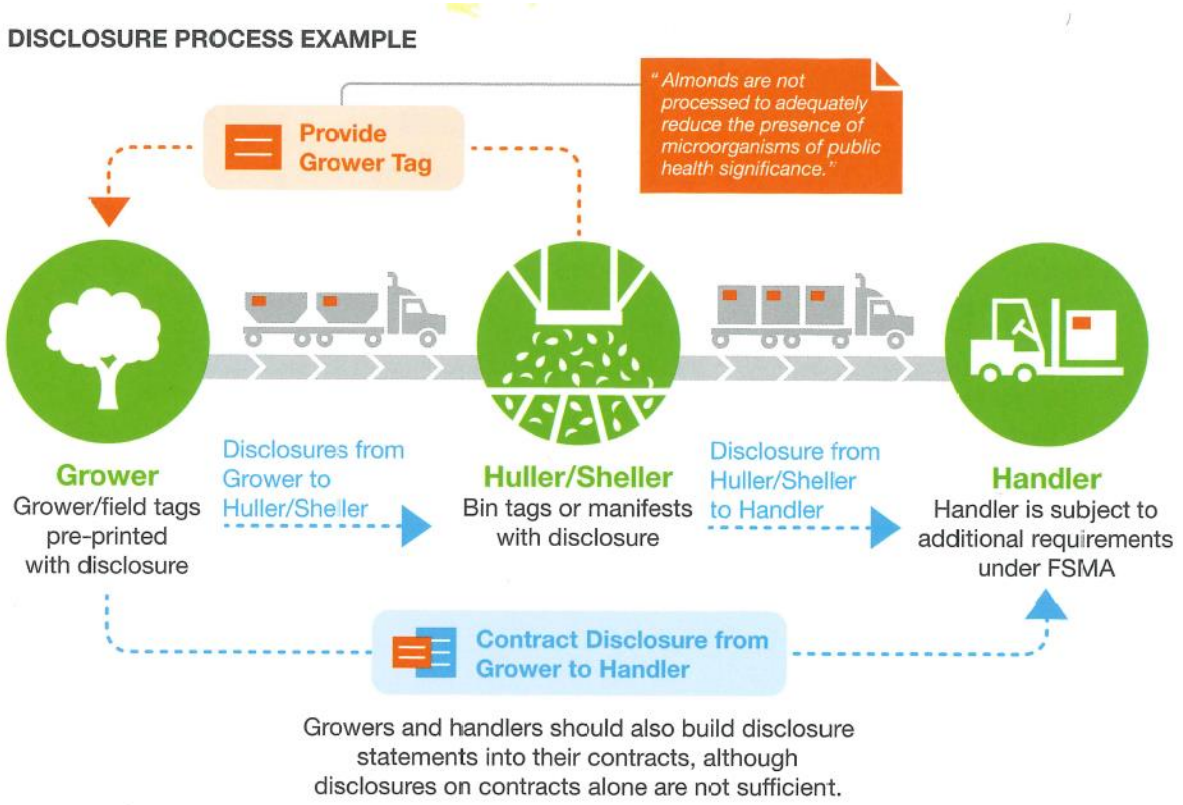
2. How to Communicate the Hazard

- The statement must be made in documents "accompanying" the food, "in accordance with the practice of trade"
  - FDA notes this requirement can be satisfied in a wide variety of documents that accompany food, "such as labels, labeling, bill of lading, shipment-specific certificate of analysis, and other documents or paper associated with the shipment that a food safety manager for the customer is likely to read"
  - FDA's position is that it is not sufficient to reference a website in a document of the trade without including the disclosure statement, itself, in the document of the trade
    - It would be permissible to use labeling that includes a disclosure statement such as "not processed to control microbial pathogens" and then direct the recipient to a website for additional information about those microbial pathogens
  - Further, FDA does not recommend that documents such as contractual agreements, letters of guarantee, specifications, or terms and conditions be used to communicate the information required in the disclosure statement
    - FDA's position is that such documents are not specific to a particular shipment, and some of these documents may not be available to the customer's food safety manager

Commercial Processing Exemption – Almond Disclosure Example

- If growers utilize the commercial processing exemption, they must make a disclosure in documents accompanying the product

"Almonds are not processed to adequately reduce the presence of microorganisms of public health significance."



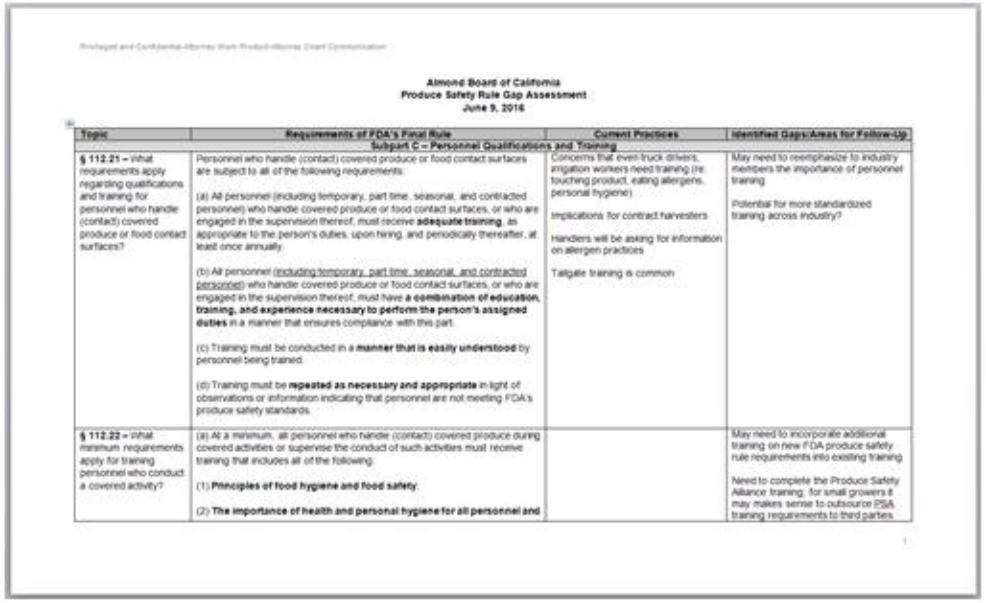
In Focus: Commercial Processing Exemption

- Written Assurance Compliance Challenges:
  - Unless there is segregation between almonds that are/are not produced under the Produce Safety rule, the written assurances are needed from **all** customers
    - Applies to exported produce
    - Applies to almonds sold under the roadside stand exemption (7 CFR 981.413)
    - Applies to kernels returned to growers
  - Complex supply chain sets up a chain link requirement for assurance letters:
    - Huller & Sheller → Grower
    - Handler → Huller & Sheller
    - Processor → Handler

- FDA is currently exercising enforcement discretion and is NOT enforcing the Written Assurance requirement for the commercial processing exemption
  - FDA is likely to modify the requirement in the Produce Safety rule, not revoke it permanently

How Growers Can Avoid Disclosures & Assurances

- Growers are only required to comply with the written disclosure/assurance provisions if they want to be exempt from the Produce Safety rule
- The Almond Board conducted a gap assessment for the Produce Safety rule and found that most of the requirements can be addressed through enhanced training programs for workers, but that the agricultural water standards may pose challenges



Almond Board of California
Produce Safety Rule Gap Assessment
June 9, 2016

Topic	Requirements of FDA's Final Rule	Current Practices	Identified Gaps/Areas for Follow-Up
Subpart C – Personnel Qualifications and Training			
§ 112.21 – What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?	Personnel who handle (contact) covered produce or food contact surfaces are subject to all of the following requirements: (a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive **adequate training**, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually. (b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have **a combination of education, training, and experience necessary to perform the person's assigned duties** in a manner that ensures compliance with this part. (c) Training must be conducted in a **manner that is easily understood** by personnel being trained. (d) Training must be **repeated as necessary and appropriate** in light of observations or information indicating that personnel are not meeting FDA's produce safety standards.	Concerns that even truck drivers, irrigation workers need training (re touching product, eating allergens, personal hygiene) Implications for contract harvesters Handlers will be asking for information on allergen practices Tailgate training is common	May need to reemphasize to industry members the importance of personnel training Potential for more standardized training across industry?
§ 112.22 – What minimum requirements apply for training personnel who conduct a covered activity?	(a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following: (1) **Principles of food hygiene and food safety**. (2) **The importance of health and personal hygiene for all personnel and**		May need to incorporate additional training on new FDA produce safety rule requirements into existing training Need to complete the Produce Safety Alliance training; for small growers it may makes sense to outsource PSA training requirements to third parties

Produce Safety Rule Compliance Dates

Business Size	Compliance Date	Comments
>$500,000 annual sales	January 26, 2018	Farms have additional time to comply with certain water-related requirements.
$250- $500K in produce sales	January 28, 2019	Farms have additional time to comply with certain water-related requirements
$25K-$250K in produce sales	January 27, 2020	Farms have additional time to comply with certain water-related requirements Exemption for farms with <$25K in produce sales 1-26-16 compliance date for records supporting eligibility for qualified exemption and compliance with modified requirements

Compliance Date Extension for Agricultural Water (Proposed)

- FDA has proposed extending and harmonizing the compliance dates for the agricultural water provisions. (FDA aims to finalize this proposed rule this winter)
- FDA is taking this action to “address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration’s policies.”
- Almond Board submitted comments in November 2017 supporting the extension
- New proposed compliance dates:

Size of Covered Farm	Proposed New Compliance Date
All Other Businesses	January 26, 2022
Small Business	January 26, 2023
Very Small Business	January 26, 2024

- FDA also is expected to use the additional time before the extended compliance dates to consider new approaches to address the concerns that have been raised with the agricultural water requirements under the rule

Overview of the PCHF Rule

- Updates and modernizes the cGMPs
  - Includes increased emphasis on allergen control
- Requires employee training for all employees involved in food manufacturing, packing, holding
- Requires facilities to develop and implement food safety plans:
  - Conduct hazard analysis
  - Identify and implement preventive controls
  - Apply the management components, as appropriate and necessary based on the nature of the preventive control
    - Monitoring
    - Verification
    - Validation
    - Corrective Actions
  - Document everything

cGMPs and Preventive Controls for Human Food Rule Coverage

- Applies to facilities and farm mixed type facilities
- Determine whether you qualify for any exemptions or modified requirements
  - Are you a facility with less than $1 million in average annual sales of human food?
  - Is your facility solely engaged in hulling/shelling, drying, packing and/or holding nuts?
  - Are you a farm mixed type facility and a small business that only conducts certain low-risk activities?
    - Exempt from PCs only
  - Are all of your products for export?

Written Disclosures and Assurances

- 21 C.F.R. § 117.136 of the PCHF regulation provides that a facility is not required to implement a preventive control if it identifies a hazard requiring a preventive control and this hazard is controlled downstream by a commercial customer, provided the facility:
  - (1) Provides documentation to its direct customer that the food is “not processed to control [identified hazard]” (the disclosure statement requirement); and
  - (2) Receives written assurance from its customer that the customer or an entity further down the supply chain will control the hazard (customer assurance requirement)
- This is similar to the provision in the Produce Safety rule
- Would apply to operations that do not pasteurize almonds, but otherwise are facilities covered by the rule
- FDA is not currently enforcing the Written Assurance requirement in the Preventive Controls rules
  - FDA aims to streamline this requirement in rulemakings this winter

Compliance for Farm-Like Facilities

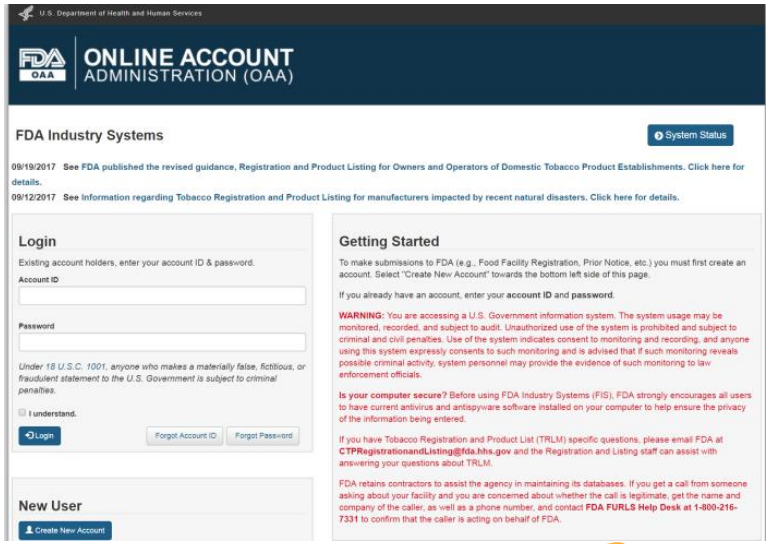
- Operations that do NOT meet the farm definition are considered “facilities”
- “Facilities” must register with FDA and are subject to the Preventive Controls for Human and/or Animal Food rules
- In August 2016, FDA extended the date for compliance with PCHF and PCAF rule for facilities that would qualify as secondary activities farms except for the ownership of the facility (so long as common ownership present)
  - FDA recognized challenges with the definition
  - FDA recognized that certain activities conducted on produce RACS are similar regardless of where they happen
  - Off-farm packinghouses should be able to draw on the Produce Rule for compliance with the PC rules

Enforcement Discretion for Farm-Like Facilities

- In January 2018, FDA announced it would not require farm-like facilities to comply with the PC rules
- Applies to: any operation, not located on a primary production farm, that is dedicated to harvesting, packing, and/or holding RACs (i.e., Hulling/Shelling Operations)
  - Do not need "common ownership" as did with compliance date extension, thus this is broader
  - Applies to facilities solely engaged in packing and/or holding activities on nut hulls and shells (e.g., brown skin facilities)
  - Applies to "farm mixed type facilities"
- Does NOT apply to manufacturing operations (e.g., chopping, roasting, packaging)
- Facilities that would qualify as secondary activities farms except for the ownership of the facility are exempt from compliance with:
  - Preventive Controls for Human Food requirements
  - Preventive Controls for Animal Food requirements
  - Animal food GMPs
- Note: Current exemptions from GMPs for "establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing)" and "establishments solely engaged in the holding and/or transportation of RACs" still apply

Implications of Enforcement Discretion for Farm-Like Facilities

- FDA intends to initiate rulemaking that could change the applicability of the preventive controls and GMP requirements to some entities that conduct farm-related activities
  - Entities that are “facilities” today could be reclassified as “farms”
  - Rulemaking may occur as soon as spring 2019
- But for now, these operations are still “facilities” and must register with FDA
  - Only exempt from the PC/GMP requirements that are tied to registration
- This means that these operations do NOT need to comply with new FSMA requirements at this time, but likely will be covered under the Produce Safety Rule in the future
- Still covered by the statutory prohibitions on adulteration in the FFDCA



Preventive Controls for Human Rule Compliance Dates

Business Size	Compliance Date	Comments
>500 FTE employees	September 19, 2016	General compliance date is one year after publication of the final rule
	March 17, 2017	Supply Chain Program general compliance date is 3-17-17 OR six months after a supplier is required to comply with the applicable PC or Produce safety rule
<500 FTE employees	September 18, 2017	General compliance date is two years after publication of the final rule
	September 18, 2017	Supply Chain Program general compliance date is 9-18-17 OR six months after a supplier is required to comply with the applicable PC or Produce safety rule
<$1M in sales + market value of food manufactured/ processed/ packed/ held without sale	September 17, 2018	The compliance date for qualified facilities to retain records to support their status as a qualified facility is 1-1-16.

Overview of the Animal Food Rule

- Same general framework as the Human Food rule
  - Requires GMPs for animal food for the first time
  - Requires food safety plans for animal food manufacturers
- Specific GMPs apply to human food by-products held for distribution as animal food without further manufacturing or processing by the human food processor:
  - Held under conditions to protect against contamination
  - Labeled by the common or usual name during distribution
  - Shipping containers and bulk vehicles generally must be examined prior to use

GMPs and Preventive Controls for Animal Food Coverage

- Applies to facilities and farm mixed type facilities
  - Consider whether you are a farm that engages in manufacturing/processing food for animals that is not all consumed on your farm or another farm under the same management
- Generally applies if you are manufacturing/processing food for animals
  - Are you a facility that only sends human food by-products to animal food without further manufacturing processing?
    - Must follow animal food by-product GMP regulations
- Determine whether you qualify for any exemptions or modified requirements
  - Are you a facility with less than $2.5 million in average annual sales of animal food (company-wide)?
  - Are you a farm mixed type facility and a small business that only conducts certain low-risk activities?
    - Exempt from PCs only
  - Are all of your products for export?

Human Food By-Products for Animal Food – Enforcement Discretion

- FDA has come to understand that certain manufacturing/processing activities performed on human food by-products for use as animal food are common in the industry, but that the safety of those activities would not be affected if they were performed in compliance with full GMP requirements (they are “low-risk”)
- FDA will not enforce the animal food preventive controls requirements for human food facilities that are subject to and in compliance with human food GMPs if the manufacturing/processing activities that are performed on the human food by-products for use as animal food are limited to the following:
  - Drying/dehydrating, evaporating, pressing, chopping, and similar activities to reduce weight and volume; and/or
  - Mixing (e.g., combining different vegetable culls and trimmings, combining juice and dairy-products, stirring), centrifuging, and similar activities to combine ingredients or separate components (e.g., water and solids)
- These activities are not performed to prevent or significantly minimize animal food hazards and do not introduce animal food hazards
- Note: heating or cooling to address pathogens, pelleting, extruding, and formulating are NOT covered by the enforcement discretion and are still manufacturing activities

Animal Food GMP and PC Compliance Dates

Business Size	Compliance Date	Comments
>500 FTE employees	September 19, 2016 for cGMPs September 18, 2017 for PCs (except for some suppliers under the supply chain program)	Includes compliance with the GMPs for human food by-products diverted to animal feed Supply Chain Program general compliance date is 9-18-17 OR six months after a supplier is required to comply with the applicable PC or Produce Safety rule
<500 FTE employees	September 18, 2017 for cGMPs September 17, 2018 for PCs (except for some suppliers under the supply chain program)	Includes compliance with the GMPs for human food by-products diverted to animal feed Supply Chain Program general compliance date is 9-17-18 OR six months after a supplier is required to comply with the applicable PC or Produce Safety rule
<$2.5M in sales + market value of food manufactured/ processed/ packed/ held without sale	September 17, 2018 for cGMPs September 17, 2019 for PCs	Includes compliance with the GMPs for human food by-products diverted to animal feed The compliance date for qualified facilities to retain records to support their status as a qualified facility is 1-1-17.

Overview of the FSVP Rule

- When potential hazards in a food are controlled by the supplier, the importer (or receiving facility in the PC rule) needs to verify:
  - That the potential hazards in the food are controlled
  - That the food is not adulterated or misbranded
  - That the food is produced in compliance with FDA requirements
- General supplier verification steps include:
  - Conduct hazard analysis
  - Identify suppliers who control hazards
  - Determine appropriate verification activities and frequency of activities for each supplier (based on food and supplier risk)
  - Conduct verification activities (e.g., audits, testing, reviewing food safety plan records)
  - Implement receiving procedures to ensure you only receive material from approved suppliers
  - Document all decisions and activities
  - Conduct records reviews
  - Take prompt corrective actions, as needed
  - Reanalyze the program periodically

Foreign Supplier Verification Programs Rule Coverage

- Applies to the “Importer” of food, which is defined as the U.S. owner or consignee
  - The U.S. owner or consignee means the person who, at the time of entry, owns the food, has purchased the food, or has a written agreement to purchase the food
  - This is NOT the same as the Importer of Record for Customs and Border Protection purposes
- Would apply to you if you import ingredients to make almond products
  - E.g., do you have a purchase order in place for spices/seasonings at the time they enter the U.S.?
- Determine whether any exemptions/modified requirements apply
  - Food from certain countries
  - Food for which you or your customer control the hazards
  - Food from very small businesses
  - You are a very small business

FSVP Compliance Dates

- All importers must comply with FSVP requirements by May 30, 2017, or 6 months after their foreign suppliers' reach their FSMA compliance deadlines, whichever is later
  - No delayed compliance based on importer size

* Determining your compliance dates can be complicated!

Overview of the Sanitary Transportation Rule

- Objective of the rule: prevent practices during transportation that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food
- Establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food to use sanitary practices to ensure the safety of that food
  - Does not apply to transportation on boats or airplanes
- Key provisions address:
  - Vehicles and transportation equipment
  - Transportation operations
  - Records
  - Training
  - Waivers
- Rule supplements general prohibition in the statute on adulteration
- Does not address food security/food defense

Sanitary Transportation of Human and Animal Food

- Applies to shippers, loaders carriers, and receivers:
  - Shipper means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially
  - Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States
  - Loader means a person that loads food onto a motor or rail vehicle during transportation operations
  - Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food
- Determine whether any exemptions apply:
  - Food that is fully enclosed in a container and does not require temperature control for safety
  - Human food by-products for use as animal food without further processing
  - Activities performed by farms
  - Shipper, loader, receiver, or carrier engaged in transportation operations that has less than $500,000, in average annual revenues

STHAF Compliance Dates

Business Size	Compliance Date
> 500 FTE employees	April 6, 2017
<500 FTE employees, except that for certain motor vehicle carriers the definition is less than $27,500,000 in annual receipts	April 6, 2018

Overview of the Intentional Adulteration Rule

- Purpose: To protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm
  - Focus is on preventing the actions of an inside attacker
- Applies to:
  - Registered Food Facilities: Domestic and foreign facilities engaged in the manufacturing, processing, packing, or holding of hold for human consumption in the United States
    - Unless covered by a specific exemption
- Uses a HACCP/HARPC framework, with terms modified for the food defense context (e.g., “food defense monitoring”)

IA Rule “in a Nutshell”

- Create a Food Defense Plan
  - Conduct a written vulnerability assessment to identify significant vulnerabilities and actionable process steps
  - Develop and implement written mitigation strategies for actionable process steps
  - Develop and implement written food defense monitoring procedures
  - Develop and implement written food defense corrective action procedures
  - Develop and implement written food defense verification procedures
- Engage in reanalysis periodically
- Document everything in records
- Train employees

Intentional Adulteration Coverage

- Applies to facilities and farm mixed type facilities
- Determine whether any exemptions apply:
  - Facilities with less than $10 million in average annual sales of food
  - Holding of food, except the holding of food in liquid storage tanks
  - Packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact
  - Animal food

Intentional Adulteration Compliance Dates

Business Size	Compliance Date	Comments
>500 FTE employees	July 26, 2019	
<500 FTE employees	July 26, 2020	
<$10M in sales + market value of food manufactured/ processed/ packed/ held without sale	July 26, 2021	Only subject to requirement to maintain documentation showing facility meets this definition

Recap

- Step 1: Understand which entities are covered by which rules
- Step 2: Determine how the activities you conduct are classified by FDA
  - Are you a farm or a facility?
  - Are you an importer?
  - Are you a shipper?
- Step 3: Look at each rule and determine whether any exemptions apply
- Step 4: If you are covered by the rule, determine your compliance date
  - Look both at business size and any extensions granted
- **Step 5: Prepare for Inspections**

Inspections

Focus on Industry Education

- Most of the first major FSMA compliance deadlines have come and gone
- FDA's mantra is "educate before and while we regulate"
- FDA has said its initial goal will be to work with industry to create a culture of food safety and this goal will apply not just in the initial months of compliance, but going forward
  - A "culture of food safety" will not trump situations with public health implications

FDA's Inspection and Enforcement Activities

- Preventive Controls for Human Food Inspections

	Domestic	Foreign	State
FY18 Planned	400	100	23
FY18 Completed	396 (173 483's)	148 (59 483's)	22 (9 483's)
FY19 Planned	500	150	231

- Enforcement Actions
  - Firm placed on import alert
  - Injunctions
  - Regulatory meetings
  - Warning Letter for sanitation violations and failure to control *Salmonella*

What Facilities Should Expect

- Modernized GMP inspections are about more than just compliance with Part 117, Subpart B
  - Also covers employee training/records of training and a review of the Food Safety Plan at a high level to look for red flags around pathogen and allergen control
  - If there are red flags, it will expand to a full PC inspection
  - Typically takes 2 days
- PC Inspection
  - Takes about 4-5 days for a full PC inspection in a manufacturing facility

What Facilities Should Expect

- Expect a very regulatory approach
  - Where there is a requirement for something to be written, FDA will inspect for adequacy of the written program followed by whether it is being implemented as written
  - Inspectors will seek to determine compliance with each and every applicable regulation and sub-regulation
- If it isn't documented, it didn't happen
  - For example, if you can't find your 15 year old validation study, FDA will document that the preventive control has not be validated
  - If you document only one of two corrective actions that were taken, you won't get credit for the rest of your work
- Inspectors will conduct their own hazard analysis (will use "Appendix 1") and compare that to the facility's hazard analysis
  - Plants need to be prepared to support the approach and decisions made in their hazard analysis (e.g., pre-requisite program vs. preventive control; why a particular control is effective)

What Facilities Should Expect

- Record requests
  - Align with FSMA requirements (e.g., request for validation, environmental monitoring program)
  - Must meet regulatory requirements for content
  - Consumer complaints
- Photography requests
- FDA may want to observe sanitation – even if it's conducted during third-shift
- FDA intends to document only serious and significant observations linked to public health outcomes
  - cGMP violations and others may not be recorded on the 483 if site has a good process in place to address issues and plant manager can clearly articulate the process
- FDA is highlighting other concerns that don't make it on to the 483 as part of the close out meeting ("discussion points")
  - These will be part of the EIR
  - Need to decide whether to respond and how

What Farms Should Expect

- Although the first Produce Safety rule compliance date was January 2018, FDA will not begin inspections for compliance until spring 2019
  - FDA is taking this action because of input from farmers and state regulators that “more time is necessary to ensure farmers have the training and information needed to comply and that states establish strong produce regulatory programs before inspections begin.”
  - The additional year was for guidance, providing training and technical assistance, and improving information for work planning such as developing farm inventories
- FDA is expected to rely heavily on state inspectors to conduct produce safety rule inspections
- States are conducting on-farm readiness reviews

Inspections

- How to Prepare
  - Determine whether you are going to comply with the Produce Safety rule or if you're claiming an exemption
    - If you want to use the commercial processing exemption, develop documentation demonstrating compliance with the requirements
      - Talking points can be helpful
    - If you plan to follow the produce safety rule, conduct a gap assessment to be sure you meet each of the requirement
  - Make sure your food safety plan meets the regulatory requirements and is well-organized
  - Make sure the facility can explain the plan
  - Understand your rights and obligations
  - Develop an inspection manual
- During Inspections
  - Accompany the investigators
  - Take immediate corrective actions
  - Take detailed notes
  - Mark records "confidential commercial proprietary information; trade secret" as appropriate

This is a marathon, not a sprint…

Conclusion

- Most of the compliance dates have passed, but FSMA implementation is far from finished
- Important open issues need to be addressed – so stay engaged!
  - Written assurances
  - Agricultural water provisions
  - Farm definition
- Inspections will increase in rigor with time, and so will enforcement

Bonus: Renewal of Food Facility Registration

- Remember to renew your facility's registration—if you're still required to register!
  - Food facilities are required to renew their registration biennially between October 1 and December 31 of every even-numbered year
  - If a facility fails to renew its registration, it is considered expired and will be removed by FDA
- Registration renewal is not required if a facility's legal requirement to register has changed as a result of FSMA
  - Farms are not required to register!

Questions?

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Thank you!


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What’s Next

Tuesday, December 4 at 1:45 p.m.

- Managing Nutrients and Salt Under Current Water Quality Regulations – Room 308-309
- What's Happening in DC? - 312-313
- The Almond Aflatoxin Menace: Addressing It Head On – Room 306-307
- Sustainability: Aligning with Food Manufacturers' Needs for the Future – Room 314


Join the social media conversation at #AlmondConf

What's Next

Tuesday, December 4

- State of the Industry – Hall C at 4:15 p.m.
- Research Poster Session – Hall A+B at 5:30 p.m.

Be sure to join us at 5:30 p.m. in Hall A+B for Dedicated Trade Show Time and Opening Reception, sponsored by FMC Agricultural Solutions