



## FSMA: Which Rules Apply to the Almond Industry?

Annual Food Quality and Safety Symposium

June 22, 2017



## Agenda

- FSMA Roadmap
  - Which rules apply to me?
    - Understanding how FDA defines and classifies certain activities
  - General requirements
  - Exemptions
  - Compliance Dates





## FSMA Roadmap

## 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

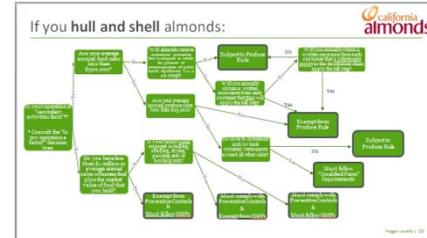
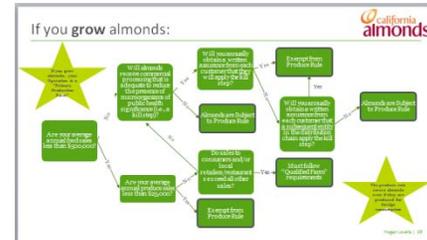
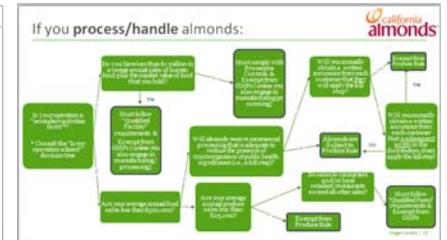
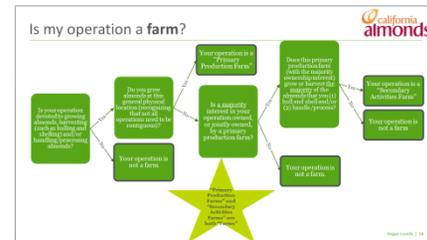
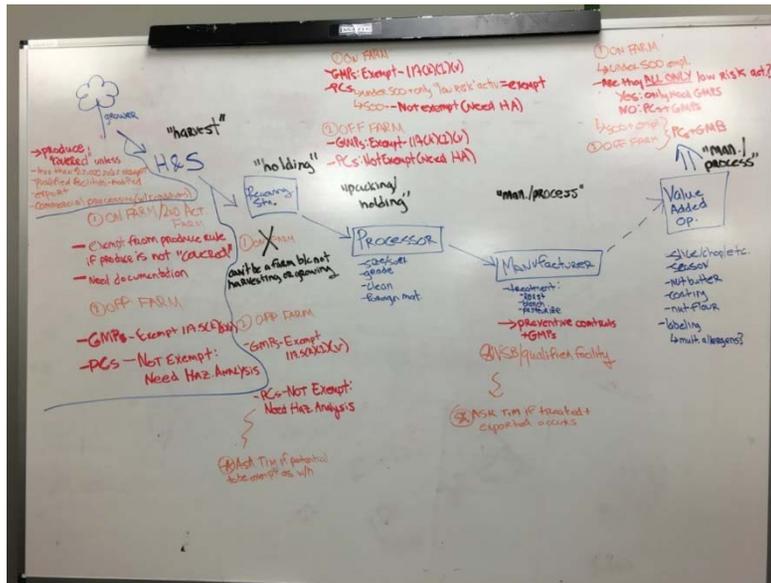
## Types of Almond Operations

- 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?

- 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

## 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.

## 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

- Last August, FDA released 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
- For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding

## Examples of Activities Classified Multiple Ways

Activity	Classification	Details
Hulling/Shelling	<ul style="list-style-type: none"><li>• Harvesting</li><li>• Packing</li><li>• Manufacturing/Processing</li></ul>	<ul style="list-style-type: none"><li>• Hulling/shelling RACs on a farm is a harvesting activity</li><li>• Hulling/shelling for safe/effective packing (such as hulling almonds to pack just the desired part of the RAC) is a packing activity</li><li>• Hulling/shelling almonds at a facility that chops the almonds is a manufacturing/processing activity</li></ul>

## Examples of Activities Classified Multiple Ways

Activity	Classification	Details
Sorting Culling Grading	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Packing</li> <li>• Holding</li> <li>• Manufacturing/ Processing</li> </ul>	<ul style="list-style-type: none"> <li>• Sorting, culling, and grading RACs on a farm are harvesting activities</li> <li>• Sorting, culling, and grading performed for the safe or effective packing of the food incidental to packing are packing activities</li> <li>• Sorting, culling, and grading performed as a practical necessity for distribution of the food are holding activities</li> <li>• 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</li> </ul>

## 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

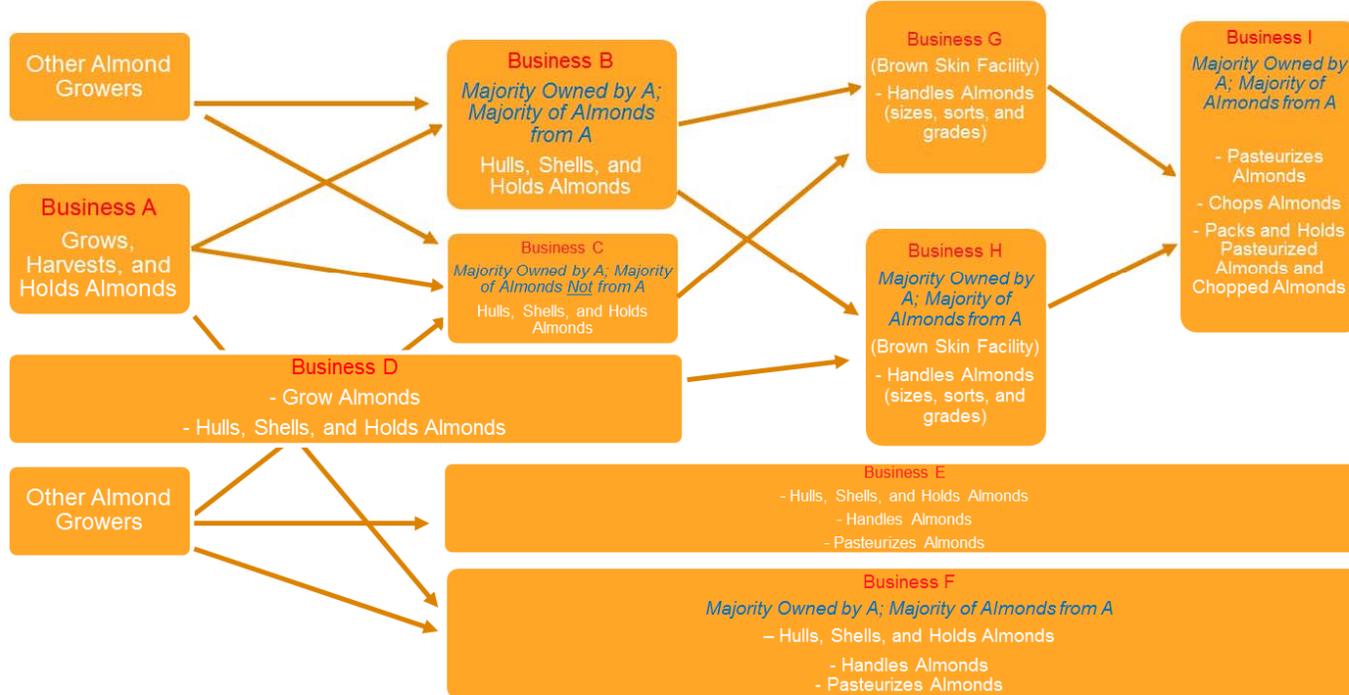
## Examples – Handlers

- 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 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

A photograph showing a glass jar filled with almonds on the right side. On the left side, there is a small, shallow glass dish containing a small amount of almond meal. The background is a warm, golden-yellow color.

**Steps 3 and 4: Determine Exemptions and Compliance Dates**

## Produce Rule Overview

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

## 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 for two years

\*\*\*NOTE that FDA has said that it will delay the compliance date for compliance with the agricultural water requirements in the produce safety rule, but the timing is unclear currently

## 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.
	January 27, 2020	For compliance with the written customer assurance requirement only; if relying upon written disclosures/assurances for exemption from the rule
\$250- \$500K in produce sales	January 28, 2019	Farms have additional time to comply with certain water-related requirements
	January 26, 2021	For compliance with the written customer assurance requirement only; if relying upon written disclosures/assurances for exemption from the rule
\$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
	January 26, 2022	For compliance with the written customer assurance requirement only; if relying upon written disclosures/assurances for exemption from 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?
    - Exempt from GMPs only
  - 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?

## 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, except as detailed below
	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
	September 19, 2018	For compliance with the written customer assurance requirement in 21 CFR 117.136 only; compliance with the written disclosure provision and the remainder of the rule is required by September 19, 2016
	January 26, 2018	For “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells.”
	January 26, 2018	For facilities that meet the definition of “secondary activities farms” except for the ownership criterion

Facilities that meet the definition of “secondary activities farms” except for the ownership criterion can take advantage of an extension for compliance with the PC rule if: (1) The operation is not located on the primary production farm; (2) The operation is devoted to harvesting, packing, and/or holding of RACs (including operations that hull, shell, and/or dry nuts without additional manufacturing); and (3) The operation is under common ownership with the primary production farm that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the operation.

## Human Food PC Compliance Dates Continued

Business Size	Compliance Date	Comments
<500 FTE employees	September 18, 2017	General compliance date is two years after publication of the final rule, except as detailed below
	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
	September 18, 2019	For compliance with the written customer assurance requirement in 21 CFR 117.136 only; compliance with the written disclosure provision and the remainder of the rule is required by September 18, 2017
	January 28, 2019	For “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells.”
	January 28, 2019	For facilities that meet the definition of “secondary activities farms” except for the ownership criterion

## Human Food PC Compliance Dates Continued

Business Size	Compliance Date	Comments
<\$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.
	January 27, 2020	For “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells.”
	January 27, 2020	For facilities that meet the definition of “secondary activities farms” except for the ownership criterion

## 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?
  - 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?

## Animal Food GMP and PC Compliance Dates

Business Size	Compliance Date	Comments
>500 FTE employees	September 19, 2016 for cGMPs	Includes compliance with the GMPs for human food by-products diverted to animal feed
	September 18, 2017 for PCs (except for some suppliers under the supply chain program)	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
	September 18, 2019	For compliance with the written customer assurance requirement only
	January 26, 2018 for cGMPS January 28, 2019 for PCs	For “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells that are used as animal food”
	January 26, 2018 for cGMPS January 28, 2019 for PCs	For facilities that meet the definition of “secondary activities farms” except for the ownership criterion

## Animal Food GMP and PC Compliance Dates Continued

Business Size	Compliance Date	Comments
<500 FTE employees	September 18, 2017 for cGMPs	Includes compliance with the GMPs for human food by-products diverted to animal feed
	September 17, 2018 for PCs (except for some suppliers under the supply chain program)	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
	September 17, 2020	For compliance with the written customer assurance requirement only
	January 28, 2019 for cGMPs January 27, 2020 for PCs	For “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells that are used as animal food”
	January 28, 2019 for cGMPs January 27, 2020 for PCs	For facilities that meet the definition of “secondary activities farms” except for the ownership criterion

## Animal Food GMP and PC Compliance Dates Continued

Business Size	Compliance Date	Comments
<\$2.5M in sales + market value of food manufactured/ processed/ packed/ held without sale	September 17, 2018 for cGMPs	Includes compliance with the GMPs for human food by-products diverted to animal feed
	September 17, 2019 for PCs	The compliance date for qualified facilities to retain records to support their status as a qualified facility is 1-1-17.
	January 27, 2020 for cGMPs	For “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells that are used as animal food” <sup>1</sup>
	January 26, 2021 for PCs	
	January 27, 2020 for cGMPs	For facilities that meet the definition of “secondary activities farms” except for the ownership criterion <sup>2</sup>
	January 26, 2021 for PCs	

## 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 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 5-30-17 OR 6 months after their foreign suppliers' reach their FSMA compliance deadlines, whichever is later
  - No delayed compliance based on importer size
- \* Means that 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	Comments
> 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 compliance!**

Questions?



## Contact Information

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