FSMA: Food Safety and Almonds

December 6, 2016
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FDA Presentation to the 2016 Almond Conference: FSMA and the Tree Nut Risk Assessment

Rhoma Johnson, Ph.D.
Outline

• FSMA Information
• Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules
• Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities
• Describing a Hazard in Foods that Need Control...Draft Guidance
• FSMA Implementation
• Tree Nut Risk Assessment
FSMA
Seven Foundational Rules

- CGMPs and Preventive Controls for Human Food (21 CFR part 117)
- CGMPs and Preventive Controls for Animal Food (21 CFR part 507)
- Produce Safety Standards (21 CFR part 112)
- Foreign Supplier Verification Programs (21 CFR part 1, subpart L)
- Accredited 3rd Party Certification (21 CFR part 1, subpart M)
- Sanitary Transportation (21 CFR part 1, subpart O)
- Mitigation Strategies for Intentional Adulteration (21 CFR part 121)
Public Information

• Web site: www.fda.gov/fsma
• Subscription feature available
• To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us
Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules

81 Federal Register 57784-57796, August 24, 2016
Final Rule
Compliance Date Extensions

• We extended the dates for compliance with certain provisions in four final rules to address concerns about the practicality of compliance with certain provisions, consider changes to the regulatory text, and better align compliance dates across the rules.
  – CGMP & PC for Human Food (21 CFR part 117)
  – CGMP & PC for Animal Food (21 CFR part 507)
  – Foreign Supplier Verification Programs (21 CFR part 1, subpart L)
  – Produce Safety (21 CFR part 112)
Compliance Date Extensions

1. For all four rules for certain provisions concerning customer assurances when controls are applied downstream in the distribution chain ("customer provisions")

2. For part 117 and part 507 for facilities solely engaged in packing and/or holding activities conducted on raw agricultural commodities (RACs) that are produce and/or nut hulls and shells

3. For part 117 and part 507 for certain facilities that would qualify as secondary activities farms except for the ownership of the facility
Compliance Date Clarification

• How we interpret the compliance dates for certain provisions related to agricultural water testing in the produce safety regulation.
“Customer Provisions”

• Provisions allowing a hazard requiring a preventive control to be addressed by an entity later in the distribution chain, including accountability.

• Similar provisions in four rules.

• Industry expressed concerns about practicality of and resources to manage thousands of written assurances.

• We extended the compliance dates for 2 years while FDA considers the best approach to address feasibility concerns.
Facilities Solely Engaged in Packing or Holding Produce RACs

• Some entities conducting these activities fall within the farm definition while others are subject to 21 CFR part 117 or part 507.

• Although they may conduct similar activities, the statutory framework did not provide for all packinghouses and hulling/shelling operations that do not have a sufficient connection to a farm to be subject to the requirements of the produce safety regulation.

• We extended compliance date for facilities subject to part 117 to make the dates the same as similar entities subject to the produce safety regulation. (Parallel extension for similar facilities subject to part 507.)
Facilities that Would be Secondary Activities Farms Except for Ownership

• For a secondary activities farm, the business must be majority-owned by the primary production farms that grows/harvests/raises the majority of RACs harvested, packed or held.

• TAN questions describe business structures that do not meet the ownership requirement (e.g., farm and packinghouse both owned by corporation).

• We extended the compliance dates for operations subject to part 117 that would be farms except for the ownership criterion to make the dates match those in the produce safety regulation. (Parallel extension for similar facilities subject to part 507.)
Compliance Dates for Certain Agricultural Water Testing Provisions

- To comply with the water criteria, for untreated surface water a microbial water quality profile (MWQP) based on a survey over a minimum of 2 years and not more than 4 years must be developed.
- We clarified that a farm has discretion as to (1) the number of sample to include in their initial survey, provided that the total is 20 or more, and (2) the time period over which the samples are taken, provided that the period must be at least 2 years and no more than 4 years. Example approaches were provided (see next slide).
Agricultural Water Testing Provisions – Example Approach

• Beginning in 2018, a farm conducts an initial survey consisting of taking 5 samples per year over 4 years (5 in 2018, 5 in 2019, 5 in 2020, and 5 in 2021) for a total of 20 samples; calculates the MWQP for the first time upon completing the 20-sample data set (e.g., at the end of 2021, early 2022); and applies any necessary corrective actions as soon as practicable and no later than the following year (e.g., in 2022-2023).
Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities

DRAFT Guidance
August, 2016
Purpose of Guidance

• Help determine whether activities are within the “farm” definition
  – Impacts whether a business is exempt from registration
  – Impacts whether a business is subject to 21 CFR part 117 (human food) and part 507 (animal food)
Harvesting

• Applies to farms and farm mixed-type facilities
• Activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities (RACs) from the place they were grown or raised and preparing them for use as food
• Limited to activities performed on RACs, or on processed foods created by drying/dehydrating a RAC without additional manufacturing/processing, on a farm
• Does not include activities that transform a RAC into a processed food
Harvesting - Examples

• Cutting (or otherwise separating) the edible portion of the RAC from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems).

• Cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing RACs grown on a farm.
Packing

• Placing food into a container other than packaging the food

• 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-repackaging of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)

• Does not include activities that transform a RAC into a processed food
Packing – Examples

• Blending, cooling, filtering, hulling, trimming, shelling, sifting, washing for safe/effective packing
Packaging

• Placing food into a container that directly contacts the food and that the consumer receives

• Examples include putting strawberries in clamshells, putting citrus fruit in net bags, putting apples in plastic bags
Holding

• Storage of food
• Includes activities performed incidental to storage of a food
  – e.g., activities performed for the safe or effective storage of 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)
• 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)),
• Does not include activities that transform a RAC into a processed food
• Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
Holding - Examples

• Aeration, coating (e.g., with wax), cooling, heat treatment for pest control (for safe or effective storage)

• Aging/curing/fermenting (that occurs passively over time), sampling food for grading, sorting/culling/grading, weighing, conveying, loading food into a vehicle (performed as a practical necessity for distribution of food)
Manufacturing/Processing

• Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients
Manufacturing/Processing - Examples

- Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing.
Manufacturing/Processing Within the Farm Definition

• Drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling the dried/dehydrated commodities, without additional manufacturing/processing activities (such as chopping or slicing the fresh or dried herbs);

• Treatment to manipulate the ripening of RACs (such as by treating produce with ethylene gas), and packaging and labeling the treated RACs, without additional manufacturing/processing activities (such as by chopping or slicing the untreated or treated RACs); and

• Packaging and labeling RACs, without additional manufacturing/processing activities (such as by irradiating the RACs or packaged RACs).
Of Note

• Our classifications for regulatory purposes may not always align with how farms think of various activities for non-regulatory purposes
  – Certain activities may be considered “harvesting” even though not performed in the growing area

• Many activities may be classified in more than one way (examples in following slides)
Cooling

• Harvesting – Cooling RACs as they are picked or in an on-farm packing house
• Packing – Cooling for safe and effective packing, e.g., icing broccoli
• Holding – refrigerating during storage
• Manufacturing/Processing – removing heat from a cooked food prior to packaging
Washing

• Harvesting – Washing RACs on a farm to remove dirt
• Packing – Washing for safe/effective packing (e.g., washing RACs to remove dirt)
• Manufacturing/processing - Washing at a facility before canning fruit or vegetables, or during the production of a fresh-cut salad mix
Practical Implications of Classification

• If all of your activities are within the “farm” definition, it generally makes no difference whether you classify an activity as harvesting, packing, or holding, or as one of the manufacturing/processing activities (such as packaging) listed in the farm definition.

• 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, and the activity may be subject to 21 CFR part 117 or part 507.
Submit Comments

• February 21, 2017
• http://www.regulations.gov

OR

• Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act

DRAFT Guidance
October, 2016

• Subpart C of Part 117 includes several provisions (“customer provisions”) that apply when a manufacturer/processor of human foods identifies a hazard requiring a preventive control, does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard. A manufacturer/processor that complies with the customer provisions is not required to implement a preventive control for the identified hazard.

- Manufacturer/processor is required to disclose, in documents accompanying the food, that the food is “not processed to control [identified hazard]”.
- This required disclosure is referred to as the “part 117 disclosure statement”.
Submit Comments

• May 1, 2017
• [http://www.regulations.gov](http://www.regulations.gov)

OR

• Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
FSMA Implementation
Key Implementation Principles

Inspections

• Gain Industry Compliance, Reduce the Risk of Foodborne Illness

• Not a “One Size Fits All Approach”

• Systems Based Inspections, Not “Observation Focused”

• Interactive, Cooperative Inspections
Key Implementation Principles

Regulatory Strategy

• Develop/implement Explicit Inspection/Enforcement Strategies that Facilitate Consistent Decision Making by Regulators

• Encourage Industry to Comply and Make Corrections on its Own

• Recognition that Not all Observations are Equal Relative to Risk and Potential for Public Health Impact

• Regulatory strategy that is dynamic
Produce Safety Rule Implementation
On-Farm Rule Readiness Program

• FDA is working with NASDA to develop/pilot a voluntary on-farm Produce Safety Rule Readiness Program

• Objectives
  – State of knowledge/readiness of farming community to comply with the Produce Safety rule; Promote compliance with the Produce Safety rule
  – Promote coordination, strengthen relationships between industry, FDA, states, other produce safety partners
  – Provide on-farm learning experience for FDA/State regulators
  – Identify knowledge/guidance gaps - regional, national, commodity

• Conduct prior to compliance dates for covered farms
• Assessment Tool made available online
Produce Safety Rule

Inspections

• Collaborating with NASDA to develop a single inspectional approach that can be implemented by State regulators and FDA
  – Routine on-farm inspections will be conducted by State regulators, as funding permits
  – FDA may do inspections in States that choose not to conduct produce inspections; FDA Specialized Produce Safety Cadre would conduct such domestic inspections and foreign inspections
Produce Safety Rule

Objectives

- Facilitate compliance through standardized, education-focused regulatory inspections using farm inspection reports that include guidance and educational references
  - Educate before and while we regulate
- Collect and evaluate inspection data to identify regional trends for targeted outreach, education, research, and work plan prioritization
- Develop relationships between produce farmers and local FDA Produce Safety Network staff & regulatory partners
- Initiate legal action as needed to protect public health
PC Rule

• While Produce Rule inspections begin in 2018, PC inspections are targeted to begin in 2017.
• Currently, we are targeting 300 PC inspections.
• Firms will be subject to the Rule due to the size “other or large”.
• Early adopter states are being targeted for training and will accompany FDA during the initial inspections but will conduct inspections independently in the future.
Salmonella Tree Nuts
Risk Assessment Update
RISK ASSESSMENT FRAMEWORK

Conduct & Manage Process

Step 1: Commission

Step 2: Data collection & evaluation

Step 3: Develop model/report

Step 4: External Peer Review & clearance

Step 5: Issue
OBJECTIVE

*Salmonella* Tree Nuts Risk Assessment

To evaluate the impact of microbial reduction treatment levels (1, 2, 3, 4 and 5 log reductions) on the risk of human salmonellosis arising from the consumption of tree nuts in the U.S.
Model adapted to incorporate specific process steps, conditions, and consumption data as they apply to each tree nut.
STATUS

• **Almonds**
  *Salmonella*-Almond risk assessment manuscript submitted
  *Journal Food Protection, September 2016*

• **Pecans**
  *Salmonella*-Pecan risk assessment manuscript cleared for submission, *Journal Food Protection, Expected December 2016*

*Salmonella* survival model
  *Published for almonds, pecans, pistachios, and walnuts*
Modeling the survival kinetics of *Salmonella* in tree nuts for use in risk assessment

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### Table 4

Descriptive statistics of the empirical posterior distributions from the Bayesian inference model describing *Salmonella* survival at 21 °C < T < 24 °C in almonds, pecans, pistachios and walnuts.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean</th>
<th>SD</th>
<th>Quantile</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.5%</td>
</tr>
<tr>
<td>$\delta_{\text{almond}}\textsuperscript{a}$</td>
<td>7.7</td>
<td>0.8</td>
<td>6.0</td>
</tr>
<tr>
<td>$\delta_{\text{pecan}}\textsuperscript{a}$</td>
<td>15.6</td>
<td>2.1</td>
<td>11.4</td>
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<tr>
<td>$\delta_{\text{pistachio}}\textsuperscript{a}$</td>
<td>20.2</td>
<td>3.7</td>
<td>13.1</td>
</tr>
<tr>
<td>$\delta_{\text{walnut}}\textsuperscript{a}$</td>
<td>3.2</td>
<td>1.4</td>
<td>0.4</td>
</tr>
<tr>
<td>$\rho_{\text{almond}}\textsuperscript{b}$</td>
<td>0.53</td>
<td>0.02</td>
<td>0.49</td>
</tr>
<tr>
<td>$\rho_{\text{pecan}}\textsuperscript{b}$</td>
<td>0.61</td>
<td>0.08</td>
<td>0.55</td>
</tr>
<tr>
<td>$\rho_{\text{pistachio}}\textsuperscript{b}$</td>
<td>0.69</td>
<td>0.09</td>
<td>0.53</td>
</tr>
<tr>
<td>$\rho_{\text{walnut}}\textsuperscript{b}$</td>
<td>0.43</td>
<td>0.02</td>
<td>0.40</td>
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<tr>
<td>$\sigma_{\delta}\textsuperscript{c}$</td>
<td>0.37</td>
<td>0.01</td>
<td>0.36</td>
</tr>
<tr>
<td>$\sigma^d\textsuperscript{d}$</td>
<td>4.05</td>
<td>0.61</td>
<td>3.02</td>
</tr>
</tbody>
</table>

See Eq. (4) for the specification of the parameters.

\textsuperscript{a} Time (in weeks) to the first log10 reduction.
\textsuperscript{b} Parameter defining the shape of the curve.
\textsuperscript{c} Standard deviation of the variability distribution of $\delta$.
\textsuperscript{d} Standard error of the residual.
Fig. 5. Top: median estimate of the log_{10} reduction as a function of time for pistachios, pecans, almonds and walnuts where vertical lines represent 0, 1, 4, 12 and 52 weeks. Bottom: second-order Monte-Carlo output of the log_{10} reductions at 1, 4, 12 and 52 weeks (from left to right) for pistachios, pecans, almonds and walnuts (from top to bottom), including the upper and lower values (in light gray) and the 2.5th and 97.5th percentiles representing the uncertainty ranges of the estimated value (in dark gray).
FOR MORE INFORMATION

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- Joann Givens
Agenda

• Determining Your Compliance Obligations
  – Draft Guidance on Classification of Activities
  – General Framework & Decision Trees

• Case Studies

• Written Disclosures & Assurances

• Compliance Date Extensions

• Preparation
Determining Your Compliance Obligations
What FSMA Means for You

• Determining the regulations that apply to your business and what you need to do to comply, is very case-specific
  – Consider applicability
    (1) GMPs
    (2) Preventive Controls
    (3) Produce Safety

• Key issues include:
  – Location of the operation
  – Ownership structure
  – Company size
  – Activities performed
    • Growing
    • Hulling and Shelling
    • Handling
    • Manufacturing

• Note: Conducting multiple activities can change your compliance obligations!
It’s Complicated!

** This just an illustration, not advice!
How to Get Started

• To determine your FSMA obligations, you need to start by determining how the activities you conduct are classified by FDA
  – Need to do this before you use the decision trees, because the decision trees assume you know whether your operation is a “farm” or a “facility” (or a “farm mixed type facility”)

• In late 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

• To determine where your activities fall:
  – 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”
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
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).
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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Classification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hulling/Shelling</td>
<td>• Harvesting</td>
<td>• Hulling/shelling RACs on a farm is a harvesting activity</td>
</tr>
<tr>
<td></td>
<td>• Packing</td>
<td>• Hulling/shelling for safe/effective packing (such as hulling almonds to pack just the desired part of the RAC) is a packing activity</td>
</tr>
<tr>
<td></td>
<td>• Manufacturing/Processing</td>
<td>• Hulling/shelling almonds at a facility that chops the almonds is a manufacturing/processing activity</td>
</tr>
</tbody>
</table>
### Examples of Activities Classified Multiple Ways

<table>
<thead>
<tr>
<th>Activity</th>
<th>Classification</th>
<th>Details</th>
</tr>
</thead>
</table>
| 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 sized, sorted, graded, and packed = 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
Case Studies
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 E
- Hulls, Shells, and Holds Almonds
- Handles Almonds
- Pasteurizes 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 F
Majority Owned by A; Majority of Almonds from A
- Hulls, Shells, and Holds Almonds
- Handles Almonds
- Pasteurizes Almonds
Is your operation devoted to growing almonds, harvesting (such as hulling and shelling) and/or handling/processing almonds?

- Yes: Your operation is a "Primary Production Farm"
- No: Do you grow almonds at this general physical location (recognizing that not all operations need to be contiguous)?
  - Yes: Is a majority interest in your operation owned, or jointly owned, by a primary production farm?
    - Yes: Does this primary production farm (with the majority ownership interest) grow or harvest the majority of the almonds that you (1) hull and shell and/or (2) handle/process?
      - Yes: Your operation is a "Secondary Activities Farm"
      - No: Your operation is not a farm.
  - No: Your operation is not a farm.
Business A: Grows, Harvests, and Holds Almonds (Grower) = Primary Production Farm + Obtains Written Assurances = Exempt from Produce Rule

- Are your average annual food sales less than $500,000?
  - Yes
    - Are your average annual produce sales less than $25,000?
      - No
        - Almonds are Subject to Produce Rule
      - Yes
        - Will you annually obtain a written assurance from each customer that they will apply the kill step?
          - Yes
            - Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?
              - Yes
                - Exempt from Produce Rule
              - No
                - Almonds are Subject to Produce Rule
          - No
            - Must follow “Qualified Farm” requirements
  - No
    - Will you annually obtain a written assurance from each customer that a subsequent entity in the distribution chain apply the kill step?
      - Yes
        - Exempt from Produce Rule
      - No
        - Almonds are Subject to Produce Rule
Business A: Grows, Harvests, and Holds Almonds
= Primary Production Farm + Does Not Obtain Written Assurances
= Covered by Produce Rule

Are your average annual food sales less than $500,000?

- Yes
  - Are your average annual produce sales less than $25,000?
    - Yes
      - Exempt from Produce Rule
    - No
      - Almonds are Subject to Produce Rule

- No
  - Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?
    - Yes
      - Will you annually obtain a written assurance from each customer that they will apply the kill step?
        - Yes
          - Exempt from Produce Rule
        - No
          - Almonds are Subject to Produce Rule
    - No
      - Do sales to consumers and/or local retailers/restaurants exceed all other sales?
        - Yes
          - Must follow "Qualified Farm" requirements
        - No
          - Exempt from Produce Rule

Will you annually obtain a written assurance from each customer that a subsequent entity in the distribution chain apply the kill step?

- Yes
  - Exempt from Produce Rule
- No
  - Almonds are Subject to Produce Rule
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

Other Almond Growers

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

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

Business G
(Brown Skin Facility)
- Handles Almonds (sizes, sorts, and grades)
Is your operation devoted to growing almonds, harvesting (such as hulling and shelling) and/or handling/processing almonds?

Yes: Your operation is not a farm.
No: Do you grow almonds at this general physical location (recognizing that not all operations need to be contiguous)?

Yes: Is a majority interest in your operation owned, or jointly owned, by a primary production farm?

Yes: Does this primary production farm (with the majority ownership interest) grow or harvest the majority of the almonds that you (1) hull and shell and/or (2) handle/process?

Yes: Your operation is a ”Primary Production Farm”
No: Your operation is a ”Secondary Activities Farm”

No: Your operation is not a farm.
Business B: Hulls, Shells, and Holds Almonds and Majority Owned by A with Majority of Almonds from A + Obtains Written Assurances = Exempt from Produce Rule

Is your operation a “secondary activities farm”?*

* Consult the “Is my operation a farm?” decision tree

Are your average annual food sales less than $500,000?

Yes

Do you have less than $1 million in average annual sales of human food plus the market value of food that you hold?

No

Exempt from Preventive Controls & Exempt from GMPs

Yes

Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?

No

Subject to Produce Rule

Yes

Are your average annual produce sales less than $25,000?

No

Exempt from Produce Rule

Do sales to consumers and/or local retailers/restaurants exceed all other sales?

Yes

Must comply with Preventive Controls & Exempt from GMPs

No

Must follow “Qualified Farm” requirements

Will you annually obtain a written assurance from each customer that a subsequent entity in the distribution chain apply the kill step?

No

Subject to Produce Rule

Yes

Will you annually obtain a written assurance from each customer that they will apply the kill step?

No

Exempt from Produce Rule

Will you annually obtain a written assurance from each customer that they will apply the kill step?
Is your operation devoted to growing almonds, harvesting (such as hulling and shelling) and/or handling/processing almonds?

- Yes: Do you grow almonds at this general physical location (recognizing that not all operations need to be contiguous)?
  - Yes: Does this primary production farm (with the majority ownership interest) grow or harvest the majority of the almonds that you (1) hull and shell and/or (2) handle/process?
    - Yes: Your operation is a “Secondary Activities Farm”
    - No: Your operation is not a farm
  - No: Your operation is not a farm
- No: Your operation is not a farm

Is a majority interest in your operation owned, or jointly owned, by a primary production farm?

- Yes: Your operation is a “Primary Production Farm”
- No: Your operation is not a farm

** unless in the “same general physical location where RACs are grown”
Business C: Hulls, Shells, and Holds Almonds and *Majority Owned by A with Majority of Almonds NOT from A (Huller/Sheller)* = Facility = Covered by PC + Exempt from GMPs

Are your average annual food sales less than $500,000?

Yes

Are your average annual produce sales less than $25,000?

No

Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?

No

Will you annually obtain a written assurance from each customer that a subsequent entity in the distribution chain apply the kill step?

Yes

Subject to Produce Rule

No

Do sales to consumers and/or local retailers/restaurants exceed all other sales?

Yes

Must follow “Qualified Farm” requirements

No

Exempt from Produce Rule

Do you have less than $1 million in average annual sales of human food plus the market value of food that you hold?

Yes

Exempt from Preventive Controls & Exempt from GMPs

No

Is your facility solely engaged in hulling, shelling, drying, packing and/or holding nuts?

Yes

Must comply with Preventive Controls & Must follow GMPs

No

Exempt from Preventive Controls & Exempt from GMPs

* Consult the “Is my operation a farm?” decision tree

Is your operation a “secondary activities farm”*?

Yes

Exempt from GMPs

No

Will you annually obtain a written assurance from each customer that they will apply the kill step?

Exempt from GMPs

Exempt from Preventive Controls & Exempt from GMPs

Exempt from Produce Rule
Business B
Majority Owned by A; Majority of Almonds from A
- Hulls, Shells, and Holds Almonds

Business G
(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

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

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

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 Almond Growers
- Grows, Harvests, and Holds Almonds

Business A
- Grows, Harvests, and Holds Almonds

Other Almond Growers
- Grows, Harvests, and Holds Almonds

- Hulls, Shells, and Holds Almonds
Is your operation devoted to growing almonds, harvesting (such as hulling and shelling) and/or handling/processing almonds?

- Yes
  - Do you grow almonds at this general physical location (recognizing that not all operations need to be contiguous)?
    - Yes
      - Is a majority interest in your operation owned, or jointly owned, by a primary production farm?
        - Yes
          - Your operation is a “Primary Production Farm”
            - Does this primary production farm (with the majority ownership interest) grow or harvest the majority of the almonds that you (1) hull and shell and/or (2) handle/process?
              - Yes
                - Your operation is a “Secondary Activities Farm”
              - No
                - Your operation is not a farm.
        - No
          - Your operation is not a farm.
    - No
      - Your operation is not a farm.
- No
  - Your operation is not a farm.
Business D: Grows, Hulls, and Shells Almonds (Grower & Huller/Sheller) + Obtains Written Assurances
= Exempt from Produce Rule

Is your operation a "secondary activities farm"*?

* Consult the "Is my operation a farm?" decision tree

Are your average annual food sales less than $500,000?

Do you have less than $1 million in average annual sales of human food plus the market value of food that you hold?

Will you annually obtain a written assurance from each customer that a subsequent entity in the distribution chain apply the kill step?

Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?

Are your average annual produce sales less than $25,000?

Do sales to consumers and/or local retailers/restaurants exceed all other sales?

Is your facility solely engaged in hulling, shelling, drying, packing and/or holding nuts?

Subject to Produce Rule

Exempt from Produce Rule

Must follow "Qualified Farm" requirements

Must comply with Preventive Controls & Exempt from GMPs

Must comply with Preventive Controls & Must follow GMPs

Exempt from Preventive Controls & Exempt from GMPs
Other Almond Growers

Business A
- Grows, Harvests, and Holds Almonds

Business D
- Grow Almonds
- Hulls, Shells, 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 G
Majority Owned by A; Majority of Almonds from A
(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

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 Almond Growers
Business E: Hulls, Shells, and Holds Almonds + Handles Almonds + Pasteurizes Almonds
(Huller/Sheller & Handler & Processor)

= Facility (Not a Farm)

Step 1 – Consider Whether Operation is a Farm

Is your operation devoted to growing almonds, harvesting (such as hulling and shelling) and/or handling/processing almonds?

Yes: Do you grow almonds at this general physical location (recognizing that not all operations need to be contiguous)?

Yes: Your operation is a "Primary Production Farm"

No: Your operation is not a farm

No: Is a majority interest in your operation owned, or jointly owned, by a primary production farm?

Yes: Does this primary production farm (with the majority ownership interest) grow or harvest the majority of the almonds that you (1) hull and shell and/or (2) handle/process?

Yes: Your operation is a "Secondary Activities Farm"

No: Your operation is not a farm.

No: Your operation is not a farm.
Business E: Hulls, Shells, and Holds Almonds + Handles + Pasteurizes = Covered by Preventive Controls and GMPs

Is your operation a "secondary activities farm"?*
* Consult the "Is my operation a farm?" decision tree

Are your average annual food sales less than $500,000?
No
Yes

Are your average annual produce sales less than $25,000?
No
Yes

Do you have less than $1 million in average annual sales of human food plus the market value of food that you hold?
No
Yes

Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?
No
Yes

Will you annually obtain a written assurance from each customer that a subsequent entity in the distribution chain apply the kill step?
No
Yes

Exempt from Produce Rule

Subject to Produce Rule

Exempt from GMPs

Must comply with Preventive Controls & Exempt from GMPs

Must comply with Preventive Controls & Must follow GMPs

Must follow "Qualified Farm" requirements

Subject to Produce Rule

Step 2 – Consider Hulling & Shelling Operation
Business E: Hulls, Shells, and Holds Almonds + Handles + Pasteurizes
= Covered by Preventive Controls and GMPs

Is your operation a "secondary activities farm"?*

Yes

Do you have less than $1 million in average annual sales of human food plus the market value of food that you hold?

Yes

Must comply with Preventive Controls & Exempt from GMPs (unless you also engage in manufacturing/processing)

No

Are your average annual food sales less than $500,000?

Yes

Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?

Yes

Will you annually obtain a written assurance from each customer that they will apply the kill step?

Yes

Exempt from Produce Rule

No

Are your average annual produce sales less than $25,000?

No

Do sales to consumers and/or local retailers/restaurants exceed all other sales?

Yes

Exempt from Produce Rule

No

Must follow "Qualified Farm" requirements & Must follow GMPs

Step 3 – Consider Brown Skin Operation
Business E: Hulls, Shells, and Holds Almonds + Handles + Pasteurizes = Covered by Preventive Controls and GMPs

Step 4 – Consider “Manufacturing” Operation

- Do you average more than $1 million in annual sales of human food plus the market value of food that you hold?
- Will any of the almonds be consumed in the United States?
- Must comply with Preventive Controls & Must follow GMPs
- Must follow “Qualified Facility” requirements & Must follow GMPs
- Exempt from Preventive Controls & Exempt from GMPs
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 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

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 F: Hulls, Shells, and Holds Almonds + Pasteurizes Almonds + Majority Owned by A with Majority of Almonds from A (Huller/Sheller & Handler & Processor) = Farm Mixed-Type Facility = Consider both Produce and PC rules

Step 1 – Consider Whether Operation is a Farm

- Is your operation devoted to growing almonds, harvesting (such as hulling and shelling) and/or handling/processing almonds?
  - Yes → Your operation is not a farm
  - No

- Do you grow almonds at this general physical location (recognizing that not all operations need to be contiguous)?
  - Yes
  - No

- Your operation is not a farm

- Is a majority interest in your operation owned, or jointly owned, by a primary production farm?
  - Yes
  - No

- Your operation is not a farm

- Does this primary production farm (with the majority ownership interest) grow or harvest the majority of the almonds that you (1) hull and shell and/or (2) handle/processing?
  - Yes
  - No

- Your operation is a Secondary Activities Farm

- Your operation is not a farm
Business F: Hulls, Shells, and Holds Almonds + Pasteurizes Almonds + Majority Owned by A with Majority of Almonds from A
= H&S Exempt from Produce Rule (with Written Assurances)

Step 2 – Consider Hulling & Shelling Operation

- Are your average annual food sales less than $500,000?
- Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?
- Will you annually obtain a written assurance from each customer that they will apply the kill step?
- Will you annually obtain a written assurance from each customer that a subsequent entity in the distribution chain apply the kill step?
- Subject to Produce Rule

Exempt from Produce Rule

- Do your average annual produce sales less than $25,000?
- Do sales to consumers and/or local retailers/restaurants exceed all other sales?
- Is your facility solely engaged in hulling, shelling, drying, packing and/or holding nuts?
- Exempt from Preventive Controls & Exempt from GMPs
- Exempt from Preventive Controls & Must follow GMPs
- Must comply with Preventive Controls & Exempt from GMPs
- Must comply with Preveitive Controls & Must follow GMPs

- Are your average annual food sales less than $500,000?
- Are your average annual produce sales less than $25,000?
- Do sales to consumers and/or local retailers/restaurants exceed all other sales?
- Is your facility solely engaged in hulling, shelling, drying, packing and/or holding nuts?
- Exempt from Preventive Controls & Exempt from GMPs
- Exempt from Preventive Controls & Must follow GMPs
- Must comply with Preventive Controls & Exempt from GMPs
- Must comply with Preveitive Controls & Must follow GMPs

- Consult the “Is my operation a farm?” decision tree

* Is your operation a “secondary activities farm”?

- Yes
  - Subject to Produce Rule
  - Exempt from Produce Rule
  - Must follow “Qualified Farm” requirements

- No
  - Subject to Produce Rule
  - Exempt from Produce Rule
  - Must follow “Qualified Farm” requirements
Business F: Hulls, Shells, and Holds Almonds + Pasteurizes Almonds + Majority Owned by A with Majority of Almonds from A = Handling Exempt from Produce Rule (with Written Assurances)

Is your operation a "secondary activities farm"?*

- Yes
  - Are your average annual food sales less than $500,000?
    - Yes
      - Are your average annual produce sales less than $25,000?
        - Yes
          - Exempt from Produce Rule
        - No
          - Must follow "Qualified Farm" requirements & Must follow GMPs
    - No
      - Must comply with Preventive Controls & Exempt from GMPs (unless you also engage in manufacturing/processing)

- No
  - Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?
    - Yes
      - Will you annually obtain a written assurance from each customer that they will apply the kill step?
        - Yes
          - Exempt from Produce Rule
        - No
          - Almonds are Subject to Produce Rule
    - No
      - Do sales to consumers and/or local retailers/restaurants exceed all other sales?
        - Yes
          - Must follow "Qualified Farm" requirements & Must follow GMPs
        - No
          - Exempt from Produce Rule

Step 3 – Consider Brown Skin Operation

* "Secondary activities farm" is defined as having less than $1 million in average annual sales of human food plus the market value of food that you hold.
Business F: Hulls, Shells, and Holds Almonds + Pasteurizes Almonds + Majority Owned by A with Majority of Almonds from A = Farm Mixed-Type Facility = Consider both Produce and PC rules

Step 4 – Consider “Manufacturing” Operation

Do you average more than $1 million in annual sales of human food plus the market value of food that you hold?

Will any of the almonds be consumed in the United States?

- Yes
  - Must comply with Preventive Controls & Must follow GMPs
  - Exempt from Preventive Controls & Exempt from GMPs

- No
  - Must follow “Qualified Facility” requirements & Must follow GMPs
Other Almond Growers

Business A
- Grows, Harvests, and Holds Almonds
  - Majority Owned by A; Majority of Almonds from A
  - Hulls, Shells, and Holds Almonds
  - Grows, Harvests, and Holds Almonds

Business B
- Handles Almonds (sizes, sorts, and grades)
- Majorly 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
- Handles Almonds (sizes, sorts, and grades)
- Majority Owned by A; Majority of Almonds from A
- Hulls, Shells, and Holds Almonds
- Grows, Harvests, and Holds Almonds

Business E
- Majority Owned by A; Majority of Almonds from A
  - 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

Business G
- Majority Owned by A; Majority of Almonds from A

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

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
Is your operation devoted to growing almonds, harvesting (such as hulling and shelling) and/or handling/processing almonds?

- Yes → Do you grow almonds at this general physical location (recognizing that not all operations need to be contiguous)?
- No → Your operation is not a farm

If Yes to above, then:

- Yes → Is a majority interest in your operation owned, or jointly owned, by a primary production farm?
  - Yes → Your operation is a “Primary Production Farm”
  - No → Does this primary production farm (with the majority ownership interest) grow or harvest the majority of the almonds that you (1) hull and shell and/or (2) handle/process?
    - Yes → Your operation is a “Secondary Activities Farm”
    - No → Your operation is not a farm
Business G: Sizes, Sorts, and Grades Almonds *(Brown Skin Facility)*

= Facility = Follow PCs and Exempt from GMPs

Is your operation a “secondary activities farm”*?

- Yes
  - Do you have less than $1 million in average annual sales of human food plus the market value of food that you hold?
    - Yes
      - Must comply with Preventive Controls & Exempt from GMPs (unless you also engage in manufacturing/processing)
    - No
      - Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?
        - Yes
          - Will you annually obtain a written assurance from each customer that they will apply the kill step?
            - Yes
              - Almonds are Subject to Produce Rule
            - No
              - Exempt from Produce Rule
        - No
          - Do sales to consumers and/or local retailers/restaurants exceed all other sales?
            - Yes
              - Must follow “Qualified Farm” requirements & Must follow GMPs
            - No
              - Exempt from Produce Rule
    - No
      - Are your average annual produce sales less than $25,000?
        - Yes
          - Exempt from Produce Rule
        - No
          - Must follow “Qualified Farm” requirements & Must follow GMPs

* secondary activities farm: A farm that engages in activities other than the primary production of food.

Hog Skin Facility: Follow PCs & Exempt from GMPs
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 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

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
Is your operation devoted to growing almonds, harvesting (such as hulling and shelling) and/or handling/processing almonds?

No

Yes

Do you grow almonds at this general physical location (recognizing that not all operations need to be contiguous)?

Yes

No

Your operation is not a farm

Is a majority interest in your operation owned, or jointly owned, by a primary production farm?

Yes

No

Does this primary production farm (with the majority ownership interest) grow or harvest the majority of the almonds that you (1) hull and shell and/or (2) handle/process?

Yes

No

Your operation is a "Primary Production Farm"

Your operation is a "Secondary Activities Farm"

Your operation is not a farm.
Is your operation a “secondary activities farm”?

- No
  - Must comply with Preventive Controls & Exempt from GMPs (unless you also engage in manufacturing/processing).

- Yes
  - Do you have less than $1 million in average annual sales of human food plus the market value of food that you hold?
    - No
      - Will almonds receive commercial processing that is adequate to reduce the presence of microorganisms of public health significance (i.e., a kill step)?
        - Yes
          - Will you annually obtain a written assurance from each customer that they will apply the kill step?
            - Yes
              - Exempt from Produce Rule
            - No
              - Almonds are Subject to Produce Rule
        - No
          - Exempt from Produce Rule
  - Yes
    - Are your average annual food sales less than $500,000?
      - Yes
        - Must follow “Qualified Farm” requirements & Exempt from GMPs
      - No
        - Are your average annual produce sales less than $25,000?
          - Yes
            - Must follow “Qualified Farm” requirements & Exempt from GMPs
          - No
            - Do sales to consumers and/or local retailers/restaurants exceed all other sales?
              - Yes
                - Must follow GMPs & Exempt from Produce Rule
              - No
                - Exempt from Produce Rule
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 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

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 A
Majority Owned by A; Majority of Almonds from A
- Grows, Harvests, and Holds Almonds

Business B
- Handles Almonds (sizes, sorts, and grades)

Business C
- Handles Almonds (sizes, sorts, and grades)

Business D
- Handles Almonds (sizes, sorts, and grades)

Business E
- Handles Almonds (sizes, sorts, and grades)

Business F
- Handles Almonds (sizes, sorts, and grades)

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

Business H
- Handles Almonds (sizes, sorts, and grades)

Business I
- Handles Almonds (sizes, sorts, and grades)
Business I: Pasteurizes and Chops Almonds + Majority Owned by A; Majority of Almonds from A (Processor) = Facility (Covered by Preventive Controls + GMPs)

Do you average more than $1 million in annual sales of human food plus the market value of food that you hold?

Yes → Will any of the almonds be consumed in the United States?

Yes → Must comply with Preventive Controls & Must follow GMPs

No → Must follow “Qualified Facility” requirements & Must follow GMPs

No → Exempt from Preventive Controls & Exempt from GMPs
Written Disclosures & Written Assurances
Customer Assurance Provisions

• The PC Rule provides that when a manufacturer identifies a hazard requiring a preventive control, does not control the hazard, and relies on an entity in its distribution chain to address the hazard, it must:

1. Provide documentation to its direct customer that the food is “not processed to control [identified hazard]”; and
2. Annually obtain a written assurance from their customer that the customer is manufacturing, processing, or preparing the food in accordance with the applicable food safety requirements, or will only sell the food to someone who agrees to do so

→ For example, if a handler is a “facility,” they likely will be covered by this provision
Customer Assurance Provisions

- 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 that:
  1. The farm provides documentation accompanying the produce that the food is not processed to adequately reduce the presence of the microorganisms of public health concern; and
  2. Annually obtains written assurance from its customer that either the customer or another entity performs commercial processing that adequately reduces the presence of microorganisms

→ Growers need to either comply with this provision or comply with the produce safety rule
FDA’s Draft Guidance on Written Disclosure Statements

• FDA recently issued a draft guidance on the disclosure statement requirements under the PC and Produce Safety rules

• 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”
Disclosure Statement Guidance – 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

• The **PC rule** requires the statement disclose that the food is “not processed to control [identified hazard]”
  – In practice, FDA expects disclosure statements will be used mostly for biological hazards
  – For **biological** hazards, FDA provides flexibility by allowing the hazard to be described by a general term (e.g., “microbial pathogens,” “microorganisms of public health significance”) rather than naming a specific biological hazard (i.e., *Salmonella* or *Listeria monocytogenes*)
Disclosure Statement Guidance – How to Communicate the Hazard

• Disclosure statements for each of the rules require the statements to 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
Almond Board Recommended Strategy for Compliance

• Based on discussions with FDA and the draft guidance, the Almond Board recommends taking the following approach for written assurances:
  – Grower provides written disclosure to handler:
    • “Almonds are not processed to adequately reduce the presence of microorganisms of public health significance”
  – Handler provides written assurance to grower:
    • Assurance must explain that the almonds will be subject to processing (following procedures under the Marketing Order that adequately reduce the presence of microorganisms of public health significance), or otherwise they will be exported with a disclosure that they are “not processed to adequately reduce the presence of microorganisms of public health significance”
    – Handlers can put the written assurance in their annual contract with the grower
  – No further documentation needed for hullers/shellers, DV users, customer processors, or export customers.

• Guidance document from Almond Board coming soon!

• Note that FDA has not formally sanctioned this approach and it is not entirely aligned with the regulations
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.
Extension of Certain FSMA Compliance Deadlines
Extension of Certain FSMA Compliance Deadlines

• In September, FDA issued a final rule extending certain compliance deadlines for four of the seven final FSMA regulations: Human Food Preventive Controls (PC), Animal Food PC, Foreign Supplier Verification Program (FSVP), and Produce Safety rules.

• These are not blanket extensions of the compliance deadlines for the FSMA rules.

• The following three* categories of compliance date extensions may affect the almond industry:
  1) The requirement to obtain customer assurances for food that will be subject to further processing;
  2) Compliance with PC rules for facilities solely engaged in packing and/or holding activities conducted on nut hulls and shells; and
  3) Compliance with PC rules for facilities that would qualify as “secondary activities farms” except for ownership of the facility.

* The guidance also contains a clarification on the meaning of the compliance date for the agricultural water testing provision.

• The new compliance dates for the customer assurance provision under the Human Food PC rule are:
  – September 19, 2018 for businesses with 500+ full-time equivalent employees
  – September 18, 2019 for small businesses (less than 500 full-time equivalent employees)

• The new compliance dates for the customer assurance provisions under the Produce Safety rule are:
  – January 28, 2019 for businesses with over $500,000 in average produce sales
  – January 27, 2020 for small businesses ($250,000-$500,000 in average produce sales)
  – January 26, 2022 for very small businesses ($25,000-$250,000 in average produce sales)
1. Scope of Customer Assurance Provisions Extension

• The original compliance dates remain in effect for the requirement under the PC Rule to disclose and provide documentation that a hazard has not been controlled when relying on a subsequent entity to control the hazard
  – For example, if a huller and sheller that is a “facility” ships raw almonds to another company that will perform the kill step, the huller and sheller must provide documentation that the food is “not processed to control Salmonella.”

• You cannot separate the facility registrations for your manufacturing/processing and hulling/shelling/handling operations in order to take advantage of the compliance date extension.
  – Even if a business has different structures engaging in different activities, it would still be considered one facility if the ownership is the same
2. Facilities Engaged in Packing/Holding Produce RACs or Nut Hulls and Shells under PC Rule

• Certain off-farm operations, such as facilities that hull, shell, pack, and/or hold nuts, are subject to the PC rule, rather than the Produce Safety rule
  – E.g., a huller and sheller that does not meet the definition of “secondary activities farm”

• FDA is extending the compliance date for “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells”
  → This extension covers almond brown skin facilities that only size, sort, grade, or pack almonds, as well as facilities that only hull and shell almonds
    – As long as the facility does not engage in manufacturing or processing activities (i.e., chopping, grinding, mixing, roasting, pasteurizing, salting) then it can take advantage of the compliance date extension
2. Facilities Engaged in Packing/Holding Produce RACs or Nut Hulls and Shells under PC Rule

• The new compliance dates for the PC rule for these facilities will align with the compliance date for the Produce Safety rule
  – These facilities now have the same time to understand the applicable provisions of the Produce Safety regulation as “farms” that conduct similar packing and holding activities
  – FDA expects that these facilities will draw from the provisions of the [P]roduce [S]afety regulation in developing [their] food safety plan,“ so the extension gives them the same amount of time as farms to understand the produce rule

→ It’s notable that FDA expects these facilities to adopt the same type of food safety practices under its Food Safety Plan as it would be required to implement under the Produce Safety rule
2. New Compliance Dates for Packing/Holding Produce RACs or Nut Hulls and Shells under PC Rule

• The new compliance dates for the human PC rule for facilities that pack, hold, shell, or hull nuts are:
  – January 26, 2018 for businesses with 500+ full-time equivalent employees
  – January 28, 2019 for small businesses (under 500 full-time equivalent employees)
  – January 27, 2020 for very small businesses (under $1 million in average sales/value of food held)
3. Facilities that Qualify as Secondary Activities Farms Except for Ownership of Facility

• 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

  • Examples of common ownership include:
    – An operation owned by (or that owns) one or more primary production farms (e.g., a packing house owned by a cooperative of individual farms)
    – Operations that are managed within the same business structure as the primary production farm (e.g., the farm and packinghouse are separate operations owned by parents and their children, respectively, and both operations are part of the same business jointly owned by the parents and the children)
3. New Compliance Dates for Facilities that Qualify as Secondary Activities Farms Except for Ownership of Facility

• For operations satisfying the criteria, the new compliance dates for the human food PC rule are:
  – **January 26, 2018** for businesses with 500+ full-time equivalent employees
  – **January 28, 2019** for small businesses (under 500 full-time equivalent employees)
  – **January 27, 2020** for very small businesses (under $1 million in average sales/value of the food held)

→ The compliance date extensions match the compliance dates for businesses in the same size categories in the produce safety rule, as well as other extended compliance dates related to the farm definition
FDA’s Clarification Regarding the Agricultural Water Testing Provision

- FDA’s guidance also contained a clarification regarding its intent of the meaning of the compliance dates for certain agricultural testing requirements in the Produce Safety rule
  - The guidance provides that farms are allowed discretion as to both the number of samples they take in their initial survey to develop a microbial quality profile for untreated surface water directly applied to growing produce, provided that the total is 20 or more samples
  - FDA is also allowing discretion as to the time period over which the samples are taken, provided that it is at least two years, and no more than four years
- This only affects you if you’re a grower that opts to comply with the Produce Safety rule rather than obtaining written assurances
Prepare Now!

• Although we have some compliance date extensions, they’re narrow:
  – Customer assurances
  – Huller/shellers and handlers that are “facilities” and also do not “manufacture” food
  – Facilities that are *almost*, but not quite, secondary activities farms
• It’s essential to start preparing now, rather than waiting until the 11\textsuperscript{th} hour
• The FSMA regulations require significant changes that will take time to implement—no matter where you’re located in the supply chain
Where to Start

- Determine which rule(s) apply to your operation and your compliance
  - Leverage the tools developed by the Almond Board!
  - Start by making a list of the activities you perform

- Growers:
  - Assess obligations under produce rule, or plan for written disclosures and written assurances

- Hullers & Shellers and Processors/Handlers:
  - Assess obligations under produce rule, or plan for written disclosures and written assurances
  - Develop a Food Safety Plan
    - Conduct and document hazard analysis
    - Plan for written disclosures and written assurances for biological hazards

- Manufacturers:
  - Develop a Food Safety Plan
    - Improve documentation under existing HACCP plan
    - Train PCQI(s)
    - Plan for providing written assurances to suppliers
    - Develop or improve supplier verification program
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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