



2017

# THE ALMOND CONFERENCE

PRODUCE SAFETY RULE FOR FARMS: HOW TO COMPLY AND  
WHAT ABOUT THE GROWER EXEMPTION?

Room 314 | December 5 2017



# CEUs – New Process

## Certified Crop Advisor (CCA)

- Sign in and out of each session you attend.
- Pickup verification sheet at conclusion of each session.
- *Repeat this process for each session, and each day you wish to receive credits.*

## Pest Control Advisor (PCA), Qualified Applicator (QA), Private Applicator (PA)

- Pickup scantron at the start of the day at first session you attend; complete form.
- Sign in and out of each session you attend.
- Pickup verification sheet at conclusion of each session.
- Turn in your scantron at the end of the day at the last session you attend.

*Sign in sheets and verification sheets are located at the back of each session room.*

# AGENDA

- **Maile Hermida**, Hogan Lovells US LLP
- **Brian Dunning**, ShoEi Foods (USA), Inc.



# Produce Safety Rule for Farms: How to Comply and What About the Grower Exemption?

The Almond Conference

December 5, 2017

Maile Gradison Hermida

Hogan Lovells US LLP



# Agenda

---

- Who is Covered by the Produce Safety Rule?
- Overview of the Rule
- Compliance Dates (and Extensions)
- In Focus: Commercial Processing Exemption
- Inspections

# Who is Covered by the Produce Safety Rule?

## • Farms!



– Legal definition (21 CFR § 1.227):

(1) **Primary production farm.** 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, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; ... or

(2) **Secondary activities farm.** 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. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

# What Operations are Farms?

- Growers
- Hullers/shellers if:
  - They grow almonds (or other raw agricultural commodities!) in the same general physical location as the H&S operation (primary production farm)
  - They are majority owned by growers that supply the majority of almonds hulled and shelled (secondary activities farm)
  - They do not grow almonds and are not owned by growers, but are in the same general physical location where almonds (or other RACs!) are grown \*\*awaiting FDA concurrence to be certain on this point\*\*



# Produce Safety Rule Overview

---

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



# Personnel Qualifications and Training

---

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

# Personnel Qualifications and Training

---

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

# Worker Health and Hygiene

---

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

# Agricultural Water

---

- Purpose: Safe and adequate sanitary quality of water
- Requirements address:
  - Safe and adequate sanitary quality of water
  - Inspection of water system under farm's control
  - Water treatment, if a farm chooses to treat water
  - Specific microbial criteria for water used for certain purposes
  - Tiered approach to water testing
  - Corrective measures
  - Records requirements
- Complex regulations are under reconsideration by FDA based on industry concerns
  - FDA has proposed to extend the compliance dates for the agricultural water requirements and is reconsidering how to reduce the regulatory burdens posed by this part of the rule

# Biological Soil Amendments of Animal Origin

---

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

# Domesticated and Wild Animals

---

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

# Growing, Harvesting, Packing, and Holding Activities

---

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

# Equipment, Tools, Buildings and Sanitation

---

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



# Produce Safety Rule Exemptions – Rarely Consumed Raw

## 1. Produce that is rarely consumed raw

- Exhaustive List: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts

→ Almonds are not on this list



# Produce Safety Rule Exemptions – Commercial Processing

2. Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance if:
  1. You disclose in documents accompanying the produce that the food is “not processed to adequately reduce the presence of microorganisms of public health significance” and you either
  2. (i) Annually obtain written assurance from the customer that performs commercial processing that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or  
  
(ii) Annually obtain written assurance from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing and that the customer:
    - (A) Will disclose in documents accompanying the food that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and
    - (B) Will only sell to another entity that agrees, in writing, it will either:
      - » (1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or
      - » (2) Obtain a similar written assurance from its customer that the produce will receive commercial processing and that there will be disclosure in documents accompanying the food that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”

# 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

# Compliance Date Extensions

## 1. Agricultural Water (Proposed)

- FDA has proposed extending and harmonizing the compliance dates for the agricultural water provisions
- FDA is taking this action to “address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration’s policies.”
- Almond Board submitted comments in November 2017 supporting the extension. Action expected before current compliance date (January 26, 2018)
- New proposed compliance dates:

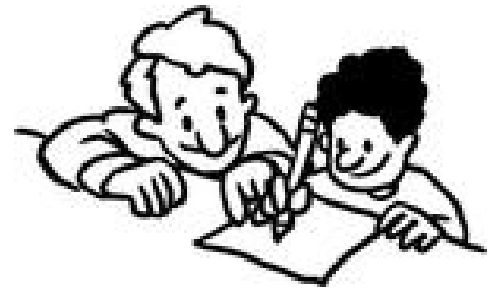
Size of Covered Farm	Proposed New Compliance Date
All Other Businesses	January 26, 2022
Small Business	January 26, 2023
Very Small Business	January 26, 2024

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

# Compliance Date Extensions

## 2. Written Assurances Under Commercial Processing Exemption

- The new compliance dates for the customer assurance provisions under the Produce Safety rule are:
  - **January 27, 2020** for businesses with over \$500,000 in average produce sales
  - **January 26, 2021** 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)
- The original compliance dates remain in effect for the requirement to disclose and provide documentation that the produce has not been processed to adequately reduce the presence of microorganisms of public health significance
  - A grower must still provide documentation accompanying the food that it is “not processed to adequately reduce the presence of microorganisms of public health significance”
- *FDA is still considering how to address this requirement longer term*



# In Focus: Commercial Processing Exemption

---

- Under the regulations, there are two components:
  - Disclosure Statement
  - Written Assurance
  
- Through **January 27, 2020**, only the disclosure statement requirement is currently in effect



# In Focus: Commercial Processing Exemption

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

## 1. How to Describe the Hazard

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

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

### **Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry**

#### ***Draft Guidance***

*This guidance is being distributed for comment purposes only.*

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2016-D-2841 listed in the notice of availability that publishes in the *Federal Register*.

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

For questions regarding this draft document as it relates to our regulation entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,” contact the Center for Veterinary Medicine (CVM) at 240-402-6346.

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

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

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

# In Focus: Commercial Processing Exemption

## 2. How to Communicate the Hazard

- The statement must be made in documents “accompanying” the food, “in accordance with the practice of trade”



– FDA notes this requirement can be satisfied in a wide variety of documents that accompany food, “such as labels, labeling, bill of lading, shipment-specific certificate of analysis, and other documents or paper associated with the shipment that a food safety manager for the customer is likely to read”



– FDA’s position is that it is not sufficient to reference a website in a document of the trade without including the disclosure statement, itself, in the document of the trade

- It would be permissible to use labeling that includes a disclosure statement such as “not processed to control microbial pathogens” and then direct the recipient to a website for additional information about those microbial pathogens



– Further, FDA does not recommend that documents such as contractual agreements, letters of guarantee, specifications, or terms and conditions be used to communicate the information required in the disclosure statement

- FDA’s position is that such documents are not specific to a particular shipment, and some of these documents may not be available to the customer’s food safety manager



# In Focus: Commercial Processing Exemption

- Written Assurance Compliance Challenges:

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



# Almond Board Recommended Strategy for Compliance

- The Almond Board is actively engaged in discussions with FDA about how to handle the written assurance requirements
- The Almond Board has proposed the following to FDA for the commercial processing exemption:
  1. Grower provides written disclosure to huller/sheller and handler stating: “Almonds are not processed to adequately reduce the presence of microorganisms of public health significance”
    - Use documents such as grower tags, delivery statements, bills of lading, annual contracts, or other means specific to grower lots
  2. Handler provides written assurance to grower as part of their annual contract (or other documentation):
    - “Almonds will be subject to processing following procedures under the Federal Marketing Order, that will adequately reduce the presence of microorganisms of public health significance. If almonds are exported without further processing or treatment, appropriate written assurances will be obtained from the export customer.”
  3. Handlers will annually provide a written disclosure to their export customer stating:
    - “Almonds are not processed to adequately reduce the presence of microorganisms of public health significance.”
  4. Handlers will include language in their annual contracts with export customers stating: “By signing this contract, the customer affirms that the Almonds will be treated in a manner to adequately reduce the presence of microorganisms (e.g., utilizing processes such as hot water blanching, oil or dry roasting, steam, etc.)”
  5. No further documentation needed for hullers/shellers, DV users, customer processors, or export customers.
- Note that FDA has not formally sanctioned this approach and it is not entirely aligned with the regulations

# Inspections

- FDA's mantra is “educate before and while we regulate”
- FDA has said its initial goal will be to work with industry to create a culture of safety and this goal will apply not just in the initial months of compliance, but going forward
  - What that really means remains to be seen
  - A “culture of food safety” will not trump situations with public health implications



# Inspections

---

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

# Inspections

---

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

# Conclusion

- In order to comply with the Produce Safety rule, there are two paths farms can follow:
  - Comply with the rule
  - Use the commercial processing exemption
- Through January 2020, it is “easy” to qualify for the commercial processing exemption, because the written assurance requirement is not in effect
- ABC is actively engaged in discussions with FDA about how to simplify the regulation long term so that farms in the almond industry can always be exempt from the rule
- **Right now growers should seek out Produce Safety Training and build out the Farm Food Safety Plan**
- Stay tuned!

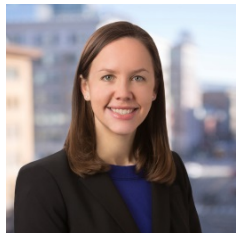


# Questions?



## Contact Information

---



Maile Hermida, Partner  
Hogan Lovells US LLP  
(202) 637-5428  
Maile.Hermida@hoganlovells.com



Elizabeth Fawell, Counsel  
Hogan Lovells US LLP  
(202) 637-6810  
Elizabeth.Fawell@hoganlovells.com



Thank you!



# What's Next

**Tuesday, December 5 at 3:00 p.m.**

- Technology in the Food Safety World: Tools Such as Whole Genome Sequencing – Friend or Foe? – Room 314
- Come See What's Happening in D.C.! – Room 306-307
- How to Manage a Young Orchard – Room 308-309
- Research Update: Soil Health, Aerial Almond Mapping and Almond Lifecycle Assessment – Room 312-313