Shine Some Light Down that Rabbit Hole: Coverage and Exclusions in the PSA Grower Training

Produce Safety Educator’s Call #31
May 21, 2018

Don Stoeckel, PSA
The PSA Team
FDA Produce Safety Network and others
Instructions

• All participants are muted.

• There will be time for questions and answers throughout the meeting.
  – We may not get around to all comments/questions, BUT you may leave additional comments in the comment box to be compiled after the session.

• This session will be recorded and notes will be shared via the listserv and on our website after the call.
Topics

• What and Why
• Farms that are Not Covered
• Produce that is Not Covered
• Produce that is (partially) Exempt
• Farms that are Qualified Exempt
• Some Devilish Details

We created a sheet of Resources with URLs for attendees. It will be archived with the meeting slides and notes.
PSA Information Comes From

- Responses of the Technical Assistance Network
- FDA Guidance and other documentation
- FDA’s Produce Safety Network, Subject Matter Experts, and Policy Analysts
  - Theresa Klaman, Diane Ducharme, Socrates Trujillo, Mary Tijerina, Stephen Hughes, Michelle Smith in particular for this topic
- Discussions with and input from many of you on the call
The Dealio

• The PSA Grower Training Curriculum contains just two slides that talk about who is covered, what is covered, by the FSMA Produce Safety Rule
  – FDA Decision Tree is in the notes and supporting documents

• WHY? Growers will do their homework and know their status before they spend a day and about $100 taking a course they might not need

• Many growers need help figuring out if they are covered, compliance dates, the meaning of some of the definitions ... and market pressure
FSMA Produce Safety Rule

• First ever mandatory federal standard for growing, harvesting, packing, and holding of fresh produce

• Some growers may be eligible for an exemption or excluded based on:
  – Commodities grown (e.g., rarely consumed raw)
  – Processing activities that include a ‘kill step’
  – Average annual produce sales
  – Average annual food sales and sales to ‘qualified end users’

• Ultimately, all growers should understand and take action to reduce food safety risks on the farm
## Produce Safety Rule Compliance

<table>
<thead>
<tr>
<th>Business Size</th>
<th>Years to Comply After Effective Date (1-26-16)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>All other businesses (&gt;$500K)</td>
<td>2</td>
</tr>
<tr>
<td>Small businesses (&gt;$250K-500K)</td>
<td>3</td>
</tr>
<tr>
<td>Very small businesses (&gt;$25K-250K)</td>
<td>4</td>
</tr>
</tbody>
</table>

*Compliance dates for certain aspects of the agricultural water requirements allow an additional two years beyond each of these compliance dates.*
Another Issue: The PSR Evolves

• Be alert to ch-ch-changes
  – Announcements about current thinking
  – Formal guidance from FDA
  – Understanding the significance to farms
  – Extensions and enforcement discretion
    • Compliance date extension for Subpart E (Ag Water)
    • [Reserved] section of Subpart F (Soil Amendments)
    • Enforcement discretion for
      – Definition as farm or facility based on ownership
        or business structure
      – Written assurances in “customer provisions”
The Point

- This information is present but not emphasized in the standardized PSA Grower Training curriculum
- Not all participants need additional information about coverage, exemptions, and definitions
- This information IS useful to many growers, and can help PSA Trainers effectively answer questions that are asked during courses
- It is important to stay current on updates and clarifications of the regulatory requirements
Review of Inspections and Audits

Inspections to enforce the FSMA PSR are different and separate from audit programs. This is not clear to some audiences.

• Participation in PSR Inspections is **required**
  – Driven by requirements in Federal law (FSMA)
  – Will be implemented by State regulators in many cases
  – Only some farms covered; inspections many not be annual

• Participation in the audit program is **voluntary**
  – Driven by access to markets/buyer requirements
  – Implemented by third-party audit programs
  – Results in GAPs certification; certification often annual
Review of Inspections and Audits

**TIP:** It helps to describe the difference between inspections and audits at the beginning of the course to save confusion later.

There is a PSA Fact Sheet on the topic behind the *References and Resources* tab.
Some Resources from FDA

• Coverage and Exemptions/Exclusions guidance
• Inflation adjusted cut off values
• Enforcement discretion announcement
• Compliance Date Extension announcement
• Rarely Consumed Raw fact sheet
• Definitions
  – Farm and Facility
  – Food and Produce
  – Qualified End User, Restaurant, and Retail Establishment
Some Resources from FDA

**TIP:** Know your audience

Consider printing some of these documents for distribution, along with your own organization’s educational documents

- Your audience may need the documentation or written support
- Your audience may not have access to internet

Some of the material (Coverage flow chart) is already in the PSA Grower Training manual
STANDARDS FOR PRODUCE SAFETY
Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of “farm” is subject to the produce rule.

Does your farm grow, harvest, pack or hold produce?
Sections 112.1 and 112.3(c)
We define “produce” in section 112.3(c).

NO: Your farm is NOT covered by this rule.

YES

Does your farm on average (in the previous three years) have $25k or less in annual produce sales?
Section 112.4(a)

YES: Your farm is NOT covered by this rule.

NO

Is your produce one of the commodities that FDA has identified as rarely consumed raw?
Section 112.2(a)(1)
If you grow, harvest, pack or hold more

YES: This product is NOT covered
Coverage and Exemptions/Exclusions

**TIP:** It is a good idea to have participants LOOK at this document before the training.

- The chart is on the FDA web site and in the PSA Grower Training manual behind the FDA/USDA Resources tab
- PSA also created a Trainer Resource PowerPoint called *FSMA Produce Safety Rule Exemptions and Exclusions* for your use
- Resources including online flow charts can help growers walk through this material (see resources)
Businesses That Are Not Covered

• Businesses that are not farms
• Farms that do not grow, harvest, pack, or hold covered produce
• Farms with annual TOTAL produce sales less than $25,000 (3-year rolling average adjusted for inflation)
  – The value for this average in 2018 (sales in 2015, 2016, and 2017) is $26,999
  – FDA publishes an updated value in March covering the average for the three prior years
Businesses That Are Not Covered

**TIP:** Know the definitions and impact

Farms, facilities, and farm mixed type facilities

Classification of activities as growing, harvesting, packing, or holding covered produce

The $25K cut off

- Applies to **all** produce sold, including but not limited to covered produce
  - Not just covered produce
  - **ALL PRODUCE**
  - Let’s say it together. **ALL PRODUCE**
- Keep up with the inflation-adjusted value
Food That Is Not Covered

• Food is not covered if it is
  – Not in the definition of produce
  – Not in the definition of Raw Agricultural Commodity (RAC)
  – Produced for personal or on-farm consumption
  – ‘Rarely Consumed Raw’ (RCR; only 34 specific things)

- asparagus
- black beans
- Great Northern beans
- kidney beans
- lima beans
- navy beans
- pinto beans
- garden beets
  (roots and tops)
- sugar beets
- cashews
- sour cherries

- chickpeas
- cocoa beans
- coffee beans
- collards
- sweet corn
- cranberries
- dates
- dill
  (seeds and weed)
- eggplants
- figs
- ginger

- hazelnuts
- horseradish
- lentils
- okra
- peanuts
- pecans
- peppermint
- potatoes
- pumpkins
- winter squash
- sweet potatoes
- water chestnuts
Food That Is Not Covered

**TIP:** It is a good idea to know:

- Food grains and most other agronomic crops are not produce
- A consumer cannot be a business, so food produced for on-farm restaurants is covered (but it is sold to a QEU)
- ONLY these 34 items are excluded from coverage for the reason “Rarely Consumed Raw”
  - Know about the FDA Fact Sheet explaining the thinking behind this list
  - FDA may revisit this list as consumption trends change over time
  - The variance process can help address other products that are normally cooked
Food That Is Exempt

• Produce that “receives commercial processing that adequately reduces the presence of microorganisms of public health significance”
  – Processed in accordance with the requirements of 21 CFR part 113, 114, or 120
    • 21 CFR 113 is thermally processed low-acid foods
    • 21 CFR 114 is acidified foods
    • 21 CFR 120 is HACCP systems
  – Treated with a validated process to eliminate spore-forming microorganisms (e.g., commercial canning processes such as tomato paste, shelf-stable tomatoes)
  – Processing such as refining, distilling, or otherwise processing to sugar, oil, spirits, wine, beer, or similar products
**Food That Is Exempt**

**TIP:** This is an exemption from most of the rule, not all of the rule. Some requirements apply

See requirements in 21 CFR 112.2 about

- Disclosing that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”
- Obtaining written assurance from the buyer that the produce will be processed
Businesses That Are Exempt

• Less than $500,000 annual food sales (adjusted)
• Majority to Qualified End Users
  – Consumer
  – Restaurant or retail food establishment
    • Same state/Reservation
    • OR within 275 miles
• Includes ALL food sales, including meats, value-added, and animal feed

Does your farm on average (in the previous three years) as per Section 112.5:
have < $500k annual food sales,
AND
a majority of the food (by value) sold directly to “qualified end-users”?
Section 112.3(c)
“Qualified End-User” as defined in Section 112.3(c) means:
• the consumer of the food OR
• a restaurant or retail food establishment that is located—
  (i) in the same State or the same Indian reservation as the farm that produced the food; OR
  (ii) not more than 275 miles from such farm.
(The term “consumer” does not include a business.)
Businesses That Are Exempt

TIP: Know the definitions

- **Food** “means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article

- **Restaurants** prepare and sell food directly to consumers for immediate consumption and include cafeterias, catering facilities, and nursing home/child care facility kitchens

- **Retail food establishments** sell food directly to consumers as the primary function, including grocery stores and vending machine locations as well as farm roadside stands, CSAs, and farmers’ markets
Businesses That Are Exempt

**TIP:** Know the difference between the inflation adjusted food sales cut off and the business size cut off

- The inflation adjusted cut off of $500,000 for annual average TOTAL FOOD sales is $539,982 for 2015-2017
  - This is the upper limit of eligibility for a QUALIFIED EXEMPTION and it is adjusted for inflation
  - Value of byproducts like cotton seed oil COUNTS as food sold if used as a component of food or used as animal feed

- The food sales in Qualified Exemptions is DIFFERENT FROM the $500,000 annual PRODUCE sales in the business size definitions of 21 CFR 112.3(b).
  - The business size cut off is NOT adjusted for inflation
  - The business size class is relevant to compliance dates
Sales to Qualified End Users

More tips related to the definitions:

• Animal feed is not usually a sale to a qualified end user because you don’t sell directly to the animal consumer
  ― BUT, pet shelters and kennels that serve food to animals ARE restaurants according to the FDA’s definition and restaurants are QEUs

• All direct sales to consumers count because there is no distance limit on consumers, including internet sales

• The same state/reservation/275-mile limit applies to distance between the location of the farm that grew the produce and the location of the restaurant or retail food establishment buying the produce, not the point of sale.
**TIP:** This is an exemption from most of the rule, not all of the rule. Some requirements apply.

See requirements in 21 CFR 112.6 about

- Disclosing on the label, if a food packaging label is required, the complete business address of the farm (compliance date Jan 1, 2020)

- Disclosing at the point of sale, if no food packaging label is required, the complete business address of the farm (compliance date Jan 26, 2019 or 2020)

Recordkeeping requirements and annual review of records to support eligibility
Sales to Qualified End Users

- Same State OR
- Same Reservation OR
- Within 275 Miles

Retail Food Establishment

Restaurant

Consumer

Retail Food Establishment
Sales to Qualified End Users

**TIP:** There are a few possible ways to describe where the restaurant or retail food establishment is “located”

- The corporate headquarters, e.g., corporate pays the invoice
- The business address of the buyer’s retail sales location(s)
- The delivery address for the sale, especially if the produce is going to an off-site warehouse for storage then distribution to the retail location(s)

Current thinking from Produce Safety Network is that the location of the qualified end user is the location where the food is going after purchase

- Food bought for a distribution warehouse is not a sale to a qualified end user, even if not a separate business from retail
- Based on requirement to register as a facility
The Devilish Details

YEAH. I'M GONNA NEED MORE DETAILS.
The Rule Is New

- Trainers should recognize that the Rule is evolving so always look for updates and new answers to questions
- Reliable information resources include (see resources)
  - FDA Technical Assistance Network
  - FDA Produce Safety Network staff
  - The regulatory authority under the FDA Cooperative Agreement Program in your state, if any
  - Regional FSMA Centers
  - Produce Safety Alliance, Local Foods Collaborative, and Indigenous Food and Agriculture Initiative
The Rule Is New

TIPs:
• TAN responses represent current thinking on specific topics but they are only released to the individual who asked
  • The Northeast Center for Advancement of Food Safety (NECAFS) hosts a Clearinghouse of resources
  • NECAFS is working toward a searchable database of user-submitted TAN questions and responses
• Don’t forget about Agricultural Extension, State Departments of Agriculture or Health, and non-governmental organizations.
• PSA developed a collection of materials and the Listserv!!
This Is a Federal Regulation

• Keep in contact with the agency that is responsible for compliance in your growers’ states

• State-enforceable legislation can include requirements not in the Produce Safety Rule
  – Whether qualified-exempt farms are required to have a person trained per 21 CFR 112.22(c) (e.g., PSA course)
  – How a qualified-exempt farm must demonstrate eligibility for the exemption
  – Whether the qualified-exempt farm can request a voluntary inspection to meet buyer requirements
Language Gets Interpreted

What does it mean to:

– 112.6 “include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown”

  • The farm with the qualified exemption, or the farm that grew it?

Proudly Brought to You by
Sweet Local Farm
13052 State Highway 42
Springfield, Utopia

OR

Proudly Grown for You by
Sweet Local Farm
13052 State Highway 42
Springfield, Utopia

OR

Family Friend Farm
620 Healthy Highway
Goodwater, Utopia

OR

Good Neighbor Farm
13161 State Highway 42
Springfield, Utopia
Guidance Has Not Been Released, Yet...

What does it mean to:

- 112.5 sell food “directly to qualified end-users”
  - Status of sales through an auction, cooperative, food hub, or informal sharing arrangement.
  - Auctions, cooperatives, food hubs can fall within the definition of a “retail food establishment” depending on the business model.
Sales Directly to Qualified End Users

- Sold Direct to Consumer
- Sold to a Restaurant that Serves it to a Consumer
- Sold to a Retail Food Establishment that Sells it to a Consumer
Sales Directly to Qualified End Users ... via Co-ops and Hubs

How does the money flow?

Consumer
Restaurant
Retail Food Establishment

Produce Safety Alliance
Sales Directly to Qualified End Users ... via Auctions

How does the money flow? Are records available?
Special Note for Mediated Sales

• Definitions of Farm/Facility and Covered Activities
  – If the business controls covered produce and carries out covered activities the business may be a covered farm or a covered facility even if it never owns the produce
    • Secondary activities farm (harvesting, packing, holding)
    • Facility (packing, holding, manufacturing/processing)
**Special Note for Mediated Sales**

**TIP:** Know the functions of the auction, cooperative, or hub. Does the business have to register as a facility?

- When produce auctions/cooperatives/ or hubs are solely a location for buyers and sellers to meet, sell, and transfer produce and the food is not stored, these facilities would not be considered “holding” food and would not be expected to register.

<table>
<thead>
<tr>
<th>HOLDING</th>
<th>NOT HOLDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Storing</td>
<td>• Labeling (including stickers)</td>
</tr>
<tr>
<td>• Blending the same RAC</td>
<td>• Removing or trimming parts of RACs</td>
</tr>
<tr>
<td>• Coating for effective storage</td>
<td></td>
</tr>
<tr>
<td>• Cooling/maintaining frozen state</td>
<td></td>
</tr>
<tr>
<td>• Heat treatment to reduce pests</td>
<td></td>
</tr>
<tr>
<td>• Loading or placing food in a vehicle or building</td>
<td></td>
</tr>
<tr>
<td>• Sampling food, e.g. sugar</td>
<td></td>
</tr>
<tr>
<td>• Weighing or conveying</td>
<td></td>
</tr>
</tbody>
</table>
Questions?

• **Summary Thought:** Answers can be very situational. Be sure to ask enough questions to understand the grower’s situation.

• Let’s use the remaining time for discussion of specific regulatory requirements and what they mean to farms
Next Meeting

• **Tentative**: June 25, 2018 at 2PM Eastern
• **Tentative topic**: TBD
• Meeting info to be sent out via the listserv closer to the time of the call
• Submit other topics for discussion to Gretchen ([glw53@cornell.edu](mailto:glw53@cornell.edu))
The PSA Website
producesafetyalliance.cornell.edu

- Like us on Facebook!
- Or Follow us on Twitter!
@Produce_Safety

Join the listserv

Elizabeth A. Bihn, Ph.D., Director, eab38@cornell.edu, 315.787.2625
Gretchen L Wall, M.S., Coordinator, glw53@cornell.edu, 607.882.3087
PSA Team

Northwest: Connie Fisk, Ph.D.

Midwest: Don Stoeckel, Ph.D.

Northeast: Betsy Bihn, Ph.D.
Gretchen Wall, M.S.
Michele Humiston
Rob Way

Southeast: Kristin Woods, Ph.D.

Southwest: Donna Pahl, M.S.