

## AT A GLANCE: KEY POINTS IN THE PRODUCE SAFETY RULE DRAFT GUIDANCE

### CHAPTER 1: GENERAL PROVISIONS (SUBPART A)

#### What is the goal of this chapter?

To help you determine if your farm and your produce are subject to the requirements of the Produce Safety Rule.

*References to “you” in this document (as well as in the Produce Safety Rule and draft guidance) mean the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of the rule.*

#### What is subject to the Produce Safety Rule?

The Produce Safety Rule establishes science-based standards for the safe growing, harvesting, packing and holding of fruits and vegetables grown domestically, or internationally and imported into the United States and its territories. In general, the requirements of the Produce Safety Rule apply when three conditions are present: “covered produce,” “covered farms,” and “covered activities.” The rule applies to farms with more than \$25,000 in average annual produce sales during the previous three years. However, some produce is not covered, and your farm or your produce may be eligible for an exemption.

This chapter is divided into the following five sections, each intended to help you determine which provisions of the Produce Safety Rule, if any, apply to your farm and the food you produce.

- **PRODUCE**
- **RAW AGRICULTURAL COMMODITY**
- **COVERED PRODUCE**
- **COVERED FARMS**
- **COVERED ACTIVITIES**

#### ■ **PRODUCE**

Under the Produce Safety Rule, “produce” generally means any fruit or vegetable and includes mushrooms, sprouts, peanuts, tree nuts, and herbs. And when we talk about produce we are referring to the harvestable or harvested part of the crop, which may include parts that are not edible. For example, when considering tree nuts, the entire unit (nut or kernel, hull, and shell) would be the harvestable or harvested part. Produce that is not reasonably expected to be consumed by people, such as produce used specifically for biofuels or animal food, is not subject to the Produce Safety Rule.



- Produce does not include food grains - meaning the small, hard fruits or seeds or the crops bearing these fruits or seeds - that are primarily grown and processed for use as meal, flour, baked goods, cereals, or oils rather than for direct consumption. Examples of food grains include barley, dent-or flint-corn, sorghum, oats, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

## ■ RAW AGRICULTURAL COMMODITY

Only foods that are both produce and a raw agricultural commodity (RAC) are subject to the Produce Safety Rule.

A RAC is any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled, natural form prior to marketing.

RACs that have been changed into “processed food” are no longer RACs and therefore no longer subject to the Produce Safety Rule in their transformed state. Changing a RAC into a processed food involves changing it into something new or distinct. Examples of activities that change RACs into processed foods include: chopping, cooking, cutting, homogenization, irradiation, and pasteurization. As an example, once irradiated, the produce is considered processed, and may be subject to the Preventive Controls for Human Foods Rule.

The following examples illustrate the distinction between RACs and processed foods:

- Whole heads of lettuce are RACs; however, they are no longer RACs once they are chopped into smaller pieces. Chopped lettuce is a processed food.
- Fresh oranges are RACs; however, they are no longer RACs once they are processed to make orange juice. Orange juice is a processed food.

## ■ COVERED PRODUCE

This is produce that falls within the scope of the Produce Safety Rule.

While most produce is subject to the Produce Safety Rule, some produce is “not covered” or is eligible for an exemption. Crops “not covered” by the rule include produce that is:

- designated rarely consumed raw (RCR)
- grown for personal or on-farm consumption
- not a RAC (for example, as shown in the preceding section, chopped lettuce or orange juice)
- In addition, some produce is eligible for the “commercial processing exemption” so long as certain conditions are met.

### *Rarely Consumed Raw (RCR)*

RCR produce includes commodities that the FDA determined are almost always eaten after being cooked. Unlike the commercial processing exemption, which requires records, you do not need any documentation of the cooking process for the produce to be considered RCR.

FDA's complete list of RCR produce includes: asparagus; black, great northern, kidney, lima, navy, and pinto beans; garden beet (root and top); sugar beet; cashew; sour cherry; chickpea; cocoa bean; coffee bean; collard; sweet corn; cranberry; date; dill (seed and weed); eggplant; fig; ginger; hazelnut; horseradish; lentil; okra; peanut; pecan; peppermint; potato; pumpkin; winter squash; sweet potato; and water chestnut. The draft guidance does not alter or change the commodities identified in this list.

#### *Produce for On-farm or Personal Consumption*

Produce that is produced by an individual for personal consumption, or for consumption on the farm on which it was produced or on another farm under the same management, is not subject to the Produce Safety Rule.

For example, if a farmer has a separate garden on the farm's property for growing produce for personal consumption by family members and employees, the fruits and vegetables in that garden would not be subject to the rule.

#### *Commercial Processing Exemption*

Produce that will receive commercial processing that adequately reduces the presence of pathogens (disease-causing bacteria) is eligible for exemption from most provisions of the Produce Safety Rule. However, you are still expected to meet certain requirements, including providing a disclosure statement with each shipment of produce, collecting annual written assurance statements from your customers, and maintaining certain records.

- **Disclosure statements:** For your otherwise covered produce to qualify for the commercial processing exemption, you must disclose, in documents accompanying the produce, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance." This helps inform other entities that a processing control has not been applied. Further, you must maintain records of disclosure statements that you have provided to your customers.

*For more information on disclosure statements and records, see the "Covered Produce" section in Chapter 1 of the draft guidance, specifically the subsection on the disclosure accompanying produce and affiliated records. See Chapter 8 of the draft guidance for additional general records requirements.*

- **Written Assurances:** FDA **announced in January 2018** that it will not be enforcing the written assurances provisions in this rule while it reconsiders options for the assurance requirements. However, the requirement for disclosure statements is still in place.

## ■ COVERED FARMS

The Produce Safety Rule applies to farms and certain farm mixed-type facilities that averaged more than \$25,000 in annual produce sales during the previous three-year period.

In your annual calculation of total produce sales to determine whether the \$25,000 threshold is met, include the following:

- All produce sold, not just produce covered by the Produce Safety Rule
- Produce that you purchased or otherwise obtained and then resold
- Produce sold directly to consumers or online

- Produce sold at farmers' markets or to grocery stores
- Produce sold by a third-party on your behalf, such as through a cooperative that takes possession, but not ownership, of your produce
- Retail sales, wholesale sales, intrastate sales, and interstate sales (including produce offered for import to the U.S. or exported from the U.S.)

Do not include the following in the calculation:

- Produce for which no payment was received (i.e., produce held without sale, or produce donated)
- The value of produce from other entities when a third-party is selling produce on your behalf along with produce from other entities. For example, when your produce is sold by a cooperative, along with produce from other growers, you should only consider the value from your produce sales.

***For more information and examples, see the "Covered Farms" section in Chapter 1 of the draft guidance, specifically the subsection on the \$25,000 threshold.***

To calculate sales, you should look to the average annual value of produce sold in the previous three years. For example, if you are a farmer in 2018 trying to determine if you meet the \$25,000 threshold, you would look to your sales in 2015, 2016, and 2017. The three-year average of produce sales is compared with the three-year average of \$25,000, adjusted for inflation, to determine whether a farm is subject to the Produce Safety Rule.

Farmers should note that the \$25,000 threshold set when the FDA Food Safety Modernization Act was enacted in 2011 must keep up with the pace of inflation. This information is available using the federal calculation for inflation adjustments provided by the U.S. Bureau of Economic Analysis or by FDA on its [website for FSMA Inflation Adjusted Cutoffs](#). For example, using the 2011 baseline, \$25,000 adjusted for inflation, is \$26,608 for 2015, \$26,956 for 2016, and \$27,433 for 2017, and the average three-year value is \$26,999 for 2015-2017 (all figures obtained from the FDA website).

### *Qualified Exemptions*

If you exceed the \$25,000 threshold, you still may be eligible for a qualified exemption.

Farms may be eligible for a qualified exemption based on their sales of all food products, not just produce sales. Examples of food products include livestock, meat, dairy products, hay, grains, wine, and other food. Livestock are within the definition of food. Specifically, a farm is eligible for a qualified exemption if it meets the following criteria:

- 1) the three-year average annual monetary value of food sold directly to qualified end-users (such as a consumer, restaurant or retail food establishment) is greater than that sold to all other buyers during the same time period, and
- 2) average annual monetary value of all food sold during the previous three-year period must be less than \$500,000, as adjusted for inflation.

***For more information and examples, see the "Covered Farms" section in Chapter 1 of the draft guidance, specifically the subsection on qualified exemptions.***

### *Records and Modified Requirements*

If you are eligible for a qualified exemption, you must establish and keep records sufficient to demonstrate that you meet the criteria for the qualified exemption. For example, receipts or ledgers of sales to customers that show the value of food items and the location of the customer (for retail or restaurant customers) can be used to document your eligibility for a qualified exemption.

You must also keep a record demonstrating that you have performed an annual review that demonstrates that you continue to meet the criteria for a qualified exemption.

If your farm is eligible for a qualified exemption, then you will still be subject to modified requirements. You must meet requirements for providing the name and the complete business address of the farm where the produce was grown by prominently displaying this information on the label when a food packaging label is required, or on a label, poster, sign, placard, or documents delivered with the produce if a food packaging label is not required.

## ■ COVERED ACTIVITIES

Covered farms are required to comply with all applicable requirements of the Produce Safety Rule when conducting “covered activities” on covered produce.

Covered activities include growing, harvesting, packing or holding covered produce on a farm.

One example of a covered activity associated with packing produce is a farm that uses a table for its produce during packing. In this case, the relevant provisions of the Produce Safety Rule related to cleaning and sanitizing of the table would apply.

*For further explanation of the underlined words, see the **Key Terms Glossary**.*

*The **draft guidance** contains more details and examples of FDA's recommendations and current thinking. It is recommended that you review the draft guidance for complete information.*