

# FSMA's Produce Safety Rule...

## Are you Covered or Exempt?



for Training, Education, Extension, Outreach, and  
Technical Assistance to Enhance Produce Safety



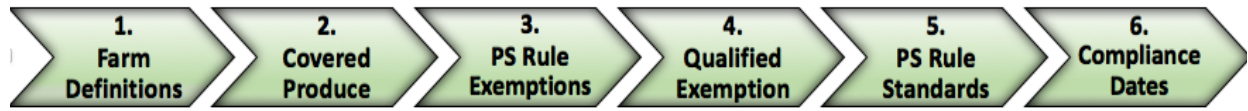
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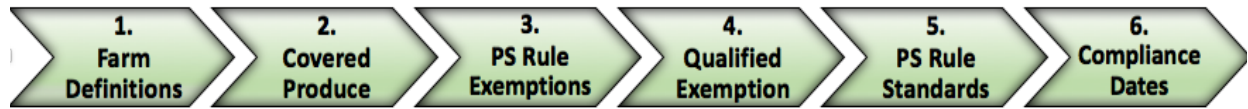
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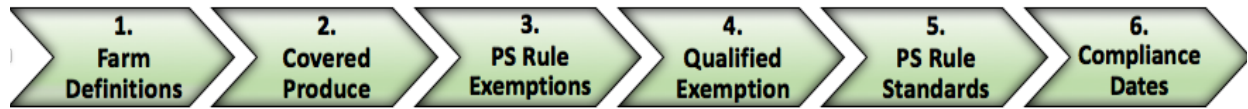


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## LEARNING OBJECTIVES

Participants will understand the following key issues regarding FSMA's Produce Safety Rule: coverage, exemptions, basic standards, and compliance dates

1. What is FSMA, and specifically what is the Produce Safety Rule? (Step 5)
2. What are the definitions of farm (all three types) and activities allowed during harvesting, packing, holding, storing and distributing of produce (Step 1)
3. The definition of a retail food establishment and whether an operation may qualify (Step 1)
4. The definition of a raw agricultural commodity (RAC); and which produce is covered and not covered under the Produce Safety Rule (Step 2)
5. What farms are exempt from the Produce Safety Rule? (Step 3)
6. What is a qualified exemption, and which farms qualify for this exemption (Step 4)
7. What records or documents are required by farms to verify and retain exempt or qualified exempt status (Step 3 & 4)
8. What are the key cornerstones (basic standards) of the Produce Safety Rule? (Step 5)
9. Compliance dates for the Produce Safety Rule (Step 6)



## STEP 1: Are You a Farm?

### I. I've heard FSMA has different rules for farms versus other businesses. How do I know if my business is a farm?

Distinguishing what rule(s) apply to your business operation(s) is critically important! In order to do this, ALL farming businesses will need to start by determine if their operations are defined as “farms” under FSMA. If your business meets FDA’s definition of a **Primary Production Farm** and/or a **Secondary Activities Farm**, and/or a **Mixed-Type Facility**, then the Produce Safety Rule likely applies to you. If you are a Mixed-Type Facility, it is possible the Preventive Controls Rules (Human Food and Animal Feed) may apply to you (See the following link at: <http://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm>).

### II. What is a Primary Production Farm?

A Primary Production Farm is an operation

- in one general area, although it may include multiple non-contiguous parcels,
- with the principal focus of growing or harvesting crops and/or raising livestock, including seafood

In addition, a Primary Production Farm may

- pack and hold raw agricultural commodities (RACs, defined as a food crop in its raw or natural state), including RACs grown on that farm and RACs supplied from other farms;
- dry/dehydrate RACs to create a distinct product with no other processing (for example drying grapes to make raisins);
- artificially ripen RACs (for example tomatoes in controlled storage);
- manufacture/ process food provided that all food is consumed on that farm or another farm under the same management;

### III. What is a Secondary Activities Farm?

A Secondary Activities Farm is an operation



- not located on a Primary Production Farm;
- majority-owned by the operator of a Primary Production Farm, or by multiple Primary Production Farm operators together;
- where the Primary Production Farms of the majority-owner or owners also provide the majority of the RACs handled by the Secondary Activities Farm; and
- that harvests, shells, hulls, washes, packs, holds, packages, and labels RACs, and/or artificially ripens RACs or dries RACs to create a distinct product with no other processing (such as grapes into raisins).

#### What it means:

If you are a Primary Production Farm or Secondary Activities Farm as defined above, you may be regulated under the Produce Safety Rule (unless exempt, described in Step 3 & 4); however, the FSMA Preventive Controls for Human Food (PC) Rule does not apply to you. For instance, the Secondary Activities Farm definition means that a farmer cooperative or farmer-owned packing house where the **majority of the product handled** by the packing house **is grown by** the farmer owner or owners is **NOT** regulated under the PC Rule, **even if it is in a different location** from a farm that grows the crops. A Secondary Activities Farm can do all the same harvesting, holding and packing activities as a Primary Production Farm and still be treated as a farm.

#### IV. What exactly does harvesting, packing and holding RACs mean?

Harvesting, packing, and holding are activities performed on RACs to remove them from the field and prepare them for storage or distribution, and includes the following:

- separating the edible portion of the crop from the plant
- field coring
- trimming or removing outer leaves, stems, roots, tops and husks
- washing
- sorting/culling
- grading
- sifting/filtering
- threshing
- shelling
- curing/drying/dehydrating that does not create a distinct commodity (curing garlic, winter squash, onions, potatoes, sweet potatoes, etc.)
- cooling and hydro-cooling



- weighing
- packaging in consumer containers
- labeling and stickering containers and individual produce items
- bunching
- braiding (garlic)
- blending different lots of the same RAC together
- mixing different intact RACs together in a container
- repacking
- waxing
- using pesticides in wash water
- fumigating during storage
- loading for transportation
- holding/storing previously frozen items

*Note: Cutting/slicing/crushing RACs after the initial harvesting, trimming and shelling/threshing activities listed above—i.e. cutting through the intact leaf, skin or flesh of a RAC—and freezing RACs (as opposed to keeping previously frozen items frozen) are **NOT** harvesting, packing or holding, and so those activities may be regulated under the PC Rule.*

**V. What if I meet FDA’s ‘farm’ requirements, but I also perform activities on food that are not listed in the definitions above?**

Farms that manufacture foods on the farm, in addition to conducting the farming activities covered above, fall into a special category: a **farm mixed-type facility or a retail food establishment**. The food manufacturing activities may be regulated under the PC Rules, but the farming activities as described in sections II, III, and IV (listed above) are not.

For example, I run a farm, but I also make foods on-farm. How are my food processing activities regulated? If you are making processed foods on farm, your operation likely can be classified as either a retail food establishment or a farm-mixed type facility.

- A **retail food establishment** is a business that manufactures foods and *sells more than half those products directly to consumers*, including through on-premises sales, farmers’ markets, community-supported agriculture, roadside stands, online, mail-order and other direct marketing platforms. Depending on state law and the kind of foods made, a retail food establishments may be regulated by the local health department or may be subject to a ‘cottage food’ law if there is one in your state. *FSMA does not apply to retail food establishments.*
- If less than half of your processed food sales are directly to consumers, you are likely operating a **farm mixed-type facility**. A farm mixed-type facility is required



to register with the US Food and Drug Administration (FDA), and the food processing performed on-farm may be subject to at least portions of FSMA's Preventive Controls for Human Food Rule or Preventive Controls for Animal Feed Rule (if the only processed foods you make are for animals).

For more information, please see Carolina Farm Stewardship Association's factsheet "*What Is a Farm Mixed-Type Facility?*" at <https://www.carolinafarmstewards.org/wp-content/uploads/2016/11/Are-You-a-Farm-Mixed-Type-Facility.pdf>.

**VI. What if my produce operation only performs the packing and holding activities listed above, but is not located on a Primary Production Farm and is not majority owned by a farmer or farmers?**

Non-farm businesses that pack, hold and store produce RACs may be facilities under FSMA, and may be covered by the Preventive Controls for Human Food Rule (See the following link at: <http://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm>).





## STEP 2: Covered Produce

### I. Is your produce one of the “covered” products that FDA has identified as raw agricultural commodities (RACs); non-exhaustive list\*?

Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Boy Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydews, huckleberries, Jerusalem artichoke, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as belland hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and mixes of intact fruits and vegetables (such as fruit baskets).

### II. Is your produce one of the commodities that FDA has identified as rarely consumed raw (And thus **NOT** covered produce by this rule)?

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

**\*NOTE:** A non-exhaustive list means the list **does not** include everything. The produce in section II is an **exhaustive list** (only products FDA has identified as rarely consumed raw). If your commodity is not listed in section II, then it is likely considered “covered” produce.



## STEP 3: Produce Safety Rule Exemptions

### I. How do I know if my farm is covered or exempt by the FSMA Produce Safety Rule?

If your farm grows produce, the Produce Safety Rule standards for growing, harvesting, packing and holding produce apply to you unless your farm falls into at least one of these categories:

#### A. You *only* grow

- produce that will be commercially processed in a manner that kills pathogens. HOWEVER, you *must* (1) **obtain documentation annually** from your customers to prove that they are properly processing those fruits or vegetables, and (2) **include a disclosure** with your produce sales that you have not processed those items to kill pathogens;

#### **AND/OR**

- produce that is rarely consumed raw. FDA has defined an exhaustive (complete) list of fruits and vegetables that it considers to fall in this category (See STEP 2).

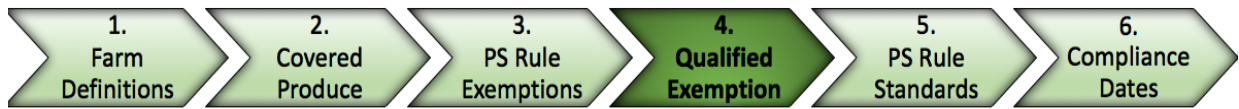
B. Your average annual **produce sales** over the previous 3 years are less than \$25,000. The dollar values for exempt (\$25,000) are to be adjusted for inflation.

C. You are qualified exempt (See Step 4)

### II. My farm does not meet any of these exemptions. What do I do now?

If your farm grows produce and does not fall into any of categories A, B or C above, your farm is fully covered by the Produce Safety Rule. Your deadline for compliance with the Produce Safety Rule depends on the value of your farm's **average annual produce sales** (See STEP 6).

For more information about what the Produce Safety Rule means for your farm, See STEP 5.



## STEP 4: Qualified Exemption

### I. You are qualified exempt if:

- A. You sold more than \$25,000 in produce/year averaged over the last 3 years;

**AND**

- B. Your average annual **food sales** (produce **and all other crops and value-added products**) over the previous 3 years are less than \$500,000 (the dollar values for qualified exempt farms (\$500,000) are to be adjusted for inflation).

**AND**

- C. More than 50% of those food sales are to **qualified end-user\*** such as: restaurants and retail food establishments (including direct-to-store sales) located in your same state, same Indian reservation, or within a 275-mile radius of your farm; and consumers through direct marketing (such as internet sales, farmers' markets, community supported agriculture, etc.).

\* Wholesalers and local distributors such as food hubs **do not** count as qualified end-users, unless the food hub is a retail food establishment, as defined by FDA.

**NOTE:** If you are *qualified exempt*, most of the Produce Safety Rule does not apply to your farm, but there are special requirements you must meet (see below section II).

### II. **What are the Special Rules for Qualified Exempt Farms?**

- My farm meets the criteria for a Qualified Exempt Farm. Does FSMA still apply to me?

Qualified Exempt Farms (QEFs) do not have to comply with FSMA's regulations that govern growing, harvesting, holding and packing produce. However, there are special requirements for QEFs related to **record-keeping, notice to customers, and losing QEF status**.

- What **record-keeping** requirements apply to Qualified Exempt Farms?

To be Qualified Exempt, your farm's three-year average of annual total food sales must be less than \$500,000 (*see note on inflation adjustment below*), and



the majority of the value of those sales must be directly to consumers and ‘qualified end-users’. (Qualified end users are restaurants and other retail food establishments, such as direct-to-store sales to grocery stores, located in your same state or within a 275-mile radius of your farm.) To claim this exemption, you must have records to prove: (1) your total food sales for each year; and (2) the location of your customers.

**DEADLINE:** You must *begin keeping these records for 2016* in order to prove your QEF status starting in 2019. If your farm is less than three years old, FDA will accept records for whatever period of time you’ve been in business.

**NOTE:** every year you must review your records to verify your QEF status, and keep a written record of what you decide. You must *start documenting this review in Jan. 2019 if your total annual produce sales are between \$250,000 and \$500,000, and if your total produce sales are less than \$250,000 you have until Jan. 2020*. These records do not have to be submitted to FDA, but they must be retained and made available upon request.

**INFLATION ADJUSTMENT:** The \$500,000 total food sales threshold for qualified exemption will be adjusted for inflation, with 2011 as the base year. So in reviewing your annual sales records, you will actually be comparing your sales to an inflation-adjusted benchmark. FDA will publish the adjusted number every year; *the actual average annual total food sales threshold most likely will be higher than \$500,000*.

- What are the **customer notice** requirements for Qualified Exempt Farms?

You must provide the name of your farm and your farm business address at the point-of-sale, such as on a sign at a farmers’ market stand; on an invoice; on an electronic receipt for online sales; or on any label that you affix to a product package. If your annual produce *sales are between \$250,000 and \$500,000, you must start providing this notice in Jan. 2019*, and if your *annual produce sales are less than \$250,000 you have until Jan. 2020*.

**PRODUCT LABELS:** If you sell any foods that are required by law to have a product label, such as value-added processed foods, that label must also include your farm’s name and business address. QEFs have until **Jan. 1, 2020** to implement this labeling requirement.

- What other conditions apply to a Qualified Exempt Farm?



FDA and state regulators working with FDA can revoke your qualified exemption if an active investigation of a foodborne illness outbreak is directly linked to your farm, or if they think withdrawing it is necessary to prevent or control an outbreak. However, there is a process regulators must follow, and a chance for a farm to contest losing QEF status.

**NOTE:** Even if you have a qualified exemption from FSMA’s Produce Safety Rule standards, you are still at risk for criminal penalties under the Food, Drug and Cosmetic Act if you distribute food contaminated with pathogens. You are also still liable in civil court for making someone sick with contaminated food. Whether you are qualified exempt or not, knowing the food safety risks on your farm and having a plan for controlling those risks is good business.

**KNOW YOUR RIGHTS:** Before FDA can issue an order to withdraw your qualified exemption, it must:

- a. Provide you with written notice of the reasons it would use to justify withdrawal of the exemption;
- b. Provide you an opportunity to respond, and
- c. Consider the actions you take to address the food safety concerns FDA identifies.

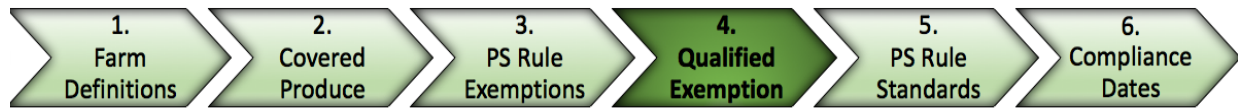
***Withdrawing a qualified exemption should be a last resort:*** FDA can also consider other actions that would address any problem, such as a warning letter, product recall, or product seizure. The FSMA regulations set timelines for responding to FDA’s notice of its intent to withdraw, and you have the ability to request any withdrawal to be revoked or to have your exemption reinstated.

**IMPORTANT PROTECTION:** If FDA takes away your exemption due to an active foodborne illness investigation directly linked to your farm, and then it determines that the outbreak wasn’t linked to your farm after all, the agency must automatically reinstate the exemption.

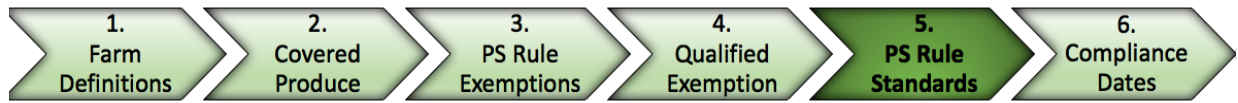
**NOTE:** If you receive a notice of FDA’s intent to withdraw your qualified exemption, you should seek assistance from legal professionals immediately.

- What happens if my **exemption gets revoked?**

If FDA or the state farm food safety agency withdraws your qualified exemption, you must come into compliance with the full requirements of the Produce Safety Rule within 120 days. For an overview of the Produce Safety Rule requirements, See Step 5.



If you believe you have grounds for restoring your qualified exemption, you must make a written reinstatement request, including data and information to show that you have resolved any problems, and that denying your QEF status is no longer necessary to protect public health or prevent a foodborne illness outbreak.



## STEP 5: Produce Safety Rule Standards

### I. Food Safety Modernization Act (FSMA)

The Food Safety Modernization Act (FSMA) was passed in 2011 by President Obama and is the most sweeping reform of our food safety laws in more than 70+ years (since the Food Drug and Cosmetic Act of 1938). The act aims to ensure the US food supply is safe by shifting the focus from responding to contamination to preventing it. The Food and Drug Administration has developed seven different regulations that encompass FSMA including (1) Produce Safety Rule, (2) Preventive Controls for Food for Human Rule, (3) Preventive Controls for Food for Animals Rule, (4) Mitigation Strategies to Protect Food Against Intentional Adulteration Rule, (5) Sanitary Transportation of Human and Animal Food Rule, (6) Foreign Supplier Verification Programs Rule, and (7) Accredited Third-Party Certification Rule. Additionally, many of the FSMA rules require food safety training to fulfill compliance.

### II. Produce Safety Rule (PSR)

The Produce Safety Rule (PSR) is one of the seven food safety regulations that are part of FSMA. The PSR sets a series of standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption, 21 Code of Federal Regulations Part 112 (<https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption>). Similar to the other FSMA rules, the PSR aims to be proactive rather than reactive by focusing on high risk practices and identification of hazards within individual operations. For example, there are no prescriptive requirements for uncontrollable factors, such as wildlife. A summary of the five major routes of contamination that the FSMA PSR focuses on are described below. Add-on curriculum are being developed by the FSMA Southern Center (<http://sc.ifas.ufl.edu/>) for specialized education and training in targeted components of the regulation.

### III. Summary of the Five Major Routes of Contamination that the PSR addresses:

#### 1. Worker Training, Health and Hygiene

The PSR standards (subparts C & D) are similar to requirements necessary for Good Agricultural Practice programs. For example, policies for reassignment of ill workers, personal cleanliness, avoiding cross contamination scenarios (e.g., avoid animal contact before cover produce contact), handwashing, restroom facilities, breaks and visitors.



## 2. *Agricultural water*

The PSR standards (subpart E) define agricultural water as “water that is intended to, or likely to, contact the harvestable portion of covered produce or food-contact surfaces”. The PSR divides the water standards into two categories: production and harvest & post-harvest activities.

- Production
  - Activities include irrigation, frost protection, protective sprays, etc.
  - Inspect the entire water system “under your control” (source, distribution system, facilities and equipment)
  - Establishment of a “Microbial Water Quality Profile” for each source
  - Sample numbers and sampling frequencies differ for types of water (for example surface vs. ground vs. municipal)
  - Profiles consist of calculations for *Geometric Mean* and *Statistical Threshold Value* based on *E. coli* levels in 100 ml
  - Timeframe to establish initial Microbial Water Quality Profiles is 2-4 years based on operation compliance dates
  - After a Microbial Water Quality Profile has been established and meets the required metrics, a farm can perform reduced sampling frequencies per year
- Harvest & Post-Harvest
  - Activities include cooling, washing, ice-making, waxing, handwashing, cleaning & sanitizing, etc.
  - No detectable generic *E. coli*

## 3. *Biological Soil Amendments of Animal Origin*

The PSR standards (subpart F) focus on amendments that “contact covered produce or surfaces, or are likely to contact covered produce or produce contact surfaces”; as well as amendments that may potentially contaminate agricultural water. Biological soil amendments are divided into two major categories:

- Untreated amendments (raw)
  - Further guidance is expected (FDA performing a risk assessment to develop science-based standards)





- Recommendation to adhere to the United States Department of Agriculture’s National Organic Program standards (See the link for “FDA’s Raw Manure under the FSMA Final Rule on Produce Safety” at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm482426.htm>).

- Treated amendments
  - Must be a validated process
  - No application to harvest time interval

#### 4. *Domesticated and Wild Animals*

The PSR standards (subpart I) addresses both domesticated and wild animals.




- Domesticated Animals
  - “Adequate waiting period” after allowing animals to graze
  - “Measures to prevent” if animals allowed where crop is planted
- Wild Animals
  - “Must monitor” during season, and immediately prior to harvest
  - If intrusion occurs (evidence of animals in field, such as tracks, crop damage), evaluate whether to harvest or not
  - Do not harvest covered produce with fecal contamination

#### 5. *Equipment, Tools, and Buildings*

The PSR standards (subpart L) focuses on equipment and tools that are “likely to contact covered produce”, as well as requirements on buildings (for example storage should prevent contamination and harborage of pests). Standard operating procedures should address cleaning and sanitizing procedures to reduce likelihood of cross-contamination.



## STEP 6: Compliance Dates

Business Size	 Compliance Dates for Sprouts	 Compliance Dates For Most Produce	 Water Related Compliance Dates <sup>1,2</sup>	Compliance Date for Qualified Exemption Labeling Requirement <sup>3</sup>	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>\$500K)	1/26/17	1/26/18	1/27/20	1/1/2020	1/26/16
Small businesses (>\$250K-500K) <sup>4</sup>	1/26/18	1/28/19	1/26/21		
Very small businesses (>\$25K-250K) <sup>5</sup>	1/28/19	1/27/20	1/26/22		

<sup>1</sup>Compliance dates for certain aspects of the agricultural water requirements allow an additional two years. Provisions with extended compliance dates include:

- The specific microbiological criteria that apply to agricultural water
- Corrective measures that must be taken if agricultural water does not meet requirements
- The frequency of testing agricultural water
- Records associated with data to support a microbial die-off rate, corrective measures, test results from a public water system, or data used to support alternative die-off rates, criteria, or sampling strategies

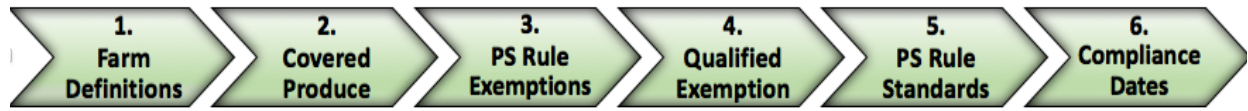
<sup>2</sup> Guidance published 8/24/16 indicates that a farm has the option of collecting surface water samples over two to four years. For example, a farm that is not small or very small would begin sampling in 2018 and complete the water quality profile in 2020, 2021, or 2022.

<sup>3</sup> A farm eligible for a qualified exemption must notify consumers as to the complete business address of the farm where the food is grown, harvested, packed, and held.

<sup>4</sup> A farm is a small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$500,000.

<sup>5</sup> A farm is a very small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$250,000.

Before the compliance date, every covered farm that does not qualify for an exemption must have a supervisor (such as a farm owner/operator) complete a standardized food safety training program. You can find out more about food safety training from the Produce Safety Alliance. <https://producesafetyalliance.cornell.edu/training>



## GLOSSARY

Produce Safety Alliance Website (<https://producesafetyalliance.cornell.edu/resources>)