

What do you need to know about FSMA's Produce Safety Rule.

**Elena Rogers
Dr. Chip Simmons**

Area Specialized Agents, Food Safety- Fresh Produce

**North Carolina State University
Department of Horticultural Sciences
NC State Extension**

Team Members
Department of Horticultural Sciences
NC State Extension
Food Safety- Fresh Produce



Elena Rogers
Area Specialized Agent
Western NC
Office- Caldwell County



Otto "Chip" D. Simmons, III
Area Specialized Agent
Eastern NC
Office- Raleigh

Outline

- What is the Produce Safety Rule?
- Produce (covered, not covered and exempt).
- Farms (covered, not covered or eligible for Qualified Exemptions).
- Steps for “covered farms” by the PS Rule and compliance dates.
- Can the Preventative Controls Rule apply to your farm?
- Questions and Answers

Standards For Growing, Harvesting, Packing And Holding Of Produce For Human Consumption

Produce Safety Rule

- This regulation focuses on setting federal regulatory standards for the **production, harvest, and handling of fruits and vegetables**, in an effort to prevent **microbial contamination** and **reduce foodborne illnesses** associated with fresh produce.
- Administered by the **Food and Drug Administration (FDA)** and the **North Carolina Department of Agriculture and Consumer Services (NCDA&CS)**.

FSMA - Produce Safety Rule

Establishes guidelines for:

- Personnel qualifications and training
- Worker health and hygiene
- Agricultural water
- Biological soil amendments of animal origin and human waste
- Domesticated and wild animals
- Equipment, tools, buildings and sanitation
- Growing, harvesting, packing and holding activities
- Sprouts

These guidelines:

- Focus on reducing routes of **microbial** contamination in fresh fruits and vegetables.
 - Prevent consumers from getting sick or dying from Salmonella, listeria, E.coli and others..
- Are science- and risk-based, they consider practices and commodities.

Produce Safety Rule

1. What **PRODUCE** is covered by the Rule?

- Raw agricultural commodities (RAC) that are grown domestically or that will be imported or offered for import in any State or U.S. territory, D.C. or Puerto Rico.

1. Fruits and vegetables that are usually eaten raw (list to follow)- AKA as “COVERED PRODUCE”

2. Mixes of intact fruits and vegetables (such as fruit baskets).

“Covered produce” by the PS Rule

Almonds	Boysenberries	Celeriac
Apples	Brazil nuts	Celery
Apricots	Broad beans	Chayote fruit
Apriums	Broccoli	Cherries
Artichokes (globe- type)	Brussels Sprouts	Chestnuts
Asian pears	Burdock	Chicory (roots and tops)
Avocadoes	Cabbages	Citrus
Babacos	Chinese cabbages (Bok Choy, mustard and Napa)	Cowpea beans
Bananas	Cantaloupes	Cress-garden cucumbers
Belgian endive	Carambolas	Curly endive
Blackberries	Carrots	Currants
Blueberries	Cauliflower	Dandelion leaves

“Covered produce” by the PS Rule

Fennel-florence	artichoke	Mushrooms
Garlic	Kale	Mustard greens
Genip	Kiwifruit	Nectarines
Gooseberries	Kohlrabi	Onions
Grapes	Kumquats	Papayas
Green beans	Leek	Parsnips
Guavas	Lettuce	Passion fruit
Herbs (such as basil, cilantro, oregano and parsley)	Lychees	<u>Peaches</u>
Honeydew	Macadamia nuts	Pears
Huckleberries	Mangos	Peas
Jerusalem	Other melons (canary, Crenshaw, Persian)	Pigeon peas
	Mulberries	Peppers (bell and hot)

“Covered produce” by the PS Rule

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

Yams

Produce NOT covered by PS Rule

1. Produce that is rarely consumed raw:

Asparagus

Beans (black,
northern, kidney,
lima, navy, pinto)

Beets

Cashews

Cherries (sour)

Chickpeas

Cocoa beans

Coffee beans

Collards

Corn (sweet)

Cranberries

Dates

Dill (seeds and
weed)

Eggplants

Figs

Ginger

Hazelnuts

Horseradish

Lentils

Okra

Peanuts

Pecans

Peppermint

Potatoes

Pumpkins

Squash (winter)

Sweet potatoes

Water chestnuts

***This is an
exhaustive list!***

What Produce is Eligible for Exemptions?

- Produce that receives commercial **processing** that adequately reduces the presence of microorganisms of public health significance.

Processing: refining, distilling, manufacturing/processing produce into sugar, oil, spirits, wine, beer or similar products.

A written assurance of commercial processing will be needed annually.

Produce that will be processed is exempt from the PS Rule



Farms under the PS Rule can be classified as:

- a. Not covered by the Rule.
- b. Eligible for a **Qualified Exemption** with modified requirements.
- c. A “covered farm” by the PS Rule if they do not meet the conditions for a qualified exemption.

a. The Produce Safety Rule does not cover:

1. A farm that sells less than \$25,000 in **PRODUCE** (average of the last 3 years- starting in 2016).
2. Produce that is grown by an individual for **personal consumption**.
3. Produce that is **not a raw agricultural commodity**.

What farms are eligible for a Qualified Exemption and modified requirements?

1. Do you sell the majority of your produce to consumers, restaurants, or retail establishments within North Carolina or not more than 275 miles from the farm or via Internet?

2. Is the food sold by the farm **less than \$500,000 annually (average of the last 3 years)**?

“Food” means articles used for food or drink for man or animals, or articles used to make components of it. Includes seeds and beans used to grow sprouts.

If the answer is “Yes” to questions 1 and 2, the Farm is eligible for a Qualified Exemption.

Qualified exemptions

If the farm is eligible for a qualified exemption the farm has to comply/ is subject to the following:

- Labeling
- Record keeping guidelines (Subpart O)
- Compliance and enforcement (Subpart Q)
- Withdrawal of a qualified exemption (Subpart R)

Qualified exemptions under the PS Rule

The good news..

Qualified Exempt operations do not have to comply with the same guidelines set for “covered farms”.

However...

If a farm does not follow the minimum labeling and recordkeeping requirements set for these qualified exempt farms

OR

If there is an active investigation for being a suspect in a food borne illness outbreak based on conduct or conditions associated with the farm.



Then the farm can lose its Qualified Exemption and will have 60 days to comply with all the provisions set for “Covered farms”.

Qualified exemptions

Records required (annually):

Effective (1/26/2016)

- A farm must establish and keep adequate records necessary to demonstrate that the farm satisfies the criteria for a qualified exemption, including a written record reflecting that an annual review has been performed and verification of the farm's continued eligibility for the qualified exemption.

Qualified exemptions

Labeling Requirements

(Effective 1/1/2020)

-Name and the business address of the farm where the produce was grown in any food packaging label.

-When food packing label is not required, display at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard or documents delivered with the produce in the normal course of business, or in the case of Internet sales, in an electronic notice.

Modified Requirements for Qualified Exemptions

Provisions	Covering	Dates
112.7(b)	Retention of records supporting eligibility for a qualified exemption	1/26/2016
112.6(b)(1)	Modified label requirements for produce sold by qualified exempt farms	1/1/2020

“Covered Farms”

Standards for Produce Safety

- Personnel qualifications and training
- Worker health and hygiene
- Agricultural water
- Biological soil amendments of animal origin and human waste
- Domesticated and wild animals
- Equipment, tools, buildings and sanitation
- Growing, harvesting, packing and holding activities
- Specific requirements for sprouts

Compliance dates for “Covered Farms”

Covering	All other businesses (Over \$500K)	Small businesses (\$250K-\$500K Produce sales)	Very small businesses (\$25K-\$250K Produce sales)
Most provisions in the Produce Safety Rule	1/26/2018	1/28/2019	1/27/2020
For water related regulations outlined in the PS Rule	1/27/2020	1/26/2021	1/26/2022
Sprouts	1/26/2017	1/26/2018	1/28/2019

Covered Farms – steps to follow.

1. Attend a PSA Grower Training- this is a one-time, all day class requirement for at least one person per farm that goes over the requirements for the different parts of the Rule. Next class: 2/7/2017 – Asheville, NC.
2. Become familiar with the standards/guidelines set for farms to determine what you are already doing vs what you will need to change. No need to duplicate records.
3. Foster a food safety culture at the Farm.
4. Implement practices by the compliance dates published.

[Home](#) » Produce Safety Rule Growers Training

Produce Safety Rule Growers Training

This is a one-day training course for growers on the Produce Safety Alliance (PSA) standardized curriculum that meets the regulatory requirements of the FDA's Food Safety Modernization Act (FSMA) Produce Safety Rule.



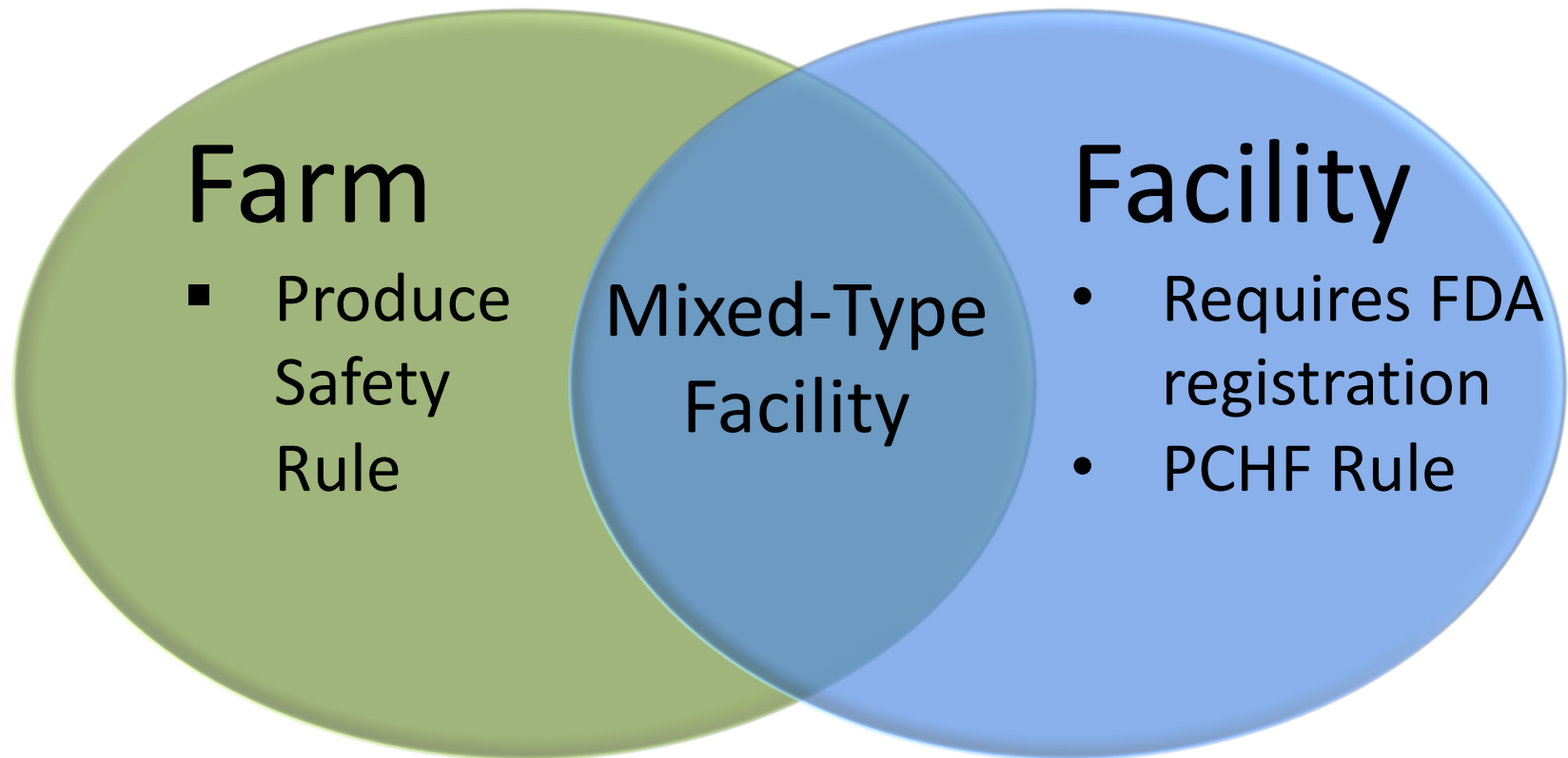
Dates and Locations:

* Workshops targeted to farming businesses with earliest [compliance dates](#).

* Register for December 6, 2016	Johnston County Agricultural Center	2736 NC Highway 210 Smithfield, NC 27577
* Register for January 12, 2017	Mountain Horticultural Crops Research and Extension	455 Research Drive Mills River, NC 28759

FDA Updated Definitions

Farms vs. Facility



*Operations defined as a “farm”
are not subject to the PCHF rule*

Can your farm fall under the PC Rule?

- *Farm Definition: Primary Production Farm and Secondary Activities.*
- If the farm does more than grow, harvest, pack and hold produce (like further process/manufacture) then the farm may also have to comply with the Preventative Controls for Human Food (PC) Rule.
- We are waiting on guidance regarding ownership and how farms are structured because under the current guidelines, a farm may have to comply with the PC Rule even though the farm is not further processing if the majority of the produce it packs or holds does not belong to the farmer.

Why is this important?

- If you are making ice cream on the farm using farm-grown peaches and selling it at a farm stand or retail, then this type of processing is exempt from the PC Rule.
- However, if the ice cream is sold retail, it is likely covered by the PC Rule.

If you need assistance or would like more information about trainings:

Elena Rogers
Area Specialized Agent
Western NC
Office- Caldwell County
Elena_rogers@ncsu.edu
828-352-2519

Otto "Chip" D. Simmons, III
Area Specialized Agent
Eastern NC
Office- Raleigh
odsimmon@ncsu.edu

<https://ncfreshproducesafety.ces.ncsu.edu>