

PRODUCE SAFETY RULE EXEMPTIONS AND EXCLUSIONS FOR WASHINGTON PRODUCE GROWERS



What Is the Produce Safety Rule?

This rule was developed by the U.S. Food and Drug Administration (FDA) to provide food safety standards for fresh produce from the field through packing and holding. This is just one regulation that was developed through passage of the Food Safety Modernization Act and aims to reduce the overall burden of foodborne illness in the United States. The formal name of the rule is *Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption* but is commonly referred to as the Produce Safety Rule, or PSR. The full text of the regulation can be found in the Code of Federal regulations in Title 21, Part 112 (U.S. FDA 2019c; Cornell Law School n.d.). It is important for food producers to know the new regulation and its requirements, even for farms which may fall under one of the exemptions, which will be discussed more below.

First, establish if produce is grown: produce is considered any fruit or vegetable (including mixes of intact fruits and vegetables), mushrooms, sprouts of any type, peanuts, tree nuts, and herbs (§112.3). Grains, such as amaranth, barley, buckwheat, corn (dent or flint), oats, quinoa, rice, rye, sorghum, and wheat, are not considered produce. Oilseeds, which include cotton seed, flax seed, rapeseed, soybean, and sunflower seeds, are also not considered produce. If produce is grown, continue to read to learn more about exclusions and exemptions to the PSR.

How Do I Determine if my Farm Must Comply with the PSR?

There are two categories that growers may fall into if their farm does not have to comply with the full PSR requirements, these are farms which are excluded from all requirements of the PSR and farms which are exempt from certain requirements of the PSR (Figure 1). It is important be knowledgeable on the details behind each of these exclusion and exemption criteria.

Exclusions		Exemptions	
1	ALL produce grown is rarely consumed raw	1	ALL produce grown receives a kill step
2	Annual produce sales <\$25,000	2	Average annual FOOD sales to qualified end users
3	ALL produce grown is for personal consumption		

Figure 1. Three criteria under which produce growers may be excluded from the requirements of the Produce Safety Rule and two criteria under which growers may be exempt from certain requirements of the Produce Safety Rule.

Exclusions from the PSR

1) All produce grown is rarely consumed raw

There are certain produce commodities which will commonly receive a cooking step prior to consumption. The FDA wanted to make allowances for growers that were only farming these commodities so that they could be exempt from the requirements of the PSR. In order to determine this list, they relied upon an annual food consumption survey conducted by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture. Any produce items which were consumed raw <0.1% of the time by the U.S. population based upon this survey were excluded from the requirements of the PSR (§112.2(a)(1)) and are shown below in Figure 2 (Federal Register 2015).

There are some limitations to the use of these data. To determine which produce is rarely consumed raw, that produce had to be consumed by at least 1% of the survey respondents in order to be considered for this exclusion—there are some commodities that are not regularly consumed by U.S. citizens. In March of 2019, the FDA announced that they recognized the low risk of certain commodities which were not

Produce Rarely Consumed Raw

Asparagus	Sour Cherries	Horseradish
Beans	Chickpeas	Hazelnuts
Black	Cocoa Beans	Lentils
Great Northern	Coffee Beans	Okra
Kidney	Collards	Peanuts
Lima	Corn (sweet)	Pecans
Navy	Cranberries	Peppermint
Pinto	Dates	Potatoes
Garden Beets	Dill	Pumpkins
Roots & tops	Seeds & weed	Squash (winter)
Sugar Beets	Eggplant	Sweet Potatoes
Cashews	Figs	Water Chestnuts

Figure 2. Produce which is rarely consumed raw and therefore excluded from requirements of the PSR.

originally considered as rarely consumed raw. As a result, producers of hops, wine grapes, pulse crops, and almonds would not be expected to adhere to the PSR (U.S. FDA 2019a). The FDA has developed a factsheet on rarely consumed raw produce where more information can be found (n.d.).

Any produce crop which is not excluded through this provision is said to be “covered” by the Produce Safety Rule and is referred to as covered produce.

If you are farming covered and non-covered produce, then the requirements of the PSR do not apply to those crops in Figure 2, but PSR requirements still apply to all other covered produce grown on the farm.

2) Annual produce sales <\$25,000

If a farm has less than \$25,000 of annual produce sales based upon a three-year rolling average, it is excluded from the PSR (§112.4) (Federal Register 2015). The \$25,000 is adjusted for inflation using 2011 as a baseline; an updated dollar value can be found at the FSMA Inflation Adjusted Cut Offs webpage (U.S. FDA 2019b). For instance, in 2019, a farm would need to have average annual produce sales of less than \$27,528 from 2016 to 2018.

3) All produce grown is for personal consumption

If produce is only grown for personal consumption or produced for consumption on another farm under the same management then it is not subject to the PSR (§112.2(a)(2)) (Federal Register 2015).

Exemptions from the PSR

1) All produce grown receives a kill step

Any covered produce grown which will be destined to further commercial processing where a kill step is applied to inactivate harmful foodborne pathogens which may be present are exempt from the provisions of the PSR (§112.2(b)). If taking this exclusion, the produce must be accompanied with documents stating that it is “not processed to adequately reduce the presence of microorganisms of public health significance.” Additionally, written assurances described in §112.2(b)(3) will be obtained from customers on an annual basis.

2) The farm meets the requirements for a qualified exemption

A farm may qualify for an exemption based on the value of annual sales of all food and the sales to qualified end users (§112.5).

Food is defined by the PSR (via the Federal Food, Drug and Cosmetic Act Sec. 201(f)) as “(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” (U.S. Congress). Based on this definition, food is inclusive of anything that can be consumed by an animal or human and includes hay, grain, meat, poultry, and produce. Also included in this definition is the sale of live animals.

A qualified end user is the consumer of the food, such as a restaurant or retail establishment, that is located within the same state or Indian reservation as the farm that produced the food or not more than 275 miles from the farm (§112.3(c)).

If a farm has less than \$500,000 of annual food sales based on a three-year rolling average and the majority of all food sales are made to qualified end users, then the farm may take the qualified exemption. As was the case with the \$25,000 exclusion, the \$500,000 is adjusted for inflation using 2011 as a baseline; an updated dollar value can be found at the FSMA Inflation Adjusted Cut Offs webpage (U.S. FDA 2019b). For example, in 2019, a farm would need to have average annual food sales of less than \$550,551 when averaging sales from 2016 to 2018.

If a farm is eligible for a qualified exemption, there are still provisions of the PSR it must adhere to:

- Requirements for records, described in Subpart O, including documentation of annual food sales and sales to qualified end users. In order to provide an

easy reference for requirements of records needed to demonstrate eligibility for the qualified exemption, the entire text of Subpart O is included below (see Appendix 1, Subpart O—Records). As discussed in §112.7, farmers and producers must keep records to demonstrate adherence to the established criteria for the qualified exemption. These records must be reviewed, signed, and dated by a supervisor or responsible party. For farms that have not been collecting this information, they should begin to do so this growing season.

- Compliance and enforcement provisions as described in Subpart Q.
- The conditions under which the FDA may withdraw a qualified exemption, described in Subpart R, which includes scenarios under which a qualified exempt farm has been associated with a foodborne outbreak or there is a reason to believe that the farm may be selling adulterated produce.
- Labeling requirements, described in §112.6(b), state that farms must include the name and business address (including street address, city, state, and zip code) where the produce was grown, either on the label or at the point of purchase. Farms have until January 1, 2020 to adhere to this labeling requirement.

Applying PSR Compliance

It is important to understand if your farm is PSR compliant. If you believe that your farm may be excluded from PSR compliance or be able to take an exemption but you would like to discuss further, reach out to Washington State University Extension to help answer your questions.

An in-depth example has been provided for accurately identifying if an exclusion or exemption applies (see Appendix 2, Activity: Turley Acres section below).

Acknowledgements

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Appendix 1

Subpart O—Records

§ 112.161

What general requirements apply to records required under this part?

- (a) Except as otherwise specified, all records required under this part must:
- (1) Include, as applicable:
 - (i) The name and location of your farm;
 - (ii) Actual values and observations obtained during monitoring;
 - (iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;
 - (iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and
 - (v) The date and time of the activity documented;
 - (2) Be created at the time an activity is performed or observed;
 - (3) Be accurate, legible, and indelible; and
 - (4) Be dated, and signed or initialed by the person who performed the activity documented.
- (b) Records required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

§ 112.162

Where must I store records?

- (a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.
- (b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.

Appendix 1, *continued*

§ 112.163

May I use existing records to satisfy the requirements of this part?

- (a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part.
- (b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 112.164

How long must I keep records?

- (a)(1) You must keep records required by this part for at least 2 years past the date the record was created.
- (2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year.
- (b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

§ 112.165

What formats are acceptable for the records I keep?

You must keep records as:

- (a) Original records;
- (b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or
- (c) Electronic records. Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 112.166

What requirements apply for making records available and accessible to FDA?

- (a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.
- (b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.
- (c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.

§ 112.167

Can records that I provide to FDA be disclosed to persons outside of FDA?

Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

Appendix 2

Activity: Turley Acres

Rhonda Turley operates a 124 acre farm in Sprague, WA where she raises an array of vegetables and small fruits for sale through her CSA and a distributor. Rhonda has a diversified farm where she raises layer hens and harvests eggs for inclusion in her CSA along with beef that is from cattle she raised. An example Farm Sales Record has been included (below). This is where all sales (those with and without receipts) are logged.

1. Using the information in the Farm Sales Record (*below*) determine for each of the sales from June 1 to June 2 if they were to a qualified end user.
 - a. _____
 - b. _____
 - c. _____
 - d. _____
 - e. _____
2. Using the information in the farm description and the Annual Review of Farm Food Sales Record (below), determine the three-year rolling average food sales.
3. Using the same information, determine the three-year rolling average food sales to qualified end users.
4. Using the answers from steps 2 and 3, determine the percentage of sales going to qualified end users during this period.
5. Is Turley Acres able to take a qualified exemption for the 2021 growing season? Use the section below: Qualified Exemption Annual Review of Three-Year Farm Food Sales (Example Record) to document your results.
6. In 2022, Turley Acres decided to focus on a business model with only wholesale sales and a limited number of crops grown, restricted to potatoes, sweet potatoes, pumpkins, and chickpeas. Rhonda is anticipating sales of \$682,976 for the 2022 growing season. Do any exemptions or exclusions apply to Turley Acres? Should Rhonda plan to make the farm PSR-compliant?

Turley Acres
 1242 Spence Ln.
 Sprague, WA 24932

Farm Sales Record

Date (mm/dd/yy)	Item Sold	Value	Sold To	Address	Qualified End User (Y/N)
06/01/17	1-CSA Share	\$515	Albert Jones	425 Lake Dr. Colfax, WA 42352	a)
06/01/17	5-24 ct 40lb box beets 2-40lb boxes of onions	\$190	Horn of Plenty Market	2459 Miner St. Spokane, WA 45924	b)
06/02/17	1-CSA Share	\$515	Mandy Davenport	425 Nolen Rd. Moscow, ID 45925	c)
06/02/17	1-CSA Share	\$515	Luke Thomas	3241 Cougar Way Pullman, WA 49521	d)
06/02/17	20-20lb bag fingerling potatoes 20-12.5pt flat 3lb raspberries 30-40lb boxes of onions	\$1,880	Noble and Sons Distributing	242 Heston Way Spokane, WA 45924	e)

Created by: _____ Date: _____

Reviewed by: _____ Date: _____

Turley Acres
1242 Spence Ln.
Sprague, WA 24932

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Sprague, WA 24932

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Sprague, WA 24932

Annual Review of Farm Food Sales

January 1, 2015–December 31, 2015

Sales Category	Value of Food
CSA shares	\$77,250
Produce sales to local retailers (qualified end users)	\$125,145
Produce sales to distributors	\$183,063
Total Food Sales	\$385,458

52.5% of sales to qualified end users.

Created by: Samantha Turley

Date: 1/17/16

Reviewed by: Rhonda Turley

Date: 1/21/16

Annual Review of Farm Food Sales

January 1, 2016–December 31, 2016

Sales Category	Value of Food
CSA shares	\$97,250
Produce sales to local retailers (qualified end users)	\$145,145
Produce sales to distributors	\$209,463
Total Food Sales	\$451,858

53.7% of sales to qualified end users.

Created by: Mike Jones

Date: 1/18/17

Reviewed by: Rhonda Turley

Date: 1/19/17

Annual Review of Farm Food Sales

January 1, 2017–December 31, 2017

Sales Category	Value of Food
CSA shares	\$63,487
Produce sales to local retailers (qualified end users)	\$137,423
Produce sales to distributors	\$217,652
Total Food Sales	\$418,562

48.0% of sales to qualified end users.

Created by: Mike Jones

Date: 1/11/18

Reviewed by: Rhonda Turley

Date: 1/14/18

Qualified Exemption Annual Review of Three-Year Farm Food Sales (Example Record)

Farm Name _____
Street Address _____
City, State Zip _____

Qualified Exemption Annual Review of Three-Year Farm Food Sales

Sales Category	Value of Food Sales ¹	Value of Food Sales to Qualified End Users ¹
1st Year (20__)	\$	\$
2nd Year (20__)	\$	\$
3rd Year (20__)	\$	\$
Average 3-Year Food Sales	\$	\$

¹Receipts and records must be retained that were used to obtain this value.

Average Value of Food Sales \$ _____ (Must be at or below \$500,000 in 2011 dollars. See <http://bit.ly/FSMAIACO> for average three-year cut-off value).

Average % Food Sales to Qualified End Users _____ % (Must be greater than 50.0%)

Created by: _____ Date: _____

Reviewed by: _____ Date: _____

References

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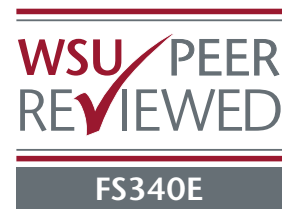
Answer Key for Appendix 2

- 1a. Yes, 1b. Yes, 1c. Yes, 1d. Yes, 1e. No
2. Previous three-year (calendar year) rolling average of food sales is \$418,626.
3. Previous three-year rolling average of food sales to qualified end users is \$215,233.
4. 51.4% of all food sales were to qualified end users.
5. Yes, the average annual sales of food were below the cut-off, adjusted for inflation of \$541,119 (\$418,626) for the previous three-year period AND the majority of all sales were to qualified end users. The cut-off value can be found online at <http://bit.ly/FSMAIACO>. In this example the three previous calendar years were 2015, 2016, and 2017. The inflation adjusted cut-off was \$533,822 (2015), \$539,672 (2016), and \$549,863 (2017).

$$\$533,822 + \$539,672 + \$549,863 = \$1,623,357$$

$$\$1,623,357 \div 3 = \$541,119$$
6. All the crops grown by Turley Acres are exempt from the PSR since they are rarely consumed raw.

By
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