

FSMA Produce Safety Rule Exemptions and Exclusions for Washington Grape Growers

Faith Critzer

Associate Professor

Produce Safety Extension Specialist



WASHINGTON STATE
UNIVERSITY

PRODUCE SAFETY



Food Safety Modernization Act (FSMA)

- Most sweeping reform of our food safety laws in more than 70 years
- Signed into law by President Obama on January 4, 2011
- Aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it
- Regulations resulting from the passage of FSMA
 - **Produce Safety**
 - Preventative Controls for Human Food
 - Foreign Supplier Verification
 - Accredited Third-Party Certification
 - Preventative Controls for Animal Food



Produce Safety Rule (PSR)

- 21 CFR Part 112: *Standards For The Growing, Harvesting, Packing, And Holding Of Produce For Human Consumption*
 - a.k.a. Produce Safety Rule (PSR)
- Overall goal- decrease the amount of foodborne illness related to produce contamination



Compliance Dates for the PSR

Business Size	General Provisions	Water-related Provisions	Qualified Exemption Labeling Requirement	Record Retention to Support Qualified Exemption	Written Assurances for Commercial Processing
All other businesses (>\$500K)	1/26/18	1/26/22	1/1/2020	1/26/16	1/26/20
Small businesses (>\$250K-500K)	1/28/19	1/28/23			1/28/21
Very small businesses (>\$25K-250K)	1/27/20	1/27/24			1/27/22



I wonder if my farm has to comply?



- Some farms may be **excluded** from the requirements of the PSR
- Other farms may be **exempt** from certain requirements of the PSR
- Our **goal** is that after this session you will know how to determine if your farm meets one of the exclusion or exemption criteria established for the PSR



Do you grow produce



- “Produce” defined as fruits and vegetables
- Produce includes mushrooms, sprouts, herbs and tree nuts
 - Section 112.1- list that is not exhaustive
- NOT Produce
 - Grains, such as amaranth, barley, buckwheat, corn (dent or flint), oats, quinoa, rice, rye, sorghum, and wheat
 - Oilseeds, which include cotton seed, flax seed, rapeseed soybean and sunflower seeds, are also not considered produce.



Am I produce?

Mung Bean Sprouts



Herbs



Mushrooms



Grapes



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

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 <u>FOOD</u> sales to qualified end users
3	ALL produce grown is for personal consumption		



Exclusions to the PSR

Exclusions

1

ALL produce grown is rarely consumed raw

2

Annual produce sales <\$25,000

3

ALL produce grown is for personal consumption

- Certain produce commodities which will receive a cooking step prior to consumption.
- FDA populated a list
- Based 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 were excluded from the requirements of the PSR ([§112.2\(a\)\(1\)](#))



Produce Rarely Consumed Raw

Asparagus

Beans

Black

Great Northern

Kidney

Lima

Navy

Pinto

Garden beets

Roots and tops

Sugar beets

Cashews

Sour cherries

Chickpeas

Cocoa beans

Coffee beans

Collards

Corn (sweet)

Cranberries

Dates

Dill

Seeds and weed

Eggplants

Figs

Horseradish

Hazelnuts

Lentils

Okra

Peanuts

Pecans

Peppermint

Potatoes

Pumpkins

Squash (winter)

Sweet Potatoes

Water Chestnuts



Limitations to the rarely consumed raw list

- Produce had to be consumed by at least 1% of the survey respondents in order to be considered for this exclusion
- Some commodities that are not regularly consumed by Americans.
- One commodity which is not regularly consumed by the public in its raw form that is widely grown in Washington is hops.
 - Hops in brewing demonstrates no consumption in a raw state, but since hops are not on the list of commodities in ([§112.2\(a\)\(1\)](#)) this exclusion does not apply



Covered Produce

- Any produce crop which is not excluded through this provision is said to be “covered” by the produce safety rule
 - Referred to as covered produce.
- If you are farming covered and non-covered produce, then the requirements of the PSR do not apply for those crops in the “rarely consumed raw list” but apply to all other covered produce grown on the farm



Photo: USDA NRCS



Exclusions to the PSR

Exclusions

1

ALL produce grown is rarely consumed raw

2

Annual produce sales
<\$25,000

3

ALL produce grown is for personal consumption

- If the farm has <\$25,000 of annual produce sales based upon a three-year rolling average it is excluded from the PSR ([§112.4](#))
- The \$25,000 is adjusted for inflation using 2011 as a baseline
 - Updated dollar value can be found at <http://bit.ly/FSMAIACO>
 - In 2018, a farm would need to have average annual produce sales of less than \$26,999 when averaging sales from 2015-2017 to receive this exclusion



Exclusions to the PSR

Exclusions

1

ALL produce grown is rarely consumed raw

2

Annual produce sales <\$25,000

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\(a\)\(2\)](#)).



Exemptions to the PSR

Exemptions

1

ALL produce grown receives a kill step

2

Average annual FOOD sales to qualified end users

- For any covered produce grown which will be destined to further commercial processing with a kill step



Question of the day, is the wine making process considered a kill step?

Exemptions

1

ALL produce grown receives a kill step

2

Average annual FOOD sales to qualified end users

- Yes, the process of fermentation has been documented to reduce microorganisms of public health significance
 - Draft Produce Safety Rule Guidance pg 13



Question of the day, is the juicing process considered a kill step?

Exemptions

1

ALL produce grown receives a kill step

2

Average annual FOOD sales to qualified end users

- Yes, all commercially processed juices must receive a pasteurization process which has been documented to cause a 99.999% inactivation of pertinent foodborne pathogens.
 - Draft Produce Safety Rule Guidance pg 13



What do I need to do if taking this exemption?

Exemptions

1

ALL produce grown receives a kill step

2

Average annual FOOD sales to qualified end users

- Documentation and Records
 - The produce must be accompanied with documents stating that it is “*not processed to adequately reduce the presence of microorganisms of public health significance*”
 - Written assurances described in [§112.2\(b\)\(3\)](#) will be obtained from your customers on an annual basis



What do I need to do if taking this exemption?

Exemptions

1

ALL produce grown receives a kill step

2

Average annual FOOD sales to qualified end users

- The produce must be accompanied with documents stating that it is “*not processed to adequately reduce the presence of microorganisms of public health significance*”
- Many people will include this statement on
 - Labels or labeling
 - Bills of lading
 - Shipment-specific certificate of analysis
 - Any other documents associated with that shipment



Written Assurances

Business Size	Written Assurances for Commercial Processing
All other businesses (>\$500K)	1/26/20
Small businesses (>\$250K-500K)	1/28/21
Very small businesses (>\$25K-250K)	1/27/22

- **Annually** obtain written assurance **from the customer that performs the commercial processing** that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or that an entity in the distribution chain subsequent to the customer will perform commercial processing
- FDA currently exercising enforcement discretion
 - May need to change the rule, but we know there is at least a two year delay as shown in the table



Exemptions to the PSR

Exemptions

1

ALL produce grown receives a kill step

2

Average annual FOOD sales to qualified end users

- A farm may be able to take a qualified exemption based upon their annual food sales and if they are selling to a qualified end user.



Qualified Exemption- Important Definitions

- This exemption is based on all food sales
- Food is defined by the PSR as a what has been established by 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”*.
- Food is inclusive of anything that can be consumed by an animal or human
 - e.g. hay, grain, meat, poultry, and produce.
 - Sale of live animals



Am I food?



Qualified Exemption- Important Definitions



- Qualified end users is another important definition
- A qualified end user is the consumer of the food, 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\(c\)](#)).



Qualified Exemption

- If a farm has less than \$500,000 of annual food sales based upon 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



Qualified Exemption

- \$500,000 is adjusted for inflation using 2011 as a baseline
- An updated dollar value can be found at <http://bit.ly/FSMAIACO>
- As an example, for last year, a farm would need to have average annual food sales of less than \$539,982 when averaging sales from 2015-2017.



Qualified Exemption Requirements- Records

- Maintain records to document annual food sales and sales to qualified end users
- You must keep records to demonstrate adherence to the established criteria for the qualified exemption
- For farms who have not been collecting this information, they should begin to do so this growing season
- Example records have been included



Qualified Exemption Requirements

- Compliance and enforcement provisions as described in [Subpart Q](#).
- The conditions under which the FDA may withdraw a Qualified Exemption, described in [Subpart R](#)
 - 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.



Qualified Exemption Requirements- Labeling

- Either on the label or at the point of purchase, you must include the:
 - Farm name,
 - Business address inclusive of street address, city, state and zip code of the farm where the produce was grown
- Farms have until January 1, 2020 to adhere to this labeling requirement.



Take Home Message

- It is important to understand where your farm falls with respect to PSR compliance
- If you believe that your farm may be excluded from PSR compliance or be able to take an exemption, but would like to discuss further, ask us now!
- If you are taking the commercial processing exemption, begin to include documentation on invoices or other documents which accompany the grapes as sold AND begin to establish a process for annually obtaining written assurances from your buyers



Thank you

Funding for this publication was made possible, in part, by the Food and Drug Administration through grant PAR-16-137. The views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.



Washington
State Department of
Agriculture





WASHINGTON STATE
UNIVERSITY
PRODUCE SAFETY

Contact Info

Faith Critzer

faith.critzer@wsu.edu

509-786-9203

