



## Idaho Produce Safety Video Series

Brought to you by:  
Idaho State Department of Agriculture  
University of Idaho Extension



# Exempt and Qualified Exemption

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*\*\*\*websites and links, CTRL+click to follow link\*\*\**

### *Introduction:*

**H**ello! This presentation will cover what it means to be exempt or qualified exempt from the Food and Drug Administration (FDA), Food Safety Modernization Act (FSMA), Produce Safety Rule (21 CFR Part 112) and what documentation is required to maintain that status.

Many, if not all, farms will be impacted by at least part of the Food Safety Modernization Act Produce Safety Rule, even those that are very small.

Record keeping is the key to documenting your farm's status. If your farm or operation is exempt from the requirements of the Food Safety Modernization Act, Produce Safety Notes

Rule, it is not subject to the requirements of part 112. If your farm is eligible for a qualified exemption, you are subject to some requirements of the Produce Safety Rule, such as Record Keeping.

It is important to note that just because your farm or some of the commodities you grow may be exempt under the Produce Safety Rule, you might not be exempt from other Food Safety Modernization Act rules. It is also important to remember that if at any time there is an active investigation of a foodborne illness outbreak that is directly linked to the farm, or if the FDA determines it is necessary to protect public health, a farm's qualified exemption may be withdrawn.

**T**hroughout this presentation please pay attention to the word **MUST** and **SHOULD**. **MUST** indicates that it is required by the Produce Safety Rule. **SHOULD** indicates suggested good agricultural practices. There are certain words you may hear throughout this video that will be helpful for you to understand. Definitions will be provided within the video as they are mentioned.

You may print out this presentation and keep it for your records to use anytime you would like. This will be available for viewing on the Idaho State Department of Agriculture and University of Idaho Extension websites. It is a good idea to have a copy of the [Produce Safety Rule](#) with you, so you can reference the rule throughout this presentation and you may pause this video at any time.

We'll discuss the definitions of each type of exemption and the records that **MUST** be maintained. There are also many tools to help you determine your status, including one developed right here in Idaho, so let's get started!

**F**irst, we'll cover what makes a farm exempt from the Produce Safety Rule. Then we'll discuss the commercial processing exemption. Next, I'll explain a qualified exemption status. Lastly, we'll go through the record keeping requirements for this part of the Produce Safety Rule.

#### *Exemption Status:*

First let's talk about exemption status. This list identifies conditions for exemption under 21 CFR 112, the Produce Safety Rule. If your farm or the commodities you grow are exempt from the Produce Safety Rule, it means that the farm or commodity is NOT subject to the requirements of The Produce Safety Rule.

Notes

The first condition is based on your average annual produce sales over the previous three years.

## What conditions make my farm Exempt from the Produce Safety Rule?

- Average annual produce sales
  - Farms with produce sales of less than or equal to \$25,000 per year are not covered. (Subpart A—General Provisions, Section 112.4(a))
- Based on commodities grown.
  - Produce that is rarely consumed raw is not covered. (Subpart A—General Provisions, Section 112.(a)(1))
  - Produce that is not a raw agricultural commodity. (Subpart A—General Provisions, Section 112.3(b))
  - Food grains are not produce; therefore, not covered. (Subpart A—General Provisions, Section 112.3)
- Produce that is produced by an individual for personal consumption or produced for consumption on the farm is not covered. (Subpart A—General Provisions, Section 112.2(a)(2))

If your farm has less than or equal to an average of \$25,000 [adjusted for inflation](#) in produce sales over the previous three years, your farm is not covered by the Produce Safety Rule.

### Commodities:

**T**he second condition for exemption is based on what commodities or produce you grow, harvest, pack, or hold. Only those commodities that are Rarely Consumed Raw are considered exempt from the Produce Safety Rule.

Exhaustive List of Rarely Consumed Raw Produce		
Asparagus	Garden Beets (roots and tops)	Hazelnuts
Black Beans	Sugar Beets	Horseradish
Great Northern Beans	Cashews	Lentils
Kidney Beans	Sour Cherries	Okra
Lima Beans	Chickpeas	Peanuts
Navy Beans	Cocoa Beans	Pecans
Pinto Beans	Coffee Beans	Peppermint
Cranberries	Collards	Potatoes
Dates	Sweet Corn	Pumpkins
Dill (seeds and weed)	Figs	Winter Squash
Eggplants	Ginger	Sweet potatoes
		Water chestnuts

Notes

In Subpart A—General Provisions, Section 112.2 there is an exhaustive list of produce not covered by the Produce Safety Rule because they are rarely consumed raw. If you ONLY grow, harvest, pack and/or hold produce included on the exhaustive list, your farm is not required to comply with the Produce Safety Rule.

For example, if you grow commodities such as asparagus, potatoes, eggplants, hazelnuts, and sweet potatoes, you are not covered by the rule, but if you grow potatoes (which are not covered) and onions (which are considered a raw agricultural commodity and therefore, covered produce), depending on your average annual sales amount, you may be covered by the rule.



Food grains are not produce; therefore, are not covered by the Produce Safety Rule. Examples of food grains include barley, wheat, and rice.

**“Covered Produce”** is produce that is subject to the requirements of the FSMA Produce Safety Rule in accordance with Section 112.1 and Section 112.2. It refers to the harvestable part of the crop

#### *Personal Consumption:*

Least but not least, produce that is produced by an individual for personal consumption or produced for consumption on the farm is not covered by the Produce Safety Rule. Therefore, farms where the produce is not for sale, are not subject to the requirements of the Produce Safety Rule.

There are several scenarios in which a farm may or may not be exempt from the Produce Safety Rule provided on the Idaho State Department of Agriculture and University of Idaho Extension websites. You can find links to these scenarios listed below in the video description.

Notes

Idaho Produce Safety Seri...

Part 3: Recordkeeping - Agricultural Water  
Run Time - 14m 47s

Idaho Produce Safety Seri...

Part 4: Exemptions and Qualified Exemption  
Run Time - 17m 5s

Idaho Produce Safety Seri...

Part 5: Health and Hygiene  
Run Time - 10m 49s

The following scenarios may help you determine if your farm/operation is exempt or qualified exempt from the FSMA Produce Safety Rule:

[Exemption Scenarios](#)

[Qualified Exemption Scenarios](#)



### Commercial Processing:

Let's discuss farms that are selling their produce for commercial processing and those farms that may be considered Qualified Exempt. If your farm is selling produce that will be commercially processed or if your farm is eligible for a qualified exemption there are still requirements you **MUST** meet to maintain that status.

The commercial processing exemption relates to growing covered produce that will not be consumed raw but will be processed instead.

Examples of commercial processing include refining, distilling, or otherwise manufacturing or processing produce into products such as sugar, oil, spirits, wine, beer or similar products.

**N**ow let's talk about what would be required of a farm that is eligible for a commercial processing exemption.

Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for an exemption from the Produce Safety Rule, as noted in Subpart A-General Provisions section 112.2(b).



In order to maintain this exemption a farm **MUST**:  
Disclose in documents accompanying the produce that the produce is "not processed to adequately reduce the presence of microorganisms of public health significance,"

AND

The farm **MUST** annually obtain written assurance from the customer that performs the commercial processing that the customer follows procedures that adequately reduce the presence of microorganisms of public health significance.

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If the produce is sold more than once, before processing, the farmer ***MUST*** obtain written assurance from their customer that an entity in the distribution chain subsequent to their customer will perform commercial processing and documents will accompany the food stating that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”.

### Commercial Processing Exemption

**Microorganisms of public health significance:** include undesirable microorganisms that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated

**R**emember, you ***MUST*** receive annual written assurances from the customer to whom you are selling. All documentation ***MUST*** be in accordance with the requirements of Subpart A -- General Provisions and Subpart O -- Records.

Now let's talk about what you need to do once you know your farm status.

If your farm or operation is selling produce that will receive commercial processing, you are only subject to the following Subparts of the Produce Safety Rule:

- Subpart A--General Provisions.
- Subpart O--Records
- Subpart Q--Compliance and Enforcement

A farm that meets these standards outlined may be eligible for a  
**COMMERCIAL PROCESSING EXEMPTION**

### *Qualified End-User:*

**P**rior to going over the eligibility requirements for a qualified exemption, you'll need to understand the definition of Qualified End User and Food as it applies to the Produce Safety Rule. Knowing your farm's annual average sales is also important.

A Qualified End-User means the consumer of the food (not a business) or a restaurant or retail food establishment, including a grocery store or farmers market, that is located in the same state or the same Indian reservation as the farm that produces the food; OR not more than 275 miles from such farm.

### “Qualified End-User”

The consumer (not a business) of the food

A restaurant or retail food establishment that is located:

- a. In the same state or the same Indian reservation as the farm that produces the food; OR
- b. Not more than 275 miles from such farm

Notes

## “Food”

Articles used for food or drink for man or other animals, chewing gum, articles used for components of any such article, and includes seeds and beans used to grow sprouts

### Guidance Regulation:

Your farm may be eligible for a qualified exemption if during the 3-year period preceding the applicable calendar year you had less than \$500 thousand dollars in average annual food sales, [adjusted for inflation](#), AND a majority of the food (by value) was sold directly to “qualified end-users”.

**Does your farm on average (in the previous three years) as per Section 112.5: have < \$500k annual food sales, AND a majority of the food (by value) sold directly to “qualified end-users”?**

Section 112.3(c)

“Qualified End-User” as defined in Section 112.3(c) means:

- the consumer of the food OR
- a restaurant or retail food establishment that is located—
  - (i) in the same State or the same Indian reservation as the farm that produced the food; OR
  - (ii) not more than 275 miles from such farm.

(The term “consumer” does not include a business.)

**YES** E

**Your farm is eligible for a qualified exemption from this rule,** which means that you must comply with certain modified requirements and keep certain documentation, as per Sections 112.6 and 112.7.

**NO**

**YOU ARE COVERED BY THIS RULE.**

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**R**emember, this is all food not just produce grown on the farm. There are several scenarios to illustrate how qualified exemptions play out in the real world provided on the Idaho State Department Agriculture and University of Idaho Extension websites. You can find links to those scenarios listed below in the video description. [Exemption Scenarios](#). [Qualified Exemption Scenarios](#).

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*Qualified Exemption:*

**N**ow let's talk about what you need to do once you know your farm status. If your farm or operation is selling produce eligible for a qualified exemption, you are only subject to the following Subparts of the Produce Safety Rule:

- Subpart A--General Provisions.
- Subpart O--Records
- Subpart Q--Compliance and Enforcement; and
- Subpart R--Withdrawal of Qualified Exemption

If your farm is eligible for a qualified exemption, you **MUST**:

Establish and keep records required under Subpart A—General Provisions section 112.7 in accordance with the record keeping requirements of Subpart O—Records. This means that the general requirements for maintenance and storage of records apply to the records required under Subpart A—General Provisions section 112.7. We'll discuss this more in depth shortly.

You **MUST** establish and keep adequate records necessary to demonstrate that you meet the criteria for a qualified exemption related to average annual monetary value of food sales, and type and location of buyers.

**R**ecords may include:

- **RECEIPTS OF YOUR SALES TO DIFFERENT BUYERS; THESE SALES RECEIPTS ARE REQUIRED TO BE DATED, BUT NOT SIGNED OR INITIALED.**
- **LOCATION OF ANY BUYERS INCLUDING RESTAURANTS OR RETAIL FOOD ESTABLISHMENTS**
- **MONETARY VALUE OF SALES OF ALL FOOD AND**
- **ANY OTHER DOCUMENTATION THAT WILL VERIFY YOUR ELIGIBILITY FOR A QUALIFIED EXEMPTION**

You **MUST** review your sales annually to confirm your continued eligibility and **MUST** establish and keep a written record reflecting that you have performed an annual review and verification of your farm's continuing eligibility for the qualified exemption.



These records **MUST** be dated and signed or initialed by the person performing the activity such as the owner, operator, or agent in charge on the farm.

As mentioned previously, you are required by the Produce Safety Rule to keep records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption, Notes



including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption.

### Templates:

These are two examples of templates that are available for your use to meet this requirement. The first form was developed by the Produce Safety Alliance and the second was created by the Idaho State Department of Agriculture. You may also create your own form or record if you would like.

### Qualified Exemption Review Template

Produce Safety Alliance  
(PSA)

Name and address of farm: \_\_\_\_\_

Date: \_\_\_\_\_

**Total food sales** (in addition to produce, these sales include all other food for humans, feed for animals, and sales of live food animals)

Year 1 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 2 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 3 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_

A must be  
smaller than B  
for eligibility

**Average** total food sales \$ \_\_\_\_\_ **A**  
Inflation adjusted<sup>1</sup> threshold for (range) \$ \_\_\_\_\_ **B**

(for example, B is \$539,982 for 2015-2017)

**Sales to qualified end users** (QEUs) (e.g. consumers anywhere, or grocery stores and restaurants within 275 miles or within the same state or Indian reservation)

Year 1 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 2 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 3 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_

**Average** food sales to QEUs \$ \_\_\_\_\_ **C**

**Sales to non-QEUs** (e.g. wholesale buyers)

Year 1 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 2 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 3 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_

C must be  
larger than D  
for eligibility

**Average** food sales to non-QEUs \$ \_\_\_\_\_ **D**

Based on this information, this farm meets the criteria for a qualified exemption.

Reviewed by: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_

Sales receipts must also be retained to support this record.

<sup>1</sup>FDA updates the inflation adjusted value (B) yearly:

<https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>

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## Idaho State Department of Agriculture

You can see that both forms provide a place to show your average annual monetary value of all food the farm sold as well as calculations to help determine if more than 50% of the annual food sales went to qualified end users

In accordance with Subpart A -- General Provisions and Subpart O-Records, these records **MUST** be reviewed, dated and signed by a supervisor or responsible party at least annually.

In addition to keeping records on file documenting your farms' status, if you are eligible for a qualified exemption there are a few additional modified requirements that apply to you that are found in Subpart A—General Provisions section 112.6.

Farms eligible for a qualified exemption are required to include the name and complete business address of the farm where the produce was grown on the food packaging label or displayed at the point of purchase.

If you are selling at a farmer's market, a sign with this information would be sufficient, but if you are selling individual containers of produce to a grocery store, it may be more appropriate to include a label on each container of produce. In the case of Internet sales, you are



## Exemption & Qualified Exemption Review Worksheet

Name and Address of Farm: \_\_\_\_\_  
Date: \_\_\_\_\_

### Section 1 Exemption from the Produce Safety Rule (PSR)

Sales receipts or records reflecting total produce sales over the previous three (3) years:

Year 1 Produce Sales: \_\_\_\_\_  
Year 2 Produce Sales: \_\_\_\_\_  
Year 3 Produce Sales: \_\_\_\_\_  
Total Produce Sales: \$ \_\_\_\_\_ - (3-Year Period)  
Total Average Produce Sales: \_\_\_\_\_ #DIV/0!

Farms that grow, harvest, pack, or hold produce and have an average annual value of produce sold during the previous three-year period of \$25,000 or less are not covered by the PSR. 21 CFR 112 § 112.4(a)

Note: Produce includes all produce that is grown, harvested, packed, or held on the farm, not just covered produce.

#### Example:

How to find your Total Average Produce Sales:

Year 1	Year 2	Year 3	Total Average Produce Sales:
\$10,000 +	\$20,000 +	\$30,000 ÷ 3 (Years)	\$20,000

### Section 2 Qualified Exemption from the Produce Safety Rule (PSR)

\*Qualified end users are consumers of food such as restaurants or retail food establishments that are in the same state or Indian reservation as the farm that produced the food, or not more than 275 miles from such farm. Both of the following requirements must be met for qualified exemption: (1) more than 50% of your annual food sales are to qualified end users and (2) annual food sales are less than \$500,000 adjusted for inflation. 21 CFR §112.5 (a)(1)(2)

\*Food: means (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, and includes seeds and beans used to grow sprouts

All Food Sales to Qualified End Users (3 year)	Total Average Sales	#DIV/0! Percent of Sales to Qualified End Users
--	---------------------	--

#### Example:

How to find your Percentage of Food Sales to Qualified End Users:

\$ 10,000 ÷	\$ 30,000 x 100 =	33%
All Food Sales to Qualified End Users (3 year)	Total Average Sales	Percent of Sales to Qualified End Users

Reviewed By: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_  
Farm Owner/Manager/PIC

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required to include an electronic notice.

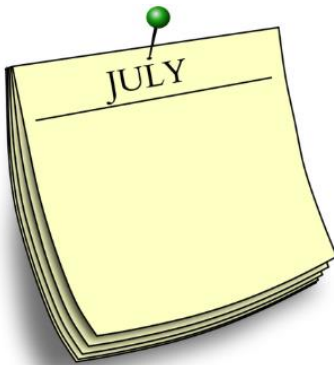
#### *Records:*

In addition to the items that ***MUST*** be listed in Subpart A -- General Provisions, Subpart O – Records includes general information about the storage of your records, allowable types of records, and acceptable formats for the records you keep.

As a reminder, if you're using records for compliance with other regulations, the records do not need to be duplicated so long as they contain the information needed for compliance with the Produce Safety Rule. You may need to adjust or supplement your current records to include required items listed in the Produce Safety Rule.

Records required by the Produce Safety rule ***MUST*** be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records.

Original records ***MUST*** be completed at the time the activity is performed and they ***MUST*** be dated and have the operator's original signature or initials on them.



Records ***MUST*** be kept for at least 2 years past the date the record was created. All required records ***MUST*** be readily available and accessible for inspection upon request. Offsite storage is permitted if records can be retrieved and provided onsite within 24 hours of a request for review by an inspector. All records obtained in accordance with the Produce Safety Rule are subject to the disclosure requirements under 21 CFR 20-The Public Information Act.

#### *Compliance and Enforcement:*

The third subpart that applies to those eligible for a qualified exemption is Subpart Q—Compliance and Enforcement.

Exemptions and qualified exemptions are not guaranteed. There are multiple situations where a qualified exemption may be withdrawn.

A farm's qualified exemption may be withdrawn: if there is an active investigation of a foodborne illness outbreak that is directly linked to the farm, or If FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm.

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## “Adulteration”

Food that is grown, harvested, packed or held in such conditions that are unfit for food OR food that has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health

### *Withdrawn Exemption:*

**B**efore a farm's qualified exemption is withdrawn, the FDA may consider other actions to protect public health and prevent or mitigate a foodborne illness outbreak including:

**A WARNING LETTER  
RECALL  
ADMINISTRATIVE DETENTION  
SEIZURE, OR  
INJUNCTION**

The FDA ***MUST*** notify the owner, operator, or agent in charge of the farm in writing of circumstances that may lead the FDA to withdraw the exemption and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the receipt of the notification; and The FDA ***MUST*** consider the actions taken by the farm to address the circumstance that may lead FDA to withdraw the exemption.



In summary, the Produce Safety Rule provides for exemptions and qualified exemptions based on circumstances that exist on some farms. The conditions that may qualify a farm for an exemption have to do with the average annual monetary produce sales, what types of commodities are grown on the farm, and if any of those commodities will receive commercial processing after harvest. It is a good idea to keep records to show annual monetary produce sales to justify an

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exemption. Those farms growing produce for commercial processing are required to show assurances about the future processing of their produce.

**F**arms that may be eligible for a Qualified Exemption are those that meet annual food sales requirements and sell to qualified end users. These farms are only subject to certain parts of the rule and are required to keep records to document the annual average food sales as well as certain record keeping requirements found in Subpart O -- Records.

It is also important to remember that just because your farm or some of the commodities you grow may be exempt under the Produce Safety Rule, you might not be exempt from other Food Safety Modernization Act rules.

We hope that you'll reach out to the Idaho State Department of Agriculture or University of Idaho Extension if you need help determining if you are eligible for any of the exemptions mentioned.

Thank you!

#### References:

1. "Produce Safety Alliance." *Welcome to the Produce Safety Alliance Website!* Produce Safety Alliance, [www.producesafetyalliance.cornell.edu/](http://www.producesafetyalliance.cornell.edu/)
2. NASDA, [www.nasda.org/](http://www.nasda.org/)
3. *US Food and Drug Administration Home Page*, Center for Biologics Evaluation and Research, [www.fda.gov/](http://www.fda.gov/)
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5. ECFR.io. "e-CFR: Code of Federal Regulations." *ECFR.io*, [www.ecfr.gov/](http://www.ecfr.gov/)
6. "Produce Safety Rule." *University of Idaho*, [www.uidaho.edu/extension/food-safety-for-produce-growers/food-safety-modernization-act/produce-safety-rule](http://www.uidaho.edu/extension/food-safety-for-produce-growers/food-safety-modernization-act/produce-safety-rule)
7. "Idaho State Department of Agriculture." *Idaho State Department of Agriculture*, [www.agri.idaho.gov/main/](http://www.agri.idaho.gov/main/)

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### **Idaho Produce Safety Video Series**

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