

Exemption Scenarios

For the FSMA, Produce Safety Rule 21 CFR Part 112



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Overview:

These scenarios are provided as examples to help those impacted by the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) better understand what it means to be exempt from the PSR. Names, characters, businesses, places, events, and incidents are either the products of the author's imagination or used in a fictitious manner. Any resemblance to actual persons, living or dead, or actual events is purely coincidental.

Your situation may be similar, simpler, or more complicated than these scenarios. If you need help determining your status, feel free to contact the Idaho State Department of Agriculture or University of Idaho Extension to visit about your situation.

FDA Coverage and Exemptions/Exclusions Decision chart

This chart was developed by the FDA as a step by step guide to help determine exemption status. It may be a helpful tool to guide you through determining your farm's status. Please see the website listed below for the full chart.



Compliance Dates

- Large/Other Businesses (>\$500,000): January 26, 2018
- Small Businesses (>\$250,000-\$5000,000): January 28, 2019
- Very Small Businesses (>\$25,000-\$250,000): January 27, 2020

💡 Dollar values represent the average annual monetary value of produce the farm sold during the previous 3-year period.



Situation

River Green Farms is a sprout operation with average annual produce sales of \$18,000.

Is River Green Farms covered or exempt from the rule?





Exempt

River Green Farms annual produce sales are less than \$25,000; therefore, not covered by the PSR.



Reminder:

- Farms with average produce sales of less than or equal to \$25,000 per year (during the previous 3 year period) are not covered by the Produce Safety Rule.



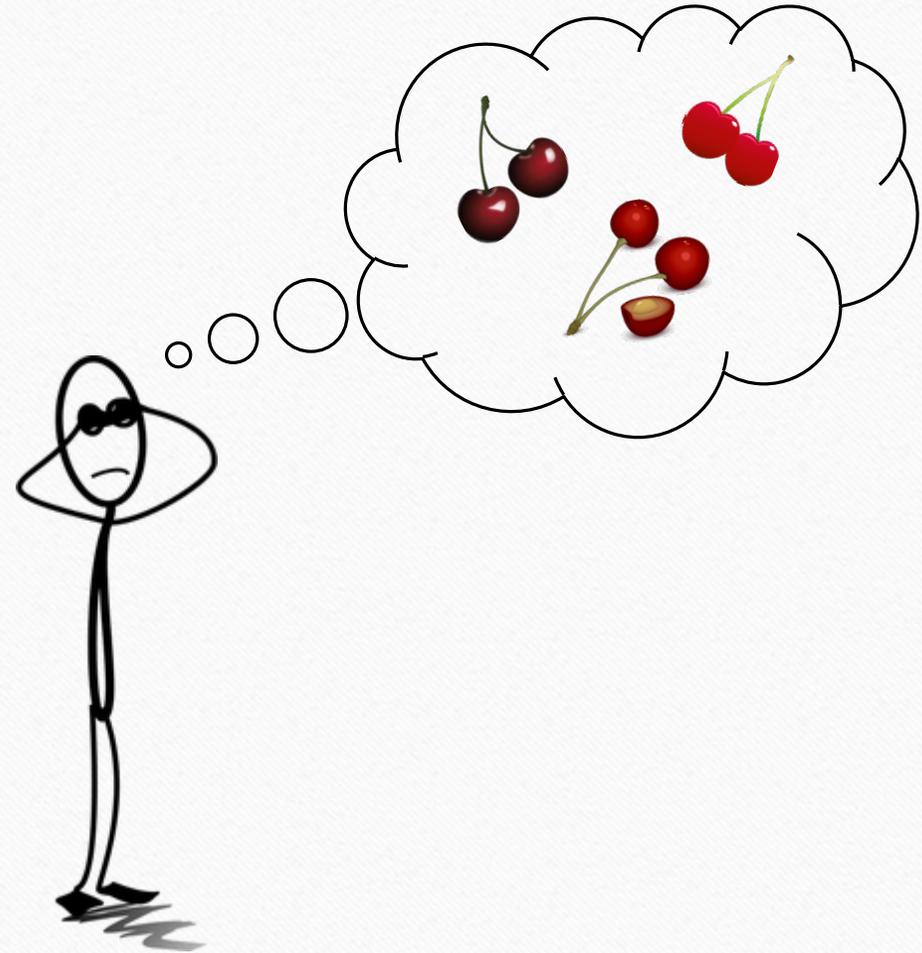
21 CFR 112.4(a)

Situation

Sweet Spring Farm is starting their third year in business and only grows three different varieties of sweet cherries.

In the **first year** the farm's produce sales were \$20,000. In the **second year** the farm's produce sales were \$35,000, for an average of \$27,500.

Is Sweet Springs Farms covered or exempt from the rule?





Covered

While Sweet Springs Farm has only been in business for two years, they would still be covered by the rule, because their average annual produce sales is over \$25,000. If a farm has been in business less than three years, use the annual produce sale values for the years in business, in this case, years 1 and 2.



Reminder:

- Farms with average produce sales of less than or equal to \$25,000 per year (during the previous 3 year period) are not covered by the Produce Safety Rule.
- The compliance date for farms of this size (\$25,000-\$250,000) is January 27, 2020.



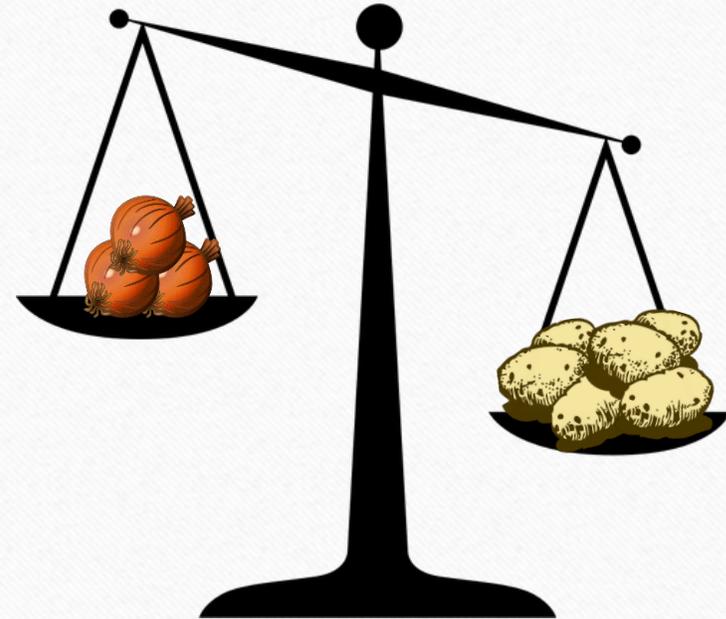
21 CFR 112.4(a)

Situation

Sunny Side Farm grows potatoes and onions. The farm's three year average annual produce sales is \$75,000. Of that, \$20,000 are from onion sales and \$55,000 are from potato sales.

Note: Produce is not for personal consumption or for consumption on the farm.

Is Sunny Side Farm covered or exempt from the rule?





Covered

Sunny Side Farm is **covered** by the Produce Safety Rule because their average annual produce sales exceed \$25,000 (on a rolling basis).

Produce includes **both** fruits and vegetables that are rarely consumed raw, like potatoes, but also fruits and vegetables that are frequently consumed raw, like onions.



Reminder:

- When calculating total produce sales, produce means any fruit or vegetable; be sure to include covered produce and non-covered produce in the annual sales calculations. Food grains are not produce; therefore, are not covered by the rule and should not be included in this calculation.
- During a regulatory inspection, the non-covered crops, in this case the potatoes, would not be subject to inspection under the Produce Safety Rule.



21 CFR 112.3



21 CFR 112.1,
112.2

Situation

XYZ Farm grows wheat and chickpeas. The farm's average annual monetary value of produce sold over the last three years averaged \$600,000.

Is XYZ Farm covered or exempt from the rule?





Exempt

XYZ Farm is **exempt** because chickpeas are on the FDA rarely consumed raw exhaustive list and wheat is considered a food grain. Rarely consumed raw produce and food grains are exempt under the Produce Safety Rule.

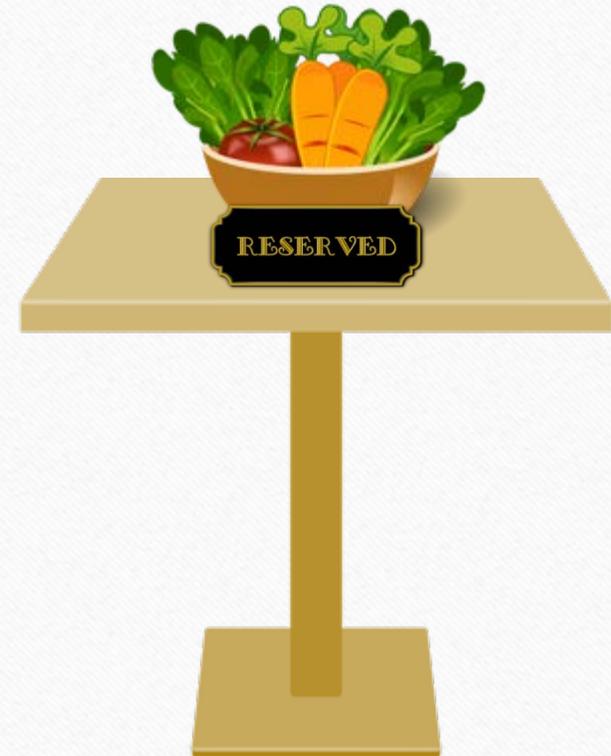


21 CFR 112.2(a)(1), 112.3

Situation

Red Steer Farm grows produce including potatoes, onions, and leafy greens for their personal consumption and for consumption on their farm.

Is Red Steer Farm covered or exempt from the rule?





Exempt

All the produce grown on the farm is for personal consumption or consumption on the farm therefore is **exempt** under the Produce Safety Rule.



Reminder:

- It is important to remember that if only part of the produce is grown for personal consumption or consumption on the farm then the farm may still be covered by the rule depending on where the rest of the produce is distributed and the average annual produce sales amount.



21 CFR 112.2(a)(2)

Thank you, and if you have questions
please contact us!



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