

Qualified Exemptions Scenarios

For the FSMA, Produce Safety Rule 21 CFR Part 112



Prepared by:
The Idaho State Department of
Agriculture and University of Idaho
Extension



Funding for this publication was made possible, in part, by grant number 5U18FD005916-02 from the FDA. The views expressed in written conference 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 mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

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 qualified 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

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



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.

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.

Qualified Exempt Requirements

Commercial Processing Exemption:

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

Modified Qualified Exemption:

- Subpart A—General Provisions
- Subpart O—Records
- Subpart Q—Compliance and Enforcement
- Subpart R—withdrawal of Qualified Exemption

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

Happy Acres Farm grows many types of covered produce on their farm.

They sell all of the produce grown on their farm to local restaurants (within 20 miles of the farm) and at local farmers markets. On Saturdays they sell at two farmers markets. One is 10 miles from the farm and the second is approximately 150 miles from the farm.

The average annual food sales for Happy Acres Farm is \$60,000 (on a rolling basis).

Is Happy Acres Farm eligible for a qualified exemption?





Yes, Happy Acres Farm is eligible for a qualified exemption.

All of the produce is being sold directly to a qualified end-user (restaurant and at the farmers market) not more than 275 miles from the farm and the farm has ≤\$500,000 in annual food sales.



Reminder:

It is important for Happy Acres Farm to keep copies of sales records to document the status of the farm. Farms eligible for a qualified exemption are still subject to some requirements of the PSR.



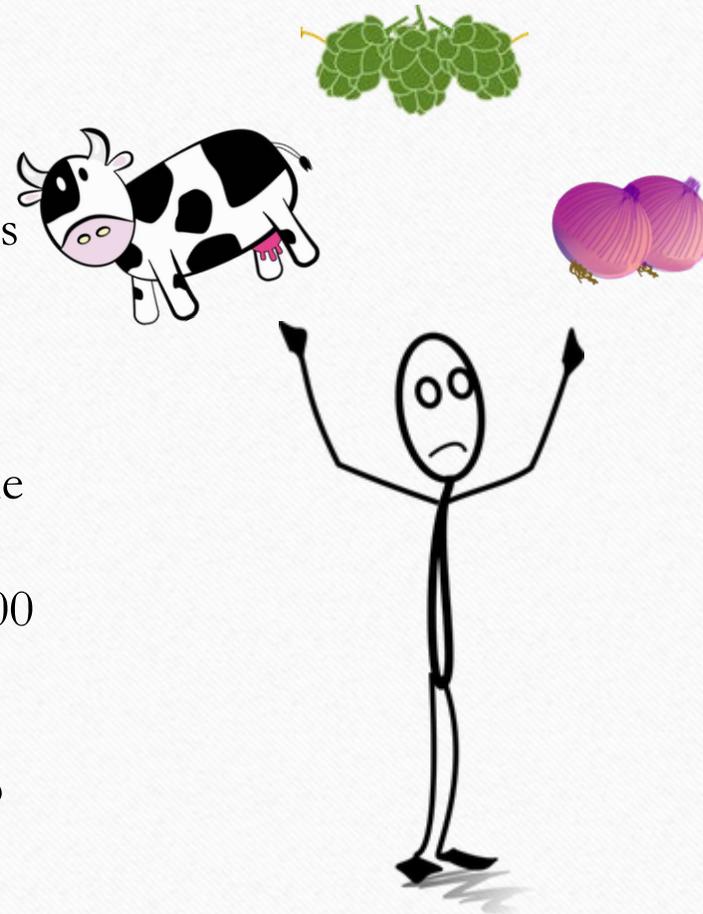
21 CFR 112.5, 112.6(a)
112.6(b), 112.201(a)

Situation

Happy Produce is a small farm operation that grows, harvests and sells onions and hops to a variety of distributors. Happy Produce's farm operation also includes a dairy. The onions and hops are distributed both domestically and internationally.

The produce operation and dairy are under the same name and ownership. The average annual food sales are \$1M; \$400,000 of sales are from produce and the other \$600,000 are generated from the dairy.

Is Happy Produce eligible for a qualified exemption?





No

Happy Produce is not eligible for a qualified exemption because their average annual food sales are over \$500,000 and the food is not sold to a qualified end-user.

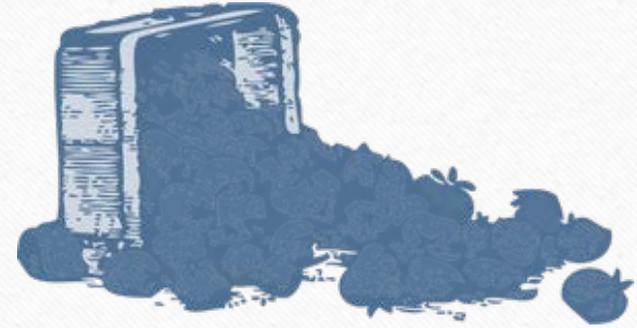


21 CFR 112.5

Situation

Berry Blue Blueberry farm is located in Idaho and sells blueberries at their farm stand and to a produce distributor located in Washington (>275 miles away from my farm). The farm's three year average annual food sales are \$120,000; \$70,000 of food sold is farm stand sales and the other \$50,000 of food sold is generated by selling to the produce distributor in Washington.

Is Berry Blue Blueberry Farm eligible for a qualified exemption?





Yes

Berry Blue Blueberry Farm's average annual value of the food sold is <\$500,000 and the majority (by value) of the food is sold directly to qualified end-users during such period.

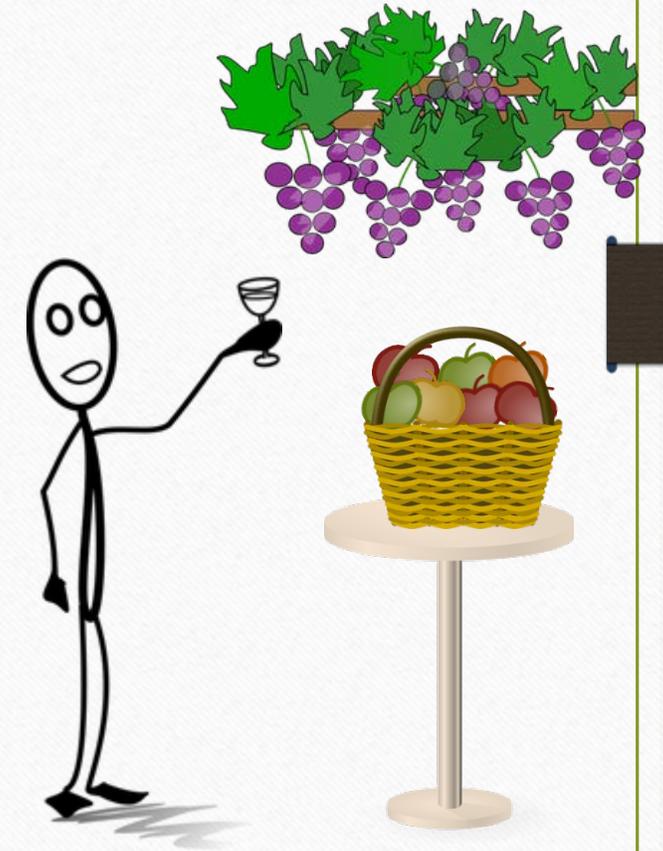
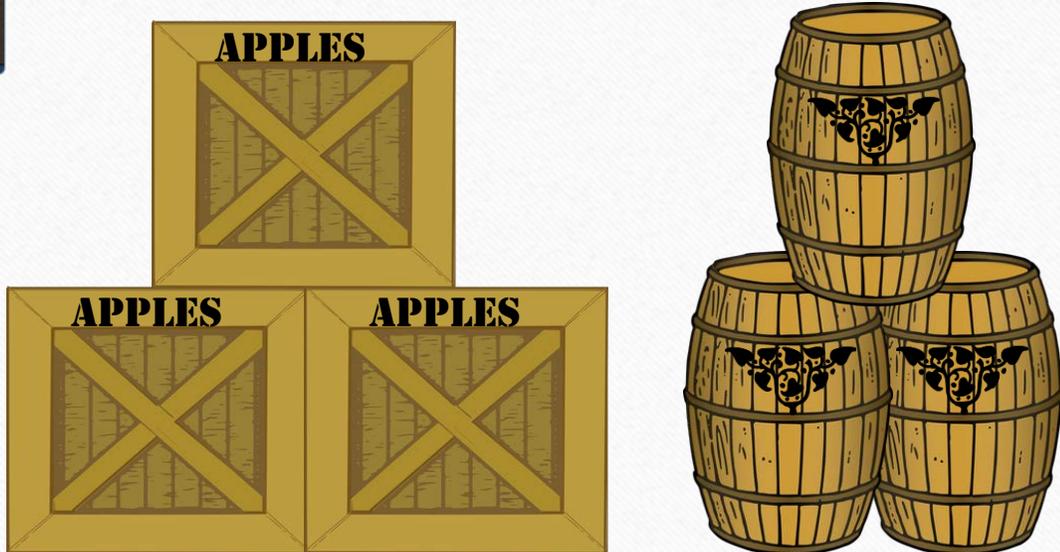


21 CFR 112.5

Situation:

Sweet Crisp Orchard grows apples and wine grapes. Their average annual food sales are \$350,000; of that \$150,000 are from apple sales to a local distributor and \$200,000 are from wine grape sales to a local wine processor for wine.

Is Sweet Crisp Orchard eligible for a qualified exemption?





No

The apples and wine grapes are sold to entities that do not meet the definition of a qualified end-user. Therefore Sweet Crisp Orchard cannot be considered for a qualified exemption. Sweet Crisp Orchard is considered a small business and is required to comply with the PSR.



Reminder:

- Small businesses have a compliance date of January 28, 2019.
- Sweet Crisp Orchard wine grapes would be subject to modified requirements because the grapes receive commercial processing.
- The farm **MUST**:
 - Disclose in documents accompanying the produce that the food (wine grapes) is “not processed to adequately reduce the presence of microorganisms of public health significance”.

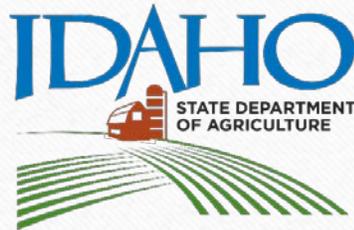


21 CFR 112.3



21 CFR 112.2(b)(3)(i)

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



Phone Number:

208-332-8500

Send ISDA an email:

fsma@isda.idaho.gov

Website:

www.agri.idaho.gov/main/inspections/fsma-main/



University of Idaho
Extension

Phone Number:

208-287-5900

Send UI Extension an email:

ariel@uidaho.edu

Website:

<https://www.uidaho.edu/extension/food-safety-for-produce-growers>