

Six Key Requirements of the Produce Safety Rule

- Agricultural water
- Biological soil amendments
- Sprouts
- Domesticated and wild animals
- Worker training and health/hygiene
- Equipment, tools and buildings

Our goal is educate farmers while we regulate to gain voluntary compliance with the Produce Safety Law.



Does Every Produce Farm in VA Need to be Inspected?

- Produce inspections are mandatory for any covered farm/operation that grows, harvests, forages or packs covered produce under the rule.
- Sprout inspections are conducted jointly by FDA/VDACS.
- Coverage is determined by a three-year gross sales average and the threshold increases with inflation. https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs
- (See FDA Decision Tree to determine coverage and exemptions).
- https://www.fda.gov/media/94332/download

Coverage and Exemption Flow Chart





STANDARDS FOR PRODUCE SAFETY Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.

Does your farm grow, harvest, pack or hold produce?

harvest, pack or hold produce Sections 112.1 and 112.3(c) We define "produce" in section 112.3(c).



Your farm i NOT covere by this rule

Does your farm on average (In the previous three years) have \$25k or less in annual produce sales?



Your farm is NOT covered by this rule.

Is your produce one of the commodities that FDA has identified as rarely consumed raw?

Section 112.2(a)(1)

If you grow, harvest, pack or hold more than one produce commodity, you must ask this question separately for each one to determine whether that particular produce commodity is covered by this rule.



This product is NOT covered by this rule.

Is your produce for personal/on-farm consumption?

Section 112.2(a)[2]



This produce is NOT covered by this rule.

Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a "kill step")?

n 112.2[b]



This produce is eligible for exemption from the rule,

provided you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation, as per Sections 112.2(b)(2) through (b)(6).

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—
- 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.)

OR establishment Your farm is eligible for a qualified exemption from this rule, which means that you must comply with certain modified requirements and keep certain apparentation as are Sections 112.5 and 112.7.

NO.

Created November 13, 2015

YOU ARE COVERED BY THIS RULE.

Does your farm grow, harvest, pack or hold produce?

Sections 112.1 and 112.3(c)
We define "produce" in section 112.3(c).



YES



Does your farm on average (in the previous three years) have \$25k or less in annual produce sales?

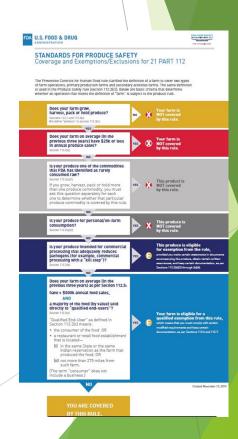
Section 112.4(a)





Your farm is NOT covered by this rule.

NO



Is your produce one of the commodities that FDA has identified as rarely consumed raw?

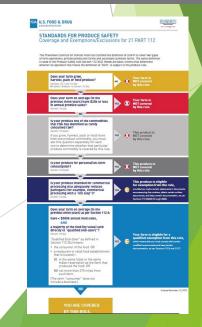
Section 112.2(a)(1)

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This product is NOT covered by this rule.

NO



Is your produce for personal/on-farm consumption?

Section 112.2(a)(2)





This produce is NOT covered by this rule.

N₀



Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a "kill step")?

Section 112.2(b)

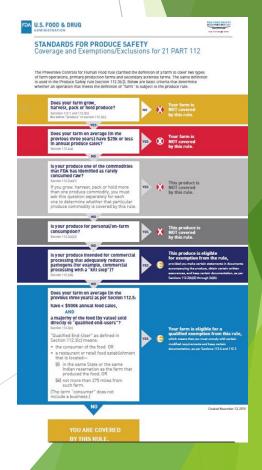




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a majority of the food (by value) sold directly to "qualified end-users"?

Section 112.3(c)

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- 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.)





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.

Created November 13, 2015

Food defined in the FD&C Act:

- 1. Articles used for food or drink for man or other animals.
- 2. Chewing gum.
- 3. Articles used for components of any such article.

FSMA Inflation Adjusted Cut Offs

Produce Safety

Qualified Exemption: A farm is eligible for a qualified exemption if the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation, and sales to qualified end-users during such period exceeded the average annual monetary value of the food sold by such farm to all other buyers.

NOTE: In May 2020, FDA issued guidance announcing flexibility in the eligibility criteria for the qualified exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Regulation due to disruptions to the supply chain during the COVID-19 public health emergency. This temporary policy is intended to remain in effect until Nov. 7, 2023. In April 2023, FDA issued guidance to help explain how farms may transition from the temporary policy back to the usual qualified exempt criteria in the Produce Safety Rule.

Baseline Value for Cut-offs (2011)	Value in 2018	Value in 2019	Value in 2020	Value in 2021	Value in 2022	Average 3 Year Value for 2020 - 2022
\$500,000	\$562,119	\$572,499	\$579,022	\$603,202	\$648,321	\$610,182

Not covered farm: A farm or farm mixed-type facility with an average annual monetary value of produce sold during the previous 3-year period of less than \$25,000 (on a rolling basis).

Baseline Value for	Value in	Average 3 Year				
Cut-offs (2011)	2018	2019	2020	2021	2022	Value for 2020 - 2022
\$25,000	\$28,106	\$28,625	\$28,951	\$30,160	\$32,416	\$30,509

What is Covered, (21 CFR 112.1) Examples:

Apples

Apricots

Avocados

Blackberries

Blueberries

Broccoli

Brussel Sprouts

Cabbage

Cantaloupes

Carrots

Cauliflower

Celery

Cherries

Citrus

Cucumbers

Grapes

Green Beans

Herbs- (wild or farm)

Kale

Leeks

Lettuce

Melons

Microgreens

Mushrooms- (wild or farm)

Mustard Greens

Onions

Peaches

Pears

Peppers

Plums

Radishes

Raspberries

Sprouts

Strawberries

Summer Squash

Swiss Chard

Tomatoes

Spinach

Turnips

Turmeric

Watermelons

Yams

Some tree nuts:

Almonds

Brazil nuts

Chestnuts

Walnuts

Pine nuts

What Produce is *Not* Covered by the Rule:

> Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance.

example: tomatoes processed for tomato paste grapes processed for wine

Produce grown by an individual for personal consumption or consumption on the farm.

- Produce that is rarely consumed raw... (21 CFR 112.2)
- Few examples are if you Only grow Corn, Collards, pumpkins, beets...



If Your Covered by the PSR, What Records are Required?

- ▶ Records to support a farms Coverage or Exemption status: 21 CFR 112.2 and 21 CFR 112.7 ex: processing or sales receipts?
- ▶ Records for Training: 21 CFR 112.30, 21 CFR 112.22
- ► Records for Post-harvest Agricultural Water: 21 CFR 112.50 (b) (Large farms)
- ► Records for Biological Soil Amendments: 21 CFR 112.60 (b) (If applicable)
- ▶ Records for Sanitation of Equipment, Tools, Buildings: 112.140 (b)(2)
- ► The PSA has created templates that can be downloaded that meet all FSMA requirements: https://cals.cornell.edu/produce-safety-alliance/resources

All Records Required by PSR, Must Contain Certain Info: 21 CFR 112.161

- The name and location of the farm.
- ▶ Actual values and observations obtained during monitoring.
- ► The date and time of the activity documented.
- ▶ An adequate description of covered produce, example lot # or type, line #.
- ▶ Be created at the time an activity is performed or observed.
- ▶ Dated, and signed or initialed by the person who performed the activity.
- Must be reviewed, dated, and signed, within a reasonable time after records are made by a supervisor or responsible party.

If you want to be eligible for a qualified exemption, you must establish and keep:



- Record that you performed an annual review and verification of your farm's continued eligibility for the exemption.
- Records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption:
 - Majority of food sales are to qualified end-users.
 - ✓ Dated sales receipts.

What is a Qualified End User?

- A qualified end user is either (1) the consumer of the food (an individual, not a business), or (2) a restaurant or other retail food establishment that is located either in same State or same Indian reservation as the farm that produced the food, or not more than 275 miles from the farm.
- Examples: farm stands, farmers markets, or community supported agriculture (CSA) customers as well as restaurants, grocery stores, and food cooperatives.
- <u>Does not include</u>: distributors, repack centers, wholesalers, food hubs and does not include restaurants or retail food establishments located more than 275 miles from the farm (unless within the same state).



Register your farm with the VDACS Produce Safety Program

All farms within Virginia that grow, harvest, pack or hold produce intended for human consumption and for sale will need to register their business with the Virginia Department of Agriculture and Consumer Services (VDACS) Produce Safety Program.

Register Here

ProduceSafety.VDACS.Virginia.gov

- Create a free, secure account and register your farm.
- Update data elements currently on file with VDACS by annually verifying your farm.
- Print out a registration certificate to use to help market your products locally.
- · Get enrolled automatically in the new VA Grown marketing program.
- · Apply for an exemption from inspection if eligible.
- Receive up-to-date information about the Food and Drug Administration (FDA) Produce Safety Rule, new water requirements, educational and training resources, periodic newsletters and guidance.

Learn more about the FDA Produce Safety Rule www.VAProduceSafety.com





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102 Governor St., Richmond, VA 23219 | VDACS. Virginia.gov

Produce Safety Rule

CERTIFICATE OF EXEMPTION

[Farm Name]

Qualified Exempt

Issue Date: November 1, 2021 Expiration Date: November 1, 2022



Erik Bungo Produce Safety Program Supervisor



Funding for this project 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.

Produce Safety Rule

CERTIFICATE OF REGISTRATION

[Farm Name]

Registered with the Virginia Department of Agriculture and Consumer Services (VDACS)
Issue Date: November 1, 2021







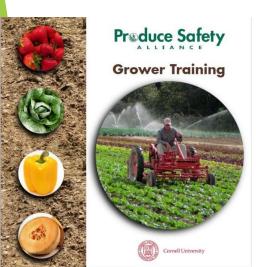
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Education and Training

Every covered farm that does not qualify for an exemption must have a supervisor (farm owner/operator) complete a standardized food safety training program.

21 CFR 112.22(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.

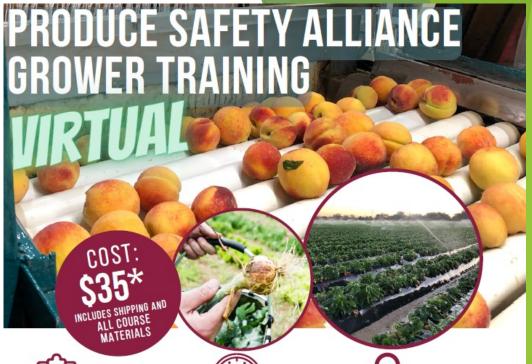
- ► Produce Safety Alliance Grower Training Course
- Sprout Safety Alliance Grower Training Course





Education and Training

- Virginia Tech/VCE has partnered with VDACS to provide Produce Safety Alliance courses
- Currently, the course is offered through VCE for \$35 per person.
- Courses without grant funding \$150-200 per person
- Offer via Zoom or self-paced. No in-person at this time.
- NEXT COURSE OFFERING: May 1st 2024 from 1-5pm and May 2nd 2024 from 1-5pm
- Contact: Dr. Laura Strawn, Virginia Tech at Lstrawn@vt.edu for more information





OVERVIEW

The Food Safety
Modernization Act (FSMA)
Produce Safety Rule is the
first federally regulated
standard for growing,
harvesting, packing, and
holding fresh produce in an
effort to reduce microbial
contamination and foodborne
illness outbreaks

If you grow fruits or vegetables, attend a training for information about best practices, and regulatory requirements.



March 6th, 2024 from 1-5 pm EST & March 7th, 2024

from 1-5 pm EST

* must attend <u>both</u> halfdays of instruction for certificate

* \$35 dollars for VA & TN and \$100 for all other states

QUESTIONS?

EMAIL: LSTRAWN@VT.EDU

-

2024 Produce operations
n EST wanting to learn more
about the FSMA Produce
Safety Rule

Produce operations needing to satisfy the FSMA Produce Safety Rule training requirement for inspections

WHO SHOULD ATTEND

REGISTER AT: HERE

Preparing For Inspection – Be Proactive!

- Consider contacting your local Virginia Extension Agent to ask about receiving a free On Farm Readiness Review (OFRR).
- An agent and yourself will conduct a mock run through of a produce inspection. This can help determine your readiness for inspection and help fix any potential violations.
- There are lots of resources available to use, PSR compliant logs, a Web tool to use for approved sanitizers for produce, training resources and much more on the Produce Safety Alliance page https://cals.cornell.edu/produce-safety-alliance/resources



Is your produce operation covered by the <u>Produce Safety Rule</u>? VDACS is teaming up with VCE to bring the On-Farm Readiness Review Program to Virginia producers.

Benefits of Participating in an OFRR:

- The free and confidential review will assess your readiness for a Produce Safety Rule inspection.
- VDACS Produce Safety Specialist and VCE Specialist/Agent will meet with your farm manager to walk through your operation. This review generally takes 2 hours of your time.
- You will receive a complimentary OFRR manual that clearly outlines the law and where each part can be applied in your operation.

On-Farm Readiness Reviews are only offered prior to compliance

dates. To schedule your OFRR, please call 804-786-4003

or visit www.VaProduceSafety.com.







On-Farm Readiness Review

Virginia Cooperative Extension | VDACS | Virginia Tech | Produce Safety Alliance | Virginia Produce Safety

Funding for this statement, publication, press release etc. was made possible. In part, by the Food and Drug Administration through grant PAR-16-137. The week expressed in written materials or publications and by speakers and moderolors 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 representation imply endormenent by the United States Government. If you are a person with a disability and desire any assistive devices, services or other accommodations to participate in this activity, please contact Louren Seltzer (mipoyonalev.edu) at the Eastern Shore AREC at 757-807-6585/TDD* during business hours of 8.00 am, and 4.00 pm, to discuss accommodations five days prior to the event. "TDD number is (800) 828-1420. Virginia Agriculture Experiment Station programs and employment are open to all, regardless of race, color, national origin, sex, religion, age, disability, political beliefs, sexual orientation, genetic information, marital, family, or veteran status or any other bases protected by law. Afrequal opportunity / offirmative action employer.

Who Can Have an OFRR?

- Any grower can take advantage of the OFRR program!
- While aimed at those growers who are covered and qualified exempt, an OFRR is a great opportunity that Virginia growers can do to look at their current food safety practices!

 Main goal is to help make small and very small farmers aware of the new law, what to expect from VDACS and how to comply with the Produce Safety Rule.



What's the difference between a VDACS inspection and a GAP audit?

- ▶ Inspections are mandatory for any covered farm, and GAP audits are voluntary.
- ▶ There are fees associated with a GAP audit and none with an inspection.
- ▶ State/FDA inspector conducts FSMA PSR Inspections and USDA conducts GAP Audits.
- ▶ A food safety plan is required for a GAP audit, both require record keeping.
- https://www.afdo.org/wp-content/uploads/2022/05/Final-AFDO-Produce-Safety-Rule-Inspections-and-Audits.pdf

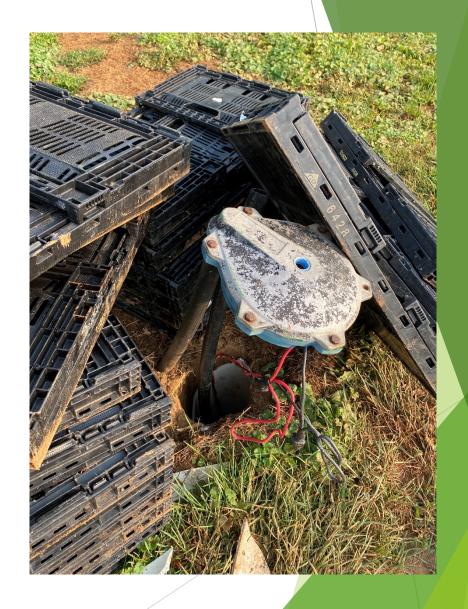
FDA Compliance Dates for Post-Harvest Water

Compliance dates for harvest and post-harvest agricultural water requirements

- January 26, 2023, for all other businesses; (Large farms)
- January 26, 2024, for small businesses; and (educational this year)
- January 26, 2025, for very small businesses.

Water use on farms.





Water use on farms.



What's the Difference?

Pre-Harvest

- Overhead sprinkler
- Spray, microspray
- Surface and subsurface drip
- Furrow
- Flood
- Seepage/subirrigation
- Pesticide, herbicide, crop sprays and mixes
- Etc.

Post-Harvest

- Dump tanks
- **Flumes**
- Cooling water
- Wash water for produce
- Handwashing water
- Cleaning water
- Etc.

Requirements for Harvest and Post Harvest Agricultural Water for Covered Produce.

- ► Safe and adequate of sanitary quality for its intended use (see § 112.41)
- ► Inspections and maintenance § 112.42, Log is Required. 1x annually, all water systems/sources.
- ► Treatment § 112.43, Log required if treatment is used.
- Microbial quality criterion § 112.44(a): must ensure there is no detectable generic E. coli per 100 ml of agricultural water and must not use <u>untreated</u> surface water for any of those purposes.
- ► Measures § 112.45(a): Corrective Measures
- Testing § 112.46 (a,c): If public supply, Certificate of Compliance. Initially testing the untreated ground water at least 4x times during the growing season, then 1x every year after.
- ▶ Who may test § 112.47: Anyone, aseptic sampling protocols.
- ► Additional management and monitoring § 112.48:
- ▶ Records § 112.50: Logs, can use PSA templates.
- ► Test methods § 112.151:

- https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule agricultural-water?utm_medium=email&utm_source=govdelivery
- PSA Ag water Inspection Fact Sheet
- https://resources.producesafetyalliance.cornell.edu/documents/AGWA-FSMA-PSR-Agricultural-Water-System-Inspection-is-Different.pdf
- Harvest and Post Harvest water fact sheet (new Jan 2023)
 - https://www.fda.gov/media/164540/download
- ► FDA Ag water assessment builder (online)
 - https://agwaterassessment.fda.gov/
- ► FDA Ag water assessment builder (paper, 33 pages)(also available in Spanish)
 - https://agwater-prod-external-interface.s3.amazonaws.com/docs/AgWaterBuilder-Paperbased July2022.pdf

In Summary...

- Start thinking or actually conduct a water assessment if selling produce.
 - ► FDA online tool or paper-based tool
- If selling produce, use the VDACS Produce Safety Portal to register your farm, so you can keep up with updates through our email list.
- Use the FDA decision tree to help decide if your farm will need to have an Inspection. Also, can apply for Exemptions on the portal and print certificates there.
- ► The PSR is mandatory to comply with under FSMA for covered produce farms, and not the same as a 3rd party audits, that are market driven.
- Use your resources available to you! Contact your extension office with questions, visit the Produce Safety Alliance website, or reach out to our Produce Safety Team with any questions.

