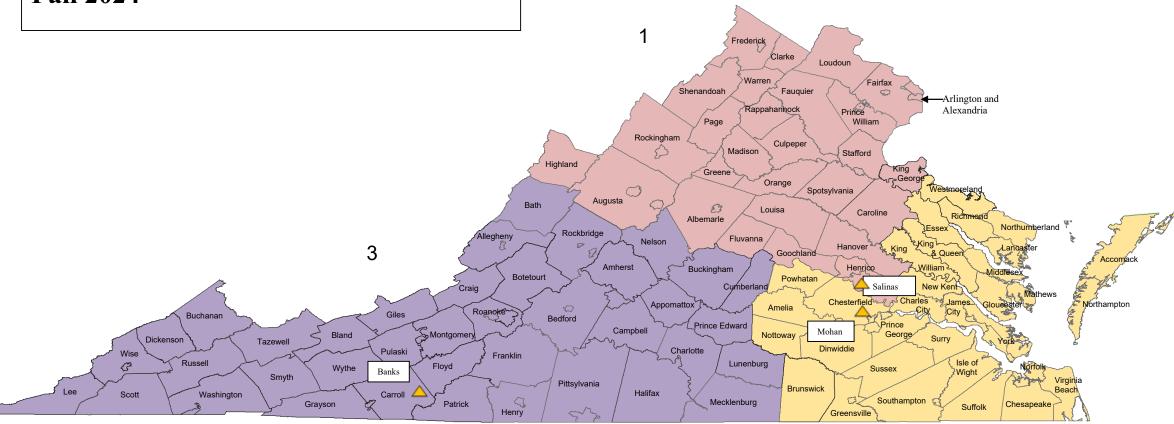




VDACS Produce Safety Territory Map Fall 2024



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
- Any farm, even if exempt, can request an inspection if they so choose. No cost.

Coverage and Exemption Flow Chart

Food defined in the FD&C Act:

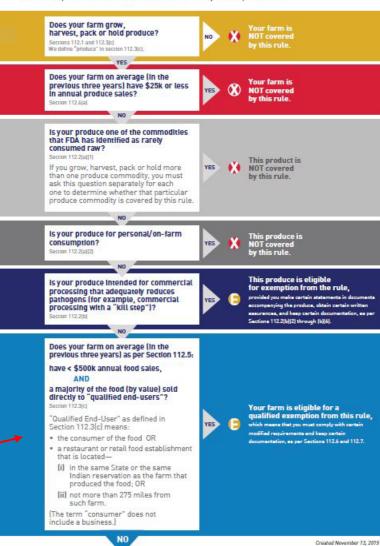
- 1. Articles used for food or drink for man or other animals.
- 2. Chewing gum.
- Articles used for components of any such article.





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.



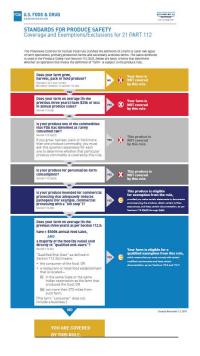
YOU ARE COVERED BY THIS RULE.

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



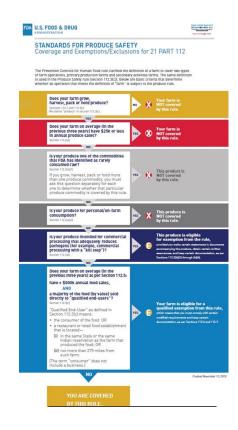
Does your farm on average (in the previous three years) have \$25k or less in annual produce sales?

Section 112.4(a)





Your farm is NOT covered by this rule.

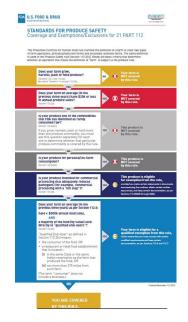


Is your produce one of the commodities that FDA has identified as rarely consumed raw?

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.

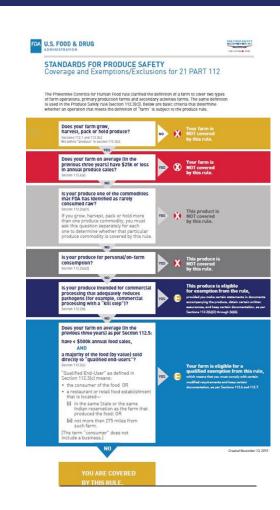
YES NOT covered by this rule.



Is your produce for personal/on-farm consumption?

Section 112.2(a)(2)





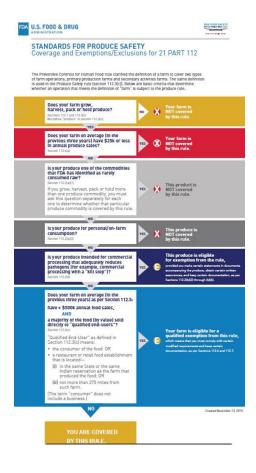
Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a "kill step")?

Section 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,

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.)





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.

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

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 (weekly, monthly) 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:



- 1. Record that you performed an annual review and verification of your farm's continued eligibility for the exemption.
- 2. 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, produce auctions, 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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Produce Safety Rule

CERTIFICATE OF REGISTRATION

[Farm Name]

Registered with the Virginia Department of Agriculture and Consumer Services (VDACS)

Issue Date: November 1, 2021







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 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.

Education and Outreach

- We attend trade shows and Farm Field days to work with growers and industry to share information about the Produce Safety Rule and upcoming changes to subpart E (ag water)
- Work with growers on FDA funded research studies
- Visit farmers markets and share Produce Safety information
- Direct farms to marketing and promotion services provided by the agency
 - Virginia Grown
 - AFID grants



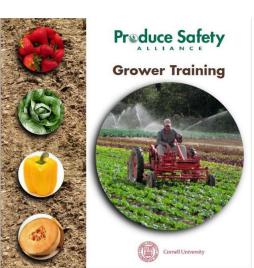


Education and Training

• Before the compliance date, every covered farm that does not qualify for an exemption <u>must</u> 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 \$50 per person.
- Courses without grant funding \$150-250 per person
- Offer via Zoom or self-paced.
- NEXT COURSE OFFERING:
 - May 5,6, 2025 (last course at discounted rate)

 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.

WHEN

May 5th, 2025
from 1-5 pm EST
&
May 6th, 2025
from 1-5 pm EST
* must attend bot
days of instructio

- * must attend <u>both</u> halfdays of instruction for certificate
- * \$50 dollars for VA & TN and \$150 for all other states

QUESTIONS? EMAIL: LSTRAWN@VT.EDU

WHO SHOULD ATTEND

Individuals wanting to learn more about the FSMA Produce Safety

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



Workshops

VDACS is partnering with FDA and Virginia Tech/VCE to bring this workshop to Virginia.

DATE: December 16, 2024

Cleaning and Sanitizing Workshop

The Cleaning and Sanitizing Workshop covers best practices of cleaning and sanitizing within the context of the Produce Safety rule, with perspectives from industry, cooperative extension, and regulatory agencies. It includes an overview on the Produce Safety rule and draft guidance to understand the current regulatory framework and requirements associated with cleaning and sanitizing for covered produce on covered farms.

Topics Covered:

- Food Safety Basics
- Cleaning
- Sanitizing
- Produce Safety Rule Overview
- Identification and Evaluation of Potential Hazards
- Establishing a Cleaning and Sanitizing Program



Inspections



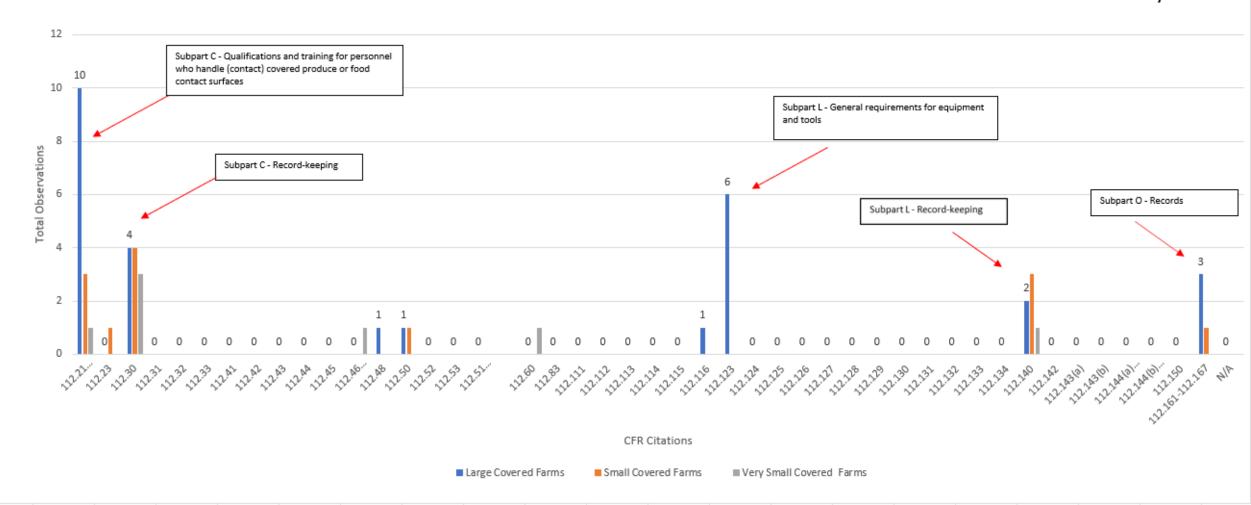
- Inspections of large covered farms began on May 1, 2019.
 - Main commodities observed: tomatoes, leafy greens, cucumbers, peppers, apples, cantaloupe and cabbage.
- Inspections of small covered farms began on June 5, 2020 (delayed because of COVID-19).
- Inspections of very small covered farms began on May 1, 2021.
- A total of 114 inspections were completed in FY23.
- A total of 95 inspections were completed in FY24.
- A total of 75 have been completed so far in FY25.
- To date, only 1 farm was observed with egregious conditions or serious violations.
 - That farm received a letter of warning and a follow-up inspection 30 days later determined that the issue had been corrected.

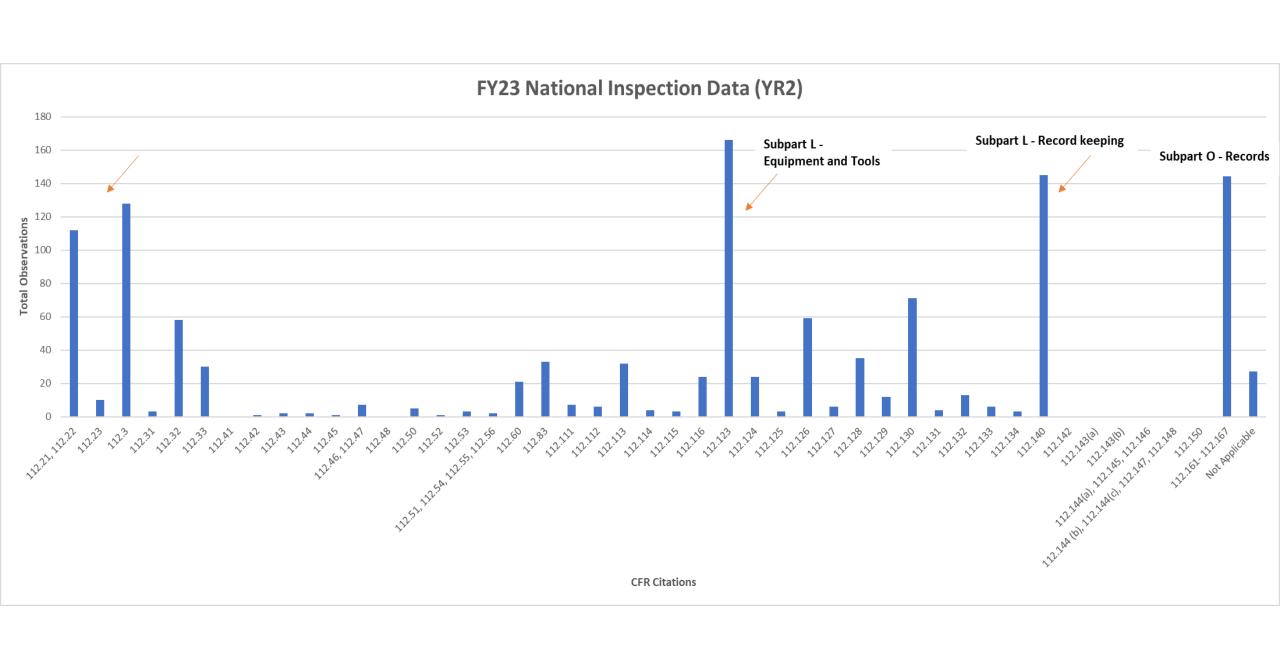
Top 3 observations (mostly technical demerits):

- Inadequate or lack of training (management, PSA, and employee training § 112.21, 112.22)
- Record keeping (not being done, not being reviewed by supervisor, not in proper format § 112.161)
- Equipment, tools and buildings (adequate design, installed and maintained § 112.123)

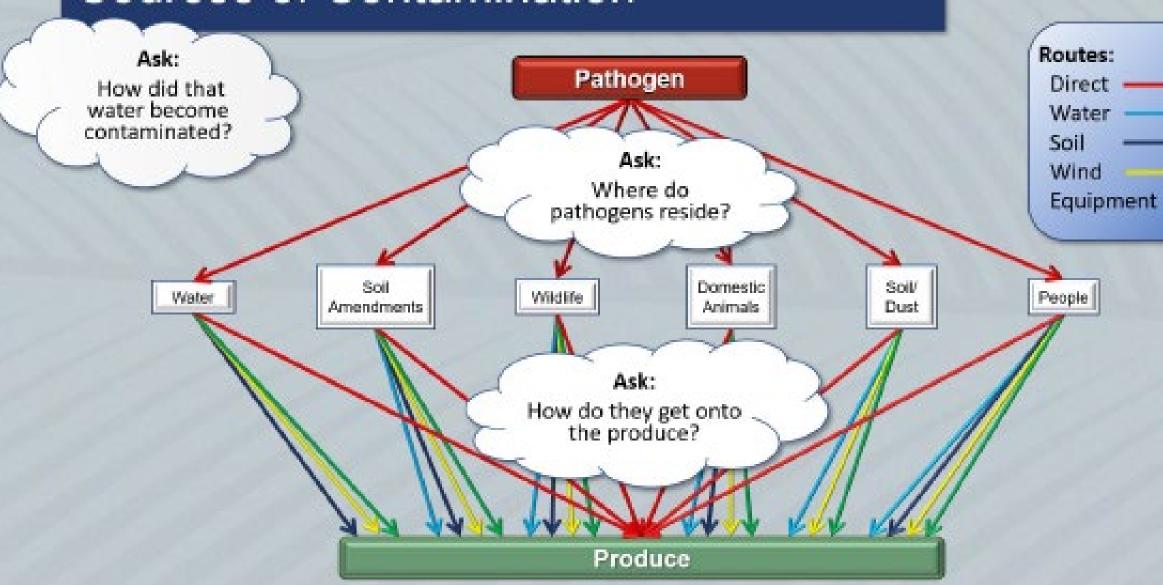
FY24 Inspection Data

95 total inspections completed
47 large farms
16 small farms
32 very small farms



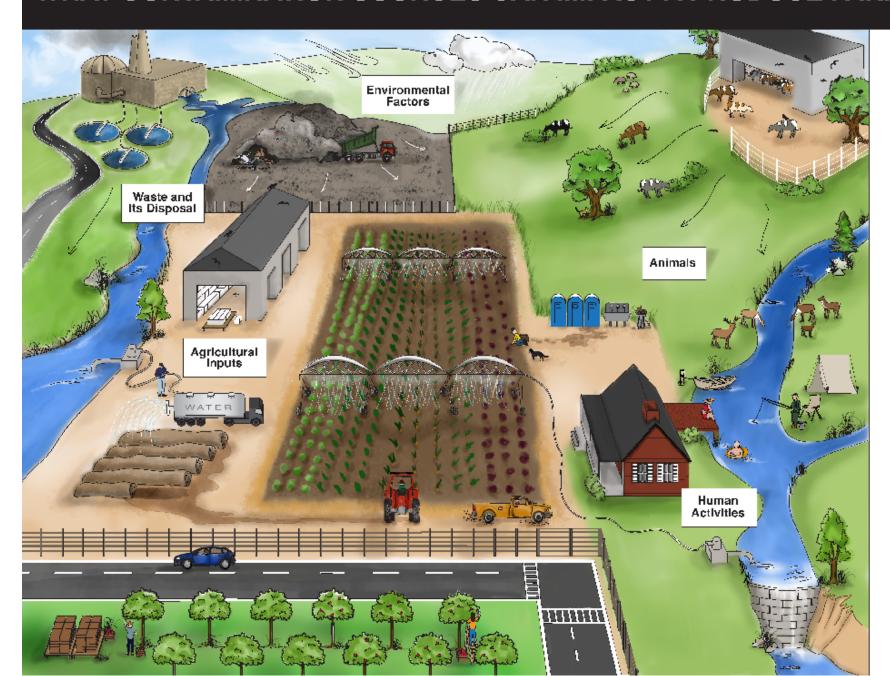


Sources of Contamination



WHAT CONTAMINATION SOURCES CAN IMPACT A PRODUCE FARM?





Potential sources or routes of contamination on farms and adjacent and nearby land can include:

Environmental Factors

- Land features, such as topography
- Land uses
- Weather events

Waste and Its Disposal

- · Toilet facilities and septic systems
- · Presence of waste or trash
- · Wastewater drainage
- · Improperly treated human waste

Animals

- Wild and domestic animals
- Animal housing
- · Animal habitats and attractants

Agricultural Inputs

- Storage and application of soil amendments and manure
- Agricultural water sources or practices
- Equipment and vehicle management and traffic patterns
- Water runoff and pooling

Human Activities

- · Worker movement patterns
- Presence of recreational areas and activities
- Proximity to urban areas, housing or recreational areas
- Adjacent agricultural practices
- · Worker and farming practices

Discussion Items

- Not all observations are noted as violations on the inspection report.
- The inspector will likely have several items for discussion with the person in charge.
 - Inspector will discuss concerns and issues talked about with farm manager.
 - These discussion items are documented at the end and included on the report under the "Discussion with Management Section"
 - However, all major observations will be marked as violations on the inspection report.

Records (21 CFR Part 112, Subpart O)	Observation	Corrective action taken
45. § 112.161 - 112.167: General record-keeping		
Other Observations	Observation	Corrective action taken
46. Other		
Additional Comments & Discussion with Management		



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

- Inspections are mandatory for any covered farm under the FSMA PSR no charge to the grower
- GAP audits are voluntary and market driven by grocers and buyers. There are fees associated with a GAP audit and these can get expensive.
- 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

Inspection Reports and Certificates of Inspection

Virginia Department of Agriculture & Consumer Services

Office of Dairy and Food - Produce Safety Program
102 Governor Street Richmond, VA 23219
Phone: 804-786-4003 Fax: 804-371-7792
www.vdacs.virginia.gov



This form lists factual observations made by VDACS representative(s) during the inspection of the farm's operation.
THIS IS NOT A FINAL DETERMINATION OF COMPLIANCE, OR NON-COMPLIANCE, WITH THE PRODUCE SAFETY RULE [21 CF PART 112] OR NAY OTHER LEGAL REQUIREMENT.

Representatives of the regulatory agency should record their observations on this form as clearly and specifically as possible and should order their observations by significance within each area (most important first). In some cases, an observation may relate to more than one topic area. Representatives of the regulatory agency should record observations in the bipic area listed below that, in the representatives for the regulatory agency should record observations applicable in every situation. In addition, representatives of the regulatory agency may not examine every aspect of the farms operation during an inspection, so a bipic area left blank should not be interpreted to mean the farm is in compliance, or not in compliance, with requirement related to that topic area.

Representatives of the regulatory agency should discuss all observations with the management of the farm or their representative as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandish when this form is issued. Discussion should include those observations which may be written on the form and those that will only be discussed with management during the observations have been recorded.

The farmmay use this opportunity to ask questions about the observations or to request darification. If the farm has implemented, or plans to implement corrective action in response to an observation, this may be discussed with the representatives of the regulatory agency during the inspection. Representatives of the regulatory agency should annotate the form, as applicable, with any completed or promised corrections discussed during the inspection. VDACS representatives are encouraged to verify the farm's completed corrective actions during the inspection as long as the verification does not unreasonably extend the duration of the inspection. Inclusion of annotations regarding corrective actions does not signify any conduction by the regulatory agency regarding the sufficiency of the actions.

VIRGINIA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES



CERTIFICATE OF INSPECTION

[Owner Name]

[Legal Name of Produce Farm /DBA Name of Produce Farm]

[Full Physical Address of Produce Farm]

Farm ID: [######]

This produce farm was inspected on [date] by the Virginia Department of Agriculture and Consumer Services Produce Safety Program in accordance with the Virginia Produce Safety Law, Title 3.2, Chapter 51.1, Sections §3.2-5146 through §3.2-5156 of the Code of Virginia.

Issued By:

Issued Date:



Erik Bungo
Program Supervisor
Produce Safety Program
Virginia Department of Agriculture & Consumer Services



Subpart E – Ag Water



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
- Etc.

Different irrigation methods may present different risks based on the extent to which the irrigation water is directly applied to the harvestable portion of the crop.



FDA Revised Subpart E Compliance Dates

 For <u>pre-harvest agricultural water</u> requirements for covered produce other than sprouts

Business Size	<u>Pre-harvest</u> Agricultural Wa Related Compliance Date	
All other businesses (>\$500K)	April 7, 2025	Large farms will be given a grace period until 4/7/2026
Small businesses (>\$250K-500K)	April 6, 2026	
Very small businesses (>\$25K-250K)	April 5, 2027	





Pre-Harvest Agricultural Water Requirements Have Changed

- FDA published a revision to Subpart E Agricultural Water on May 6,
 2024 (QR code and URL below)
 - https://www.fda.gov/food/food-safety-modernizationact-fsma/fsma-final-rule-pre-harvest-agricultural-water
- The revised Subpart E moves from reliance on testing pre-harvest water for decision making to an agricultural water assessment of the whole water system
- The expectation is that each grower understand their water quality and how their water management practices minimize risks to the crops they grow.
 - Should be prepared to explain during inspectional visits







FDA Subpart E Compliance Dates

• Enforcement for <u>harvest and postharvest agricultural water</u> requirements has begun.

Business Size	Postharvest Agricultural Water Related Enforcement Dates
All other businesses (>\$500K)	January 26, 2023
Small businesses (>\$250K-500K)	January 26, 2024
Very small businesses (>\$25K-250K)	January 26, 2025

Large farms must comply starting 1/26/2024

Small farms must comply starting 1/26/2025

Very Small farms will be given a grace period until 1/26/2026



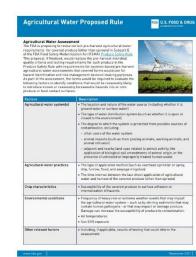


- https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-agricultural-water?utm medium=email&utm source=govdelivery
- FDA Ag water fact sheet
 - https://www.fda.gov/media/154334/download
- Harvest and Post Harvest water fact sheet
 - https://www.fda.gov/media/164540/download
- FDA Ag water assessment builder (online)
 - https://agwaterassessment.fda.gov/
- Pre Harvest Ag water (final 2024)
 - https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-pre-harvest-agricultural-water
- 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

Agricultural Water Assessment Builder

This section of the tool walks the user through the proposed requirements for agricultural water assessments found in the agricultural water proposed rule in an interactive format

- Clicking the new button below will allow you to start an assessment from the beginning without any previous assessment data.
- If you had previously started an assessment and did not finish, click the continue button below to upload the saved assessment file to continue where you had
 eft off.
- If you had previously completed an assessment and need to do an update change for an annual re-assessment or significant changes, click the re-assessment button below to import the saved assessment file and make changes where necessary.



← BACK NEW
☐ CONTINUE
☐ RE-ASSESSMENT ○

Webpage

www.VaProduceSafety.com

- Provides links to various resources as well as federal and state law
 - Organized into categories
- Provides contact info for the program



ABOUT VDACS+ JOBS SERVICES/FORMS MEDIA+ EMPLOYEE+ CONTACT SEARCH



MENU

ABOUT VDACE

ANIMALS

CONSERVATION & ENVIRONMENTAL

EDUCATION

FOOD, FOOD SAFETY & CONSUMER PROTECTION

Chartable Gerring

Chartable Solicitation

Credit Services Susinesses

Dary & Foods

Extended Service Contract Providers

Fantasy Contests

Food Distribution

Food Safety

Health Clubs

Membership Campgrounds

Festicide Information

Prepaid Legal Senice Plan Sellers

Produce Safety

State Mik Commission

Transporters of Waste Kitchen Greese

Travel Clubs:

Weights & Measures

INSPECTION & GRADING SERVICES

OCALITIES

MARKETING & ECONOMIC DEVELOPMENT

MARKETS & FINANCE

MEDIA

PESTICIDES

PLANT, PEST, FEED, FERTILIZER & SEED

SERVICES/FORMS

PRODUCE SAFETY

The Virginia Department of Agriculture and Consumer Services received federal grant funding in 2016 to establish a Produce Safety Program within the Office of Dairy and Foods. This new regulatory program will work to address the growing, packing, holding and dissemination of produce grown on farms and will encourage the safe production of fruits and vegetables and promote understanding and compliance with the FDA Produce Safety Rule and state legislation.

Produce Safety Program

- · Exemptions (pdf)
- FDA Produce Safety Rule
- . Final Rule on Produce Safety Fact Sheet (pdf)
- · Rack Card (pdf)
- Rarely Consumed Raw Produce (pdf)
- · Virginia Produce Safety Law (pdf)

Covered Farms

- · Coverage and Exemptions Flow Chart (pdf)
- · Rack Card (pdf)
- · Register Your Farm (pdf)

Education & Training

- Grower Training Courses
- Rack Card (pdf)

Safe Water

- Agricultural Water Geometric Means, Statistical Threshold Values, and Microbial Die-Off Rates (pdf)
- Adricultural Water Overview by VCE (pdf)
- List of Water Testing Labs (pdf)
- . Online Tool for Determining Your Microbial Water Quality Profile
- Rack Card (pdf)
- VDACS/OLS Testing Flyer (pdf)

Compliance Dates

- Compliance Dates (pdf)
- · Rack Card (pdf)

Information & Resources

- Produce Safety Alliance
- Required Records and Templates (pdf)
- Sprout Safety Allance
- Virginia Cooperative Extension Produce Safety
- Virginia Rapid Response Team (pdf)

Contact

Erik Bungo

Program Supervisor 804.786.1006

Erik bungo@vdacs.virginia.gov

Anne Magee

Assistant Program Supervisor 804.225.4535

Anne.magee@vdacs.virginia.gov

General information

produce safety@vdacs.virginia.gov

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