



*VIRGINIA DEPARTMENT
OF AGRICULTURE AND
CONSUMER SERVICES*

PRODUCE SAFETY PROGRAM

Presented by:

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Produce Safety Specialist Senior

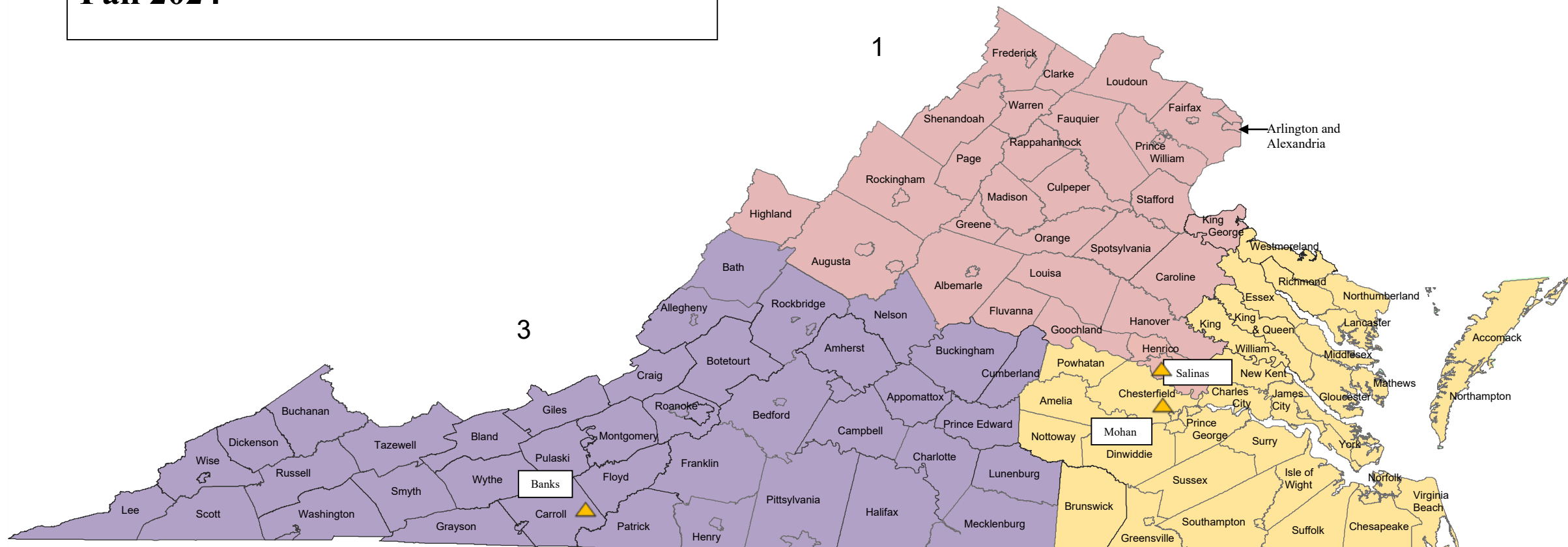
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VDACS Produce Safety Territory Map

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.



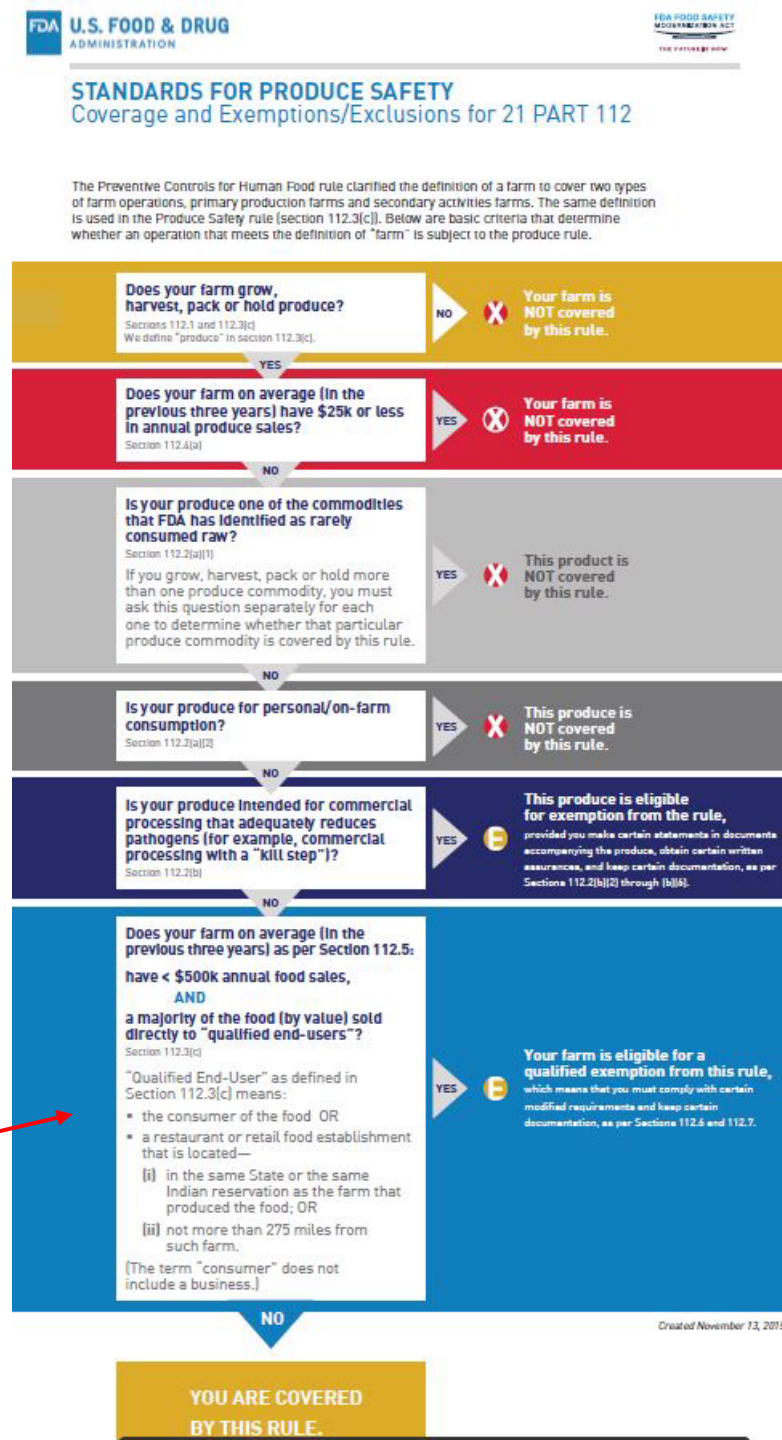
Does Every Produce Farm in VA Need to be Inspected?

- ▶ 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.
3. Articles used for components of any such article.



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

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

NO



Your farm is **NOT** covered by this rule.

YES

FDA U.S. FOOD & DRUG ADMINISTRATION

FOOD SAFETY AND INSPECTION SERVICE

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(b)). 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? <small>Sections 112.1 and 112.3(c) We define “produce” in section 112.3(c).</small>	YES	Your farm is NOT covered by this rule.
Does your farm on average in the previous three years have \$25k or less in annual produce sales? <small>Section 112.3(b)</small>	NO	Your farm is NOT covered by this rule.
Is your produce one of the commodities that FDA has identified as rarely consumed raw? <small>Section 112.3(c)(1)</small> 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	This product is NOT covered by this rule.
Is your produce for personal/on-farm consumption? <small>Section 112.3(d)(1)</small>	NO	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”)? <small>Section 112.3(d)(2)</small>	YES	This produce is eligible for exemption from this rule, provided you meet certain conditions to determine exemption. For more information, see our website at www.fda.gov/food/food-safety/modernizing-food-safety-laws/produce-safety-rule-21-cfr-part-112-3-d-kill-step-exemption, or see Section 112.3(d)(2) through 112.3(d)(4).
Does your farm on average in the previous three years (a) as per Section 112.5, have < \$500k annual food sales, AND (b) a majority of the food (by value) sold directly to “qualified end-users”? <small>Section 112.3(e)</small> “Qualified End-User” as defined in Section 112.3(e)(2) 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 that comply with certain qualified requirements and conditions. For more information, see our website at www.fda.gov/food/food-safety/modernizing-food-safety-laws/produce-safety-rule-21-cfr-part-112-3-e-qualified-end-user-exemption, or see Sections 112.3(e) and 112.3(f).
YOU ARE COVERED BY THIS RULE.		

Updated November 12, 2021

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

Section 112.4(a)

YES



Your farm is **NOT** covered by this rule.

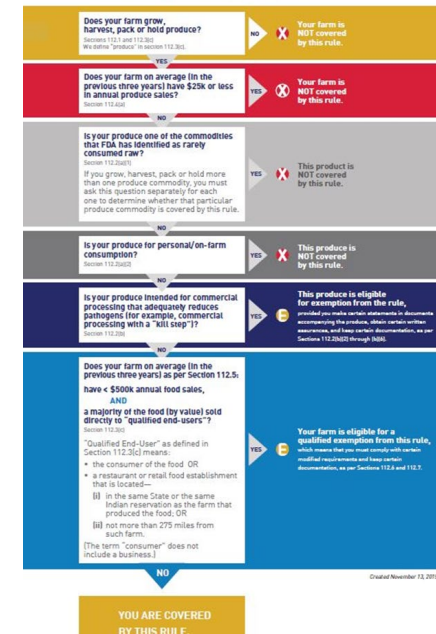
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FDA U.S. FOOD & DRUG ADMINISTRATION

FOOD SAFETY INSPECTION SERVICE

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.



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.

NO

YES



This product is **NOT** covered by this rule.

FDA U.S. FOOD & DRUG ADMINISTRATION

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

The Food Safety Inspection Service (FSIS) has started the decision of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same decision is used in the produce safety rule Section 112.2(a)(1). Below are basic criteria you determine whether an operation that meets the decision of "farm" is subject to the produce rule.

Does your farm grow, harvest, pack or hold produce? <small>Section 112.2(a)(1)(i)</small>	YES Your farm is NOT covered by this rule.
Does your farm on average in the previous three years have \$25K or less in annual produce sales? <small>Section 112.2(a)(1)(ii)</small>	YES Your farm is NOT covered by this rule.
Is your produce one of the commodities that FDA has identified as rarely consumed raw? <small>Section 112.2(a)(1)(iii)</small> <i>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.</i>	YES This product is NOT covered by this rule.
Is your produce for personal/on-farm consumption? <small>Section 112.2(a)(1)(iv)</small>	YES This produce is NOT covered by this rule.
Is your produce intended for commercial processing that adequately reduces pathogens for export, commercial processing with a "kill step"? <small>Section 112.2(a)(1)(v)</small>	YES This produce is eligible for exemption from this rule, provided you meet all other applicable requirements in Part 112, including Section 112.2(a)(1)(vi) through (vii).
Does your farm on average in the previous three years as per Section 112.2, have < \$500K annual food sales, AND a majority of the food (by value) sold directly to "qualified end users"? <small>Section 112.2(a)(1)(vi)</small> "Qualified End User" as defined in Section 112.2(a)(1)(vi): <ul style="list-style-type: none">• the consumer of the food OR• a restaurant or retail food establishment and its customer• in the same State or the same Indian reservation as the farm that produced the food OR• sell not more than 275 miles from such farm. <small>(The term "consumer" does not include a business.)</small>	YES Your farm is eligible for a qualified exemption from this rule, provided you meet all other applicable requirements in Part 112, including Section 112.2(a)(1)(vii) through (viii).

NO

YOU ARE COVERED BY THIS RULE

Updated November 13, 2019

Is your produce for personal/on-farm consumption?

Section 112.2(a)(2)

YES



This produce is NOT covered by this rule.

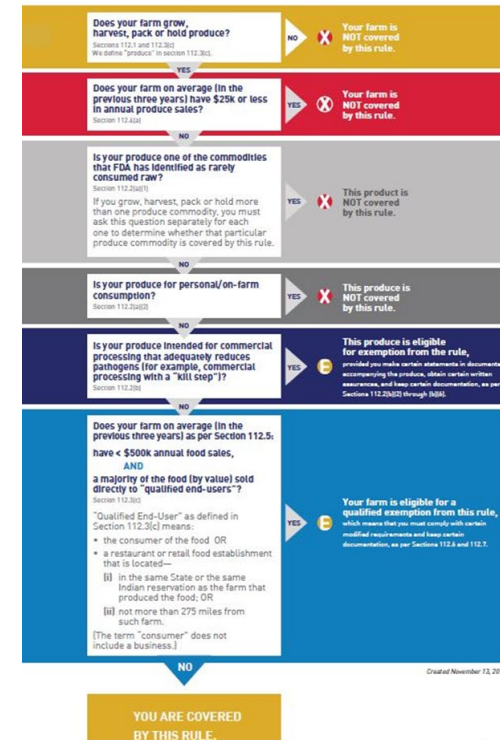
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FDA U.S. FOOD & DRUG
ADMINISTRATION

NEW FOOD SAFETY
MODERNIZATION ACT
"Produce"

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.



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

Section 112.2(b)

YES



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).

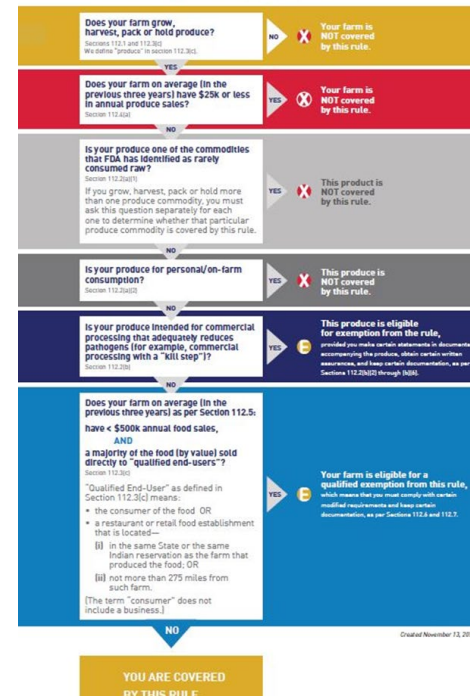
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FDA U.S. FOOD & DRUG
ADMINISTRATION

FOOD SAFETY
INSPECTION SERVICE
FSIS

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 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.

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

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:

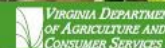


1. Record that you performed an annual review and verification of your farm's continued eligibility for the exemption.
2. Records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption:
 - ✓ Majority of food sales are to qualified end-users.
 - ✓ Dated sales receipts.

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.
- **Does not include:** 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).

VIRGINIA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES



Does Your Farm Grow Fruits and Vegetables?

*Register Your Farm with
the Produce Safety Program*

Visit ProduceSafety.VDACS.Virginia.gov to Register!



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



*VIRGINIA DEPARTMENT
OF AGRICULTURE AND
CONSUMER SERVICES*

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



Erik Bungo
Produce Safety Program Supervisor



*VIRGINIA DEPARTMENT
OF AGRICULTURE AND
CONSUMER SERVICES*

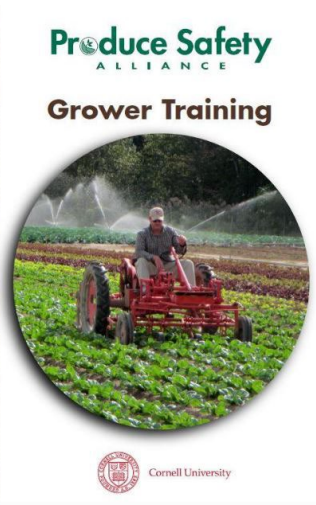
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Education and Training

- ▶ 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 **\$50** per person.
- Courses without grant funding \$150-200 per person
- Offer via Zoom or self-paced.

- **NEXT COURSE OFFERING:**

- **December 17,18, 2024**
- **January 28,29, 2025**
- **March 25,26, 2025**
- **May 5,6, 2025**

- Contact: Dr. Laura Strawn, Virginia Tech at Lstrawn@vt.edu for more information



**PRODUCE SAFETY ALLIANCE
GROWER TRAINING
REMOTE**

COST: \$50
INCLUDES ALL COURSE MATERIALS



 OVERVIEW	 WHEN	 WHO SHOULD ATTEND
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.	December 17th, 2024 from 1-5 pm EST & December 18th, 2024 from 1-5 pm EST	Individuals wanting to learn more about the FSMA Produce Safety Rule
If you grow fruits or vegetables, attend a training for information about best practices, and regulatory requirements.	* must attend <u>both</u> half-days of instruction for certificate * \$50 dollars for VA & TN and \$150 for all other states	Produce operations needing to satisfy the FSMA Produce Safety Rule training requirement for inspections
	QUESTIONS? EMAIL: LSTRAWN@VT.EDU	REGISTER AT: HTTPS://TINYURL.COM/3DK8D4W6



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>

BE FSMA READY.

Schedule Your On-Farm Readiness Review TODAY.

Is your produce operation covered by the Produce Safety Rule? 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.



OFRR



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 FAR-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 organizations imply endorsement 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 Lauren Selzer (lmselzer@vce.edu) at the Eastern Shore ARRC at 757-807-6585/TDD* during business hours of 8:00 am. and 4:00 p.m. to discuss accommodations five days prior to the event. *TDD number is (800) 828-1120. 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 basis protected by law. An equal opportunity/affirmative 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>

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.

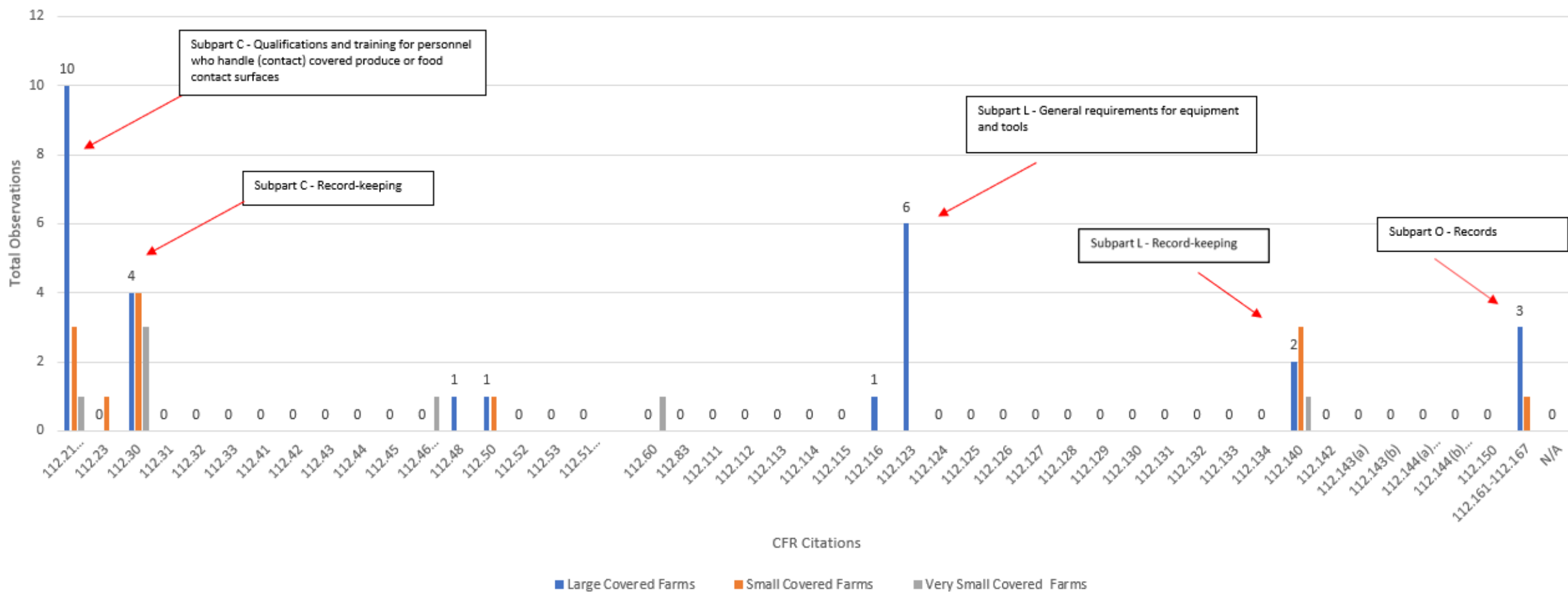
- A total of 114 inspections were completed in FY23.
- A total of 95 inspections were completed in FY24.
- To date, only 1 farm was observed with egregious conditions or serious violations.
 - That farm received a letter of warning and a follow-up inspection 30 days later determined that the issue had been corrected.

Top 3 observations (mostly technical demerits):

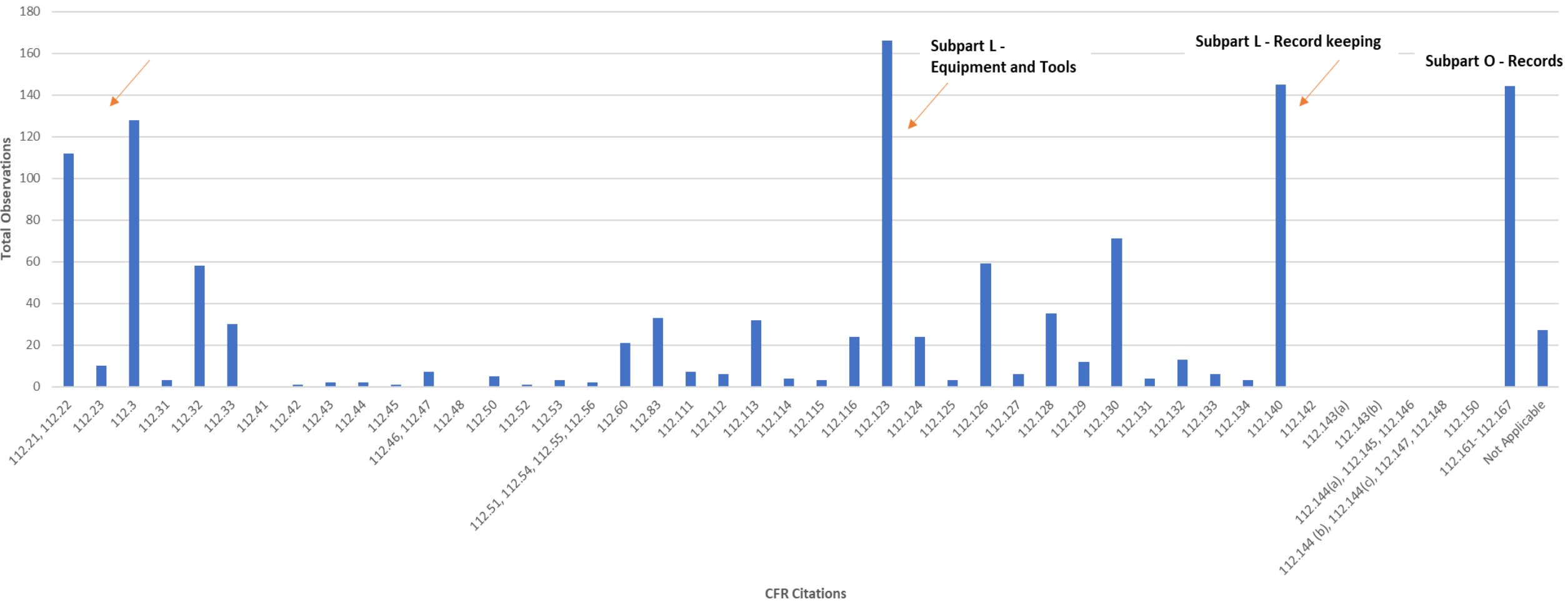
- **Inadequate or lack of training (management, PSA, and employee training § 112.21, 112.22)**
- **Record keeping (not being done, not being reviewed by supervisor, not in proper format § 112.161)**
- **Equipment, tools and buildings (adequate design, installed and maintained § 112.123)**

FY24 Inspection Data

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



FY23 National Inspection Data (YR2)



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 in the farm file on the “notes tab” section and not included on the report.
 - However, all major observations will be marked as violations on the inspection report.

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 pre-harvest agricultural water requirements for covered produce other than sprouts

Business Size	<u>Pre-harvest</u> Agricultural Water Related Compliance Dates	
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-modernization-act-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





Pre-Harvest Water Uses Include:

- Irrigation
- Fertigation
- Crop sprays
- Cooling
- Frost protection
- Dust abatement
- Other uses where water directly contacts produce





Evaluating Risks Related to Pre-Harvest Water

Three main impact points for produce safety risks related to pre-harvest water are:

1. Pre-harvest water source and quality
 - Public water supply, ground water, surface water
 - Testing frequency and sampling location
2. Application method
 - Water that does not contact the harvestable portion
 - Water that contacts the harvestable portion of the crop
3. Timing of application
 - At planting or close to harvest



Probability of Contamination



Public Water Supply



Treated

Ground Water



Surface Water



Open to
Environment



Agricultural Water Systems Inspection: Source and Distribution System

- Water can be contaminated at the source, or it can become contaminated in the distribution system
- Mapping all water distribution systems is recommended
- Water sources and distribution systems must be inspected at least annually
- Must keep water sources free of debris, trash, domesticated animals, and other hazards





Agricultural Water Assessment: Key Requirements

- **Must** identify conditions that are likely to introduce hazards to covered produce (other than sprouts) or food contact surfaces
- **Must** be done at the beginning of the growing season, but at least annually
- **Must** be reassessed whenever there is a significant change relevant to the assessment
- **Must** be written, reviewed, dated, and signed, in a reasonable time by a supervisor or responsible party



Agricultural Water Assessment: Elements

An agricultural water assessment must be conducted to evaluate:

- Agricultural water system
 - Location and nature of water source
 - Type of water distribution system
 - Degree of protection from possible sources of contamination
- Agricultural water use practices
- Crop characteristics
- Environmental conditions
- Other relevant factors

Agricultural water assessment means an evaluation ... to:

- (1) Identify any condition(s) that are reasonably likely to introduce ... hazards; and
- (2) Determine whether measures are reasonably necessary to reduce the potential for contamination ...

Full definition is in the notes

An Agricultural Water Assessment Builder tool is available through FDA



Agricultural Water Assessment:

Outcomes follow a risk-based tiered approach

If...

Then...

Ag water not safe or not of adequate sanitary quality	Immediately discontinue use AND Take corrective measure(s) before use at pre-harvest
Condition(s) on adjacent or nearby land uses pose risk related to animal activity, BSAAO, or human waste	Implement mitigation measures promptly, and no later than the same growing season
Other conditions that may introduce known or reasonably foreseeable hazards, not related to animal activity, BSAAO, or human waste on adjacent or nearby lands	Implement mitigation measures as soon as practicable, and no later than the following year OR Test water as part of the agricultural water assessment and implement measures as needed
No known or reasonably foreseeable hazards for which mitigation is necessary	Inspect and maintain water system regularly and at least once a year



Agricultural Water Assessment: Corrective and Mitigation Measures

Corrective measures

- Re-inspecting the entire affected agricultural water system under the farm's control and, among other steps, making necessary changes
- OR**
- Treating the water in accordance with the standards in FSMA PSR

Mitigation measures

- Making necessary changes such as repairs
- Increasing time interval between last direct application and harvest (microbial die-off)
- Increasing time interval between harvest and end of storage (microbial die-off)
- Other activities that result in die-off or removal
- Changing water application method
- Treating water (PSR standards)
- Taking alternative mitigation measures supported by scientific information



Reassessment

- Conduct each year, **AND**
- Anytime there is a significant change in:
 - The agricultural water system(s)
 - Agricultural water practices
 - Crop characteristics
 - Environmental conditions
 - Other things likely to introduce a hazard
 - i.e. changing to a surface water source
- Evaluate: Impact of the changes, new hazards
- Record: Written determination of whether corrective or mitigation measures needed



SUPPLEMENTAL MATERIAL



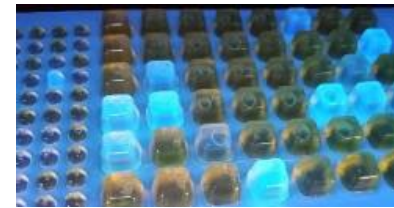
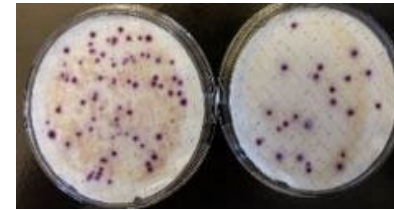
Agricultural Water Assessment: Exemptions

- Farms are exempt from conducting a pre-harvest agricultural water assessment if the water:
 - Is the same quality as harvest and postharvest agricultural water
 - No detectable generic *E. coli* in 100 mL and meets other postharvest agricultural water testing requirements
 - Is not untreated surface water
 - Is received from a public water system or supply with documentation (i.e., public system certificates of compliance, public supply generic *E. coli* monitoring results), **OR**
 - Is treated in accordance with FSMA PSR
- Reasonably likely the water quality will not change prior to use
- Each exemption condition requires supporting records



Testing

- The agricultural water assessment does not require testing under most conditions
- Growers may test their water to better understand their water quality
 - Testing may be used as part of an assessment
 - Must use generic *E.coli* or other scientifically valid indicator organism and associated microbial criteria
 - Must use scientifically valid and appropriate frequency of sampling
- If testing as a third-party food safety audit requirement, growers should continue testing
 - This testing is critical to maintaining market access





FDA Subpart E Compliance Dates

- Enforcement for harvest and postharvest agricultural water requirements has begun.

Business Size	<u>Postharvest</u> 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

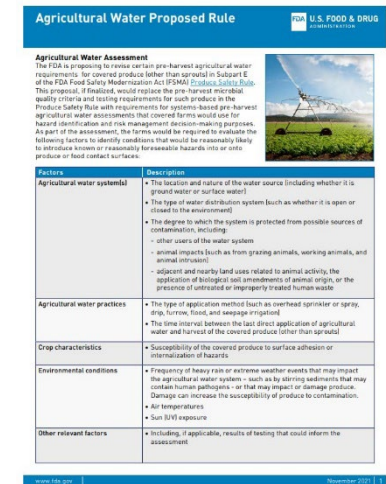
Small farms will be given a
grace period until
1/26/2025



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 of water § 112.46, Log required and monitoring if treatment is used.
- Microbial quality criterion § 112.44 (a and b): must ensure there is no detectable generic E. coli per 100 ml of agricultural water and must not use untreated surface water for any of those purposes.
- Measures § 112.45(a): Corrective Measures
- Testing § 112.44 (b and 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. Records required.
- Who may test § 112.47: Anyone, aseptic sampling protocols.
- Records § 112.50 and § 112.161: Logs available for review, 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
- 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.

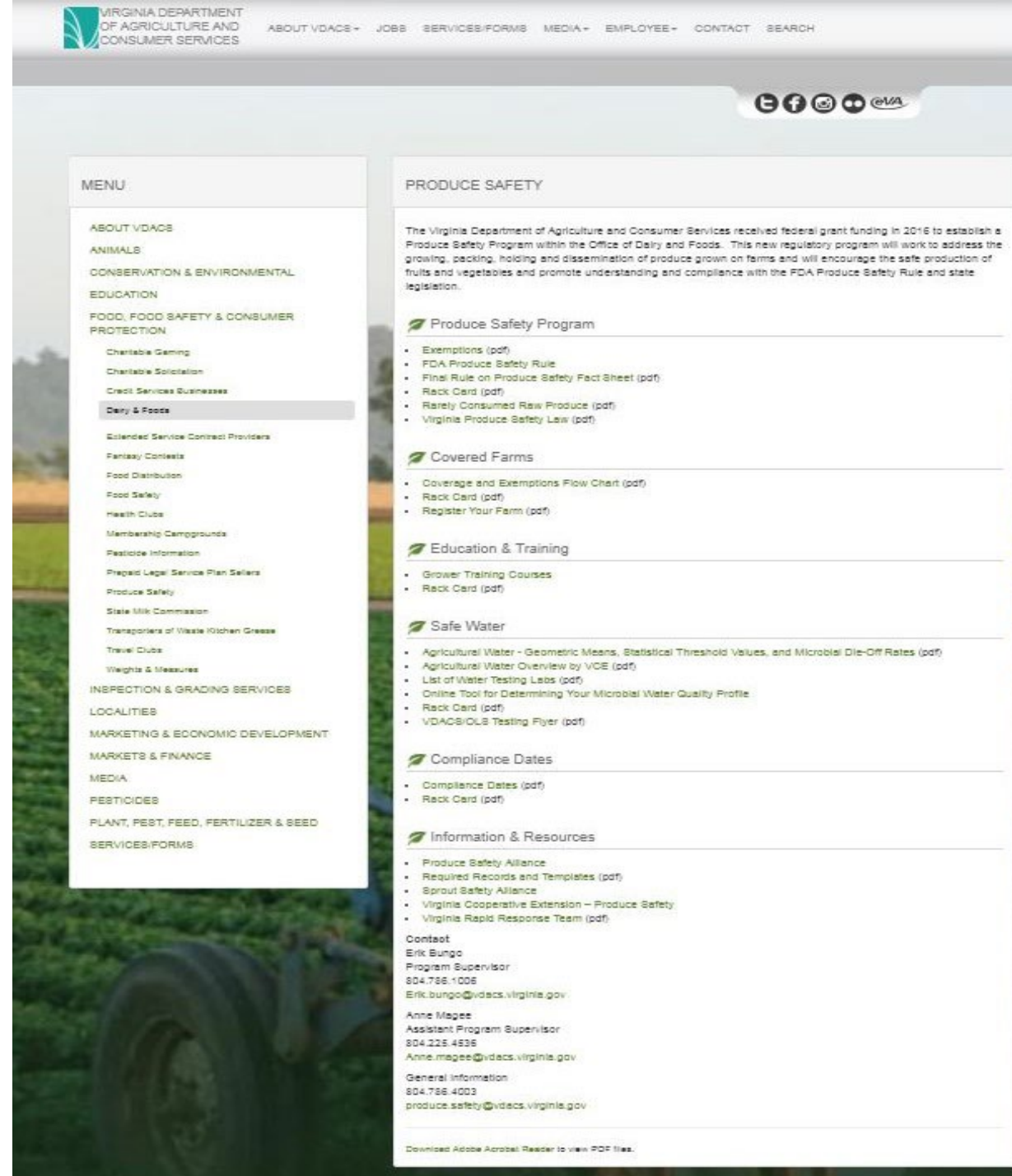
- Clicking the **new** button below will allow you to start an assessment from the beginning without any previous assessment data.
- If you had previously started an assessment and did not finish, click the **continue** button below to upload the saved assessment file to continue where you had left off.
- 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.

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.

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





VaProduceSafety.com

