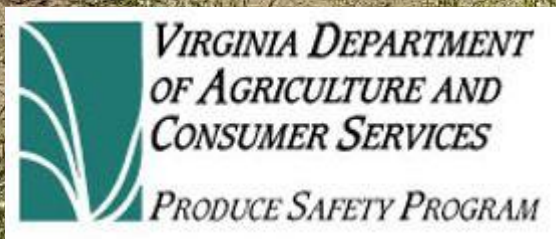


Implementation of the FSMA Produce Safety Rule in VA



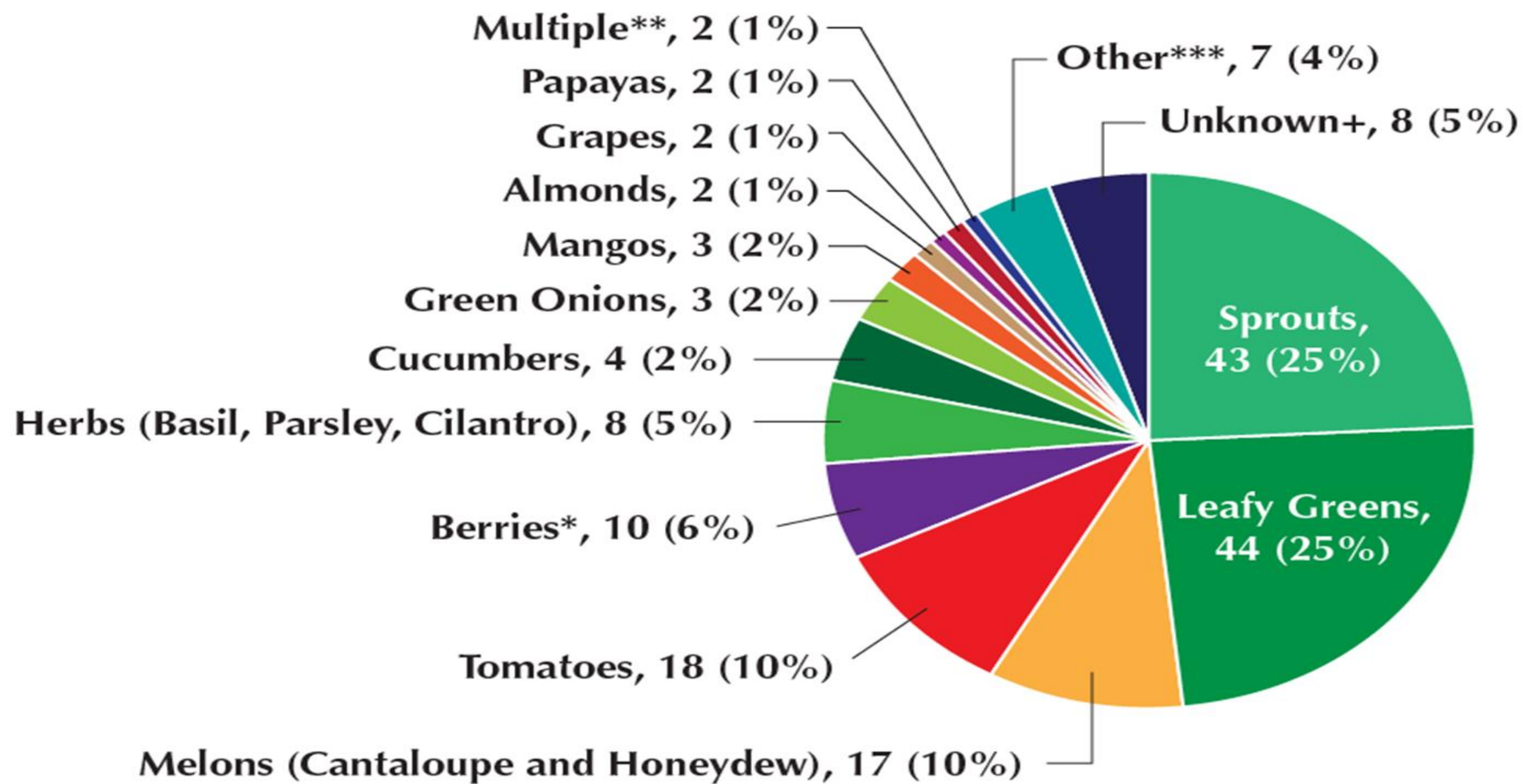
Why Produce Safety?

- From 1998 to 2016, data from the CDC¹ indicates that:
 - 754 produce-related reported outbreaks occurred
 - resulting in 27,000 outbreak-related illnesses
 - 2,592 hospitalizations
 - and 85 deaths
- A significant public health burden that is ***largely preventable***.
- These outbreaks were associated with approximately 40 different fresh produce commodities.

1 Centers for Disease Control and Prevention (CDC). Foodborne Outbreak Online Database. Atlanta, Georgia: U.S. Department of Health and Human Services, Center for Disease Control and Prevention. Available from URL: <http://wwwn.cdc.gov/foodborneoutbreaks>. Accessed 12/19/2017.



FDA Outbreaks Linked to Produce Contamination Likely Prior to Retail: 1996–2014



FSMA Produce Safety Rule (PSR)

- The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law on January 4, 2011.
- Aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it from happening.
- There are seven total rules in FSMA, one of which is the PSR.
- The rule establishes science-based *minimum* standards for the safe growing, harvesting, packing, and holding of fresh fruits and vegetables grown for human consumption.

FSMA Produce Safety Rule (PSR)

- New standards were developed for farmers in the following areas:
 - Agricultural water quality
 - Employee health and hygiene
 - Wild and domestic animals
 - Biological soil amendments
 - Equipment, tools and buildings
 - Sprouts



FDA Produce Safety Grant

- USDA NASS data from the 2012 Ag Census indicates at least 400-500 (or more) farms in Virginia subject to the Produce Safety Rule
- FDA is partnering with states to ensure enforcement of the PSR
- VDACS applied for a FDA grant for the establishment of a Virginia based Produce Safety Program
- Awarded \$3,625,000 to be provided over a five year term.
- VA received Notice of Award from FDA on September 9th, 2016
- Produce Safety Program formally established after Administration approval in December 2016
- Produce Safety Program involved in both education and outreach and traditional regulatory activities
- Entered into 5 year partnership with Virginia Tech to help ensure a robust level of training and education for the farming community as well as to assist in inventory development

Five Year Overview

- **Year 1 (9/9/16 – 6/30/17)**
 - Focused on jurisdictional self-assessment, legislative authority, infrastructure development (Program Supervisor, Asst. Supervisor, Admin Assistant), strategic plan, farm inventory and education and outreach with \$500,000 budget and \$170,000 sub award to Virginia Tech
- **Year 2 (7/1/17 – 6/30/18)**
 - Focusing on infrastructure development (3 Produce Safety Specialists), farm inventory, education and outreach, and on-farm readiness reviews with \$725,000 budget and \$170,000 sub award to Virginia Tech
- **Year 3 (7/1/18 – 6/30/19)**
 - Focus on infrastructure development, farm inventory, IT database, education and outreach, on-farm readiness reviews, and compliance/enforcement inspections with \$755,000 budget and \$75,000 sub award to Virginia Tech
- **Year 4 (7/1/19 – 6/30/20)**
 - Similar to YR3 with \$770,000 budget and \$75,000 sub award to Virginia Tech
- **Year 5 (7/1/20 – 6/30/21)**
 - Similar to YR4 with the addition of 3 more Produce Safety Specialists, \$875,000 budget and \$75,000 sub award to Virginia Tech

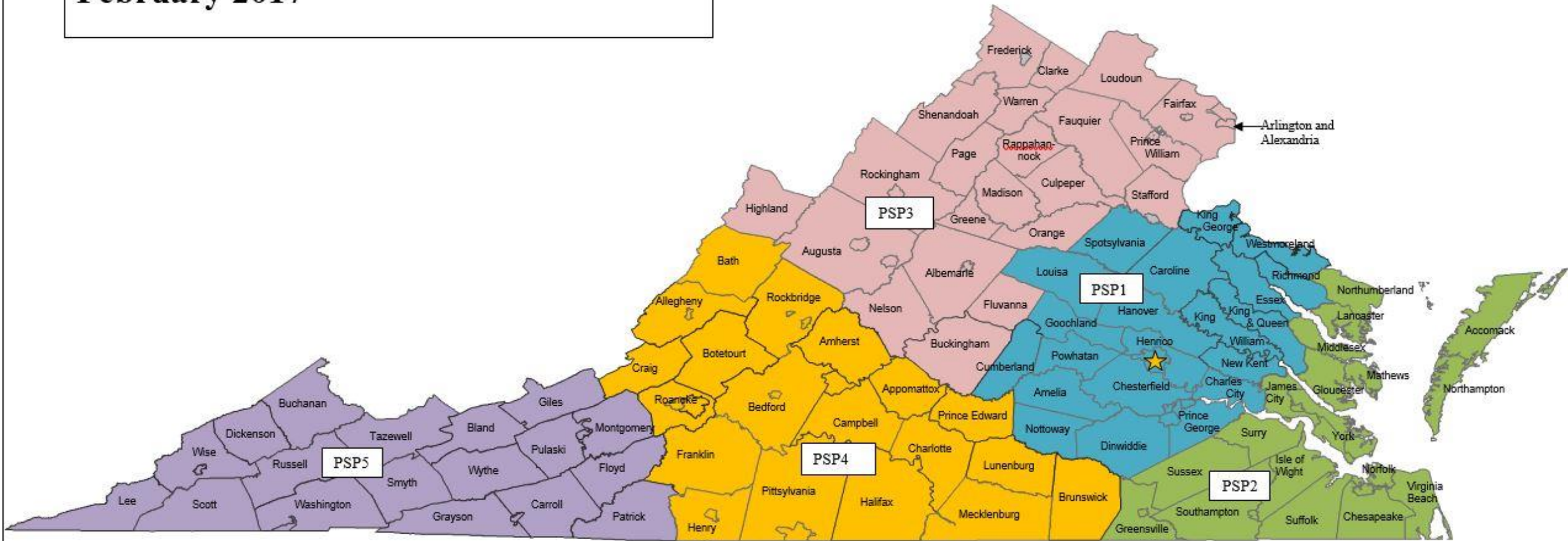
Legislative Authority

- Agency did not have clear regulatory authority necessary to enforce the Produce Safety Rule on farms
- Agency drafted and introduced SB1195 during the 2017 General Assembly
- Received support from VA Farm Bureau and Agribusiness Council
- Opposition from some groups but ultimately industry preferred to have VDACS working with farmers and providing inspections instead of the FDA
- SB1195 provides VDACS with the authority to inspect farms and enforce the federal PSR on farms that are subject to that rule
- Signed by the Governor on March 16th and became effective July 1, 2017

Infrastructure Development

- Current staff of 6 employees
 - Program Supervisor- hired January 2017
 - Assistant Program Supervisor- hired May 2017
 - Admin Support Technician- hired June 2017
 - Produce Safety Inspector (Eastern)- hired July 2017
 - Produce Safety Inspector (Central)- hired August 2017
 - Produce Safety Inspector (Mid-Western)- hired November 2017
 - 2 to 3 additional inspector positions in YR5 (2020)

VDACS Produce Safety Territory Map February 2017



Jurisdictional Self-Assessment

- Jurisdictional self-assessment was performed to determine size and scope of the new Produce Safety Program
- Utilized USDA NASS data, USDA AMS GAPs inventory data, and Virginia Grown data
- Estimated that >500 covered farms subject to Produce Safety Rule
 - Virginia Tech estimates closer to 1,000+ farms
- Will require a staff of 9 to effectively implement the program

Virginia's Top 20 Agricultural Commodities	
Crop/Livestock	Farm Cash Receipts
1. Broilers	\$918,000,000
2. Cattle/Calves	\$714,000,000
3. Milk	\$478,000,000
4. Turkeys	\$326,000,000
5. Greenhouse/Nursery (Misc. Crops*)	\$298,000,000
6. Soybeans	\$259,000,000
7. Corn, Grain	\$219,000,000
8. All Other Animals*	\$216,000,000
9. Hay	\$119,000,000
10. Tobacco (Unprocessed Leaf)	\$117,000,000
11. Eggs	\$114,000,000
12. Wheat (Winter)	\$112,000,000
13. Cotton Lint	\$72,000,000
14. Hogs	\$58,000,000
15. Apples	\$37,000,000
16. Tomatoes (Fresh Market)	\$30,000,000
17. Potatoes (Summer)	\$19,000,000
18. Grapes	\$15,000,000
19. Cottonseed	\$11,000,000
20. Peanuts	\$10,000,000

*Misc. Crops includes Greenhouse/Nursery, roughly 90 percent of the total, plus mushrooms, sunflowers, rye, sorghum, seed crops and other field crops.
*All Other Animals includes horses, aquaculture and all other livestock.

Source: 2014 USDA NASS and ERS data figures rounded to the nearest million dollars.

#15, 16 and 18 are all covered commodities under the FSMA Produce Safety Rule

Education and Outreach

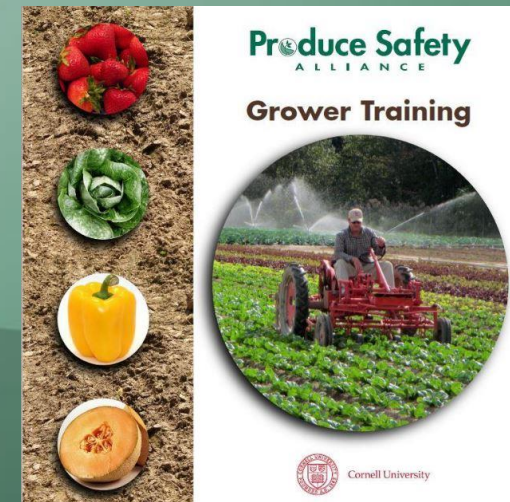
- Sub-award with Virginia Tech to provide outreach to the farming community and to provide the needed education and training regarding compliance with the new rule
- VDACS allocated \$170,000 or 34% of YR1 funding
 - Virginia Tech held six (6) Produce Safety Alliance (PSA) courses (required for farmers) and trained over 200 people in YR1
- VDACS allocated another \$170,000 of YR2 funding
 - Virginia Tech plans to hold an additional five (5) PSA courses and assist VDACS with on-farm readiness reviews

Education and Training

- Before the compliance date, 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*



Upcoming PSA Courses in VA

- Carroll County (Southwest Virginia) – March 29th (contact Ashley Edwards aledwards@vt.edu)
- Winchester, VA – June 28th (contact Mark Sutphin masutph2@vt.edu)

Industry Education and Outreach

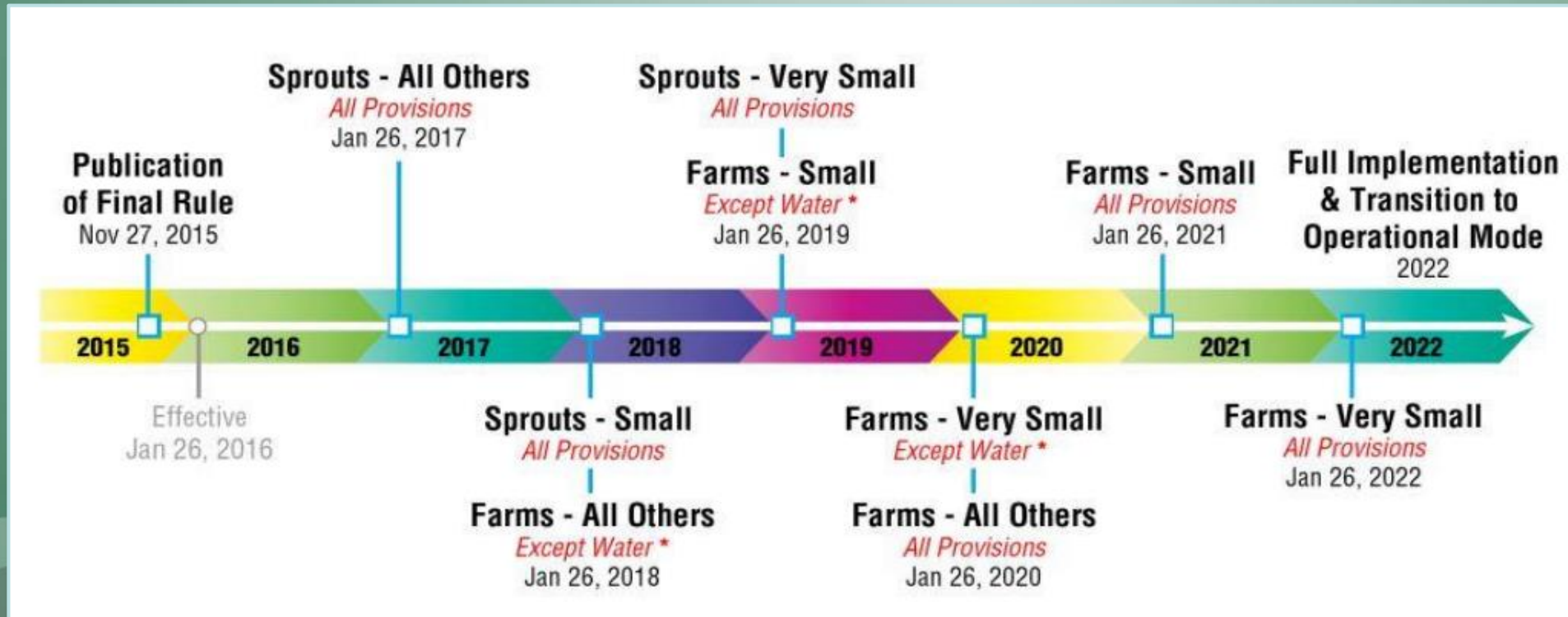
- Presentations and marketing materials have been developed to ensure that farmers, farm workers and related organizations are familiar with the VDACS Produce Safety Program and the Produce Safety Rule.
- Main goal is to help make small and very small farmers aware of the new law, what to expect from VDACS and how to comply with the Produce Safety Rule.

On-Farm Readiness Reviews

- On Farm Readiness Reviews (OFFRs) will be initiated around April/May 2018
- Purpose of the OFFRs is to provide on-site (farm) education and training to identify areas of concern at the farm and to ensure that farmers have a thorough understanding of how to comply with the produce safety rule
- OFRRs can only occur after certain required FDA training courses have been completed
- OFRRs will likely occur between April 2018 and June 2019
 - large farms priority as they are expected to comply with FSMA PSR by Jan 26, 2018
- Virginia Tech extension agents will also be present for OFRRs and these reviews will be conducted in a team approach
- OFRRs for small and very small farms will be conducted later in 2018 and in early 2019
- Virginia Tech is organizing the OFRRs and if you are interested in this opportunity please contact Tommy Saunders tshokie@vt.edu

Compliance Inspections

- Will occur only after the compliance date for the covered farm is in effect
- VDACS Produce Safety Specialists must complete all required online and FDA classroom courses prior to conducting inspections



Compliance Dates

- **Large Farms**

> **\$500,000** average annual monetary value of produce sold during the previous 3-year period

January 26, 2018 – Begin keeping records

Inspections won't begin until Summer of 2019

Water testing compliance date = January 26, 2022 (proposed)

Compliance Dates

- **Small Farms**

>\$250,000 and < \$500,000 average annual monetary value of produce sold during the previous 3-year period.

January 28, 2019 - Begin keeping records

Inspections won't begin until Spring of 2020

Water testing compliance date = January 26, 2023 (proposed)

Compliance Dates

- **Very Small Farms**

>\$25,000 and < \$250,000 average annual monetary value of produce sold during the previous 3-year period

January 27, 2020 - Begin keeping records

Inspections won't begin until Spring of 2021

Water testing compliance date = January 26, 2024 (proposed)

Compliance Dates for Sprout Growers

- Large sprout growers
 - Compliance and inspection date = January 26, 2017
- Small sprout growers
 - Compliance and inspection date = January 26, 2018
- Very small sprout growers
 - Compliance and inspection date = January 28, 2019



Compliance Inspections

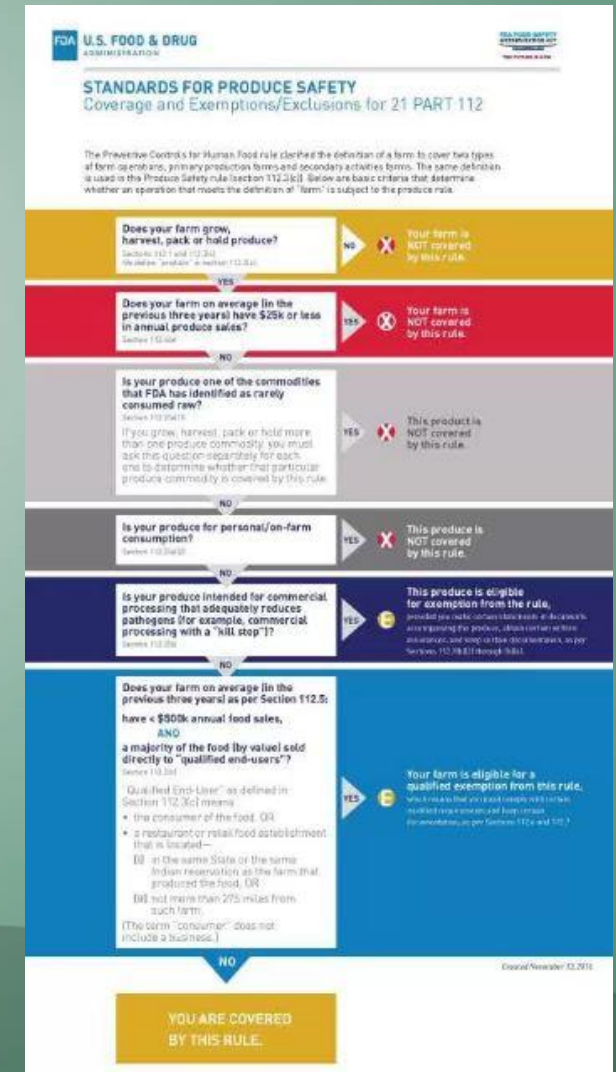
Common Principles:

- Drive compliance through education and implementation of corrective actions when noncompliance is identified
 - Educate while we regulate approach
- Establish constructive relationships between industry and regulators
- Apply a standardized approach to training, inspection and compliance strategies that results in consistent and fair decision making

Are You Covered?

- If you sold **<\$25,000*** average annual monetary value of produce during the previous 3-year period – **you are *not* covered by this rule.**

*This monetary figure is adjusted for inflation over time



Exempt Produce Commodities

- Asparagus
- Black beans
- Great northern beans
- Kidney beans
- Lima beans
- Navy beans
- Pinto beans
- Garden beets
- Sugar beets
- Cashews
- Sour cherries
- Chickpeas
- Cocoa beans
- Coffee beans
- Collards
- Sweet corn
- Cranberries
- Dates
- Dill
- Eggplants
- Figs
- Ginger
- Hazelnuts
- Horseradish
- Lentils
- Okra
- Peanuts
- Pecans
- Peppermint
- Potatoes
- Pumpkins
- Winter squash
- Sweet potatoes
- Water chestnuts

Eligible For Exemption

- If your produce is intended for **commercial processing** that adequately reduces pathogens
 - Such as processing to produce tomato paste or shelf-stable tomatoes.
 - Apples for sauce, etc.

Specific documentation is needed



Qualified Exempt Farms

“Tester-Hagan”

1. During the previous 3-year period, more than half of the average annual monetary value of the food the farm sold was directly to qualified end-users

- a) The consumer of the food (CSAs, farmers market, etc)
- b) 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

AND

2. The average annual value of all food the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000

Qualified Exempt Farms

Modified Requirements

- Labeling
 - Display name and complete business address of the farm where the produce was grown
 - On food packaging label
 - On poster or sign where produce is sold (if no package) – CLEARLY VISIBLE
 - Compliance
 - January 1, 2020

Qualified Exempt Farms

Modified Requirements

- Records
 - Demonstrate farm is below sales threshold, selling to more qualified end users than not, and that the purchaser is a qualified end user
 - Farm must begin keeping records as of January 26, 2016 (~3 month after published rule)
 - Farm must also keep written record that reflects annual review and verification of farm's continued eligibility of qualified exemption

Qualified Exempt Farms

Modified Requirements

- Other aspects to know:
 - Withdrawal of qualified exemption
 - Active investigation of a foodborne illness outbreak that is linked to your farm
 - Necessary to protect public health and prevent an outbreak (based on conduct or conditions)
 - Reinstatement of qualified exemption
 - FDA **did not** adopt the “one strike and you’re out” approach

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.

Baseline Value for Cut-offs (2011)	Value in 2012	Value in 2013	Value in 2014	Value in 2015	Value in 2016	Average 3 Year Value for 2014 - 2016
\$500,000	\$509,199	\$517,417	\$526,645	\$532,170	\$539,121	\$532,645

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 Cut-offs (2011)	Value in 2012	Value in 2013	Value in 2014	Value in 2015	Value in 2016	Average 3 Year Value for 2014 - 2016
\$25,000	\$25,460	\$25,871	\$26,332	\$26,608	\$26,956	\$26,632

New Webpage

- www.VAproducesafety.com
- Provides links to various resources as well as federal and state law
- Provides contact info for the new program
- Establishes a registration process for farms
 - Not required but helps with inventory of farms

The screenshot displays the website for the Virginia Department of Agriculture and Consumer Services (VDACS). The top navigation bar includes links for ABOUT VDACS, JOBS, SERVICES/FORMS, MEDIA, EMPLOYEE, CONTACT, and SEARCH. Social media icons for Facebook, Instagram, and Twitter are also present. The main content area is divided into two columns. The left column contains a 'MENU' with various categories such as ABOUT VDACS, ANIMALS, CONSERVATION & ENVIRONMENTAL, EDUCATION, FOOD, FOOD SAFETY & CONSUMER PROTECTION, and SERVICES/FORMS. The 'Produce Safety' link is highlighted. The right column is titled 'PRODUCE SAFETY' and contains an introductory paragraph about the program's funding and goals. Below this, there are four main sections: 'Produce Safety Program' with links to Exemptions, FDA Produce Safety Rule, Final Rule on Produce Safety Fact Sheet, Rack Card, Rarely Consumed Raw Produce, and Virginia Produce Safety Law; 'Covered Farms' with links to Coverage and Exemptions Flow Chart, Rack Card, and Register Your Farm; 'Education & Training' with links to Grower Training Courses and Rack Card; and 'Safe Water' with links to Agricultural Water - Geometric Means, Statistical Threshold Values, and Microbial Die-Off Rates, Agricultural Water Overview by VCE, List of Water Testing Labs, Online Tool for Determining Your Microbial Water Quality Profile, Rack Card, and VDACS/OLB Testing Flyer. At the bottom, there are sections for 'Compliance Dates' and 'Information & Resources', both with links to Compliance Dates, Rack Card, Produce Safety Alliance, Required Records and Templates, Sprout Safety Alliance, Virginia Cooperative Extension - Produce Safety, and Virginia Rapid Response Team. Contact information for Erik Bungo and Anne Magee is provided, including phone numbers and email addresses. A footer note mentions 'Download Adobe Acrobat Reader to view PDF files.'

Quiz 1

A farm sells \$19,000 in produce average over a 3 year period at a local farmer's market and through a CSA.

Is this farm covered by the FSMA Produce Safety Rule?

- A.) Yes
- B.) No
- C.) I'm not sure

Quiz 1

A farm sells \$19,000 in produce average over a 3 year period at a local farmer's market and through a CSA.

Is this farm covered by the FSMA Produce Safety Rule?

A.) Yes

B.) No

C.) I'm not sure

Answer: B. This farm would NOT BE COVERED by the PSR since <\$25K produce is sold.

Quiz 2

A farm sells \$35,600 in produce, and also sells \$650,000 in other food products, including sauerkraut and jam (3-year rolling average). Do they satisfy the 'qualified exemption' requirements?

- A.) Yes
- B.) No
- C.) I'm not sure

Quiz 2

A farm sells \$35,600 in produce, and also sells \$650,000 in other food products, including sauerkraut and jam (3-year rolling average). Do they satisfy the 'qualified exemption' requirements?

A.) Yes

B.) No

C.) I'm not sure

Answer: B – No. Since the farm has more than \$25,000 in average annual produce sales (calculated over the previous 3-year period), they would be covered by the Produce Safety Rule. They also do not qualify for the qualified exemption since they sell over \$500,000 of food products.

Quiz 3

A farm sells \$475,000 in produce (3-year rolling avg)

- \$200,000 wholesaler out-of-state/more than 275 miles,
- \$200,000 to a local restaurant, and
- \$75,000 to a local grocery store.

Do they satisfy the requirements for a qualified exemption?

- A.) Yes
- B.) No
- C.) I'm not sure

Quiz 3

A farm sells \$475,000 in produce (3-year rolling avg)

- \$200,000 wholesaler out-of-state/more than 275 miles,
- \$200,000 to a local restaurant, and
- \$75,000 to a local grocery store.

Do they satisfy the requirements for a qualified exemption?

A.) Yes

B.) No

C.) I'm not sure

Answer: A – Yes. The farm is likely to be eligible for a qualified exemption because the sales to qualified end users exceed the sales to other buyers, and the sales are below \$500,000.

Questions?

