

# Introducing the New York State Produce Safety Program

‘Educate – Before and While – We Regulate’



**Agriculture  
and Markets**



# FSMA Becomes Law

What is FSMA?

The Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011.

FSMA aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.





# The Development of the Final Rules

## What is FSMA's Produce Safety Rule?

The Food and Drug Administration (FDA) is responsible for the implementation of FSMA in cooperation with states, tribes and other partners. FDA has released final versions of several major rules to implement FSMA, including the Produce Safety Rule.



# FSMA Includes 7 Final Rules

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Intentional Adulteration
- Foreign Supplier Verification
- Third-Party Certification
- Sanitary Transportation of Human and Animal Food
- Produce Safety





# The Produce Safety Rule

- Published November 27, 2015 and went into affect 60 days later.
- Under FSMA, you do not *need* a written food safety plan, but some records are required.
- The Produce Safety Rule will not replace a third party audit if your buyer requires it.



# The Produce Safety Rule in New York State

Who will implement the Produce Safety Rule?

New York State has worked with the FDA to adopt, implement and enforce the Produce Safety Rule as part of New York State Department of Agriculture and Markets Rules and Regulations.

This approach will ensure New York is safeguarding the interests of its growers, while at the same time continuing to provide protection for its consumers through its longstanding public health mission.





# The Produce Safety Rule in New York State

What has happened in NYS in the last year?

- January 2017 - Two Produce Safety administrators were hired
- July 2017 - NYS adopted *most* parts of CFR 112 (PSR) by reference
- September 2017 - Five Produce Safety/Food Inspectors were hired
  - Erie County, Monroe County, Wayne County, Albany County and Orange County
- November 2017 – Program Aide was hired in Albany to assist with building our Farm Inventory database



# Goals of the NYS Produce Safety Program

- Improve produce safety
- Protect public health
- Increase market access
- Protect viability of NY farms





# How will we implement the Produce Safety Rule?

PHASE IN  
APPROACH

DATA  
GATHERING

OUTREACH

TRAINING

ON-FARM  
READINESS  
REVIEW



**Agriculture  
and Markets**



## Phase 1 – Information Gathering

- As we travel down this regulatory path, we will need to reach out to growers in New York State to determine applicability to the Produce Safety Rule
- In order to determine how to best capture key information about each grower the Department will work with stakeholders to seek feedback on the informational/data gathering process
- Once the process is defined, each farm location will be verified either by calling, emailing or visiting to ensure the name and address on file are correct



## Phase 1 – Information Gathering (cont.)

- After farm location and addresses are verified, each New York State grower will receive an informational packet to complete and mail back to the Department
- This informational packet will be used as a means to communicate with the grower
- There will be *no fees* associated with this process

Informational  
Packets are  
available.



## Phase 2 – Outreach

- As Produce Safety on farms has never been regulated in New York State and as we move toward the implementation phase, the Department will host multiple educational outreach training events
- The Department will use these events to not only educate those affected by the rule, but also as an opportunity to understand the regulated industry and hear your concerns
- For a listing of upcoming Produce Safety outreach events that the Department will be hosting this year, check out our website: <https://www.agriculture.ny.gov/FS/general/fsma.html>



## Phase 4 – On-Farm Readiness Review (OFRR)

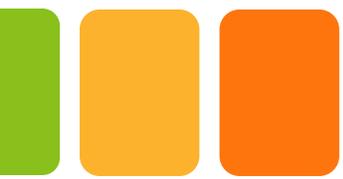
- How? The Department wholeheartedly believes in FDA's FSMA mantra of 'Educate While We Regulate' and as such are going to collaborate with the PSA group, our Cornell Cooperative extension partners, our growers and retailers to perform mock inspections through a program called 'On-Farm Readiness Reviews'.
- Why? The OFRRs will take an educational approach by physically walking the farm to understand what it will take to become compliant with the Produce Safety Rule



# Phase 4 – On-Farm Readiness Review (OFRR)

- Benefits

- We are thrilled with this “first of it’s kind” approach and formation of this collaboration, as it truly will result in a more pragmatic approach to achieving regulatory compliance
- If you would like to volunteer your farm for an OFRR or participate in an OFRR training you can do so by emailing:
  - Betsy Bihn – PSA Director: [eab38@cornell.edu](mailto:eab38@cornell.edu)
  - Aaron Finley – Produce Safety Office Administrator: [Aaron.Finley@agriculture.ny.gov](mailto:Aaron.Finley@agriculture.ny.gov)
  - Steve Schirmer – Produce Safety Field Administrator: [Steve.Schirmer@agriculture.ny.gov](mailto:Steve.Schirmer@agriculture.ny.gov)



Is my business covered or  
exempt from the  
Produce Safety Rule?





# What is the definition of a farm?

## Primary Production Farm

- Operation under one management at one location
- Grows/harvests crops and/or
- Raises animals (including seafood)
- Can pack or hold Raw Agricultural Commodities(RAC) and may conduct certain manufacturing/processing activities (dehydrating, slicing, irradiating, etc.)

## Secondary Activities Farm

- NOT located at the Primary Production Farm
- Harvests, packs or holds RAC
- MUST be majority owned by the Primary Production Farm that supplies the majority of the RAC harvested, packed or held by the Secondary Activities Farm.



## Is my farm exempt?

In the previous 3 years, has your farm averaged \$25,000 or less in **PRODUCE\*** sales?

- Yes, then you are exempt.
- No, then you aren't exempt yet.

**\*Produce** – any fruit or vegetable, including mushrooms, sprouts, peanuts, tree nuts and herbs; does NOT include food grains such as barley, field corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, oilseeds, rapeseed, soybean or sunflower seed



# Is my farm exempt?

Do you sell *any* produce the FDA has NOT identified as 'rarely consumed raw'\*?

- No, then you are exempt.
- Yes, then you aren't exempt.

\*Produce commodities that FDA has identified as '**rarely consumed raw**' include:

asparagus; black beans; great Northern beans; kidney beans; lima beans; navy beans; pinto beans; garden beets (roots and tops); sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes and water chestnuts



## Is my farm exempt?

Will the produce you sell undergo any type of commercial processing that will reduce pathogens?

- Yes, all produce will, then you are exempt.\*
- No, or only some produce will, then you are not exempt.

\* 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)



## Is my farm exempt?

Were your average annual **FOOD\*** sales for the previous 3 years less than \$500,000?

**AND**

Was the majority of the **FOOD** (by value) sold directly to ‘qualified end-users’?





## Is my farm exempt?

\*Food - includes, but is not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods



# Is my farm exempt?

\*Qualified end-user either:

- The consumer of the food OR
- A restaurant or retail food establishment that is located
  - In the same state as the farm that produced the food OR
  - Not more than 275 miles from the farm that produced the food



## Is my farm exempt?

Were your average annual **FOOD** sales for the previous 3 years less than \$500,000?

**AND**

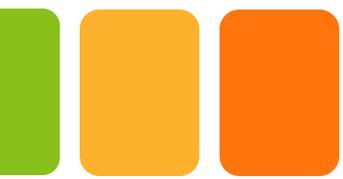
Was the majority of the **FOOD** (by value) sold directly to ‘qualified end-users’?

- Yes to both, you are exempt.
- No to either, you are covered by the Produce Safety Rule.



# Labeling requirements even if farm is exempt

- Name and complete business address on the label starting January 2020.
- When label is not present (bulk displays)
  - Prominently display, at point of purchase, name and complete business address



# Key Requirements of the Produce Safety Rule



# Key Requirements of the Produce Safety Rule

- Personnel health, hygiene and training
- Agricultural water (irrigation and washing)
- Biological soil amendments of animal origin
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities
- Equipment, tools, buildings and sanitation
- Specific requirements for sprouts



# Personnel health, hygiene and training

- All workers that handle produce must be trained\*
- One supervisor per farm must complete training under a FDA recognized curriculum
- Visitors must be made aware of food safety policies set by the farm



# Personnel health, hygiene and training

- Resources that MUST be provided:
  - Toilets
  - Toilet paper
  - Soap
  - Clean water
  - Paper towels
  - Container to catch waste water



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# Agricultural water (irrigation and washing)





# Two Sections on Water

- Part 1: Production Water
  - Water used in contact with produce during growth
  - Irrigation, fertigation, foliar sprays and frost protection
- Part 2: Postharvest Water
  - Water used during or after harvest



# Agricultural water (irrigation and washing)

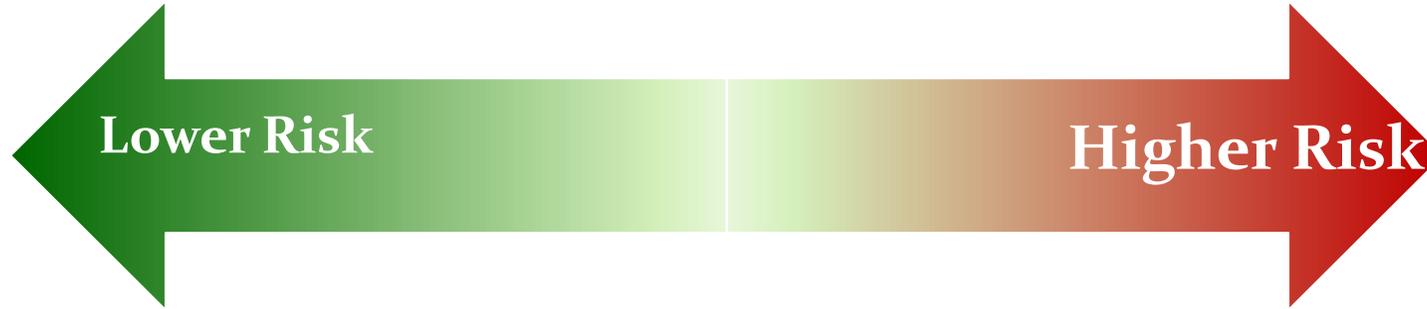
- Agricultural water – water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces

# Risk analysis for production water

- Three criteria to consider:
  1. Water source and quality
    - Municipal water, ground (well) water or surface
  2. Application method
    - Water that does NOT contact the harvestable portion
    - Water that DOES contact harvestable portion
  3. Timing of application
    - At planting
    - Close to harvest



# Probability of Contamination



**Public Water Supply**

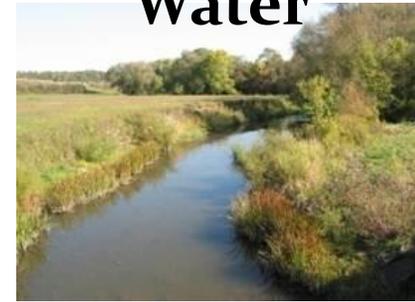


Treated

**Ground Water**



**Surface  
Water**



Open to  
Environment



# Key Requirements of the Produce Safety Rule

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# Biological soil amendments of animal origin – Subpart F

- Addresses the requirements for handling, conveying and storing soil amendments
- Prohibits untreated human waste for growing covered produce
- Records required



# Untreated Soil Amendments of Animal Origins

- Considered the **highest risk** since they have not been treated to reduce or eliminate pathogens
- These soil amendments would be considered **untreated**:
  - Raw manure
  - ‘Aged’ or ‘stacked’ manure
  - Untreated manure slurries
  - Compost teas made with raw manure
  - Any soil amendment mixed with raw manure

# Reducing Soil Amendment Risks

- Selection
- Treatment
- Application Timing
- Application Methods
- Handling and Storage
- Recordkeeping



# Recordkeeping: Soil Amendments

- Treatments, certificates of analysis and any microbial test results (must be obtained annually)
- On-farm composting
  - Temperature, turning, time, etc.





# Key Requirements of the Produce Safety Rule

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# Domesticated and wild animals – Subpart I

- Describes the requirements regarding animals in areas where covered activities take place
  - Monitor for animal intrusion and if observed, evaluate for harvest (no harvesting of visibly contaminated covered produce above or below ground)
    - No records are required to be maintained



# Domesticated and wild animals – Subpart I

- Describes the requirements regarding domestic and working animals in areas where covered produce is grown
  - If working animals are used in a planted growing area, take measures to prevent pathogens from being introduced onto the produce





# Key Requirements of the Produce Safety Rule

- Personnel health, hygiene and training
- Agricultural water (irrigation and washing)
- Biological soil amendments of animal origin
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities
- Equipment, tools, buildings and sanitation

# Growing, harvesting, packing and holding activities

- Describes the measures that must be taken during harvest
- Describes requirements when handling and packing covered produce
- Addresses the separation of covered and exempt produce





# Key Requirements of the Produce Safety Rule

- Personnel health, hygiene and training
- Agricultural water (irrigation and washing)
- Biological soil amendments of animal origin
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities
- Equipment, tools, buildings and sanitation

# Equipment, tools, buildings and sanitation – Subpart L

- Addresses sanitation of tools and equipment
- Describes the requirements that apply to pest control
- Addresses toilet and hand-washing facilities





## GAP vs. Produce Safety

While many growers are already meeting similar voluntary requirements through third party certification programs such as USDA GAP and other voluntary food safety audits, the Produce Safety Rule aims to fine tune such voluntary requirements into a regulatory approach.



# GAP Audits vs. Produce Safety Inspections

## GAP Audit

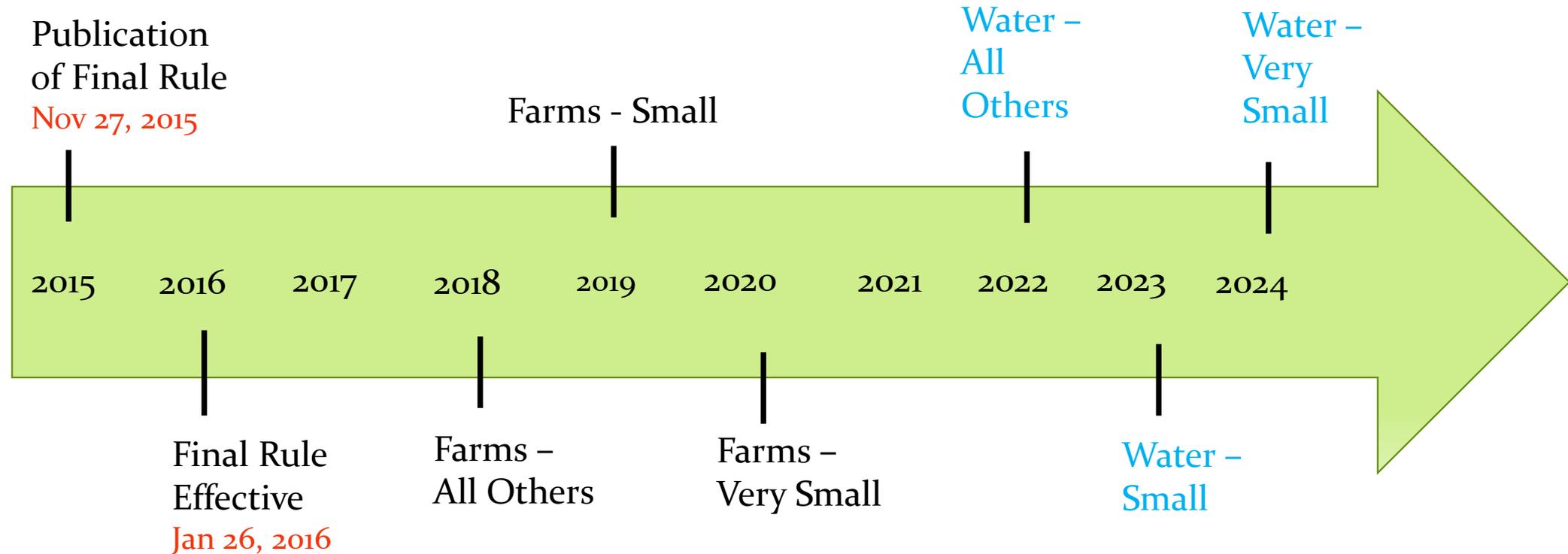
- Audit
- Voluntary
- Fee-for-Service
- Applicant chooses commodities to be audited
- Applicant chooses scopes of audit

## Produce Safety Inspection

- Inspection
- Regulatory, if covered under PSR
- “Free”
- Encompasses all covered commodities
- Encompasses all covered activities of all covered commodities



# Produce Safety Rule Compliance Timeline



All Others (Very Large) - average produce sales over 3 years > \$500,000

Small - average produce sales over 3 years > \$250,000 and ≤ \$500,000

Very Small - average produce sales over 3 years > \$25,000 and ≤ \$250,000



# Resources

NYS Dept. of Agriculture & Markets website:

<https://www.agriculture.ny.gov/FS/GENERAL/FSMA.HTML>

PSA website:

<https://producesafetyalliance.cornell.edu>

FDA website:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

NYS Dept. of Agriculture & Markets contacts:

Steve Schirmer (315) 487-0852 [Steve.Schirmer@agriculture.ny.gov](mailto:Steve.Schirmer@agriculture.ny.gov)

Aaron Finley (518) 457-3846 [Aaron.Finley@agriculture.ny.gov](mailto:Aaron.Finley@agriculture.ny.gov)



# Questions ?



# Celebration of Knowledge

1. Farmer Brown uses drip irrigation to irrigate his apple orchard. Does the water source need to be tested? If so, how often? If not, why not?

Answer: No, the water source does NOT need to be tested, as it does not meet the definition of agricultural water because it is not coming into contact with the edible portion of the crop.



## Celebration of Knowledge

2. Farmer Brown uses overhead irrigation to irrigate his potato fields. Does the water source need to be tested? If so, how often? If not, why not?

Answer: No, the water source does NOT need to be tested, as it does not meet the definition of agricultural water because it is not coming into contact with *covered* produce.



## Celebration of Knowledge

3. Farmer Brown has averaged over \$25,000 in **produce** sales over the past 3 years. He/she grows potatoes, onions and sweet corn. They have averaged over \$500,000 in annual **food** sales over the past 3 years. The majority of their food is sold directly to qualified end users. Is Farmer Brown covered under the Produce Safety Rule?

**Answer:** Yes, the farm would need to have averaged *less than* \$500,000 in annual food sales over the past 3 years **AND** sold the majority of the food directly to qualified end users to be qualified exempt.