



RIDEM Division of Agriculture

Rhode Island Produce Safety Program

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Overview

- What is FSMA?
- Basis for agency transfer
- Food safety aligns with Division of Agriculture's values
- External driving forces for produce safety
- Produce Safety Rule breakdown
- RI's Produce Safety Program
- Trainings and Outreach



What Is FSMA?

Food Safety Modernization Act (FSMA)

- Signed into law in 2011
- First comprehensive federal food safety law in over 70 years

Need for a National Food Safety Regulation:

- Annual CDC data shows:
 - 48 million sick
 - 128,000 hospitalized
 - 3,000 deaths
- Cause: foodborne disease
- Preventable public health burden
- Uniform standards across the industry

Food Safety Modernization Act (FSMA)

- President Obama signed into law on Jan. 4, 2011
- **Responsibility of FDA to implement**
 - Enables FDA to better protect public health by strengthening the food safety system.
- Involves FDA partnership with state and local authorities
- Based on prevention and risk-based food safety standards
- Provides FDA with enforcement authorities
 - Achieve higher rates of compliance
- Holds imported foods to the same standards as domestic food

Food Safety Modernization Act (FSMA)

Contains 7 major Rules:

1. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Controls for Human Food (2015)
2. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Controls for Animal Food (2015)
3. Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption (2016)
4. Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (2015)
5. Accredited Third Party Certification (2015)
6. Sanitary Transportation of Human and Animal Food (2016)
7. Mitigation Strategies to Protect Food Against Intentional Adulteration (2016)

Food Safety Modernization Act (FSMA)

FDA Compliance Date Extensions

Compliance Date Extensions for Four of FSMA Rules:

1. Preventive Controls for Human Food*
2. Preventive Controls for Food for Animals*
3. Produce Safety Final Rule – Agricultural Water, earliest compliance date January 26, 2022
4. Foreign Supplier Verification Programs (FSVP)*

*For all other rules, provisions concerning written customer assurances are extended 2 years from original compliance date

- E.g. Manufacturer must obtain written assurance from customer that food will be processed according to applicable food safety requirements

Produce Safety Rule

FDA's Produce Safety rule establishes, *for the first time*, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

- Effective January 26, 2016.
- First time produce is regulated and inspected on farms

Agency Transfer

- RI Department of Health (RIDOH) was the grantee agency for FY17 and FY18
- RI Legislation in 2017 transferred authority to RIDEM
- FDA Cooperative Agreement transferred from the RIDOH to the RIDEM– Division of Agriculture, effective **July 1 2018** (FY19 – FY21).

RIDEM Division of Agriculture

List of Programs and Services

- *Produce Safety*
- Good Agricultural Practices
- Animal Health and Welfare
- Marketing and Promotion
- LASA and Farm Viability Grants
- Farm Energy Grants
- Pesticide Regulation
- Wetlands Permitting
- Composting Registration
- Organic Certification
- Farmland Designation
- Agricultural and Consumer Protection Standards
- Consumer Protection
- Invasive Pest and Disease Monitoring
- Mosquito Abatement
- Saltmarsh Restoration Projects

Produce Safety Education & Training

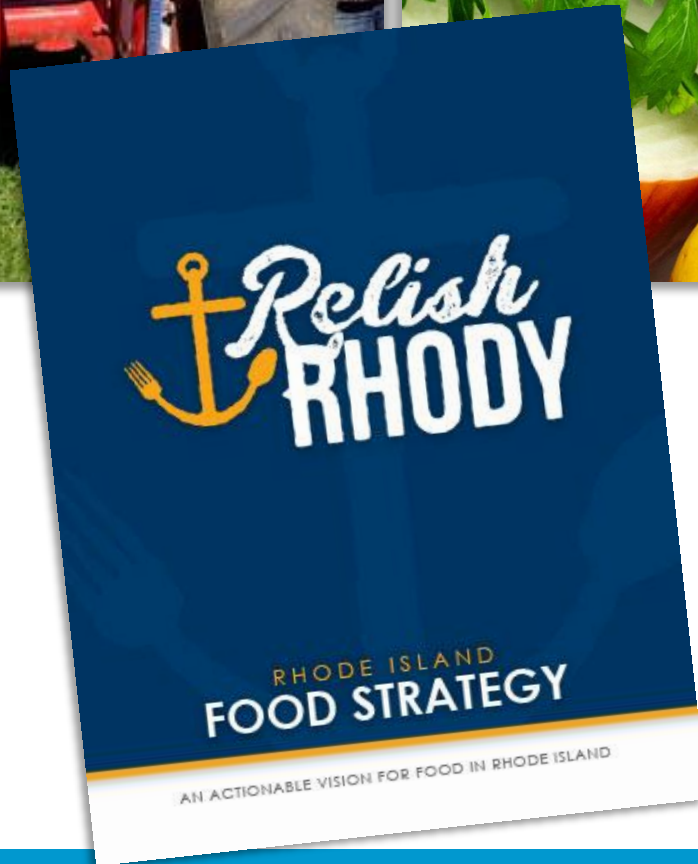
RI Good Agricultural Practices (GAP)

- Program established by RIDEM/URI over a decade ago
- Voluntary certification program
- Audited annually
- Focuses on food safety practices during growing, harvesting, processing and transporting produce
- RI GAP program Key Components:
 - Application of manure
 - Irrigation water
 - Worker hygiene practices
 - Sanitation practices
- Currently 29 farms certified



**A GROWER
CERTIFICATION PROGRAM**

**R I DEPT OF ENVIRONMENTAL
MANAGEMENT
DIVISION OF AGRICULTURE
AND
UNIVERSITY OF RHODE ISLAND
COOPERATIVE EXTENSION
FOOD SAFETY EDUCATION
PROGRAM**



An actionable vision for food in Rhode Island



Northeast Economic Engine

Agriculture, Forest Products and Commercial Fishing

A recent study by Farm Credit East

STUDY HIGHLIGHTS

Impacts of agriculture, commercial fishing, forestry and related businesses in eight Northeast states

STATE	ECONOMIC IMPACT (\$ BILLION) ⁴	NUMBER OF FARMS ⁵	ACRES IN FARMLAND ⁶	JOB SUPPORTED
CONNECTICUT	4.8	5,977	436,539	25,495
MAINE	13.9	8,173	1,454,104	79,011
MASSACHUSETTS	12.7	7,755	523,517	60,760
NEW HAMPSHIRE	3.1	4,391	474,065	18,773
NEW JERSEY	12.8	9,071	715,057	58,006
NEW YORK	48.2	35,537	7,183,576	197,745
RHODE ISLAND	1.1	1,243	69,589	6,591
VERMONT	6.6	7,338	1,251,713	36,994
TOTAL	103.4⁷	79,485	12,108,160	483,375



Commercial fishing and agriculture create more than \$1 billion in economic activity

- With 1,243 farms and 69,589 acres in farmland, agriculture is a key part of the Ocean State's economy and working landscape.
- Greenhouse and nursery production is the largest farm production sector in Rhode Island, with a \$46.9 million impact.
- Altogether, agriculture and related processing generated \$439 million in direct sales, \$599 million in impact and supported 2,983 jobs.
- Rhode Island's large commercial fishing industry generated \$184 million in direct sales, \$286 million in economic impact and 2,668 jobs.

Rhode Island Farm Sales



- 58% Fishing
- 20% Greenhouse & Nursery
- 6% Vegetable
- 4% Forestry & Logging
- 3% Fruit
- 3% Other Livestock
- 2% Other Crops
- 2% Dairy
- 1% Aquaculture
- 1% Poultry & Egg

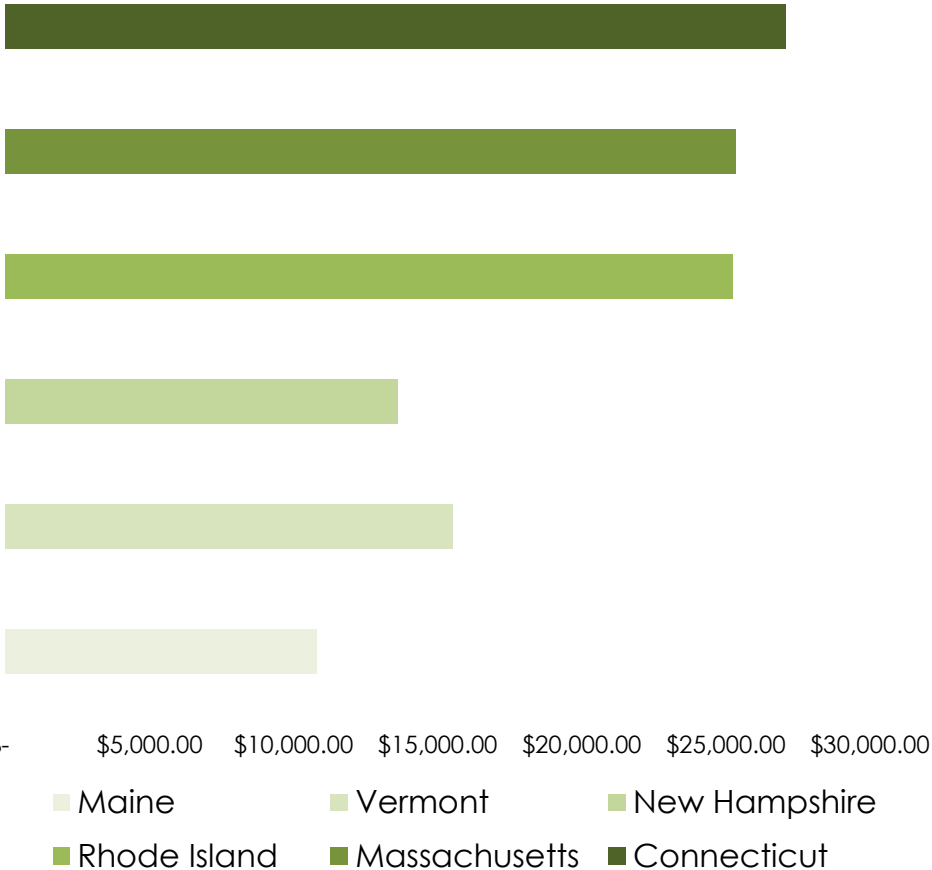
Average Direct Market Sales per Farm

New England States Rankings

- Connecticut, \$27,072 per farm, 1st
- Massachusetts, \$25,356 per farm, 2nd
- **Rhode Island, \$25,270 per farm, 3rd**
- New Hampshire, \$13,615 per farm, 5th
- Vermont, \$15,541 per farm, 8th
- Maine, \$10,803 per farm, 12th

2012 USDA Census of Agriculture

Average Direct Market Sales (USD)



Food Miles

Food miles is a term which refers to the distance food is transported from the time of its production until it reaches the consumer

- National average **1300 – 1600** miles from farm to consumer
- CA produces 55-60% of all produce in the US



Produce Safety is Market Driven

Wegmans Food Markets

“The FDA [Food and Drug Administration] Food Safety Modernization Act has an exemption for small farms, but we believe that rigorous food safety standards should apply to all farms we work with.” - Bill Pool, Food Safety Manager



Sid Wainer & Son® follows all FSMA guidelines

“All partner farms are put through a vendor approval process. If they cannot meet food safety standards, Sid Wainer & Son® works with them to put the right processes in place to ensure that customers receive the safest quality food without breaking the cold chain.” – sidwainer.com



Produce Safety Outbreaks 2018

Pre-Cut Melon Outbreak

- Multistate outbreak of *Salmonella* Adelaide infections linked to pre-cut melon
 - Recall on fresh cut watermelon, honeydew melon, cantaloupe, and fruit medley products containing these melons
- Resulted in:
 - 77 cases in 9 states
 - 36 hospitalizations
 - No deaths

Romaine Lettuce Outbreak

- Multistate outbreak of *E. coli* O157:H7 due to romaine lettuce sourced from Yuma growing region
- Resulted in:
 - 210 people in 36 states ill
 - 96 hospitalizations
 - 5 deaths
- Traceback investigation found presence of outbreak *E. coli* strain in canal water in the Yuma growing region



CDC, 2018



CDC, 2018



Produce Safety Rule

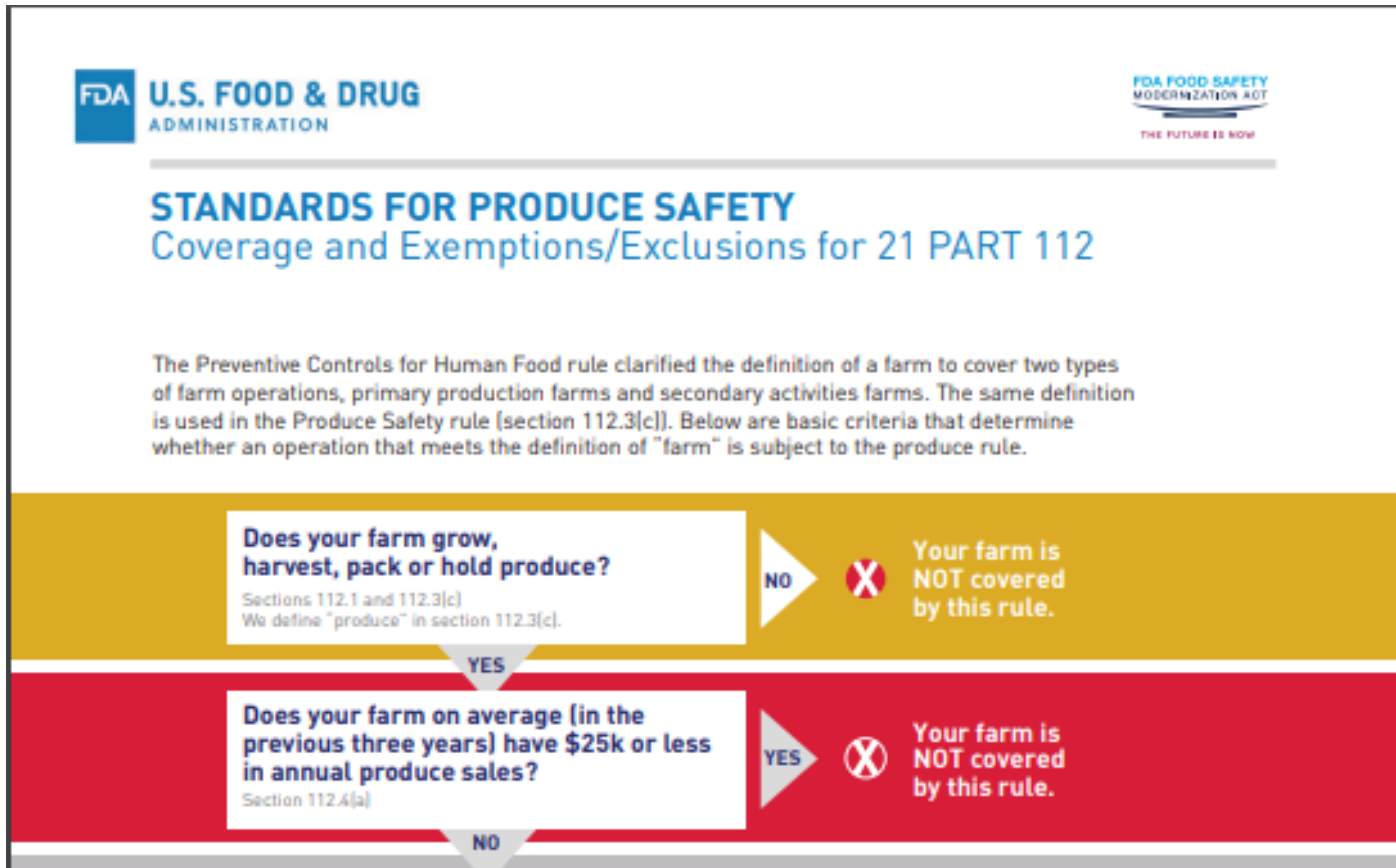


Produce Safety Rule Key Requirements

The Produce Safety rule establishes, *for the first time*, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

- 1. Agricultural Water**
- 2. Biological Soil Amendments of Animal Origin**
- 3. Domesticated and Wild Animals**
- 4. Worker Training, Health and Hygiene**
- 5. Equipment, Tools, Buildings and Sanitation**

Produce Safety Rule Exemptions



FDA Coverage and Exemptions/Exclusions Flowchart, November 13, 2015

RIDEM Division of Agriculture

Does not apply to:

- Farms not performing covered activities
- Farms making \leq \$25k

Farms must keep documentation to Support Exemption or Exclusion from the Produce Safety Rule.

Produce Safety Rule Exemptions



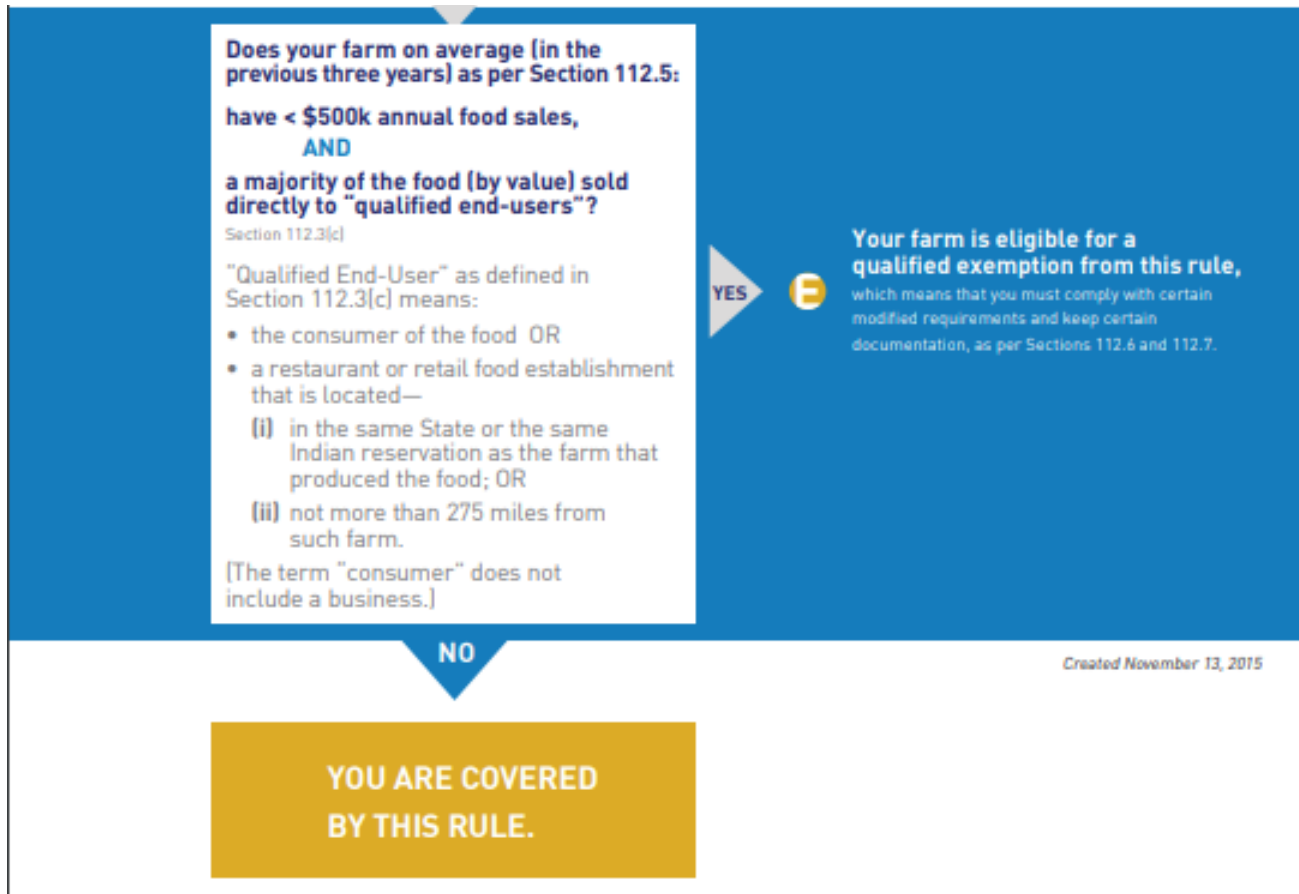
The Produce Safety Rule applies to all produce EXCEPT:

- Rarely Consumed Raw
- On-farm consumption
- Commercially processed

Farms must keep documentation to Support Exemption or Exclusion from the Produce Safety Rule.

FDA Coverage and Exemptions/Exclusions Flowchart, November 13, 2015

Produce Safety Rule Exemptions



Eligible for Qualified Exemption if:

1. Average total food sales for previous 3 years falls between \$25k - \$500k
2. More than 50% of those sales go to "Qualified End-Users"

Farms must keep documentation to Support Exemption or Exclusion from the Produce Safety Rule.





Produce Safety Rule Exemptions

FDA gives explicit detail for growers to keep records to establish themselves as Qualified Exempt (§ 112.5)

“You must establish and keep adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption that are described in § 112.5, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption.”

Under the Produce Safety Rule farms are considered “covered” unless this documentation is provided.

Produce Safety Rule Compliance Timeline

Business Size	Compliance Dates for Sprouts 	Compliance Dates For Most Produce 	Routine Regulatory Inspections 	Water-Related Compliance Dates 	Compliance Date for Qualified Exemption Labeling Requirement	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>\$500,000)	1/26/2017	1/26/2018	Spring 2019	1/26/2022	1/1/2020	1/26/2016
Small businesses (\$250,000 - \$500,000)	1/26/2018	1/28/2019	Spring 2020	1/26/2023		
Very small businesses (<\$250,000)	1/28/2019	1/27/2020	Spring 2021	1/26/2024		



Produce Safety Rule Compliance Dates

- Compliance dates based on **farm size**
 - Average annual monetary value of produce the farm sold during the previous 3-year period
 - Assessed on a rolling basis
- **Upcoming Compliance Dates***:
 - January 26, 2018: Large Farms
 - January 28, 2019: Small Farms
 - January 27, 2020: Very Small Farms

* Does not include sprouts (which have additional requirements and earlier compliance dates)



RI Produce Program

RIDEM Division of Agriculture



Cooperative Agreement with FDA

This means:

- Program monitoring by FDA
- FDA can take any necessary action to ensure compliance under this cooperative agreement
- FDA retains the right to conduct assessments, progress reports, on-site visits, and audits
- **FDA requires the promulgation of state regulations for the Produce Safety Rule**
 - **RI is in the process of establishing this Regulatory Authority**
 - **Authority remains with the FDA until State regulations are in place**

New England Farm Data

- 2012 NASS Survey Data for New England

State	Estimated Total Number of Farms	Estimated Number of Produce Farms	Estimated Number of Covered Farms
Rhode Island	1,243	310	+/- 31
New Hampshire	4,391	880	100
Vermont	7,338	1,144	143
Connecticut	5,977	1,227	193
Maine	8,175	2,218	343
Massachusetts	7,755	2,217	396

Rhode Island Farm Data

- 2012 NASS Survey Data for Rhode Island

Total Number of Farms	Total Number of Produce Farms	Total Number of Covered Farms
1,243	310	31

- 2018 RI Farm Survey Data
- **Survey Response:**
 - **30% of produce farms responded**



RIDEM Farm Survey

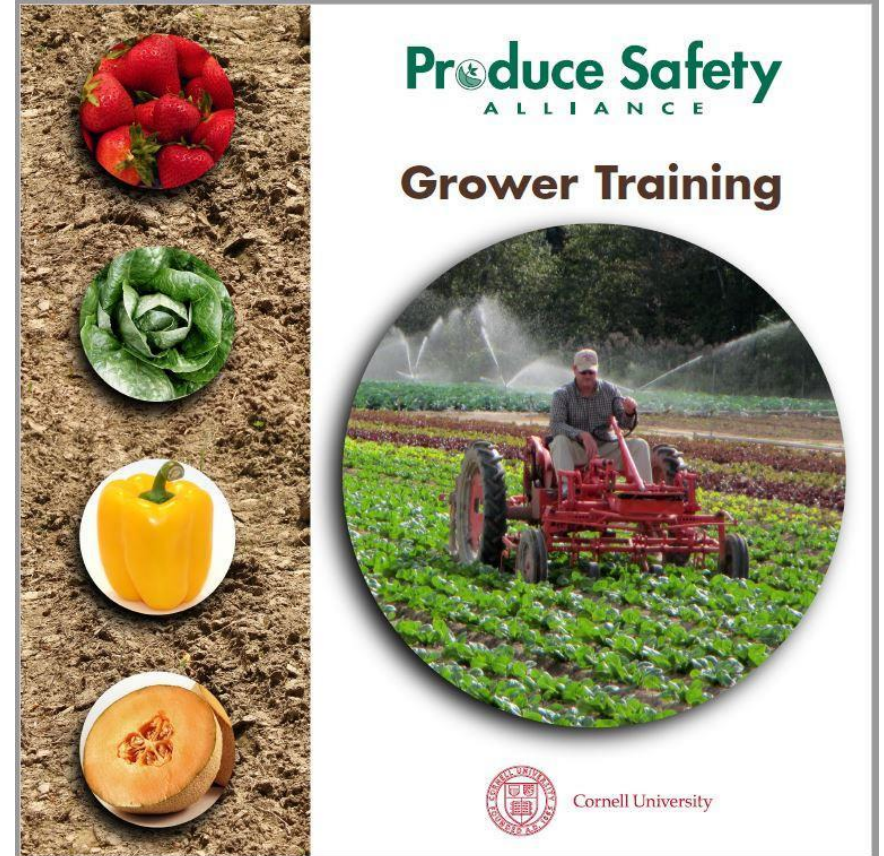
Purpose:

- Update Division of Agriculture's Farm Inventory
 - Provide accurate picture of RI's agricultural community
 - Utilize to disseminate regular outreach material
 - Determine farm coverage under the Produce Safety Rule.
- **Inventory Data will be submitted in aggregate format to FDA upon request**
 - **All information is confidential**

PSA Grower Training Course

PSA Grower Training Course

- At least one responsible party per farm must receive FDA approved produce safety training §112.22(c)
- Covers PSR key requirements
- URI Cooperative Extension has two PSA Lead Trainers
 - 3 courses to date; ~40 growers attended
 - Additional courses offered bi-annually
 - Next offerings will take place December 2018 and March 2019.



On-Farm Readiness Review (OFRR)



On-Farm Readiness Review

Developed by Cooperative Extension, Produce Safety Alliance,
State Departments of Agriculture/Health, USDA, FDA and NASDA

- Non-regulatory, confidential, and free assessment of farm's readiness for the Produce Safety Rule
 - On-farm Q&A with Produce Safety Staff
- All visits are scheduled in advance
- OFRRs are currently being offered **in 46 States throughout** the US.
- **Regional**
 - ~300 completed
- **Rhode Island**
 - 8 completed in 2018

State	OFRRs in 2018
Connecticut	8
Maine	40+
Massachusetts	100
New Hampshire	14
New Jersey	100
Vermont	30

DEM Agricultural Water Testing Program

- Voluntary, free water tests to monitor water quality
- Includes:
 - 2 tests per growing season
 - Surface and groundwater sources
 - Test for generic E. Coli
 - Samples processed at RI Department of Health Laboratory
- Objective:
 - Educate growers on water sampling techniques
 - Strengthen water quality monitoring practices
 - Reduce financial burden of water testing
- 33 Farms have utilized the service for approx. 50 tests



Outreach – Information Materials

- RI Produce Safety Info Binders
- Pocket PSR
- Fact Sheets for OFRRs and Qualified Exemptions
- FDA Fact Sheets
- New Materials Being Developed
 - Worker Training for the Produce Safety Rule
 - On-Farm Produce Safety Posters and Signage
 - E-Newsletter
 - Multi-lingual resources

Reduce risks in packing areas

- Keep area clean and organized.
- Regularly inspect and maintain equipment.
- Provide proper hygiene facilities and break areas for workers.
- Try to eliminate or reduce pest presence.
- Prevent build-up of standing water.

Post-Harvest Handling and Sanitation

Creating sanitation practices will help keep facilities clean. This reduces the chance of post-harvest contamination of produce. Concepts include general upkeep of facilities, training workers to follow sanitation practices properly, getting rid of pests and debris, and minimizing standing water.



Types of packing houses

- **Open:** Open to the environment; may or may not be covered
- **Closed:** Has doors and windows with some ability to control entry into the building

Packing house zones

- **Zone 1** includes any surface that directly contacts fresh produce.
 - » Biggest concern because contamination could result in cross-contamination of produce
 - » Includes harvest and storage bins, workers' hands, conveyors, belts, brushes, rollers, sorting tables, racks, and utensils
 - » Requires most effort because it has the most immediate impact on food safety
- **Zone 2** includes surfaces not in direct contact with, but near, produce.
 - » Includes internal and external parts of washing or processing equipment such as sidewalls, housing, or framework
- **Zone 3** includes all other areas inside the packing house, such as trash cans, cull bins, floors, drains, forklifts, phones, and foot traffic areas.
- **Zone 4** includes areas outside of or next to the packing house, such as loading docks, warehouses, manure or compost piles, and livestock operations.

...ces
... from the food contact surface.
... at removing carbohydrates, such as sugars
... making sure to remove all the detergent
... on food contact surfaces (when
... air dry.
... so they can be properly cleaned and
... y-contamination.
... te, to prevent contamination of covered
... ed to make cleaning and sanitizing as easy
... spaces.
... ers, and nozzles for cleaning and sanitizing.
... ontainers clean.
... in a covered area, off the floor, to reduce
... indblown dirt, and other contaminants.

next page >>

Rhode Island Produce Safety Program
For more information call (401) 222-2750
PRODUCE SAFETY AREA 21 OR 110

Cleaning and Sanitizing Record

Farm name and address: _____

List the date, time, tool or equipment name, and method for each cleaning or sanitizing activity.

DATE	TIME	LIST OF TOOLS OR EQUIPMENT	CLEANED OR SANITIZED?	METHOD USED	CLEANED BY (INITIALS)
10/11/16	10:07 am	Harvest tools	cleaned	See Cleaning SOP (removed dirt with brush, washed with detergent, rinsed, air dried)	EAB
10/11/16	10:30 am	Dump tank	cleaned and sanitized	See Dump Tank Cleaning and Sanitizing SOP (drained tank, washed with detergent, rinsed, sanitized with 150 ppm NaOCl)	EAB

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.140(b)(2) Confidential Record

Outreach – Off Season Meetings

- Upcoming Workshop Topics
 - Post-Harvest Activities under the Produce Safety Rule by Chris Callahan of UVM on November 13 2018.
 - Produce Safety Rule for Buyers
 - Funding Opportunities for RI Growers
 - Interstate alignment for Produce Safety (MA and CT)
- Upcoming Grower Meetings
 - Produce Safety Staff attend/ will attend NOFA/RI, RI Ag Council, Farm Bureau, Fruit and Berry Growers Assoc., Young Farmers Network
 - Division of Agriculture will sponsor grower meetings in the coming months.

Outreach – Upcoming Workshop



RHODE ISLAND DEM | DIVISION OF AGRICULTURE

PRODUCE SAFETY PROGRAM

ANNOUNCEMENTS & NEWS

Save the Date! Planning for Postharvest Facilities: Washing, Packing and Storage

Tuesday, Nov. 13 | 8:00-11:00 AM | [URI Coastal Institute Auditorium](#)

*SPEAKER: CHRIS CALLAHAN, EXTENSION ASSOCIATE PROFESSOR OF
AGRICULTURAL ENGINEERING, UNIVERSITY OF VERMONT*



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Outreach – Regular Meetings

- Outreach to date:
 - Farmers Markets – Produce Staff attended State Sponsored Farmers Markets as well as Farm Fresh Markets.
 - Ag Community Meetings – In 2018 Produce Program Staff have attended 13 different agriculture community meetings or events.
 - Voluntary Farm Visit – Produce Program staff have conducted 18 educational farm visits. (Not including OFRRs)

Outreach – Past Workshops and Meetings

- RI Women in Ag pre-planning meeting 2/15/2018
- NOFA/RI Annual Winter Conference for Organic Farm, Garden and Livestock 3/4/2018
- Wildlife Pest Management and Sweet corn 3/5/2018
- Women in Agriculture Conference 3/6/2018
- Food to Institution Event 3/7/2018
- Rhode Island Agricultural Council Meeting 3/15/2018
- RI Fruit Grower Association Annual Meeting 3/22/2018
- Rhode Island Agriculture Day 5/30/2018
- Voluntary Farm Visit 6/11/2018
- Voluntary Farm Visit 6/12/2018
- Voluntary Farm Visit 6/14/2018
- Produce Safety/GAP Training 6/27 – 6/28/2018
- Farmers Market 7/13/2018
- Voluntary Farm Visit 7/13/2018
- Produce Safety Advisory Committee Meeting 7/16/2018
- Produce Buyer Meeting 7/17/2018
- Voluntary Farm Visit 7/20/2018
- RI Farm Bureau - OFRR outreach 7/23/2018
- On-Farm Readiness Review 7/24/2018
- On-Farm Readiness Review 8/7/2018
- On-Farm Readiness Review 8/16/2018
- Young Farmers Network Meeting 8/22/2018
- Farmers Market Visit 8/24/2018
- On-Farm Readiness Review 8/28/2018
- Farmers Market Visit 8/30/2018
- Farmers Market Visit 8/31/2018
- On-Farm Readiness Review 9/5/2018
- On-Farm Readiness Review 9/6/2018
- GAP Advisory Meeting 9/7/2018
- On-Farm Readiness Review 9/26/2018
- Voluntary Farm Visit 10/2/2018

Outreach - Web Resources

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- RI Produce Safety Website
www.dem.ri.gov/producesafety
- URI Cooperative Extension - Food Safety Website
<https://web.uri.edu/foodsafety/>
- Produce Safety Alliance Website
<https://producesafetyalliance.cornell.edu/>
- FDA's Produce Safety Network

Produce
Safety
ALLIANCE

FDA FOOD SAFETY
MODERNIZATION ACT