FSMA Produce Safety Rule

One of 7 FDA Food Safety Modernization Act (FSMA) Rules

Final as of November 27, 2015

“Effective” as of January 26, 2016

Compliance for some businesses begins in 2018
VT Required Agricultural Practices

Established by Act 64

Replaces Accepted Agricultural Practices (2006–2015)

Revised draft RAPs published February 22, 2016

RAPs will become final on July 1, 2016
Who’s covered?

Farms with greater than $25,000 in annual produce sales (averaged over 3 years) are covered by the FSMA Produce Safety Rule—but requirements vary.

- Qualified Exempt Farms
- Very Small Businesses
- Small Businesses
- “All Other Businesses”

All Vermont farms are covered by RAPs—but only some farms are required to certify compliance.

- Act 64 defines Small Farm Operations (SFOs), Medium Farm Operations (MFOs) & Large Farm Operations (LFOs)
- All MFOs & LFOs are required to certify compliance with the Agency of Agriculture.
- Only some SFOs will be required to certify. The threshold to determine which SFOs need to certify will be determined through rulemaking.
FSMA Produce Safety Rule & RAPs

FSMA Produce Safety Rule
Requirements vary based on produce and food sales

Certified SFO, MFO & LFO
Certify compliance with RAPs
Obtain Farm Operator Training
Pay permit fee

Uncertified SFO
Comply with RAPs

Remember: All Vermont farms are covered by RAPs even if they do not need to certify.
FDA Definition of a Farm

Primary Production Farm
- An operation “under one management” & “in one general location”
- Devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities

Secondary Activities Farm
- An operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs
- Provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm
- A secondary activities farm may also conduct those additional activities allowed on a primary production farm.

Additional Activities
- Treatment to manipulate the ripening of RACs and packaging and labeling the treated RACs without additional manufacturing/processing
- Drying/dehydrating RACs to create a distinct commodity falls within the “farm” definition (e.g., drying/dehydrating grapes to produce raisins), but some types of manufacturing/processing will cause an operation that dries/dehydrates RACs to create a distinct commodity to fall outside the “farm” definition (e.g., slicing)
Covered Activities

Growing, Harvesting, Packing, or Holding of Produce for Human Consumption
Covered Produce

Produce that is a raw agricultural commodity (RAC) except for “produce that is rarely consumed raw,” specifically the produce on the following exhaustive list:

- asparagus
- black, great northern, kidney, lima, navy, and pinto beans
- beets
- 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
- water chestnuts.
Implementation Timeline

2017
Vermont will pilot On-Farm Readiness Reviews

2018
Compliance begins for larger businesses

2019
Compliance begins for small businesses

2020
Compliance begins for very small businesses

Compliance dates for certain aspects of the rule’s water quality standards begin two years beyond each compliance date for the rest of the final rule. Inspection dates/frequency not yet determined.
Specific Requirements for Sprouts

The final rule includes new requirements to prevent the contamination of sprouts.

Sprout operations will have less time to come into compliance with the rule than farms growing other types of produce.

Sprout operations will have one to three years to comply based on the size of their operation, with no additional time to meet the water requirements.
<table>
<thead>
<tr>
<th>Category</th>
<th>Threshold</th>
<th>Compliance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Covered</td>
<td>Less than $25,000 in annual produce sales</td>
<td>n/a</td>
</tr>
<tr>
<td>Qualified Exemption</td>
<td>Must have food sales averaging less than $500,000 per year during the previous three years; and more than 50% of the farm’s sales must be to qualified end-users</td>
<td></td>
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<tr>
<td></td>
<td>A qualified end-user is (a) the consumer of the food or (b) a restaurant or retail food establishment within the same state or not more than 275 miles away—direct to consumer; direct to restaurant; direct to retail</td>
<td></td>
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<tr>
<td></td>
<td><strong>Compliance date for retention of records supporting qualified exemption</strong></td>
<td>January 26, 2016</td>
</tr>
<tr>
<td></td>
<td><strong>Compliance date for labeling requirements</strong></td>
<td>January 26, 2020</td>
</tr>
<tr>
<td>Very Small Business</td>
<td>Less than $250,000 in annual produce sales</td>
<td>January 26, 2020</td>
</tr>
<tr>
<td>Small Business</td>
<td>Less than $500,000 in annual produce sales</td>
<td>January 26, 2019</td>
</tr>
<tr>
<td>All Other Businesses</td>
<td>Not in the above categories</td>
<td>January 26, 2018</td>
</tr>
</tbody>
</table>
Vermont State Impact

FSMA Produce Safety Rule in Vermont

- Farms growing produce with annual produce sales $500,000+
  - 15 farms

- Farms growing produce with annual produce sales $25,000–$499,000
  - 400 farms
  - 135 farms

- Farms growing produce with annual produce sales <$25,000
  - 500 farms

*Estimates based on 2012 U.S. Census of Agriculture data provided by the National Agricultural Statistics Service (NASS) for the National Association of State Departments of Agriculture (NASDA) in August 2015.*
Key Requirements

Agricultural Water (Testing)
- Water used for washing hands, on food contact surfaces, to directly contact produce, for sprout irrigation, and other uses where dangerous microbes could be transferred to produce through direct or indirect contact
- Water applied directly to growing produce (other than sprouts)

Biological Soil Amendments
- Raw Manure
- Stabilized Compost

Domesticated and Wild Animals

Worker Training & Health and Hygiene

Equipment, Tools & Buildings

Variances
Take the decision tree survey online!

https://www.surveymonkey.com/r/vtfsma
State Collaboration with FDA

Over the past three years, states have worked with FDA to develop an Operational Plan for Produce Safety Rule Implementation.

• FDA does not have the resources or expertise to inspect farms.
• States are preparing to build programs to provide outreach, education, and technical assistance as well to eventually conduct inspections.
• We want to ensure that producers can meet market demand for food safety/FSMA compliance certification.
Objectives of State Produce Program

1. FSMA Produce Safety Rule will impact Vermont farmers and we want a local liaison between industry and FDA
2. Ensure that producers can meet market demand for food safety and compete in the regional marketplace
3. Provide education and technical assistance to ensure compliance prior to enforcement ("educate before—and while—you regulate")
4. Support public health
DRAFT Mission Statement

The Vermont Produce Safety Program will help to grow Vermont’s produce industry—in the face of new federal regulations and changing market expectations—by aiding produce farms of all sizes and stages of development to meet food safety requirements, access markets, and promote public health.

This cross-divisional program will serve Vermont farms that grow and sell produce covered under FDA’s Produce Safety Rule and engage critical external partners across a produce safety program continuum.
Produce Safety Continuum for Farms

DRAFT
a produce safety plan

ATTEND
a UVM Practical Produce Safety Workshop

JOIN the VVBGA CAPS program

COMPLETE
GAP certification

PARTICIPATE
in a Produce Safety Alliance training

TAKE PART
in an On-Farm Readiness Review

SEEK
FSMA-compliance certification

TAKE PART
in an On-Farm Readiness Review

COMPLETE
GAP certification

PARTICIPATE
in a Produce Safety Alliance training

JOIN the VVBGA CAPS program

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DRAFT
a produce safety plan
**Produce Safety Program Model**

**Regulatory Compliance**
- Focus on FSMA, eggs, strawberries, apples, potatoes & maple inspections
- Conduct on-farm readiness reviews
- Assist with GAP audits, retail & farmers market inspections
- Conduct on-farm FSMA inspections (produce & preventive controls)

**Industry Development (could include certification)**
- Conduct FSMA inspections (produce & preventive controls)
- Focus on market access & development
- Conduct on-farm readiness reviews
- Provide outreach, education & technical assistance
- Establish farm inventory & build program infrastructure

**Industry Development** (could include certification)
- Conduct on-farm readiness reviews
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- Conduct on-farm readiness reviews
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- Establish farm inventory & build program infrastructure
Stages of Program Development

- **Stage 0.5**
  - 2015
  - Initiate stakeholder & industry outreach

- **Stage 1**
  - 2016
  - Obtain expanded statutory authority at the state legislature

- **Stage 2**
  - 2016
  - Locate resources

- **Stage 3**
  - 2017
  - Propose a state program

- **Stage 4**
  - 2017
  - Accept public comment & feedback

- **Stage 5**
  - 2018
  - Roll out program
• Program development work group
• Educational meetings

**Winter/Spring 2016**

• Vermont pilots on-farm readiness reviews

**June 2017**

• Compliance begins for businesses with produce sales >$500,000

**January 2018**

• Compliance begins for small businesses

**January 2019**

• Compliance begins for very small businesses
• Labeling requirement for Qualified Exemption

**January 2020**

*Inspection dates and frequency not yet determined*
Food Safety Modernization Act
Educational Workshops

FSMA Produce Safety Rule & Program Development Workshop
March 31, 2016 2:00–4:00 PM
Pavilion Auditorium 109 State Street, Montpelier

FSMA Preventive Controls & Produce Safety Rule Workshop
CO-HOSTED BY THE VERMONT DEPARTMENT OF HEALTH
April 4, 2016 2:00–4:00 PM
Vermont Department of Health 108 Cherry Street, Burlington

FSMA Produce Safety Rule & Program Development Workshop
April 5, 2016 5:30–7:30 PM
Rutland Free Library 10 Court Street, Rutland
Agreement of Agriculture
Food & Markets

Food Safety & Consumer Protection

“Food policies need to be for the consumer, by the consumer, and about the consumer.”

RENEW ONLINE
Online renewal is currently unavailable.
License renewal forms will be posted soon.

HOT TOPICS
Click HERE to sign up for our AgriView E-Newsletter
12-8-15 Fresh Kielbasa recall
12-3-15 FTP Active Recall
11-2-15 Vermont Harvest Festival

BUY LOCAL/BUY VERMONT
Vermont Vacation
Vermont Nurseries
Vermont CSA's
Vermont Farmers' Markets
Vermont's Fruits and Vegetables

DIG IN
VERMONT.gov
Consumer Protection Handbook

Contact us
AGR.FSMA@vermont.gov
(802) 522-7811
What are the RAPs?

VAAFM was directed by the Legislature to draft the RAPs pursuant to Act 64, signed into law on June 16, 2015.

VAAFM has been charged with revising the RAPs by rule on or before July 1, 2016.

AAPs Since 1995
Act 64 requires that the revised RAPs include requirements for:
- small farm certification,
- nutrient storage,
- soil health,
- buffer zones,
- livestock exclusion, and
- nutrient management.

*Tile Drainage Rules for Jan 15, 2018*
1st Draft of RAPs Released
Comment Period Begins
Small Group Meetings Begin

St. Albans Coop, NOFA-VT, Farmers Watershed Alliance,
VT Grass Farmers Assoc, VACD, NRCD's, CLF, ENR/C,
Sierra Club, VT Conservation Voters, VT Trout Unlimited,
Linthicum Foundations, Lake Champlain Committee, South
Lake Farmers, VT Farm Bureau, VT Veggie and Berry
Growers Assoc., Legislators, CT River Farmers Watershed
Alliance, VT Planners Association, TROC RPC, Chittenden
City RPC, VT League of Cities and Towns.

1st Draft Comment Collected
Begin Drafting 2nd Draft

Oct 2015
Nov 2015
Dec 2015
1st Draft of RAPs Released
Comment Period Begins
Small Group Meetings Begin

Nov 2015

Oct 2015

1st Draft Comment Collected
Begin Drafting 2nd Draft

Dec 2015

10 Statewide Public Meetings
St. Albans, Enosburg, Middlebury, Rutland,
White River Jct., Brattleboro, St. Johnsbury,
Newport, Montpelier and Randolph

Jan 2016

Legislature Returns
Provide Technical Corrections
- Unretorted vs. Improved Stacking Silts clarified
- Exempt waste storage facilities designed by an engineer
  from setback requirements

Feb 2016

2nd Draft: RAPs Released
for Public Review

Mar

Pre-Filing with Int.
on Administrative

March 15, 2016 FILED
Rule Mak
- Jan 2016: 2nd Draft RAPs Released for Public Review
  Estimate available on Agency website February 15, 2016
- Mar 2016: Proposed Rule Filed with Secretary of State
- Apr 2016

Dec 2015
- Draft Comment Collected
- Begin Drafting 2nd Draft
Jan 2016: 2nd Draft RAPs Released for Public Review

Mar 2016: Proposed Rule Filed with Secretary of State

May 2016: Legislative Committee on Administrative Rules (LCAR) Review

Feb 2016: Legislature Returns Provide Technical Corrections

Apr 2016: Pre-Filing with InterAgency Committee on Administrative Rules (ICAR)

June 2016: Public Hearings & Official Comment Period on Proposed RAP Rule

March 15, 2016: FINAL DRAFT of RAPs will begin Rule Making Process
Comment To:

AGR.RAP@vermont.gov

2\textsuperscript{nd} Draft RAPs Available week of 2/22 @ VAAFM RAP Website

Additional Information:

http://agriculture.vermont.gov/water-quality/regulations/rap
Comment To:
AGR.RAP@vermont.gov

2nd Draft RAPs Available week of 2/22 @ VAAFM RAP Website

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