Vermont Produce Safety & Market Access Program

2/17/2016

The Food Safety Modernization Act (FSMA): What is it?

- Signed into law in 2011; largest update of the Food, Drug & Cosmetic Act since 1938.
- Grants FDA broad new regulatory authority over food production, processing, and distribution.
- FDA charged with establishing rules to prevent foodborne illness and protect public health.
- Rules cover human and animal food; domestic food and imported food; production, processing, and transportation

The Produce Safety Rule: Why is it important?

- New Regulations: For the first time, the produce industry will be regulated for food safety across the country.
- Farm Viability: Produce industry understands the value of high quality, safe products.
- Market Access: Market may drive compliance with federal produce safety rules beyond covered farms and before FDA-mandated inspections occur.
- State Program: Vermont producers have expressed support for the development of a state-level program to provide interface between growers and FDA.

Final FSMA Rules

RULE	EARLIEST COMPLIANCE DATE
Preventive Controls for Human Food	September 2016
Preventive Controls for Animal Food	September 2016
Produce Safety Rule	January 2018*
Accredited Third-Party Certification	N/A – 3 rd -party certification bodies apply to FDA
Foreign Supplier Verification Programs (FSVP)	March 2017

*Sprout producers have only 1–3 years, depending on business size, to comply with specific sprout requirements.

Rules Final in May 2016

- Sanitary Transportation of Human and Animal Food
- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration

About the Produce Safety Rule

COVERED ACTIVITIES

Growing, harvesting, packing or holding produce

COVERED PRODUCE

Produce that is a raw agricultural commodity (RAC) <u>except</u> for "produce that is rarely consumed raw," specifically the produce on the following <u>exhaustive</u> list: asparagus; beans, black; beans, great northern; beans, kidney; beans, lima; beans, navy; beans, pinto; 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.

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About the Produce Safety Rule

COVERED FARMS

Not Covered: Less than 25,000 in annual produce sales

Very Small Business: Less than \$250,000 in annual produce sales – Comply by January 2020

Small Business: Less than \$500,000 in annual produce sales - Comply by January 2019

Qualified Exemption: (1) The farm must have <u>food</u> sales averaging less than \$500,000 per year during the previous three years; <u>and</u> (2) more than 50% of the farm's sales must be to qualified end-users.

- 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)
- A farm eligible for a qualified exemption must still meet certain modified requirements and is required to establish and keep certain documentation.
- A farm's qualified exemption may be withdrawn.
- Compliance date for retention of records supporting qualified exemption January 26, 2016

All Other Businesses – Comply by January 2018



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.

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Consequences for Produce Industry

- The FSMA Produce Safety Rule will impact *at least* 500 Vermont farms that grow fruits & vegetables, with full compliance required as early as January 2018.
- FDA does not want to inspect farms and is committed to providing resource to states (most likely under a cooperative agreement) to build state programs and conduct FSMA inspections.
- Many producers will need to meet market demands for food safety and/or FSMA compliance certification regardless of whether they are fully covered under the rule.
- The Vermont Agency of Agriculture is committing to providing education and technical assistance to ensure compliance prior to enforcement. ("Educate before you regulate.")
- Infrastructure improvement costs for all fruit & vegetable farms in Vermont to comply with food safety standards could be as high as \$5–12 million (estimates based on costs required to meet Good Agricultural Practices (GAP) standards; analysis conducted by Ginger Nickerson, UVM Extension, 2012).

Feedback from Industry Stakeholders & Vermont Vegetable & Berry Growers Association

- Industry has expressed overall support for the Agency to stand up a program and provide FSMA compliance inspections. Buy-in for the "produce safety continuum" concept—education and technical assistance for all farms—and tiered approach (focus on farms that are required to comply with the federal rule first).
- Meeting participants have expressed concerns that FDA will be looking at VT farms through eyes that are used to CA and NJ farms.
- Growers would prefer Agency presence on farms.
- Meeting participants felt that they have a better relationship with the Agency than with FDA and that the enforcement process would be more reasonable.
- Agency is mission-driven to support agriculture.

Estimated Timeline

- **January 2016** Seek expanded statutory authority necessary to implement FSMA Produce Safety Rule
- **Spring/Summer/Fall 2016** Partner with UVM Extension & VT Dept. of Health to provide outreach, education and technical assistance around FSMA Rules
- **January 2017** Seek state funding for grant program to support food safety infrastructure improvements
- Summer 2017 Pilot "On-Farm Readiness Reviews" (OFRR)
- **January 2018** Roll out full produce program, including OFRR, inspections, and industry support
- June 2018 Likely earliest date for inspections