



Produce Safety Rule Negotiated Rulemaking

**Idaho State
Department of
Agriculture**

Agenda



- Introductions
- Background on Idaho Implementation of Produce Safety Rule
- Overview FDA Produce Safety Rule
- HB 537
- Comments on Idaho Strawman Rule
- Outreach and Education

Background



- 2013
 - Began actively following development of Food Safety Modernization Act (FSMA) rules
- 2015
 - Formed the ISDA FSMA Advisory Committee
- 2016
 - Applied and received 5-year FDA grant for Produce Safety
 - Education, Outreach and Technical Assistance
 - Began outreach and education efforts
- 2017
 - Applied and received 4-year FDA grant for Produce Safety
 - Compliance and Enforcement
- 2018 Statutory Authority for implementation

Food Safety Modernization Act

- Signed into law January 2011
- FDA authorized to promulgate rules
- Rules are preventive, science-based controls
- Apply domestically and internationally
- Rules affect everyone from farm-to-fork
- Phased adoption beginning August 2015



FSMA – 7 Rules

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (**Produce Rule**)

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (**Preventive Control for Human Food Rule**)

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (**Preventive Control for Animal Food Rule**)

- Sanitary Transportation of Human and Animal Food (**Transportation Rule**)



FSMA – 7 Rules

Continued



- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (**Intentional Adulteration Rule**)
- Accreditation of Third-Party auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (**3rd Party Auditor Rule**)
- Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (**Import Rule**)

Produce Safety Rule

- On-farm activities
- Established science-based minimum standards for:
 - Growing, harvesting, packing, holding
- Covers Raw Ag Commodities (RACs)
 - Produce generally consumed raw



Who must comply

Covers

- Domestic and imported produce
- Produce for human consumption

Does not cover

- Produce for personal or on-farm consumption
- Specified produce rarely consumed raw
- Farms with annual produce sales of \leq \$25,000
- **Eligible for exemption (with modified requirements)**
- Produce that will receive commercial processing (“kill-step” or other process that adequately minimizes hazards)



Qualified Exemption (QE)



Farms are eligible for a qualified exemption (and must meet modified requirements) if:

During the previous 3-years;

- Majority of food sold to qualified end users; AND
- Average, annual monetary value of food sold was less than \$500,000
- Sold in the same state as the farm or not more than 275 miles from farm

QE Modified Requirements

- Must comply with Subparts:
 - A – General Provisions
 - O – Records
 - Q – Compliance and Enforcement
 - R – Withdrawal of Qualified Exemption
 - Some food package labeling and POS labeling



Key Requirements

- Standards set for:
 - Employee health and hygiene
 - Training
 - Buildings, tools and equipment
 - Water standards and testing
 - Domestic/wildlife intrusion
 - Biological soil amendments of animal origin
 - Sprouts
 - Documentation/Recordkeeping



Compliance Dates

- Compliance

- Farms and mixed-type facilities with more than \$25,000 in annual produce sales sold during the previous 3-year period (rolling basis)

- Very Small- \$25,000-\$250,000 in annual produce sales (compliance date Jan 2020)




- Small - >\$250,000-\$500,000 in annual produce sales (compliance date Jan 2019)

- Other farms - \$500,000 and above in annual produce sales (compliance date Jan 2018)



Compliance Dates



Business Size	 Compliance Dates for Sprouts	 Compliance Dates For Most Produce	 Water Related Compliance Dates ¹	Compliance Date for Qualified Exemption Labeling Requirement ²	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>\$500K)	1/26/17	1/26/18	1/26/22	1/1/2020	1/26/16
Small businesses (>\$250K-500K) ³	1/26/18	1/28/19	1/26/23		
Very small businesses (>\$25K-250K) ⁴	1/28/19	1/27/20	1/26/24		

¹ According to the [Proposed Rule](#) issued 9/13/17, Compliance dates for Subpart E, Agricultural Water, allow an additional four years.

² A farm eligible for a qualified exemption must notify consumers as to the complete business address of the farm where the food is grown, harvested, packed, and held.

³ A farm is a small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$500,000.

⁴ A farm is a very small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$250,000.

Before the compliance date, every covered farm that does not qualify for an exemption must have a supervisor (such as a farm owner/operator) complete a standardized food safety training program. You can find out more about food safety training from the Produce Safety Alliance. <https://producesafetyalliance.cornell.edu/training>

Revised 10/09/17



Variance

- Petition submitted to FDA through state, tribe or country (regulatory authority)
- Meeting a rule requirement would be problematic in light of local growing condition
- Demonstrate the requested variance is likely to ensure produce is not adulterated
- Demonstrate the variance provides same level of public health protection
 - Must contain
 - Scientifically valid information



Variance

- What must be included:
 - Statement of Grounds
 - Who does this variance apply to
 - Demonstrate the requested variance is likely to ensure produce is not adulterated
 - Demonstrate the variance provides same level of public health protection
 - Scientifically valid information to support grounds for petition



ISDA Activity



- **Voluntary Anonymous Survey Tool**
 - Helps determine coverage under Produce Safety Rule
- **On Farm Readiness Reviews**
 - Voluntary, non-regulatory on-farm assessment
 - What to expect from regulatory inspection
 - Provides guidance on how to comply with rule
- **Produce Safety Alliance trainings**
 - Have trained ~300 participants in Idaho
 - Additional classes will be scheduled for fall and winter of this year (2018)
- **FSMA web pages**
- **Outreach and education materials for industry**

ISDA Activity



- Working with FDA to better educate federal officials on regional practices
 - Farm tours
- Working with NASDA, FDA and other States to develop inspectional materials
- Idaho Videos to supplement training
 - 10-12 minutes each
 - Spanish and English

ISDA Contact Information

Website:

www.agri.idaho.gov/main/inspections/fsma-main/

Email rule comments to fsma@isda.idaho.gov

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