

WRC



Western Regional Center to
Enhance Food Safety

Food Safety Modernization Act (FSMA)

Food Safety Modernization Act (FSMA)

MODULE I

Introduction to Food Safety Modernization Act (FSMA)

Sign-Up for FSMA Email Updates

About 48 million people in the U.S. are hospitalized, and 3,000 die each year from foodborne illness, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA) is designed to transform the nation's food safety system by shifting the focus from responding to foodborne illness to preventing it. This is a significant public health burden that is largely preventable. The FSMA rules are designed to make clear specific

FDA has finalized seven major rules to implement FSMA, recognizing that ensuring the safety of the food supply is a shared responsibility among many different points in the global supply chain for both human and animal food. The FSMA rules are designed to make clear specific



Spotlight

- FDA Issues Guidance Documents to Help Importers and Food Producers meet FSMA Requirements
- Oversight of January 2011
- FDA Issues Guidance Documents to Help Importers and Food Producers meet FSMA Requirements

Learning objectives

- Gain understanding of what Food Safety Modernization Act (FSMA) is and why it was introduced.
- Become familiar with seven rules of FSMA and who is impacted by them.
- Learn about business definitions and size classifications under different FSMA rules.
- Review compliance dates.
- Learn which guidance documents exist and where to find them.

What is FSMA?

- The Food Safety Modernization Act (FSMA) was signed into law Jan 2011.
- FDA was responsible for writing the rules for the law.
- FSMA was a sweeping change for the food industry.
- Numerous public meetings were held by FDA for public input.



Photo source: CNN

FSMA

Intended to build a food safety system for the future that makes modern, science, and risk-based preventive controls the norm across all sectors of the food system.

1 in 6 

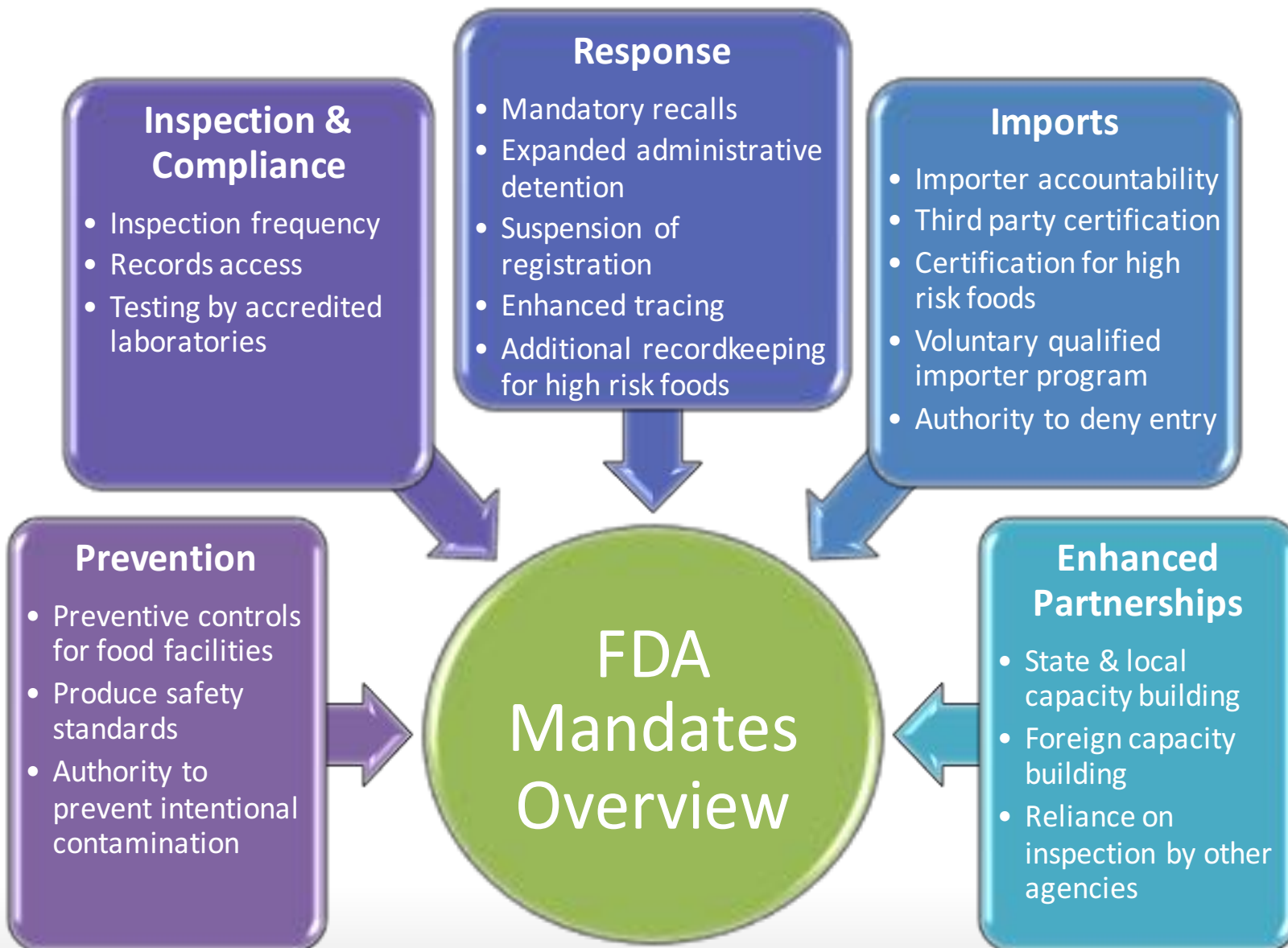
About 1 in 6 (or 48 million) people gets sick each year from contaminated food.

 **50%**

E. coli O157 infections have been cut about in half since 1997.

\$365 Million

Salmonella infection accounts for \$365 million in direct medical costs each year.



How is FSMA different?

- Broad *prevention mandate* and *accountability*
- Emphasizes *farm-to-fork responsibility*
- Better *import oversight*
- Improved *partnerships*

FSMA – Seven Foundational Rules

Preventive Controls for Human Food

- September 10, 2015

Preventive Controls for Animal Food

- September 10, 2015

Produce Safety

- November 13, 2015

Foreign Supplier Verification Program

- November 13, 2015

Third Party Certification

- November 13, 2015

Sanitary Transportation

- April 5, 2016

Intentional Adulteration

- May 27, 2016

Who is affected by FSMA?

Depends on the rule...

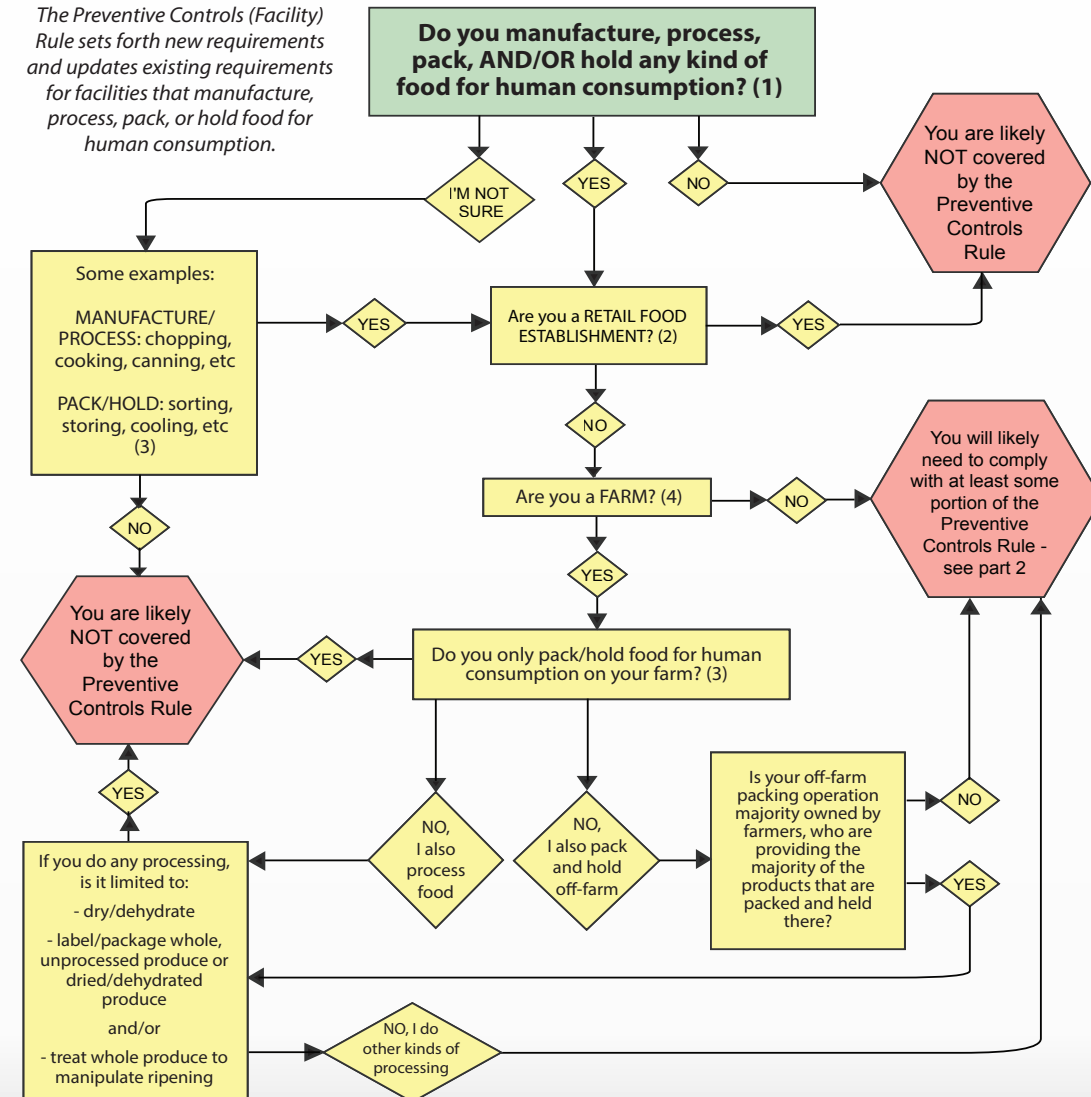
Which rule applies to which business?



What Are PCHF Requirements?

Am I Affected by the FSMA Preventive Controls (Facility) Rule?

The Preventive Controls (Facility) Rule sets forth new requirements and updates existing requirements for facilities that manufacture, process, pack, or hold food for human consumption.



1) If you are manufacturing, processing, packing, or holding food **for personal consumption on farm only**, the Preventive Controls Rule does not apply.
 2) Retail Food Establishment: grocery stores, farm stands, and restaurants that sell the majority of their food directly to consumers; details: <http://bit.ly/nsacprule>
 3) Find definitions of manufacturing, processing, packing, and holding, along with examples of what "off-site" and "on-farm" mean, here: <http://bit.ly/nsacprule>
 4) Find details on FDA's "farm" definition and on packaging, labeling, dehydrating, other on-farm activities that do and don't trigger the "facility" definition: <http://bit.ly/nsacprule>

What Are PCHF Requirements?

FACILITIES EXEMPT FROM PCHF: must register with FDA and continue complying with already-existing rules and practices (like Current Good Manufacturing Practices), but do not need to develop Hazard Analysis and Risk-Based Preventive Controls plans and procedures (3)

Am I Affected by the FSMA Preventive Controls (Facility) Rule?

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What Are PCHF Requirements?

QUALIFIED FACILITIES: must register with FDA and submit certain attestations; not required to develop full food safety plans and procedures but must follow certain basic requirements (e.g. recordkeeping); if sales < \$1M, 3 yrs to come into compliance (3)

Am I Affected by the FSMA Preventive Controls (Facility) Rule?

The Preventive Controls (Facility) Rule sets forth new requirements and updates existing requirements for facilities that manufacture, process, pack, or hold food for human consumption.



What Are PCHF Requirements?

FACILITIES SUBJECT TO FULL REQUIREMENTS: must register with FDA; must develop full food safety plans and procedures laid out under the PCHF; facilities have 1 year to come into compliance (3)

FULL REQUIREMENTS as a SMALL BUSINESS: Same as above but with 2 years to come into compliance (3)

Am I Affected by the FSMA Preventive Controls (Facility) Rule?

The Preventive Controls (Facility) Rule sets forth new requirements and updates existing requirements for facilities that manufacture, process, pack, or hold food for human consumption.



(1) If you are manufacturing, processing, packing, or holding food for personal consumption on farm only, the Preventive Controls Rule does not apply.
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*Who is affected by
FSMA?*

Depends on the rule...

*Which rule applies
to which business?*



What type of business are you operating?



FARM

- Do you grow, harvest and pack produce on your farm?

... A **primary production farm** is an operation devoted to the **growing, harvesting, the raising of animals (including seafood), or any combination of these activities** in **one general location** and under **one general management**.

What type of business are you operating?



- Do you conduct off-farm packing activities?

PACKING
OPERATION

... A **location** where **harvested produce** is placed into containers and shipped for further distribution.

What type of business are you operating?



PROCESSING
FACILITY

- Do you operate a food processing facility?

... An **establishment, structure, or structures under one ownership at one general physical location**, or, in the case of a mobile facility, traveling to multiple locations, that **manufactures/ processes, packs, or holds food for consumption in the United States.**



FARM



**PACKING
OPERATION**



**PROCESSING
FACILITY**



FARM*I grow, harvest and pack produce on my farm.*

I ONLY grow
produce that is
rarely
consumed raw.

Produce almost
always eaten cooked
e.g. beets, beans,
sour cherries,
peanuts, pecans,
potatoes



FARM

I ONLY grow produce that is rarely consumed raw.

Produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; kidney; beans, lima; beans, navy; bean garden (roots and tops); beets, garden (sour); chickpeas; cocoa beans; corn, sweet; cranberries; eggplants; okra; pumpkins; horseradish; lentils; peppermint; potatoes; winter; sweet potatoes; and water chestnuts.

Exempt
(Not covered by the Produce Safety Rule)

If produce is not included in the exhaustive list above, then it is considered “covered produce” by the Produce Safety Rule, unless an exemption applies.





FARM

I ONLY grow produce that is rarely consumed raw.

Produce almost always eaten cooked
e.g. beets, beans, sour cherries, peanuts, pecans, potatoes

SOME of the produce I grow is likely to be consumed raw.

Fruits, vegetables, greens, nuts and herbs

Full list available here:

<https://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf>

Ave. annual produce sales are **LESS THAN \$25,000**

Ave. annual produce sales are **AT LEAST \$25,000**

Not covered by the Produce Safety Rule

At least **SOME** of your produce **IS** covered under the Produce Safety Rule



FARM

**You may qualify for exemptions, depending on other factors!*

Your **processed food products ARE** covered under **Preventive Controls Rule***

I **ONLY** grow produce that is rarely consumed **RAW.**

Produce almost always eaten cooked
e.g. beets, beans, sour cherries, peanuts, pecans, potatoes

SOME of the produce I grow is likely to be consumed raw.

Fruits, vegetables, greens, nuts and herbs

Full list available here:
<https://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf>

Also **PROCESS** food on the farm

e.g. Slicing, peeling, canning, freezing, cooking, baking, drying, fermenting and other processing



FARM



PROCESSING
FACILITY



PACKING
OPERATION

....I process foods.



Your **processed food products** ARE covered under **Preventive Controls Rule***

**You may qualify for exemptions, depending on other factors!*



FARM



PROCESSING FACILITY



PACKING OPERATION

...I pack fresh produce at a location that is NOT a farm.

MORE THAN 50% of the packed produce is grown on a farm(s) under a different ownership than the packing house.

50% OR LESS of the packed produce is grown on a farm(s) under a different ownership than the packing house.

Your packing activities **ARE** covered under the **Preventive Controls Rule**

Your packing activities **ARE** covered under the **Produce Safety Rule**

Why do sales and size matter?

- Compliance dates are different based on the size of businesses/facilities
- May qualify for exemptions

*****NOTE: Size definitions are DIFFERENT for different rules! *****

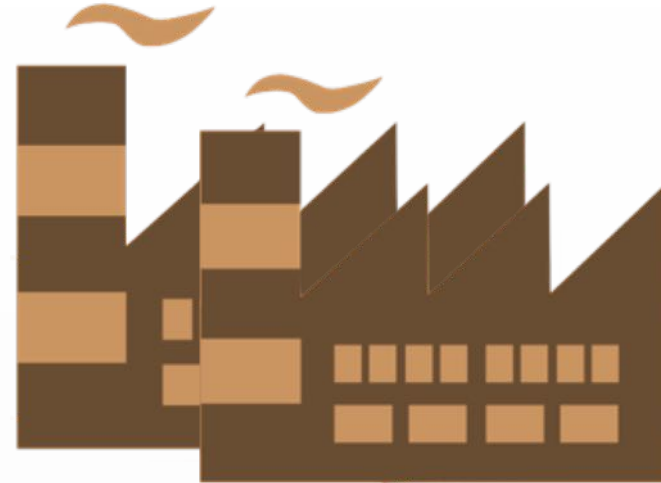
Business size definitions



Very small business



Small business



All other businesses sizes

Preventive Controls for Human Food



<\$1 million/year
sales* of human
& animal food



<500 full-time
employees



>\$1 million/year
sales* of human
& animal food

Produce Safety Rule



>\$25K - <\$250K
average annual
produce sales
during previous
3 years



>\$250K -
<\$500K average
annual produce
sales during
previous 3 years

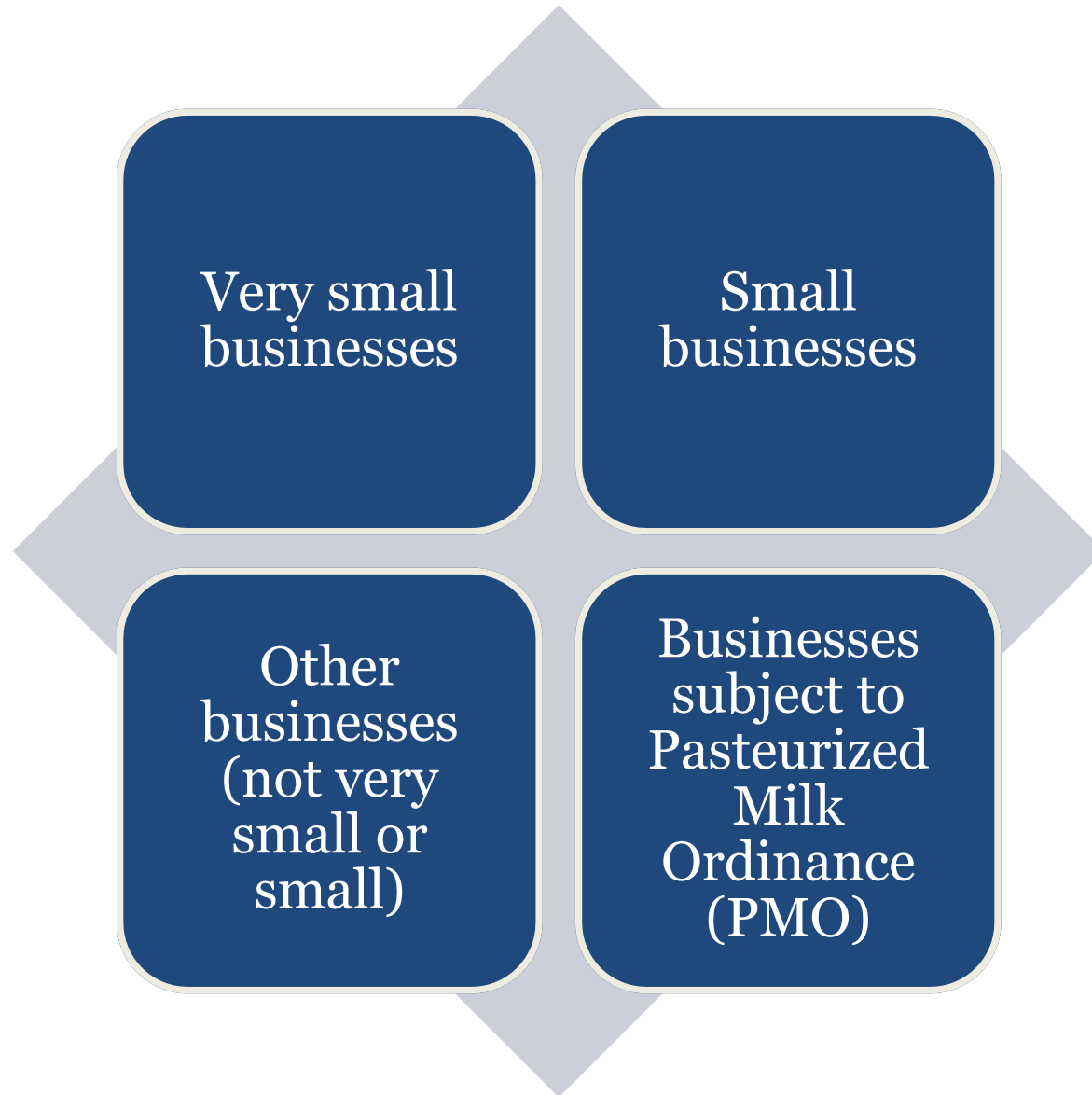


>\$500K
million/year
sales* of human
& animal food

**adjusted for inflation*

Final rule publications

REGULATION	FINAL RULE PUBLICATION
Preventive Controls for Human Food (PCHF)	Sep. 17, 2015
Preventive Controls for Animal Food (PCAF)	Sep. 17, 2015
Produce Safety	Nov. 27, 2015
Foreign Supplier Verification Program (FSVP)	Nov. 27, 2015
Accredited Third-Party Certification	Nov. 27, 2015
Sanitary Transportation of Human and Animal Food	Apr. 6, 2016
Mitigation Strategies Against Intentional Adulteration	May 27, 2016



Preventive Controls for Human Food (Part 117)

Compliance dates



Very small
businesses

Extended Compliance Dates

- Facilities solely engaged in packing and/or holding activities on produce RACs

Compliance Date: January 27, 2020

- Certain facilities that would qualify as secondary activities farms except for ownership

Compliance Date: January 27, 2020

- Facilities that would qualify as farms if they did not color RACs

Compliance Date: January 27, 2020

Very small business means a business (including any subsidiaries and affiliates) that averages **less than \$1 million (adjusted for inflation) per year during the three-year period** preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (e.g., for a fee).

- Compliance Date**
September 17, 2018



Very small
businesses

Small
businesses

Extended Compliance Dates

- Facilities solely engaged in packing and/or holding activities on produce RACs
Compliance Date: January 28, 2019
- Certain facilities that would qualify as secondary activities farms except for ownership
Compliance Date: January 28, 2019
- Facilities that would qualify as farms if they did not color RACs
Compliance Date: January 28, 2019
- Written assurances in the customer provisions in sections 117.136(a)(2)(ii), (3)(ii), and 4(ii)
Compliance Date: September 18, 2019

Small businesses are businesses (including any subsidiaries and affiliates) employing fewer than **500 full-time equivalent employees.**

• **Compliance Date**
September 17, 2017



Very small
businesses

Small
businesses

Subpart G (Supply-Chain Program)

- Receiving facility is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule.

Compliance Date: September 18, 2017

- Receiving facility is a small business and its supplier is subject to the human preventive controls rule or the produce safety rule.

Compliance Date: The later of September 18, 2017 or six months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule.

Small businesses are businesses (including any subsidiaries and affiliates) employing fewer than **500 full-time equivalent employees.**

•Compliance Date
September 17, 2017

Extended Compliance Dates

- Facilities solely engaged in packing and/or holding activities on produce RACs
Compliance Date: January 26, 2018
- Certain facilities that would qualify as secondary activities farms except for ownership
Compliance Date: January 26, 2018
- Facilities that would qualify as farms if they did not color RACs
Compliance Date: January 26, 2018
- Written assurances in the customer provisions in sections 117.136(a)(2)(ii), (3)(ii), and 4(ii)
Compliance Date: September 19, 2018

Other
businesses
(not very
small or
small)

A business (including any subsidiaries and affiliates) that averages equal to or more than \$1 million (adjusted for inflation) per year, during the three-year period preceding the applicable calendar year in sales **AND** that has more than 500 full-time equivalent employees.

•**Compliance Date**
September 19, 2016

Subpart G (Supply-Chain Program)

- Receiving facility is not a small business or a very small business and its supplier will be not be subject to the human preventive controls rule or the produce safety rule.

Compliance Date: March 17, 2017

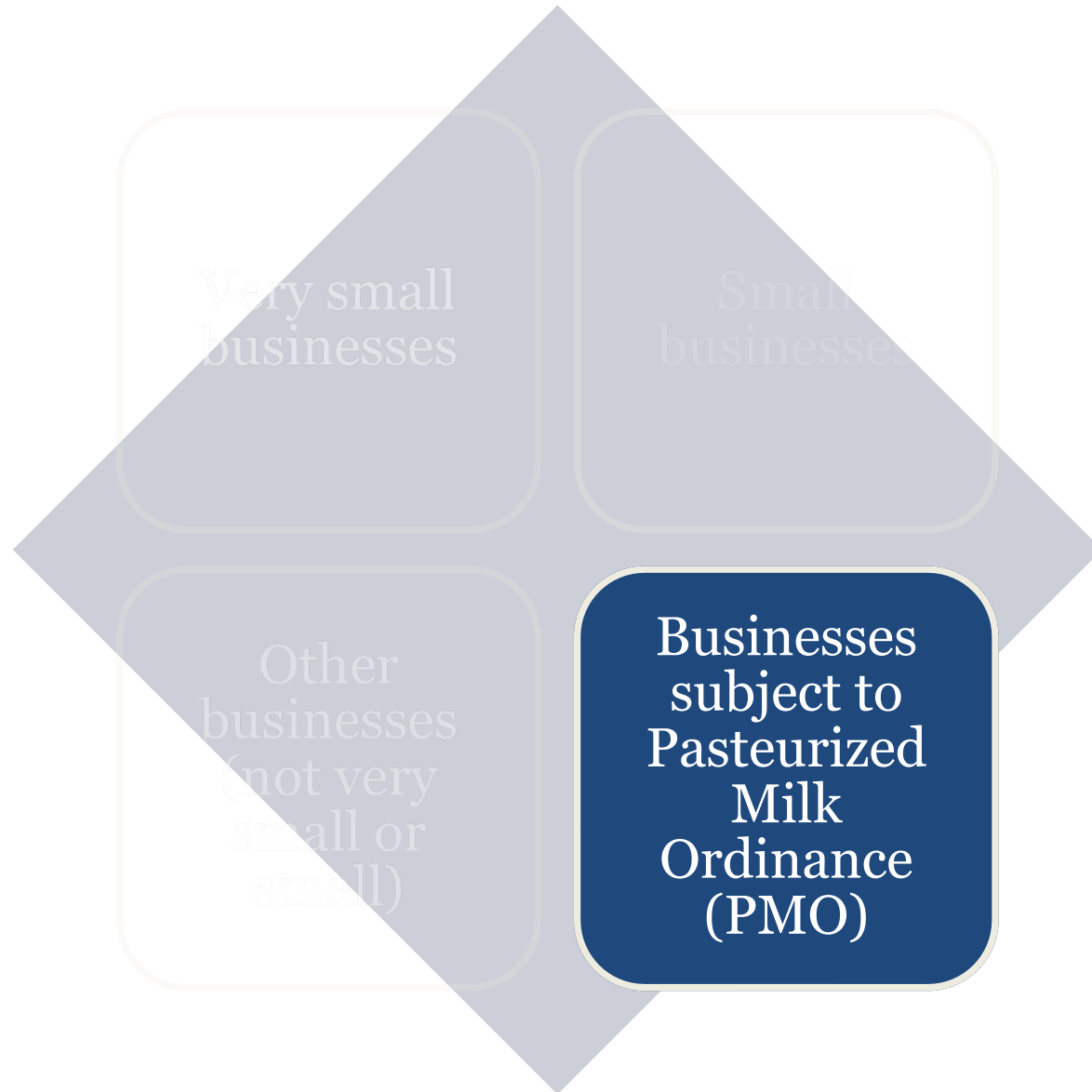
- Receiving facility is not a small business or a very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule.

Compliance Date: 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule.

Other
businesses
(not very
small or
small)

A business (including any subsidiaries and affiliates) that averages equal to or more than \$1 million (adjusted for inflation) per year, during the three-year period preceding the applicable calendar year in sales **AND** that has more than 500 full-time equivalent employees.

•**Compliance Date**
September 19, 2016



Extension only applies to Grade “A” milk and milk products covered by the National Conference of Interstate Milk Shipments (NCIMS) under the PMO, and not to the manufacturing, processing, packing, or holding of other food produced in such facilities.

Extended Compliance Date
September 17, 2018

What about trainings and resources?



Photo source:
<http://www.buildingwise.com.au/wp-content/uploads/2016/10/training-pic.jpg>

Standardized FSMA curricula

- FDA recognized standardized curricula developed by Alliances

- Food Safety Preventive Controls Alliance

- <http://www.iit.edu/ifsh/alliance>

- **Produce Safety Alliance**

- <http://producesafetyalliance.cornell.edu>

- **Sprout Safety Alliance**

- http://www.iit.edu/ifsh/sprout_safety



FSPCA

- Managed by the Illinois Institute of Technology (IIT)
- Developed core curricula, training, and outreach programs
 - Preventive Controls for Human Food (PCHF)
 - Preventive Controls for Animal Food (PCAF)
 - Foreign Supplier Verification Program (FSVP)
 - Intentional Adulteration for Human Food

<http://www.iit.edu/ifsh/alliance>



FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Menu

Intentional Adulteration

New FSPCA Webinar Series on the FSMA IA Rule

The Food Safety Preventive Controls Alliance (FSPCA), in collaboration with the Food and Drug Administration (FDA), will host a series of new webinars specific to the FSMA Final Rule - Mitigation Strategies to Protect Food against Intentional Adulteration (IA Rule). These webinars will provide stakeholders with more information about the IA Rule and assist food facilities that are required to comply with the IA rule to have a more in-depth understanding of those requirements.

The webinars will be 1 hour in length which includes a short Q&A session. For more information or to watch a video overview presentation of the IA Rule, please visit www.fda.gov/fooddefense.

Please register for FSPCA Webinar Series on the FSMA IA Rule by clicking the links below. After registering, you will receive a confirmation email containing information about joining the webinar.

Jun 20, 2017 11:00 AM CDT [Recording](#) | [Presentation](#)
Aug 22, 2017 11:00 AM CDT [Recording](#) | [Presentation](#)
Oct 24, 2017 11:00 AM CDT [Recording](#) | [Presentation](#)

Produce Safety Alliance (PSA)

- Managed by Cornell University
- Developed core curriculum, training and outreach program for Produce Safety



Produce Safety
ALLIANCE

Grower Training



Cornell University

<http://producesafetyalliance.cornell.edu>

Sprouts Safety Alliance (SSA)

- Managed by Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH)
- Developed core curriculum, training and outreach program for sprout production community

Safer Sprout Production for
Produce Safety Rule
Compliance



Second Edition – 2017



Version 2.3

Public Version

<https://www.ifsh.iit.edu/ssa>

Other stakeholders

Regional Centers



National Coordinating Center

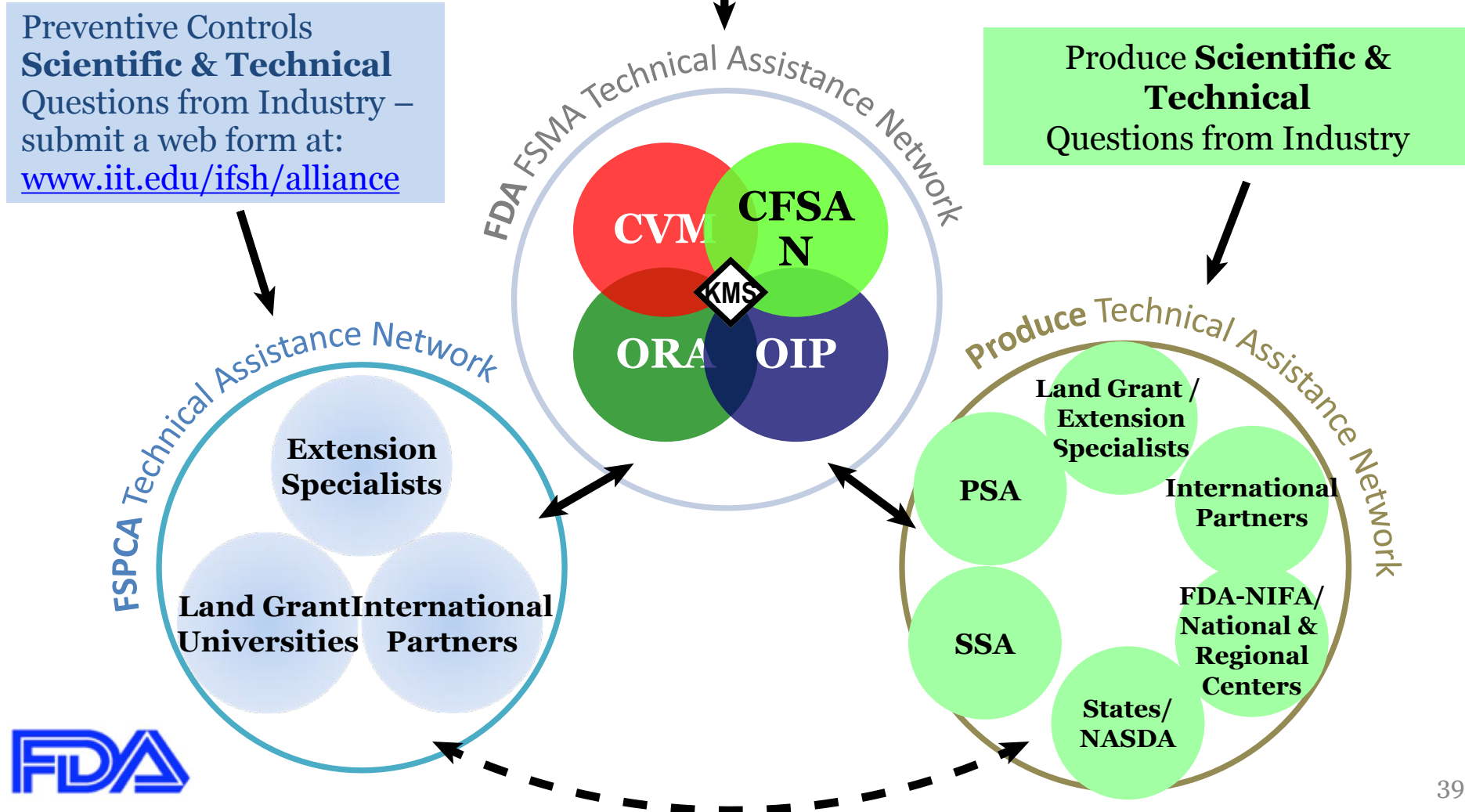


North Central Region
Center for FSMA Training, Extension
and Technical Assistance



FSMA Technical Assistance Networks

FSMA Regulation & Policy Interpretation
Questions – submit a web form at: www.fda.gov/fsma



FSPCA - TAN



- Technical and scientific questions can be submitted to the FSPCA Technical Assistance Network (TAN) through the FSPCA Community directly or via IIT's FSPCA pages
 - <https://www.ifsh.iit.edu/fspca/fspcatechnical-assistance-network>
- FSMA rule interpretation questions must be submitted to FDA's TAN
 - <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

Summary

- **Food Safety Modernization Act**
 - FDA Mandate and seven rules
- **Implementation of FSMA**
 - Timelines depend on rules and facilities
 - Based on facility size and operations; types of products
 - Grey areas for mixed facility operations
- **Standardized curricula and Alliances**
- **Resources available through FDA, NCC, Regional Centers (North East, North Central, Southern, Western), Extension groups at universities**