



Agricultural Marketing Service

FSMA

Update

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW

USDA AMS SCP

Marketing Order & Agreement Division

Marketing Order Management Conference

Leanne L. Skelton
Liaison to FDA on FSMA Issues
Specialty Crops Program, AMS, USDA
September 20, 2017

Today's Presentation -- Food Safety Modernization Act

Broad Overview of FSMA

- Suite of 7 Rules – Highlights & Important Dates
 - Produce Safety Rule, Preventive Controls for Human Food & Foreign Supplier Verification Program
- Some Specificity
 - Focus on Produce Safety Rule

Outreach & Resources

Recent Updates



Based on “Anticipated Attendee List” ...

Potentially Subject to:

- Produce Safety Rule
- Preventive Controls for Human Food
- Foreign Supplier Verification Program
- Others...

Considerations:

- Not covered (§112.2) rarely consumed raw or commercial processing
- “Qualified” exemptions (all)
- Size categories for compliance dates (all)

USDA & FDA Working Relationship

- 2 Federal/National Departments
 - Separate/Different Missions
- Memoranda of Understanding
- Government Review Process
 - led by the Office of Management & Budget
- Ongoing Relationship
 - Liaison Position at USDA to FDA
 - Various activities - FSMA-focused & other
 - Joint GAPs Alignment & LGMA Alignment Projects
 - Linkages to other USDA Agencies



FSMA Central Principles



- Move food system from reaction to prevention
- High rates of compliance critical to success
- Domestic and import parity
- Educate before and while regulating
- Risk based approach to inspection and work planning
- Critical role of partnerships
 - Other federal agencies
 - Integrated food safety system
 - Foreign partnerships

FSMA Implementation



- Signed into law in 2011
- Seven foundational rules **finalized in 2015 & 2016**
 - Preventive controls for human food
 - Preventive controls for animal food
 - Produce safety rule
 - Foreign supplier verification programs
 - Accredited third-party certification
 - Sanitary transportation
 - Intentional adulteration
- Additional rulemaking: Lab accreditation, tracing, food registry, technical amendments, compliance date extensions
- Staggered implementation by rule and by size
- Related activities – guidance, technical assistance, fact sheets, constituent updates...

“Farm” Definition

- Cross-cuts all FSMA Regulations
- Definition revised within Bioterrorism Act, 2002
 - Provides for definitions of:
 - Primary Production Farm
 - Secondary Activities Farm

Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities

<http://www.fda.gov/Food/GuidanceRegulation>

Food Safety Modernization Act (FSMA)

[The Law, Rules & Guidance](#)

[Fact Sheets & Presentations](#)

[Frequently Asked Questions on FSMA](#)

[FDA Actions and Meetings](#)

[FSMA Training](#)

[FSMA Technical Assistance Network \(TAN\)](#)

FSMA Final Rule on Produce Safety

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Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

[Produce Safety Standards under the FSMA Main Page](#)

View the Final Rule Contents in the [Federal Register Notice](#)

Below is a fact sheet provided by FDA.

In this fact sheet:

- [Introduction](#)
- [Key Requirements](#)
- [Exemptions](#)
- [Variances](#)
- [Compliance Dates](#)
- [Environmental Impact Statement](#)
- [Assistance to Industry](#)

Introduction

The FDA Food Safety Modernization Act (FSMA) Produce Safety rule is now final, and the earliest compliance dates for some farms begin one year after the effective date of the final rule (see "Compliance Dates" below). The 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.

This rule was first proposed in January 2013. In response to input received during the comment period and during numerous public engagements that included public meetings, webinars, listening sessions, and visits to farms

About the Final Rule

- [Federal Register Notice](#)
- Docket Folder [FDA-2011-N-0921](#)
- [Questions & Answers](#)
- [Coverage and Exemptions/Exclusions Flowchart \(Color PDF: 95KB\)](#)
- [Coverage and Exemptions/Exclusions Flowchart \(Black & White PDF: 67KB\)](#)
- [How Did FDA Establish Requirements for Water Quality and Testing of Irrigation Water?](#)
- [What the Produce Safety Rule Means for Consumers](#)
- [Print-Friendly Fact Sheet \(PDF: 405KB\)](#)
- [Proposed Extension of Agricultural Water Compliance Dates \(Federal Register\)](#)

Related Guidance

- [Draft Guidance for Industry: Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations](#)
- [Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying](#)

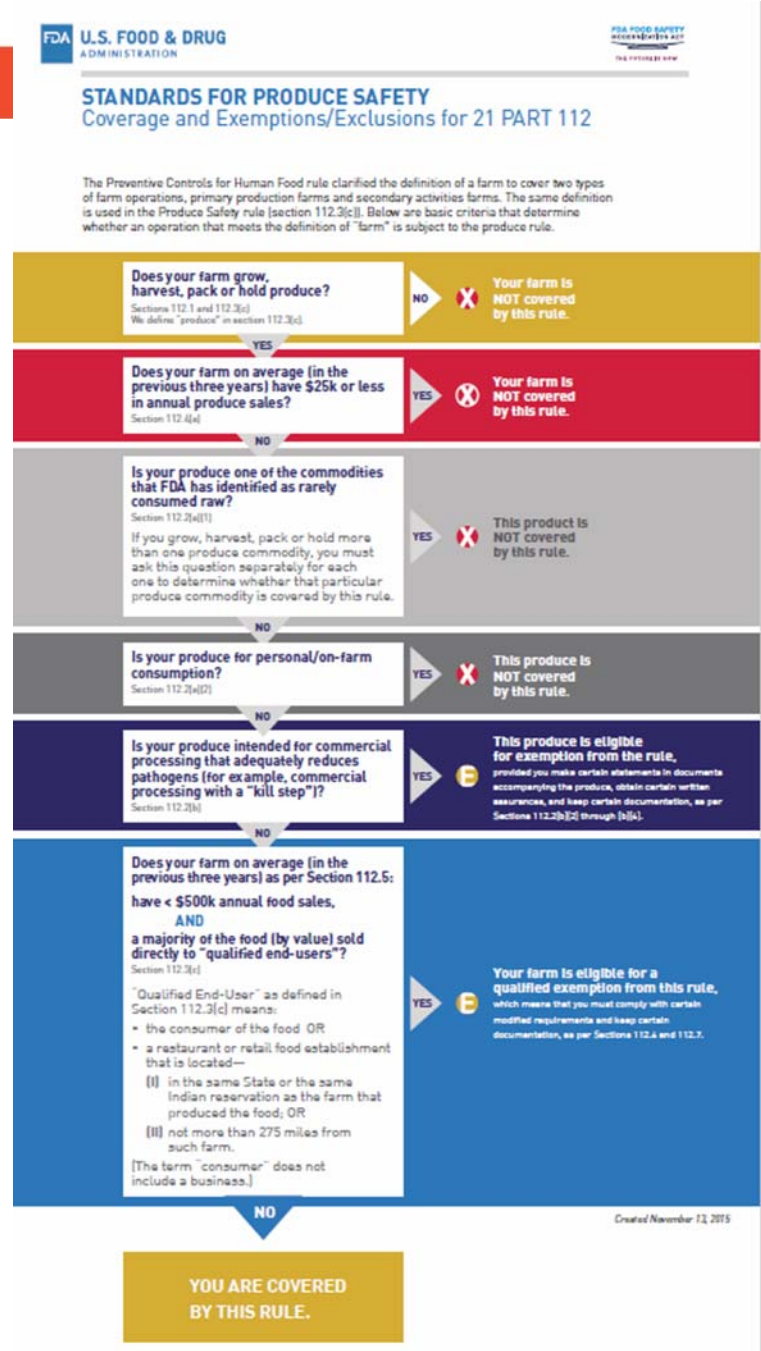
FDA's Produce Safety - Highlights

- Definitions & General Provisions
- General Requirements & Alternatives
- Personnel Qualifications & Training
- Health & Hygiene
- Technical Provisions
- Analytical Methods
- Records
- Variances
- *Recent Updates*

FDA Decision Tree

Coverage & Exemptions ...Am I subject to Produce Safety Rule?

[http://www.fda.gov/downloads/
Food/GuidanceRegulation/FSMA/
UCM472499.pdf](http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf)



Recent Updates

September 12, 2017

The screenshot shows the FDA website's navigation bar with the logo and 'U.S. FOOD & DRUG ADMINISTRATION'. Below the navigation bar, there are tabs for 'Home', 'Food', 'Drugs', 'Medical Devices', 'Radiation-Emitting Products', 'Vaccines, Blood & Biologics', 'Animal & Veterinary', 'Cosmetics', and 'Tobacco Products'. The 'Food' section is active, and a sub-menu shows 'Home', 'Food', 'News & Events', and 'Constituent Updates'. The 'Constituent Updates' tab is selected, displaying a news article. The article title is 'FDA Commissioner Addresses State Agriculture Commissioners; Announces New Steps to Enhance Collaboration with States and Ensure Farmers Are Prepared for FSMA'. Below the title are social media sharing buttons for 'SHARE', 'TWEET', 'LINKEDIN', 'PIN IT', 'EMAIL', and 'PRINT'. The article is dated 'September 12, 2017'. The text of the article describes the FDA Commissioner's speech at the NASDA conference, outlining next steps for FSMA implementation. A red circle highlights the sentence: 'The next steps include the following:'.

- Ag Water Compliance Dates
- Stakeholder Engagement, i.e., Water Summit
- Water Test Methods
- Produce Farm Inspections
- Training

Sprouts

The largest covered sprout operations required to be in compliance with all applicable provisions of the Produce Safety Rule (including water) by this past **January 26, 2017.**

- Small operations compliance is January 26, 2018
- Very small operations compliance is January 28, 2019

Draft guidance to help sprout operations comply with new standards issued on January 19, 2017

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments/RegulatoryInformation/ucm510578.htm>

Home Food Guidance & Regulation Food Safety Modernization Act (FSMA)

Food Safety Modernization Act (FSMA)

FSMA Final Rule for Preventive Controls for Human Food

The Law, Rules & Guidance

Fact Sheets & Presentations

Frequently Asked Questions on FSMA

FDA Actions and Meetings

FSMA Training

FSMA Technical Assistance Network (TAN)

PIN IT EMAIL PRINT

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

[Preventive Standards under the FSMA Main Page](#)

Generally, domestic and foreign food facilities that are required to register with section 415 of the Food, Drug, & Cosmetic Act must comply with the requirements for risk-based preventive controls mandated by the FDA Food Safety Modernization Act (FSMA) as well as the modernized Current Good Manufacturing Practices (CGMPs) of this rule (unless an exemption applies). It is important to note that applicability of the CGMPs is not dependent upon whether a facility is required to register.

This rule, which became final in September 2015, requires food facilities to have a food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards.

Compliance dates are staggered, based on the size of the business, with separate dates for the requirements of the supply chain program. Training, education, and technical assistance are available for those covered by this rule.

Upcoming Compliance Dates

September 18, 2017: Small businesses (businesses with fewer than 500 full-time equivalent employees)

September 17, 2018: Very small businesses (businesses averaging less than \$1 million per year (adjusted for inflation) in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale)

September 17, 2018: Facilities subject to the Pasteurized Milk Ordinance (for their Grade "A" milk and

Final Rule

- [Federal Register Notice](#)
- Docket Folder [FDA-2011-N-0920](#)
- [Questions & Answers](#)
- [Clarification of Compliance Date for Certain Food Establishments](#)

Public Meetings & Webinars

- [Preventive Controls for Human and Animal Food Final Rules Public Meeting](#) [ARCHIVED]
- [Webinar: Preventive Controls Hazard Analysis and Risk-Based Draft Guidance](#)
- [Webinar Series](#) [ARCHIVED]

Related Guidance

- [Guidance for Industry: What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Small Entity Compliance Guide](#)
- [Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA](#)
- [Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food](#)
- [Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities](#)

Supporting Material

FDA's Preventive Controls for Human Food Highlights

- Definitions & General Provisions
 - Coverage, Exemptions & Limitations, Farm definition
 - Packinghouses not meeting farm definition
- Current GMPs -- updated & clarified
- Establish & Implement:
 - Food Safety System (documented in Food Safety Plan)
 - Supply-Chain Program (documented)
- Records

Food Safety Modernization Act (FSMA)

The Law, Rules & Guidance

Fact Sheets & Presentations

Frequently Asked Questions on FSMA

FDA Actions and Meetings

FSMA Training

FSMA Technical Assistance Network (TAN)

FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

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- [Introduction](#)
- [Key Requirements](#)
- [Compliance Dates](#)
- [Assistance to Industry](#)

Introduction

The FDA FSMA rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals is final, and the first compliance dates begin **May 30, 2017**.

The final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. This rule is the product of a significant level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local, tribal and international regulatory counterparts, academia and other stakeholders. The FDA first proposed this rule in July 2013.

After input received during the comment period and during numerous engagements that included public meetings, webinars, and listening sessions, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions included providing importers flexibility in determining appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods.

The final rule has elements of both the original and supplemental proposals, with the addition of greater flexibility in meeting certain requirements to better reflect

About the Final Rule

- [Federal Register Notice](#)
- [Docket Folder FDA-2011-N-0143](#)
- [Compliance Dates for the Final Rule](#)
- [FSVP: What Do Importers Need to Know?](#)
- [Questions & Answers](#)
- [What Foreign Supplier Verification Programs Mean for Consumers](#)
- [Am I Subject to FSVP? \(Color PDF: 69KB\)](#)
- [Am I Subject to FSVP? \(Black & White PDF: 78KB\)](#)
- [Print-Friendly Fact Sheet \(PDF: 249KB\)](#)
- [FSVP Final Rule At-A-Glance \(PDF: 220KB\)](#)

Related Guidance

- [Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA](#)
- [Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation](#)
- [Guidance for Industry: Recognition of Acceptable Unique Facility Identifier \(UFI\) for the Foreign Supplier Verification Programs Regulation](#)

Public Meetings & Webinars

FDA's Foreign Supplier Verification Program Highlights

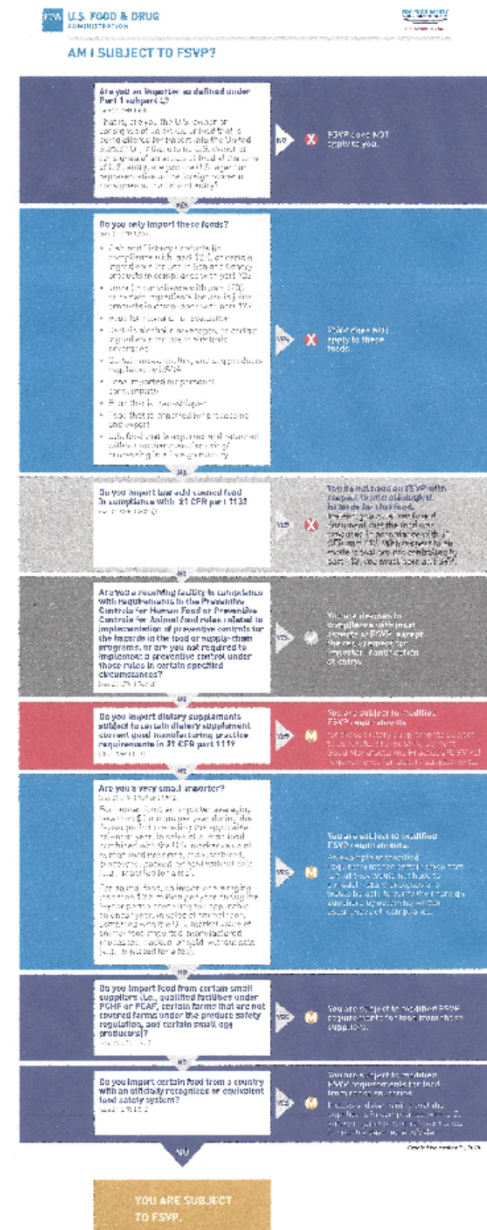
- Definitions & General Provisions
 - Coverage, Exemptions & Limitations, Farm definition
 - Program Development
- Hazard Analysis
- Supplier Approval Program & Verification Activities
- Records

FDA Decision Tree

Coverage & Exemptions

...Am I subject to FSVP?

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf>



Compliance Dates

No easy chart or table....FDA's webpages contain the most up-to-date information. Considerations:

- Only packing/holding RACs
- Except "ownership" would be secondary activity's farm
- Color added RACs (manufacturing)
- FSVP -- based on size & rule supplier subject to...
- Support qualified exemption
- Customer written assurances
- Supply Chain Program
- Other...



Outreach, Resources & Technical Assistance

“Educate before and while we regulate” (FDA Leadership)

- Outreach Activities
- Training Strategy
 - 3 Alliances & Other Cooperative Agreements
- Technical Assistance Network
- Produce Safety Network
 - FDA On-Farm experiences/opportunities
- Guidance Document development & updates
 - GAPs, Implementation & Compliance, Small Entity Guide
- Implementation Strategy
 - NASDA-FDA Implementation Strategy Workgroup
 - Including “On-Farm Readiness Review” Program
 - State Cooperative Agreement Program
 - Consider Results of Marketplace Activities

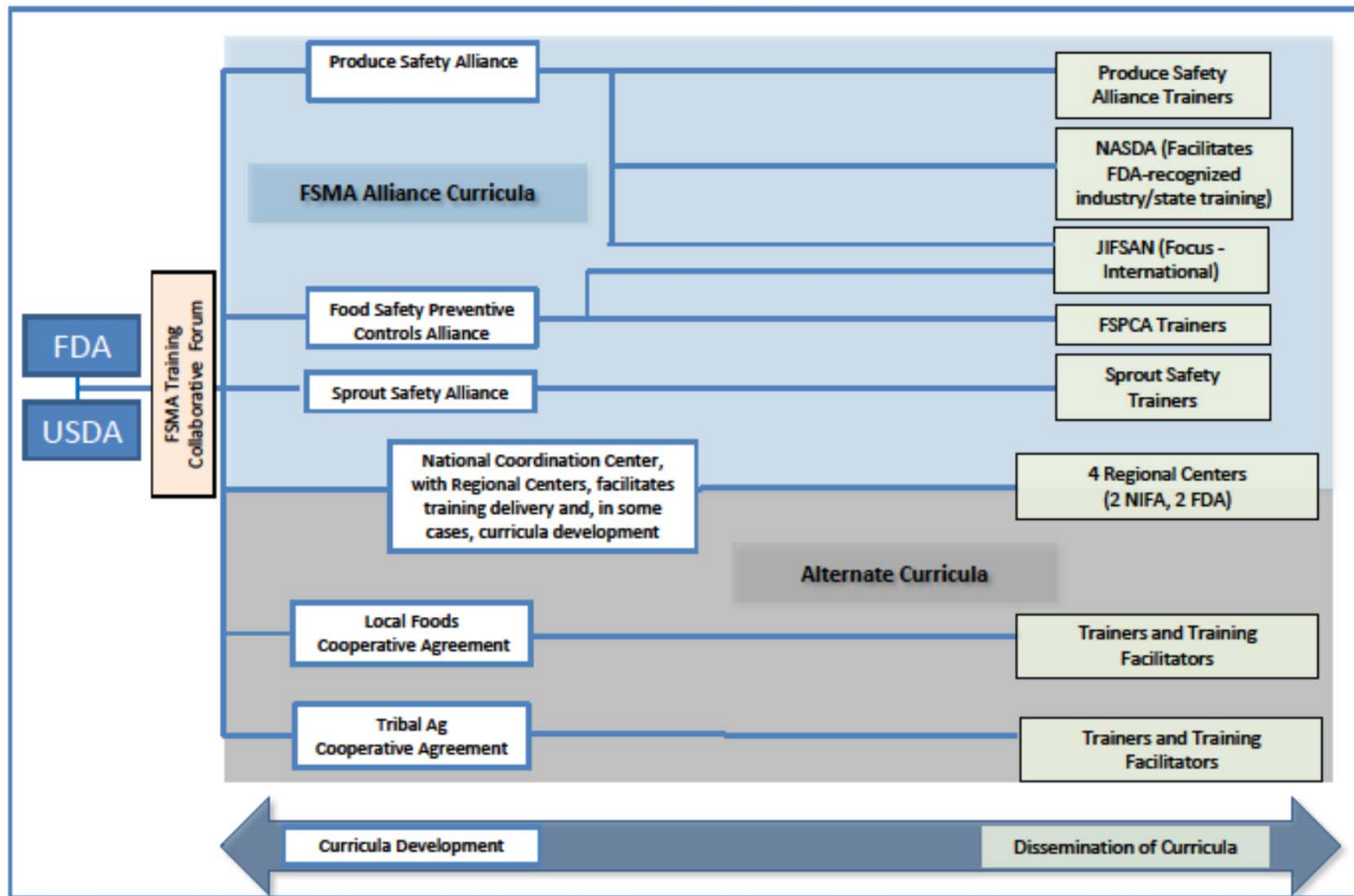
Outreach

- USDA AMS
 - *This Presentation*
 - Variety of on-going activities
 - Liaison Position
- USDA National Institute of Food & Agriculture, Food Safety Outreach Program
 - <https://nifa.usda.gov/food-safety-outreach-program>
- USDA Natural Resources Conservation Service
 - Balancing conservation and food safety considerations
- FDA
 - Cooperative Agreements
 - Website postings & Stakeholder/Constituent Updates
 - Presentations

FDA's Training Strategy

FSMA Framework for Industry Curriculum Development and Dissemination

October 2015



This is not an all-inclusive list of entities that will be developing training curricula and delivery for domestic and foreign food businesses.



- Grower training course available to help the domestic and foreign produce industry identify risks on the farm, implement practices to reduce risks, and understand requirements.
 - § 112.22(c) *At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by FDA.*
- Developing web-based grower training course to ensure access to online training.

Technical Assistance Network

[http://www.fda.gov/
Food/
GuidanceRegulation/
FSMA/
ucm459719.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm)

The screenshot shows the FDA website's navigation bar with the U.S. Food & Drug Administration logo and a search bar. Below the navigation bar, the 'Food' section is highlighted, and the 'Food Safety Modernization Act (FSMA)' sub-section is selected. A sidebar on the left lists various resources under the FSMA heading, with 'FSMA Technical Assistance Network (TAN)' selected. The main content area features the title 'FSMA Technical Assistance Network (TAN)' with social media sharing options (Share, Tweet, LinkedIn, Pin It, Email, Print). Below the title, there is a paragraph explaining that the TAN is a central source of information for questions related to FSMA rules, programs, and implementation strategies. A section titled 'Have a FSMA Question? Start Here.' provides information about the compiled answers to common FSMA TAN questions and a link to frequently asked questions on FSMA. Further down, there are sections for 'Submit Your Question' and 'Mail Your Question', both providing instructions on how to contact the TAN for assistance. At the bottom, there are two buttons: 'How the TAN Works' and 'Additional FSMA Resources'.

U.S. FOOD & DRUG ADMINISTRATION

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Food

Home Food Guidance & Regulation Food Safety Modernization Act (FSMA)

Food Safety Modernization Act (FSMA)

- The Law, Rules & Guidance
- Fact Sheets & Presentations
- Frequently Asked Questions on FSMA
- FDA Actions and Meetings
- FSMA Training
- FSMA Technical Assistance Network (TAN)**

FSMA Technical Assistance Network (TAN)

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The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

Have a FSMA Question? [Start Here.](#)

The Technical Assistance Network staff has compiled answers to **common FSMA TAN questions**. In addition, the complete set of [frequently asked questions on FSMA](#) contains answers to questions on specific provisions of the rule.

Submit Your Question

Didn't find your question above? Please [submit your question](#) to TAN for assistance.

Mail Your Question

If you prefer to mail in your question, please send it to the address below:
Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

Note: For Food Safety Preventive Controls Alliance (FSPCA) training and scientific/technical questions, please contact the FSPCA Technical Assistance Network using their web form at <http://www.ilt.edu/fsh/alliance>.

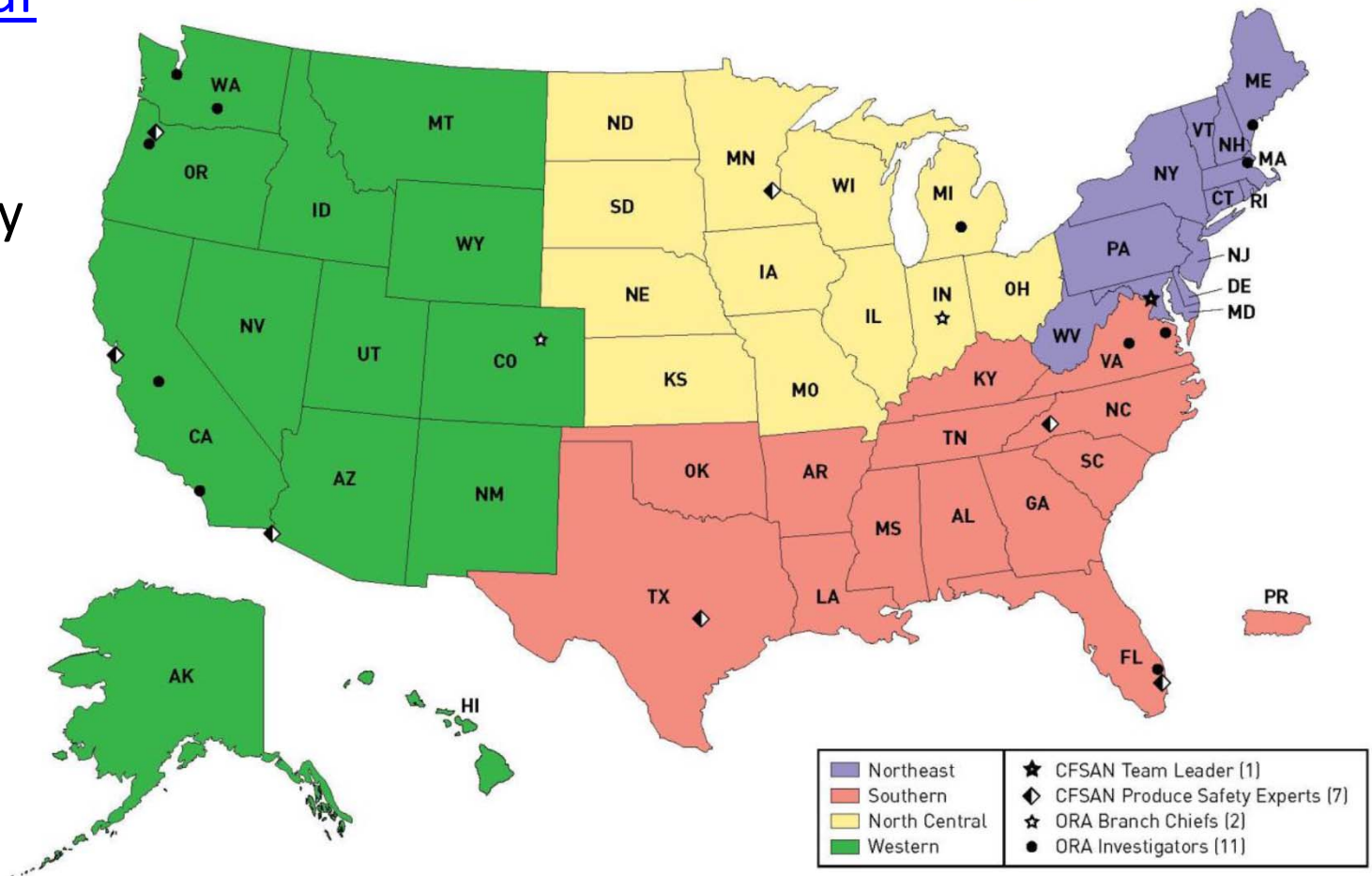
[How the TAN Works](#)

[Additional FSMA Resources](#)

FDA's Produce Safety Network (PSN)

<https://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm560008.pdf>

Lists
Contact Info by
Region/State



Guidance Documents

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#guidance>

- Typically Issued as “Draft Guidance for Industry” with comment period.
- 22 FSMA-related documents issued since 2016. Many more in development.
- Recent:
 - “Small Entity Compliance Guides”
 - Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities

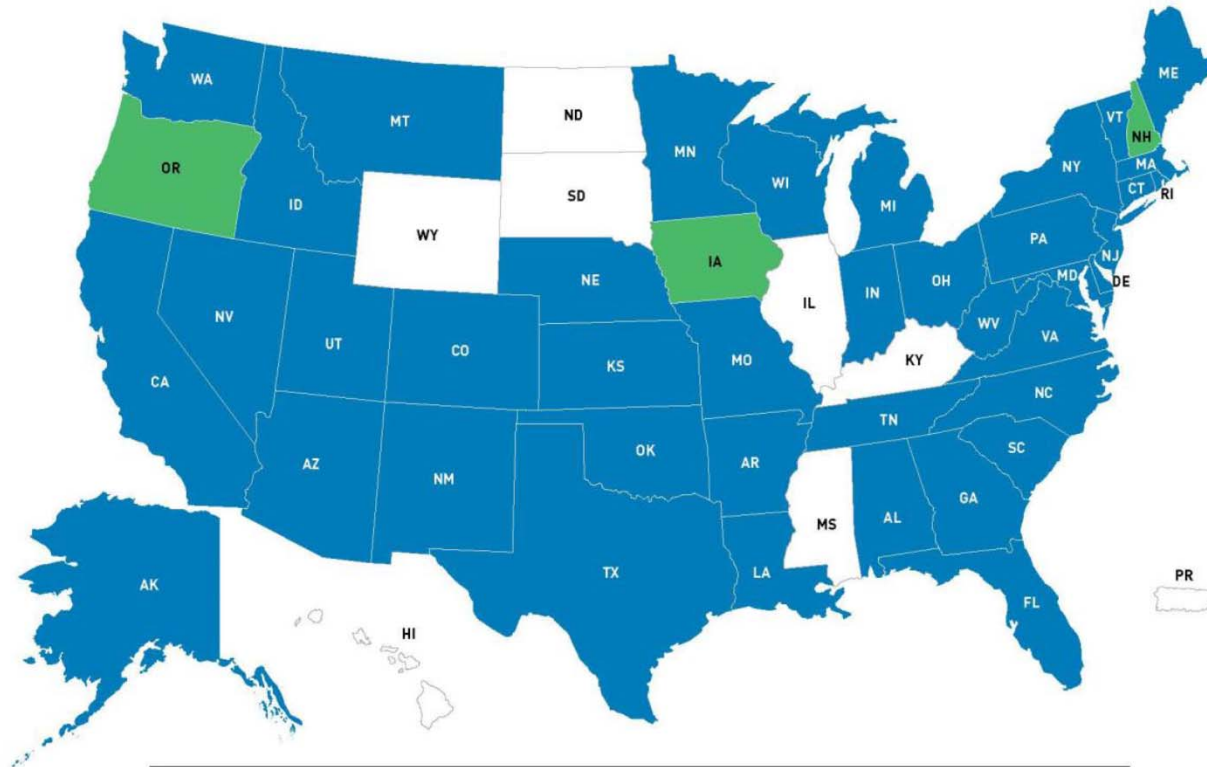
FDA's Implementation Strategy

“Educate before and while we regulate” (FDA Leadership)

- NASDA-FDA Implementation Strategy Workgroup
 - “On-Farm Readiness Review” Tool
 - Regulatory Inspections
- State Cooperative Agreement Program @FDA
- Leveraging Existing Mechanisms
 - Within the Produce Stakeholder Community
 - Support public & private parties involved in audits and other accountability functions with technical assistance and other collaborative support
 - Considering Alignment Projects

State Produce Implementation Cooperative Agreement Program (CAP)

<https://www.fda.gov/forfederalstateandlocalofficials/fundingopportunities/grantscoopagrmts/ucm517991.htm>



Competition A includes Infrastructure, Education, Technical Assistance, and Inventory Program.
Competition A/B includes Competition A components AND an Inspection, Compliance and Enforcement Program.

...Considering Alignment Projects...

Aligned...to reflect consideration of all components (minimums) of Produce Safety Rule

- Not “identical” or “equivalent”

USDA GAPs Alignment Project

- USDA’s *Produce Harmonized* GAP Audit
- “Aligned” and being utilizing this season

LGMA Alignment Project

- LGMA Metric (CA & AZ) now “aligned”
- CA LGMA beginning outreach/training campaign

Your Industry...

- Consider alignment or other demonstrations of compliance

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FOOD SAFETY PROGRAM

[Food Safety Practices](#)[Certified Members](#)[Training \(LGMA Tech\)](#)[Food Safety Modernization Act](#)[Government Audits](#)[For Retail & Food Service](#)[For Wellness Professionals](#)

FOOD SAFETY MODERNIZATION ACT

Produce Rule Resource Center

Government regulations are not new to producers of California leafy greens. The California Leafy Greens Marketing Agreement (LGMA) has been in place since 2007 as the best model to produce safe food because it establishes a culture of food safety on the farm. In January 2013 new federal laws overseeing fruits and vegetable food safety were issued as part of the Food Safety Modernization Act (FSMA). Visit this page for the latest information on FDA's proposed Produce Rule and how it will affect leafy green farmers.

SEE HOW

The LGMA aligns with proposed FSMA guidelines

[DOWNLOAD PDF >](#)

**FDA FOOD SAFETY
MODERNIZATION ACT**



Resources for More Information

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

Each Rule

Additional Resources

Have questions?

The screenshot shows the FDA's website for the Food Safety Modernization Act (FSMA). The page is titled "FDA Food Safety Modernization Act (FSMA)" and includes a search bar, navigation tabs for various FDA categories, and a sidebar with links to "The Law, Rules & Guidance", "Fact Sheets & Presentations", "Frequently Asked Questions on FSMA", "FDA Actions and Meetings", "FSMA Training", and "FSMA Technical Assistance Network (TAN)". The main content area features a "Most Popular" section with links to "Full Text of the Law", "Rules and Guidance for Industry", "Public Meetings", "Information by Topic", and "FSMA Technical Assistance Network (TAN)". Below this is a "Rules" section listing "Final Rule for Preventive Controls for Human Food", "Final Rule for Produce Safety", "Final Rule on Accredited Third-Party Certification", and "Final Rule for Foreign Supplier Verification Programs (FSVP)". The "Implementation Activity" section lists "Mitigation Strategies to Protect Food Against Intentional Adulteration Final Rule", "Sanitary Transportation of Human and Animal Food Final Rule", "Produce Safety Final Rule and Environmental Impact Statement", "Foreign Supplier Verification Programs (FSVP) Final Rule", and "Accredited Third-Party Certification Final Rule". A "Contact Us" section at the bottom provides information on how to submit FSMA questions. Arrows from the text on the left point to these various sections: "Each Rule" points to the "Rules" section; "Additional Resources" points to the "Implementation Activity" and "Resources" sections; and "Have questions?" points to the "Contact Us" section.