



FSMA Produce Safety Rule Implementation Update

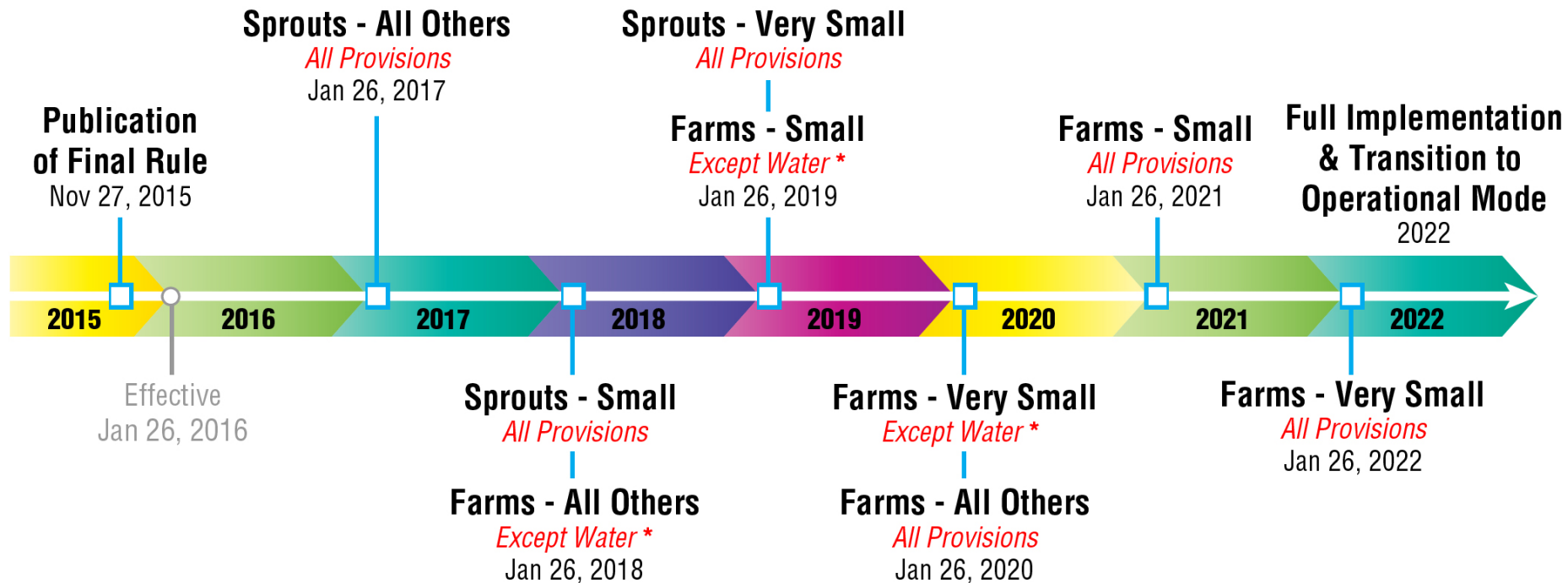
Center for Food Safety and Applied Nutrition
Food and Drug Administration
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FSMA Implementation

“A Continuum”

- Phase 1: Set Standards
 - Develop regulations, guidance, policy
- Phase 2: Design Strategies to Promote and Oversee Industry Compliance
 - Identify performance metrics to measure success
- Phase 3: Implement, Monitor, Evaluate, Refresh
 - Transition strategies and performance metrics from design to operational, evaluate success

Produce Safety Regulation Compliance Dates



* Only applies to certain water requirements

Small Businesses – average produce sales over 3 years > \$250,000 and ≤ \$500,000

Very Small Businesses – average produce sales over 3 years > \$25,000 and ≤ \$250,000

≤ \$25,000 in average produce sales over 3 years is not a covered farm



Key Principles

Domestic & International

- Utilize a risk-based approach to prioritize and allocate resources for implementation activities
- Invest in specialized training and implement produce safety in a way that:
 - Promotes consistency in regulatory approach and decision making
 - Allows the flexibility needed to recognize the diversity and complexity of the produce farming community

Key Principles

Domestic & International

- Work closely with the farming community, government agencies, academia, and other partners
- Recognize the role of the marketplace in influencing and expanding industry compliance with the produce safety rule
- Develop meaningful public health metrics to measure success, such as reductions in produce-related foodborne illnesses

Partnerships

- Partnerships are key to successful implementation.
- FDA is partnering with multiple organizations both domestically and internationally, including:
 - Other federal, state, and foreign government agencies and organizations
 - Land grant universities and other academic institutions
 - Produce farm and food industry associations
 - Food safety professional organizations

Leveraging

- FDA recognizes many produce safety initiatives with significant farm accountability systems have already been implemented through private audits, farm associations, the USDA/AMS, and other organizations.
- FDA will continue to explore ways to leverage these market-driven produce safety programs to assist in risk-based resource allocation and to inform current thinking both domestically and internationally.

Inspections and Compliance

- By increasing education and accessibility to technical assistance, the agency intends to foster and facilitate compliance.
- Inspectional approach includes new ways to enhance collaboration and assist U.S. State Agencies to perform the majority of on-farm activities (as funding permits) domestically, while FDA provides scientific support and assistance, as needed.

On-Farm Rule Advisory Review

- FDA is working with the National Association of State Departments of Agriculture (NASDA) to develop/pilot a voluntary on-farm readiness review program in the United States
- Objectives
 - Assess readiness of farms to comply with the Produce Safety rule
 - Promote compliance with the Produce Safety rule
 - Strengthen relationships between farms, FDA, States, other produce safety partners
 - Provide on-farm learning experience for FDA/State regulators
 - Identify knowledge/guidance gaps - regional, national, commodity
- Conduct prior to compliance dates for covered farms
- Tool to be made available online, including to the international audience

Inspections

Domestic & International

- Collaborating domestically with partners to develop an inspectional approach that can be implemented by U.S. State regulators and FDA
 - Routine domestic on-farm inspections will be conducted by State regulators, as funding permits
 - FDA may do inspections in States that choose not to conduct produce inspections;
 - FDA specialized staff would conduct such domestic inspections and all foreign inspections

Inspection Approach

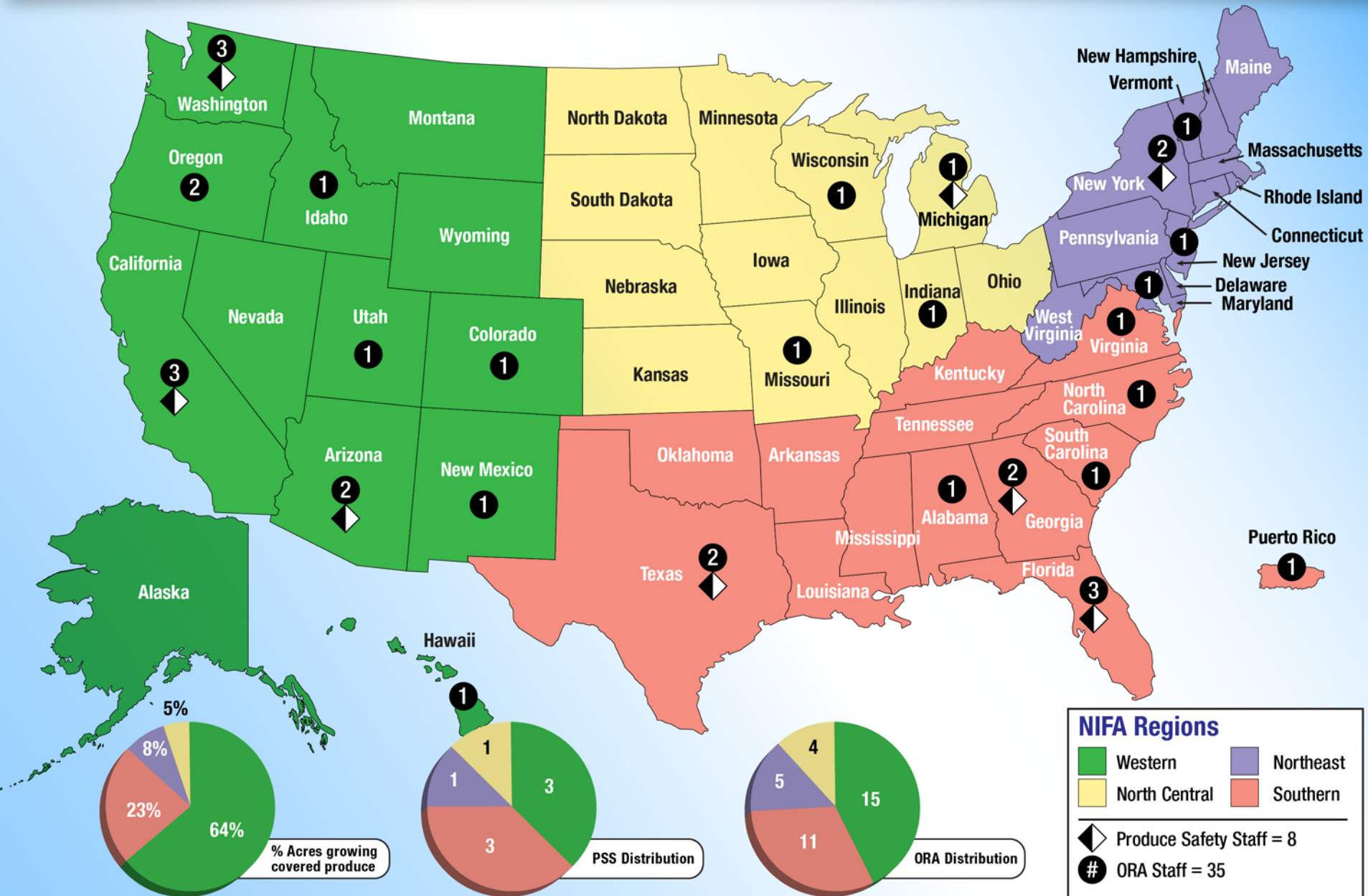
Domestic & International

- Objectives
 - Facilitate compliance through standardized, education-focused regulatory inspections using farm inspection reports that include guidance and educational references
 - Collect and evaluate inspection data to identify regional trends for targeted outreach, education, research, and work plan prioritization
 - Develop relationships between produce farmers and local FDA Produce Safety Network staff & regulatory partners
 - Initiate legal action as needed to protect public health

Reporting

- Developing new FDA reporting tools for both domestic and international inspections
 - Use of intelligent questionnaires to guide regulators to improve efficiency and consistency of inspections, facilitate analysis and information sharing, and generate informative reports
 - Comprehensive farm report including specific resources (e.g., links to guidance) as needed to help the farmer achieve compliance

FDA Regional Produce Safety Network



FDA's Produce Safety Network

Roles and Responsibilities

- Technical assistance
- Outreach and training
- Work planning
- Outbreak investigations
- Inspections
- Enforcement

Industry Training - Alliances

Produce Safety Alliance (PSA)

- Centered at Cornell University
- Developing a curriculum to train the farming community

Sprout Safety Alliance (SSA)

- Centered at the Illinois Institute of Technology
- Developing a curriculum to train sprout growers

Food Safety Preventive Controls Alliance (FSPCA)

- Centered at the Illinois Institute of Technology
- Developing curricula to train those that manufacture, process, hold and distribute human and animal food

Training: Regulators

- In addition to attending Alliance training on the requirements of the rule, FDA and State regulators will also attend regulator-specific training.
- Regulator training will incorporate new tools and introduce techniques needed to perform farm inspections and achieve consistency
 - Farm regulatory inspection approach protocols
 - FDA produce farm inspection reporting tools
 - On-farm bio-security and behavior protocols

Technical Assistance Domestic & International

- Establish an FDA FSMA Technical Assistance Network to provide central, consistent sources of outreach and technical assistance for industry and regulators
 - Part 1: FSMA Rule Interpretation Questions
 - Part 2: Food Safety Regulatory Community
- Leverage existing internal infrastructure, business processes and IT systems (Knowledge Management System - KMS)

FDA Technical Assistance Network

Part 1

- Launched FDA's FSMA Technical Assistance Network on September 10, 2015
 - Provide technical assistance to industry, regulators, academia, and consumers regarding FSMA
 - Address questions related to FSMA rules, programs, and implementation
- Collaborate with external technical resources, e.g. Alliances, Extension Specialists, Universities, International Partners

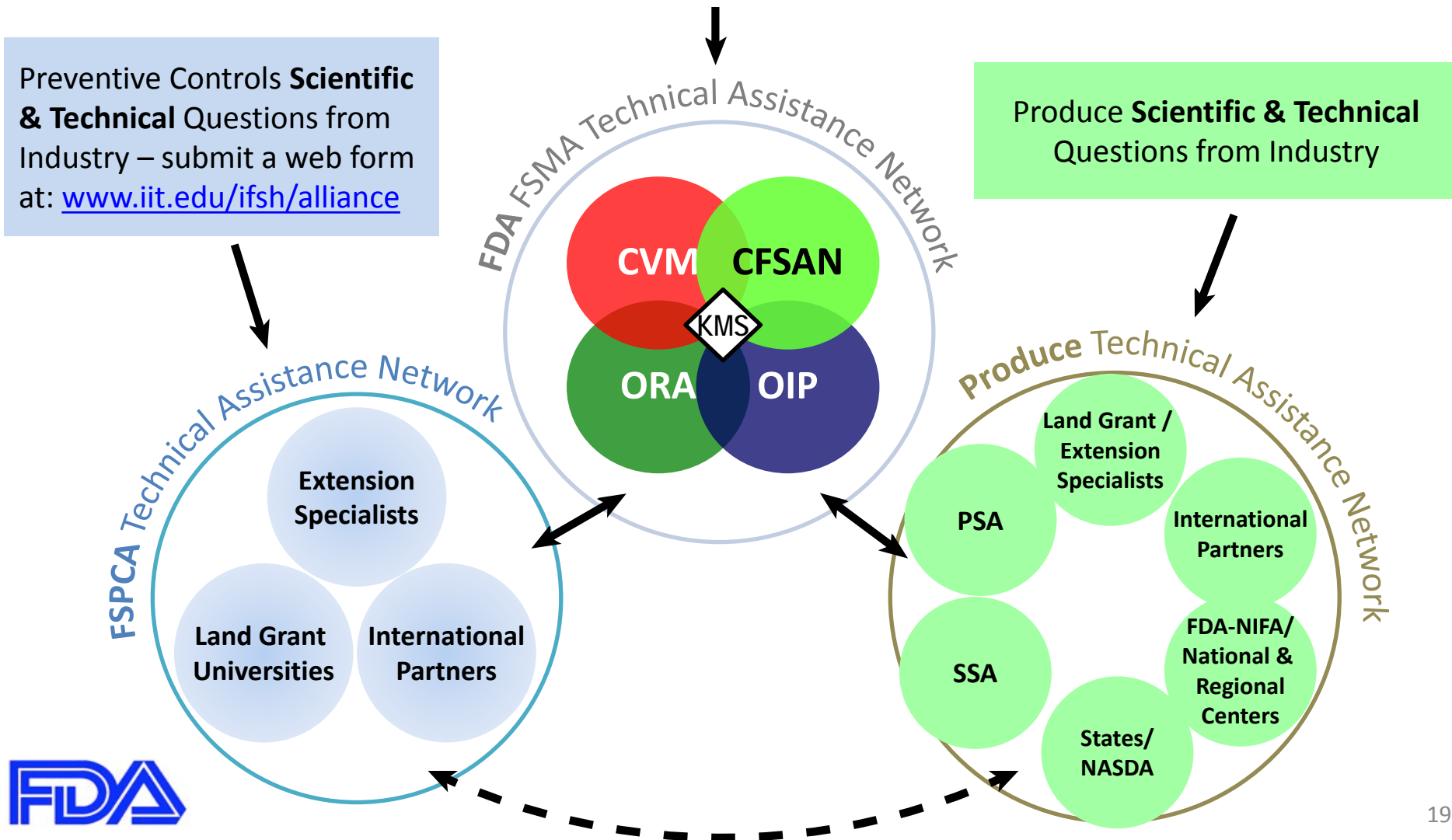
FSMA Technical Assistance Networks

FSMA Regulation & Policy Interpretation

Questions – submit a web form at: www.fda.gov/fsma

Preventive Controls **Scientific & Technical** Questions from Industry – submit a web form at: www.iit.edu/ifsh/alliance

Produce **Scientific & Technical** Questions from Industry



FDA Technical Assistance Network

- Questions will be tracked and trended using the Knowledge Management System
- Repeat questions will be addressed in FAQs or guidance documents posted on www.fda.gov/fsma
- Future efforts will include a Public Knowledge Base

Produce Safety Alliance (PSA) Goals

- Develop a standardized educational curriculum to increase understanding of produce safety
 - Requirement 112.22 (c) At least one supervisor or responsible party from the farm must have successfully completed food safety training at least equivalent to the standardized curriculum recognized as adequate by the FDA
- Build national networks for produce safety
- Conduct training to develop lead certified and certified trainers to build cadre of qualified instructors
- Conduct grower trainings
- Collaborate with partners for international training

PSA Curriculum – Grower Training

- ~Seven hours of dedicated instruction delivered in one day:
 - Introduction to Produce Safety
 - Worker Health, Hygiene and Training
 - Soil Amendments
 - Wildlife, Domesticated Animals and Land Use
 - Agricultural Water: Production Water
 - Agricultural Water: Postharvest Water
 - Postharvest Handling and Sanitation
 - How to Develop a Farm Food Safety Plan

PSA Train the Trainer

- Two day training
- Includes trainer specific information
 - Training options and partnerships
 - PSA Training Protocol
 - Interview process
 - Evaluations and other course logistics
- Individuals completing training may apply and interview for lead, certified trainer status

Public Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to [Contact Us](#)

