Produce Food Safety Overview
Produce Food Safety Landscape

- FDA is the regulatory authority for the safety produce
- AMS serves as a partner agency in support of FDA Produce Safety efforts
- AMS supports the industry in meeting buyer industry and regulatory food safety requirements
- USDA provides food safety training and outreach support
USDA and FDA Working Relationship

- 2 Federal/National Departments
  - Separate/Different Missions
- Memoranda of Understanding, pre 1975
- Food Safety Modernization Act, 2011
- USDA & FDA Cooperation & Coordination Workgroup
  - Liaison position USDA to FDA, primarily FSMA-focused
- Government Review Process, ongoing
  - Led by the Office of Management and Budget
Food Safety Modernization Act

- FSMA signed in 2011
- Seven Foundational Rules
  - Preventive Controls for Human Food
  - Preventive Controls for Animal Food
  - Produce Safety Rule
  - Foreign Supplier Verification Program
  - Accredited Third Party Certification
  - Sanitary Transportation
  - Intentional Adulteration
Preventive Controls for Human Food

FSMA Final Rule for Preventive Controls for Human Food

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

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

- Federal Register Notice
- Docket Folder FDA-2011-N-0920 provides the full text of the Rule.
Produce Safety Rule

FSMA Final Rule on Produce Safety
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Introduction
The Produce Safety 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. The rule is part of the agency’s ongoing efforts to implement the Food Safety Modernization Act (FSMA).
Produce Safety Rule

Materials created to determine if a business is subject to the Produce Safety Rule

Exemptions based on
- Sales
- Commodities
- End use/customer

https://www.fda.gov/media/94332/download
Produce Safety Rule
Inspections
Performed by:
• FDA inspectors
• FDA-trained state cooperators
Inspections began on large farms in 2018
Covid-19 resulted in changes in inspection activity for 2020
Additional Rulemaking/Guidance

- **Posted in 2020/2021**
  - Produce Safety Rule translations
  - Draft Traceability Rule
  - Agricultural Water Treatment Development and Registration Protocol
  - Information Collection on Rarely Consumed Raw list

- **Awaiting Finalization**
  - Farm Definition
  - Ag Water Requirements (Subpart E)
  - Biological Soil Amendments of Animal Origin
USDA and FDA Outreach and Assistance to Industry

• **USDA National Institute of Food & Agriculture, Food Safety Outreach Program**
  - Cooperative Agreements

• **USDA Natural Resources Conservation Service**
  - Balancing conservation and food safety considerations

• **FDA**
  - Cooperative Agreements
  - Website postings and Stakeholder/Constituent Updates
  - Guidance documents
  - Presentations, webinars, workshops

• **USDA AMS**
  - Variety of on-going activities
USDA and FDA Outreach and Assistance to Industry

**USDA AMS**
- Liaison Position
- Guidance Review and Development
- USDA GAP Audit Alignment
- Cooperative Agreement oversight and participation
  - Produce Safety Alliance
  - Local Foods
  - Tribal
USDA GAP Audit Program

The USDA GAP Service for You

Buyer Requirement:
- Adherence to Industry and FDA Best Practices
- FSMA Produce Safety Rule Alignment
- Produce GAP Harmonization Initiative Alignment
- Global Food Safety Initiative Technical Equivalence

USDA GAP Audit for You:
- USDA Harmonized GAP Plus+ Audit
- USDA Harmonized GAP Audit
- USDA GAP & GHP
USDA GAP Audit Program

USDA Harmonized GAP Audit

What One USDA Audit Can Do For You

Market Access AUDIT

USDA GAP / FDA PSR Alignment

One Audit – Multiple Uses

Regulatory INSPECTION

USDA’s alignment of the requirements of USDA Harmonized GAP audit to the minimum regulatory requirements of the FDA’s Produce Safety Rule means your USDA GAP audit will:

- Confirm you are in compliance with the Produce Harmonized GAP Standard AND implementing the relevant technical components of the Produce Safety Rule
- Provide you metrics that help you meet the Produce Safety Rule’s ultimate goals of increasing food safety

FDA

Produce Safety Rule

- Confirms compliance with Produce Safety Rule
- Mandatory
- Intermittent
- No cost
- FDA or State regulatory inspector
- Documentation provided to farmer
- Significant deficiencies recorded for correction
USDA and FDA Outreach and Assistance to Industry

• **USDA AMS**
  • Liaison Position
  • Guidance Review and Development
  • USDA GAP Audit Alignment
  • Cooperative Agreement oversight and participation
    • Produce Safety Alliance
    • Local Food Safety Collaborative
    • Indigenous Food and Agriculture Initiative
Produce Safety Alliance

- Cooperative agreement between USDA, FDA, and Cornell
  - Managed by USDA AMS
- Established in 2010

- Developed and maintains standardized curriculum for PSR
- Ensure effective training process
- Offer outreach, guidance, training, and technical assistance
Other Training Alliances for PSR

• **Local Food Safety Collaborative**
  • Training, outreach, and education to local food producers
  • National Farmers Union
  • Alternate Curriculum

• **Native American Tribal Center for Food Safety Outreach, Education, Training, and Technical Assistance**
  • Food safety training for Indian Country
  • Indigenous Food and Agriculture Initiative (IFAI) at the University of Arkansas
Thank you
Audrey Draper
Liaison to FDA on Produce Safety Issues
Audrey.Draper@usda.gov
202-720-9136