

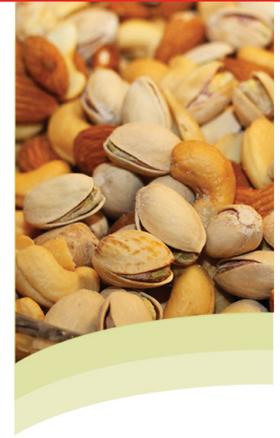


United States Department of Agriculture

Agricultural Marketing Service

Creating Opportunities for American Farmers & Businesses





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

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Food Safety Modernization Act (FSMA)

[Frequently Asked Questions on FSMA](#)

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

Content current as of:
07/10/2020

Regulated Product(s)
Food & Beverages

Produce Safety Rule

An official website of the United States government [Here's how you know](#)



Search

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FSMA Final Rule on Produce Safety

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

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Food Safety Modernization Act (FSMA)

Frequently Asked Questions on FSMA

FSMA Rules & Guidance for Industry

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

About the Final Rule

- Federal Register Notice
- Final Rule: Extension of Agricultural Water Compliance Dates (Federal)

Content current as of: 03/10/2021

Regulated Product(s)
Food & Beverages

Law(s) & Regulation(s)
Food Safety Modernization

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>

is used in the Produce Safety Rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.



Produce Safety Rule Inspections

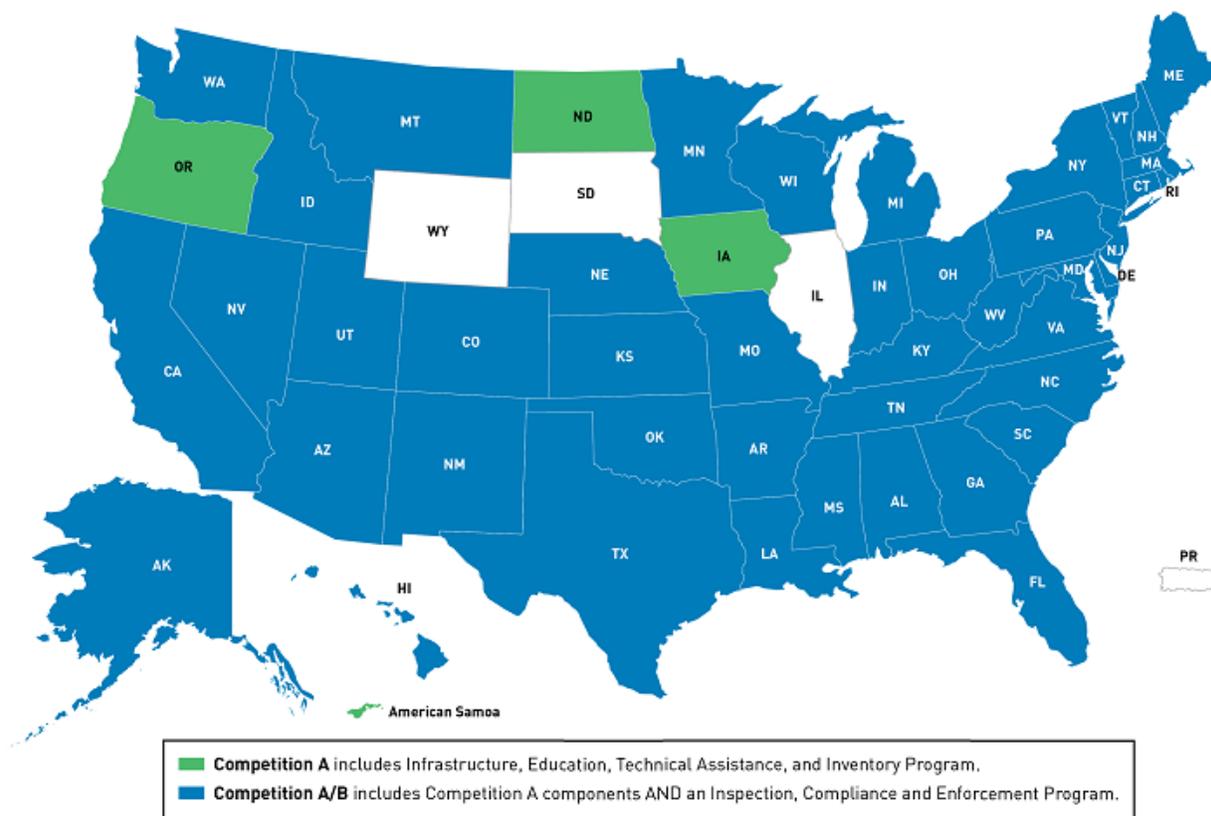
Performed by:

- **FDA inspectors**
- **FDA-trained state cooperators**

Inspections began on large farms in 2018

Covid-19 resulted in changes in inspection activity for 2020

Competition A Only & Competition A / B Map



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**
 - <https://nifa.usda.gov/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

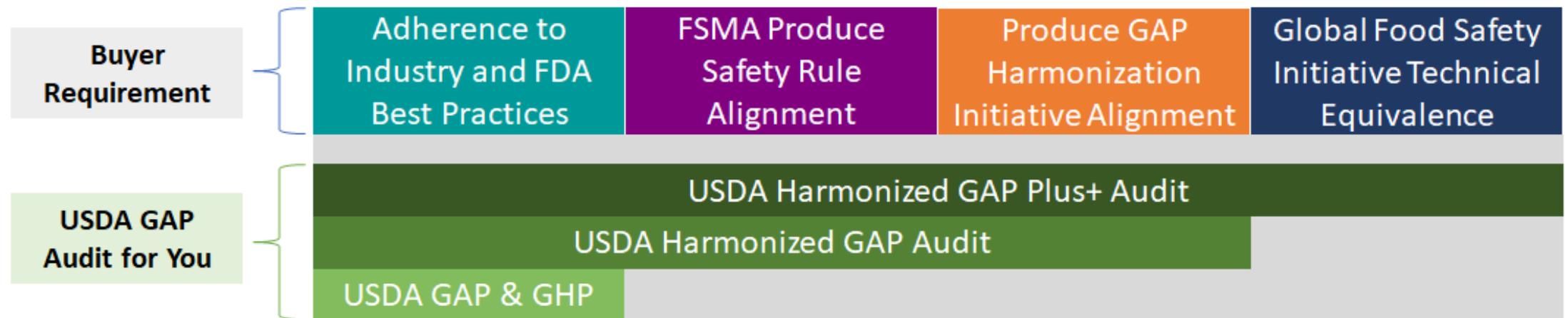
USDA and FDA Outreach and Assistance to Industry

- **USDA AMS**

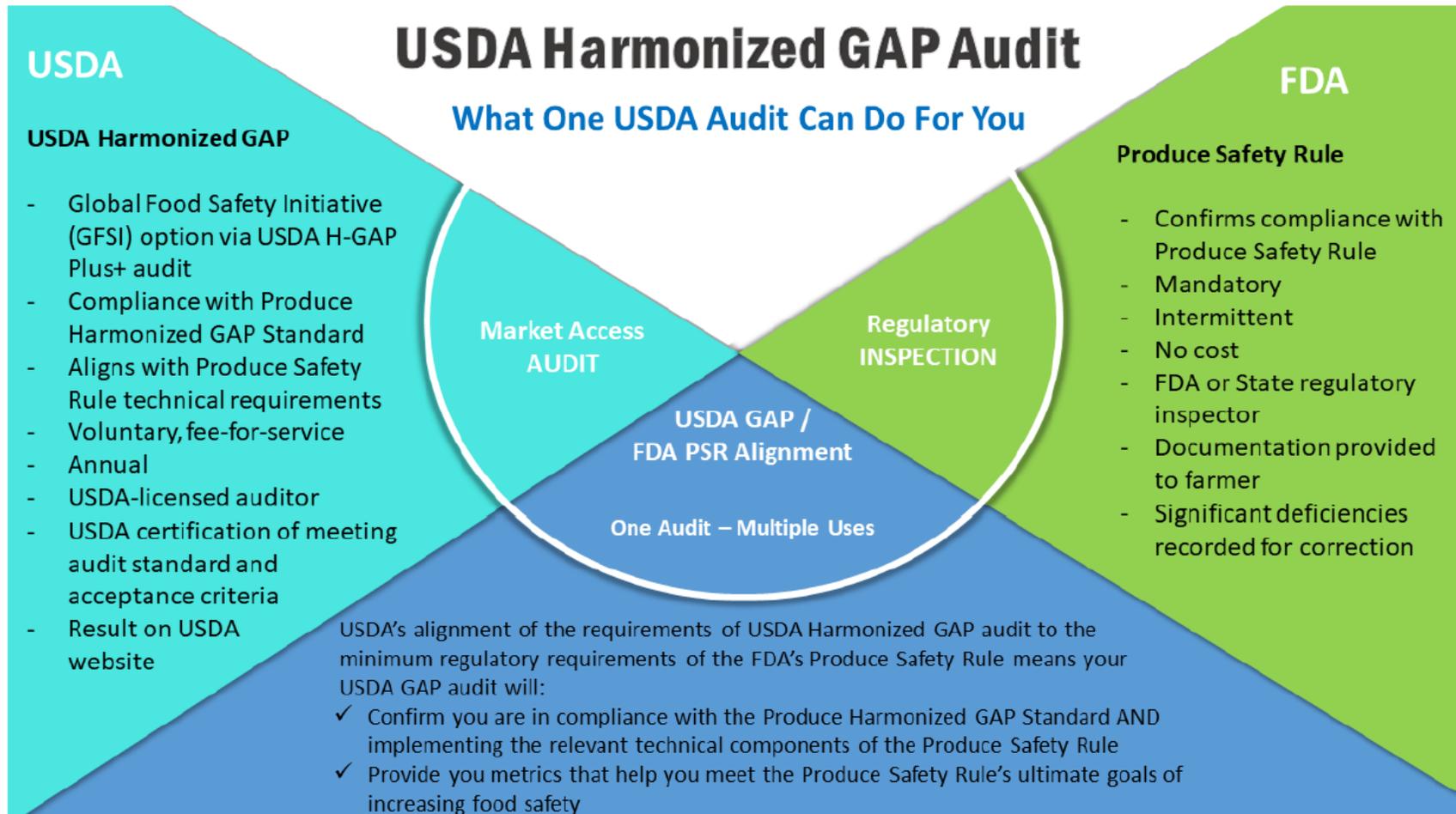
- Liaison Position
- Guidance Review and Development
- USDA GAP Audit Alignment
- Cooperative Agreement oversight and participation
 - Produce Safety Alliance
 - Local Foods
 - Tribal

USDA GAP Audit Program

The USDA GAP Service for You



USDA GAP Audit Program



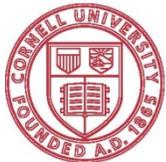
USDA and FDA Outreach and Assistance to Industry

- **USDA AMS**

- Liaison Position
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- 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**



Cornell University



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

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