



United States Department of Agriculture

Harmonization of Audits

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The USDA GAP&GHP Program

- **Voluntary, user fee based program offered by USDA's Agricultural Marketing Service (AMS)**
- **Verifies an operation developed and implemented a food safety program that incorporates good agricultural practices (GAP) and good handling practices (GHP)**
- **Audits based on FDA Guidance and industry best practices**



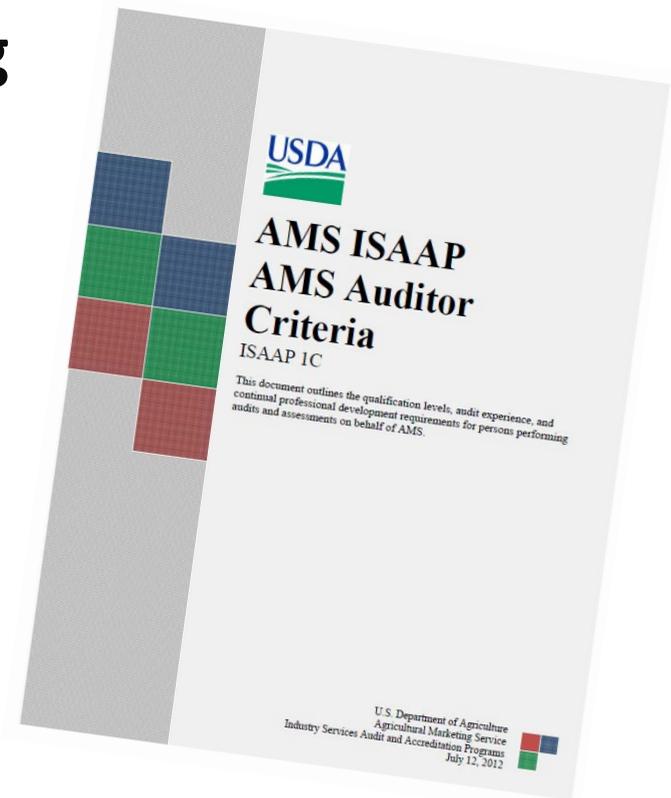
The USDA GAP&GHP Program

- **Used by producers, packers, and handlers to gain market access to retailers, food service and institutional buyers who require third-party verification of food safety**
- **In FY 2014, AMS conducted more than 4,000 GAP audits in the United States, Puerto Rico, Canada, and Chile**



The USDA GAP&GHP Program

- Audits performed by 250 trained, licensed Federal personnel and/or Federal-State cooperators
- All auditors meet strict training and evaluation requirements as outlined in the AMS Auditor Criteria





The USDA GAP&GHP Program

- **AMS is not a food safety agency**
 - **Food and Drug Administration (FDA) and USDA's Food Safety and Inspection Service set food safety standards**
- **Audits are conducted using FDA Guidelines or industry best practices**
- **AMS or AMS-licensed personnel conduct all USDA GAP audits**
 - **We do not accredit outside entities to perform audits**



Proliferation of Audits and Audit Fatigue

Over the past 10 years, outbreaks associated with fresh produce triggered industry-led initiatives to address concerns about the safety of fruits and vegetables, including:

- **Commodity Specific Best Practices**
- **Commodity Specific Audit Programs**
- **Marketing Agreements/Orders specific to food safety**
- **State-level regulations (e.g., Florida tomato)**
- **Private certification systems**



Proliferation of Audits and Audit Fatigue

These initiatives have had some unintended consequences:

- **Multiple food safety standards**
- **Multiple audits**
- **Buyer preferences of specific standards**
- **Buyer-specific riders or addendums**



Proliferation of Audits and Audit Fatigue

- **What should a food safety standard include?**
 - **Microbiological food safety?**
 - **Food defense?**
 - **Sustainability?**
 - **Social accountability?**
 - **North American vs. European models?**
- **Who can perform audits to these standards?**

Proliferation of Audits and Audit Fatigue

- **Effects of proliferation of audits on the producer community**
 - **Confusion about what standard to use**
 - **Confusion about what audit organization to use**
 - **Multiple audits needed to meet multiple buyers' requirements**
 - **Inconsistencies in interpretations of food safety standards**





Harmonization and Benchmarking

- **No generally accepted system or scheme that:**
 - **Everyone agrees to follow**
 - **Defines an acceptable food safety standard**
 - **Defines an acceptable audit process**
- **As a result, there are duplicative, often competing systems**
 - **GAPs Harmonization Initiative**
 - **Global Food Safety Initiative (GFSI)**



Harmonization and Benchmarking

GAPs Harmonization Initiative

- **Industry-led initiative to harmonize fruit and vegetable food safety standards typically used in North America**
- **Started in 2009, completed and implemented in 2012**
- **Integrates 14 audit standards, including commodity-specific, GFSI benchmarked, and government-based standards**



**Produce GAPs
Harmonization Initiative**

Harmonization and Benchmarking

GAPs Harmonization Initiative

- **Produce GAPs Harmonized Food Safety Standard**
 - Meets requirements of the proposed Food Safety Modernization Act (FSMA) Produce Safety Rule
 - Purposely did not address the audit process, i.e. auditor competence.



Produce GAPs
Harmonization Initiative

Harmonization and Benchmarking

GAPs Harmonization Initiative

- **AMS**
 - **Participated in the GAPs Harmonization Initiative**
 - **Was an early adopter of the Standard**
 - **Has performed more than 1,000 audits using the Harmonized Standard over the past 2 years**
 - **Serves on the Technical Working Group and Calibration Committee**



**Produce GAPs
Harmonization Initiative**



Harmonization and Benchmarking

Global Food Safety Initiative (GFSI)



- **A benchmarking organization founded in Europe in the early 2000s by major manufacturers and retailers**
- **Goal is to standardize suppliers' food safety processes**
- **Mission is to provide continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide**

Harmonization and Benchmarking

Global Food Safety Initiative (GFSI)



- **Board of Directors, who represent major retailer, manufacturer, and food service operators, provide strategic direction**
- **Technical working groups comprised of volunteers make policy recommendations**
- **Working to gain acceptance in the United States**
 - **Walmart, U.S. Foods, among others require their suppliers to be audited against a GFSI-recognized scheme**

Harmonization and Benchmarking

Global Food Safety Initiative (GFSI)

- **Recognizes food safety management schemes that meet their requirements**
 - **12 schemes that cover food safety systems throughout the supply chain are currently benchmarked and recognized by GFSI**
 - **Some schemes are specific to a specific industry, some are broadly based.**



Harmonization and Benchmarking

Global Food Safety Initiative (GFSI)

- **Scheme owners manage their own GFSI-benchmarked food safety standard and the associated audit processes, but do not perform certification activities. They accredit certification bodies to perform actual audits.**
- **Several GFSI schemes are working to adopt the Harmonized GAP Standard into their schemes for their North American clients**



Harmonization and Benchmarking

Key Obstacles for GFSI

- **Not widely used by most U.S. buyers**
- **Many producers feel GFSI requirements are too strict/restrictive or not applicable to production agriculture**
- **Requirements for food safety standards include components that are not traditionally associated with food safety audits in United States, e.g., pesticide use, Integrated Pest Management, and propagation material**





Food Safety Modernization Act

Market Access vs. Regulatory Issues

- **Producers want to use food safety audits**
 - **For market access**
 - **To show compliance with FSMA and other regulations**
- **Foreign governments want farms to be certified**
- **USDA-FDA Joint GAPs Review Project**





Current Market Conditions

- **Audits are primarily used for market access**
- **There is no generally accepted method for determining equivalency between audit standards/audit processes**
- **Result is current state of audit proliferation/audit fatigue**
- **Numerous industry efforts to reduce audit proliferation and audit fatigue have had varying levels of success**



How AMS Can Help

- **AMS performs audits using FDA Guidance and industry best practices**
- **AMS is working to gain wider acceptance of our programs by the buying community**
- **AMS and FDA are collaboratively reviewing the USDA-AMS GAPs Program to make it more useful and valuable in light of FSMA requirements**



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Questions?

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