Harmonization of Audits

Ken Petersen

Chief, Audit Services Branch

Specialty Crops Inspection Division

FVIAC Meeting March 2015
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
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.
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
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
Questions?

Ken Petersen
ken.petersen@ams.usda.gov
202-720-5021