Food Safety Modernization Act:
Risk Based Determination of Mechanisms to Verify
Control of Hazards

Collaborative Food Safety Forum: Foreign Supplier Verification
Program Workshop
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Who is the Grocery Manufacturers Association?

- GMA represents the world’s leading food, beverage and consumer product companies
- GMA provides leadership to the industry in food safety through promotion of scientific excellence
  - State of art research and analytical laboratory
  - Training in regulatory and food safety issues
  - Collaboration with U.S. government on food issues
- GMA promotes sound public policy and champions initiatives for productivity and growth
GMA Members

General Members

Associate Members

*Represents a sample of GMA members
Overview

- GMA members fully support establishment of supplier verification requirements through FSVP
  - One of the four pillars of food safety
  - FSVP should allow for implementation of state of the art practices that deliver safe food cost effectively
  - FSVP should be practical to implement, risk-based and flexible
Guiding Principles for FSVP

• Requirements in FSVP rule must add value:
  • Implementable and enforceable
  • Improve food safety
  • Have costs balanced with benefits
• Support innovation and continuous improvement
• Minimize burdensome bureaucratic activity
• Avoid barriers to trade
• Wherever possible, we support advancement of comparability assessments for foreign countries
Role of Audits

- Effective food safety management systems ensure delivery of safe food
- Auditing is an important tool but a sub-part of food safety management if conducted effectively
  - Provides independent real time assessment
  - Identifies problems and compliance issues
  - Drives continuous improvement
- Auditing alone is insufficient to deliver safe food
FSVP Option 1 vs. Option 2

- FDA co-proposed two alternative approaches to verification activities for hazards controlled by a foreign supplier
  - Option 1 is prescriptive and not based on risk
  - Option 2 is flexible and risk-based
- **GMA strongly supports Option 2**
Benefits of FSVP Option 2

- Option 2 represents state-of-the-art practice that consistently delivers safe food
- A risk-based approach allows efficient use of resources
  - Provides flexibility to determine the verification activities assessments of product risks and supplier risks
  - Allows resources to be directed at solving real problems
- Encourages critical thinking across the supply chain
- Considers issues broader than Class I hazards
- Encourages investment in supplier improvement programs
Issues with FSVP Option 1

• Option 1 represents a major step backwards versus state-of-the-art practice
• A single standard audit envisioned in Option 1 decreases rigor and removes motivation for continuous improvement
• Results in unnecessary operational burden without corresponding food safety and public health benefit
  • Audit overkill diverts resources to cover bureaucratic overhead
  • Limits resources available to improve food safety procedures
• Availability of trained auditors to conduct yearly audits is a significant issue
  • Capability
  • Cost
## Economic Analysis

### Annualized Costs of FSVP Option 1 and Option 2

<table>
<thead>
<tr>
<th></th>
<th>Option 1</th>
<th>Option 2</th>
<th>Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRIA Annual Foreign Supplier Audits</td>
<td>47,679</td>
<td>43,364</td>
<td>4,315 or ~10% more audits for Option 1</td>
</tr>
<tr>
<td>PRIA FSVP Annualized Costs</td>
<td>$473M</td>
<td>$461M</td>
<td>$12M added cost to audit 10% more foreign suppliers</td>
</tr>
<tr>
<td>GMA Member Data: % of Foreign Suppliers required for an annual audits as proposed in FSVP</td>
<td>30-50%</td>
<td>10%</td>
<td>3-5 fold increase for Option 1</td>
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</tbody>
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**Increased Annualized Costs to Implement FSVP Option 1 or 2**

|                              | $1.4 – 2.3B | $460M       |
Smaller less capable businesses will need support

- Small and very small foreign suppliers will need robust guidance on effective implementation
  - Elements of option 1 must be included in guidance framework
  - Available for use by businesses as needed
- Qualified Individuals
  - Will be essential supporters of smaller businesses
  - Will bring critical thinking and good decision-making into these operations
  - Build capability to operate flexible risk-based food management systems
Summary

- GMA strongly supports Option 2, a flexible and risk-based approach to supplier verification with a long history of successful use.
- Option 1 represents a step backwards in food safety: implementation of a prescriptive codified approach will waste resources and stifle innovation.
- The needs of smaller business can be met through:
  - Development and implementation of robust guidance.
  - Training of Qualified Individuals who will drive continuous improvement.
Thank you for your interest!

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FSVP Option 1

Are there hazards that are reasonably likely to occur?

Yes

For hazards controlled by importer or by its customer:
- Document importer or customer is controlling hazard

For hazards controlled by foreign supplier that could cause serious adverse consequences or death:
- Conduct initial onsite audit and then at least annually

For microbiological hazards in produce:
- Conduct initial onsite audit and then at least annually
- Conduct supplier verification from among:
  - Onsite auditing
  - Sampling and testing
  - Review of foreign supplier food safety records
  - Other appropriate procedure

For other hazards:
- Conduct investigative & corrective actions (as needed)

No
FSVP Option 2

Are there hazards that are reasonably likely to occur?

For hazards controlled by importer or by its customer:

Document importer or customer is controlling hazard

For other hazards:

Conduct verification from among:
- Onsite auditing
- Sampling and testing
- Review of foreign supplier food safety records
- Other appropriate procedure

Conduct investigative & corrective actions (as needed)
FSVP Recommended Approach for Supplier Verification

Robust Guidance

- Conduct investigative & corrective actions (as needed)
- Conduct supplier verification from among:
  - Onsite auditing
  - Sampling and testing
  - Review of foreign supplier food safety records
  - Other appropriate procedure

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GMA
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