

GMA

Representing the Makers of the World's Favorite Food, Beverage and Consumer Products



Food Safety Modernization Act *An Industry Perspective*

*JIFSAN Feeding the World Population
May 16, 2012*



Peggy Rochette
Senior Director, Global Strategies

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*Represents a sample of GMA members

Today's Discussion

- Focus on Key Import Provisions
- GMA Recommendations to FDA
- Explore Potential Trade Implications

Accountability

- FSMA holds responsible for ensuring food safety all entities involved in food production, distribution and oversight.
- FSMA applies to all Registered Facilities including Warehouses.
- Foreign Suppliers are held to the same standard as domestic producers – must meet U.S. requirements.

The Impact on our Trading Partners is Significant!

Import Safety Mandates

Section 301-Foreign Supplier Verification Program – FSVP

- *Importers are required to verify that imported food and ingredients is produced in accordance with U.S. standards.*
- *Records must be maintained documenting risk assessment and verification activities.*
- *Records must be maintained for two years.*

Import Safety Mandates - FSVP

GMA Recommendations

- *Regulations should be outcome based – build a safer supply chain.*
- *Regulations should consider the risk imposed by the import – what are the elements to assess risk?*
- *Requirements must take into account the differences in importers and products.*
- *Verification activities should be goal oriented – not prescriptive.*
- *Regulations should be practical and reasonable to achieve.*
- *Regulations should be consistent with international trade expectations.*

Import Safety Mandates - FSVP

Trade Considerations:

- Costs and burdens for smaller importers;
- Production and distribution practices in less developed countries;
- Diversion of supply sources?– Is it easy and cheaper to source domestically? Impact on costs and competition?
- Can trading partners adapt to new scrutiny? Are they willing?

Import Safety Mandates: VQIP

Section 302. Voluntary Qualified Importer Program

- *FDA will create a voluntary program for expedited reviews and importation of products from participating importers.*
- *Application and user fees will apply.*
- *VQIP imports will require 3rd party certification.*
- *VQIP importers will be re-evaluated every three years.*

Import Safety Mandates: VQIP

GMA Recommendations:

- *Allow flexibility in application: facility, importer, source of import or product line.*
- *Apply transparent methodology for scoring program admission based on “risk scores.”*
- *Seek “lessons learned” from existing CBP programs and integrate with CBP where possible.*
- *In determining “risk score” importer practices that are CONTROLLABLE should be the predominant factor.*
- *To benefit importers and FDA VQIP requirements must be rigorous but achievable.*

Import Safety Mandates: VQIP

Trade Implications:

- Will the benefits of participation balance the costs?
- Will expedited entry for “low risk” importers allow FDA to better target border resources: yield better food safety outcomes?
- How will importers be assessed for risk?
- Will this discriminate against imports from LDCs?

Acquiring the 3rd party certification?

Import Safety Mandates: Certification

Sec. 303 Authority to Require Import Certification

- *Authorizes FDA to require 3rd party certification for specific types or sources of foods based of risks associated.*
- *Requires FDA to identify inadequacies and develop process for improvement.*
- *If certification required, imported food may be refused entry without assurances.*
- *Certification does not prevent random checks and testing at import.*

This certification is not related to VQIP

Import Safety Mandates: Certification

GMA Recommendations:

- *3rd party certification can be an effective food safety tool.*
- *3rd party certification can increase regulatory compliance allowing re-allocation of resources based on risk.*
- *FDA should establish a system to recognize accredited bodies that accredit food safety certifiers.*
- *Certification should be performed by an independent 3rd party organization.*
- *FSMA 3rd party certification should build on existing international standards (e.g. Codex, ISO, GSFI).*

Import Safety Mandates: Certification

Trade Implications & Concerns

- Costs to suppliers and importers
- Potential duplication/multiplication of existing audit/certification practices
- Justification for certification based on cause – national treatment fears.

Confusion and questions from trading partners!

Import Safety Mandates: Accreditation

Section 307. FDA must implement a system to recognize accredited bodies to operate in accordance with established standards.

- *Accredited bodies will directly accredit 3rd party auditors*
- *FDA will issue model standards for auditors.*
- *FDA will publish a list of accredited bodies and 3rd party auditors.*
- *False statements from auditors are considered criminal.*
- *Accreditation may be withdrawn if food from a certified facility is implicated in a food safety incident.*

Foreign Governments Can be Accredited!

Import Safety Mandates: Accreditation

Section 202. FDA will provide for the recognition of accreditation bodies to accredit laboratories.

- *A registry will be published of recognized accreditation bodies and labs.*
- *Accredited labs must be used to support testing for admission of imported foods.*
- *Laboratory results will be reported directly to FDA and the importer.*

Import Safety Mandates: Accreditation

GMA Recommendations:

- *Recognition of an existing accreditation model (rather than the 3rd party auditors) is the best allocation of resources.*
- *FDA's approach should ensure independence between the schemes and the certification bodies.*
- *IAF/ISO is a widely used scheme to ensure implementation of food/feed safety systems.*
- *Accreditation should be required for FSMA regulatory testing; but NOT for in-house routine testing.*
- *If a facility uses an accredited lab for routine testing, results should only be shared with the client.*

Import Safety Mandates: Accreditation

Trade Implications

- Complexity of process, demands on FDA resources
- Global availability of competent accreditors, auditors, laboratory infrastructure
- Potential capacity building needs in LDCs
- Possible duplication redundancy in audit process for facilities
- Increased costs and shipping delays for exporters

Comparability and Capacity Building

Section 305. FDA is required to develop a plan to expand the regulatory capacity of foreign governments exporting to the U.S.

- Plan must include recommendations for agreements for data sharing, mutual recognition of inspections, training and multilateral acceptance of laboratory methods.

Section 306. Requires FDA to establish offices in foreign countries to provide assistance with respect to exporting to the U.S.

- Report published in February 2012 – 13 posts in six regions.

Comparability and Capacity Building

Section. 307 Provides that foreign governments can be accredited as third party accreditation body or auditors after a review of food safety programs, systems and standards to:

- *“Determine that the foreign government or agency of the foreign government is capable of adequately ensuring that eligible entities or foods certified ...meet the requirements with respect to food...for import into the United States.”*
- *FDA is exploring options to identify nations with “comparable” food safety systems. Developing an international comparability assessment tool.*
- *FDA can leverage resources of “comparable” nations to make more informed risk based systems regarding admissibility and inspections.*

Comparability and Capacity Building

GMA Recommendations:

- *Build public/private partnerships to leverage capacity building resources (APEC PTIN).*
- *Take advantage of existing trade fora to meet these mandates (RCC with Canada and Mexico).*
- *Utilize comparability assessments to minimize duplications and facilitate trade.*

Industry Hoping for Measurable Outcomes

Comparability and Capacity Building

Trade Implications and Challenges

- *Comparability Assessments – Resource Demands*
- *Comparability vs. “Equivalence” – WTO consistency?*
- *National Treatment – “Mature” Systems vs. LDCs*
 - *First in the Queue? Canada or New Zealand?*
- *Actual deliverables for FDA? For Industry?*
- *Responding to an incident from a “comparable” partner?*
- *Capacity building resulting from “incomparable” partner?*

International Compliance

Section 404. FSMA requirements must not be construed in a manner inconsistent with the World Trade Organization (WTO) Agreements.

- *Trading partners are watching closely.*
- *Comments filed by: Canada, Mexico, EU, Japan, Costa Rica, Malaysia*
- *Copycat or “retaliatory” measures likely.*
- *Technical Barriers to Trade?*

International Compliance

WTO Obligations:

- *SPS Measures:*
 - *Shall be based on international standards... (Codex);*
 - *Shall be justified by science if more restrictive;*
 - *Shall be applied “only to the extent necessary to protect health...”:*
 - *Shall not “arbitrarily or unjustifiably discriminate:”:*
 - *Shall not “constitute a disguised restriction on international trade.”*

International Compliance

- **Comments focus on:**
 - *Excessive burdens on small exporters or importers;*
 - *FDA foreign inspections frequencies and excessive fees for re-inspections;*
 - *Criteria for determining “risk;”*
 - *National treatment – discrimination and equal treatment;*
 - *Transparency and compliance deadlines;*
 - *Measuring comparability.*

Will FDA be challenged?

Can FDA provide risk based justifications for decisions?

Summary

- *Implementation is just around the corner.*
- *Now is the time to put your documentation procedures in order*
 - *FDA will have legal access to see and copy food safety plans and FSVP and extended Access in Emergency: “A reasonable belief that an article of food presents a threat of serious adverse health consequences or death” to include related products/ingredients*
- *The world is watching and changes in supply chains and trade flows are likely.*
- *FSVP provides new opportunities for regulatory cooperation and harmonization of practices.*
- *FSVP also presents challenges to businesses, to suppliers and to our trading partners. The price may be high.*

Be Prepared for a New Trade Paradigm.

Thank you for your time!

Contact Information:

Peggy Rochette,
Senior Director, Global Strategies
Grocery Manufacturers Association
(202) 639-5921
prochette@gmaonline.org