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

Foreign Supplier Verification Program (FSVP) and Exports to the USA:

Perspective from Further Down the Supply Chain – How will FSMA Impact ASTA members?

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FDA FOOD SAFETY MODERNIZATION ACT

Shannon Cooksey, MS, PMP

Senior Director, Science Program Management

Grocery Manufacturers Association

www.gmaonline.org

Agenda

- How suppliers will be verified
  - Guiding Principles for Foreign Supplier Verification Programs
  - How domestic facilities importing will verify foreign suppliers
  - What exporters should be thinking about
- Multi-National Corporation Exemptions
- Next Steps in FSMA Process
- GMA WG Accomplishments

About the Grocery Manufacturers Association

Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day.

The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders.

GMA Member Companies

*Represents a sample of GMA members

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Industry's Goal: Safety, Quality & Brand Protection

The primary goal of a food company is to deliver SAFE, quality products to our customers & consumers while promoting & protecting our brands & trademarks.

We would like to work with regulating bodies to foster transparency from both sides.

Food Safety is NOT a Competitive Advantage!!

Analytical Philosophy is Changing

- Reactive Approach
  - Regulatory testing
  - “Compliance” testing

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- Preventive Approach
  - Environmental Testing
  - Supplier Verification

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Guiding Principles

- FSVP regulations should build a safer supply chain, resulting in improving public health.
  - Improve consumer confidence in imported food and brands
- In developing FSVP requirements, consideration should be given to the risk posed by the import.
  - What are the elements involved in assessing the risk?
  - One size does not fit all

Guiding Principles

- FSVP requirements must take into account the differences among importers and imported foods
  - Must provide program flexibility to accommodate supply chain complexity

- Required verification activities should include specific performance objectives, rather than specifying behavior or procedure requirements
  - Should be goal-oriented vs. prescriptive
  - Should be flexible and outcome based
  - Should allow for innovation and new technologies

Guiding Principles

- Regulations should be practical and reasonable to achieve
  - Regulations should be science-based
  - Regulatory requirements should include a cost/benefit analysis
  - Requirements should take into account limitations of small and medium businesses
  - The relative roles of regulations versus guidance should be considered

Guiding Principles

- FSVP regulations must be consistent with international trade expectations
  - They should not be unfairly discriminate against any one nation, supplier or product
  - National capabilities should be taken into account and capacity building should be in place to support identified specific needs
  - Standards and regulations should take into account existing international standards, harmonizing where possible
  - Regulations should not unnecessarily disrupt trade

How domestic facilities importing food and ingredients will verify foreign suppliers

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What exporters to the USA should be thinking about

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Standard FSVP Requirements

1. Compliance Check – Importers would be required to review the compliance status of foods and foreign suppliers:
   - Warning Letters
   - Import Alerts
   - Mandatory import certification orders

Note: this information is a factor to be considered but would not automatically disqualify a supplier

Standard FSVP Requirements

2. Hazard Analysis for each food
   - Identify hazards “reasonably likely to occur” (same as in preventive controls)
   - Identify the severity of the illness or injury if each hazard were to occur
   - Document the hazard analysis
   - Consider biological, chemical, physical, and radiological hazards

Standard FSVP Requirements

3. Apply Verification Activities that provide "adequate assurances" that the hazards identified are adequately controlled
   - Importers would need to:
     - Maintain a list of foreign suppliers
     - Establish and follow adequate written procedures for conducting verification activities.
   - FDA seeks comment on two alternative proposed options regarding the specific verification activities required
   - Where there are no hazards, importers would only need to keep a list of foreign suppliers

Standard FSVP Requirements

4. Corrective Actions – Review complaints, investigate possible adulteration/misbranding, take corrective actions when appropriate, revise FSVPs when appropriate
5. Importer Identification – If no U.S. owner or consignee, the foreign owner or consignee would need to designate a U.S. agent or representative responsible for FSVPs.
   - All importers would need to:
     - Obtain a DUNS number for company
     - Provide name and DUNS number electronically to CBP when filing for entry of food

Standard FSVP Requirements

6. Reassessment – For each imported food, the FSVP must be reassessed at least every 3 years; reassessment also is required if you become aware of new information about potential hazards associated with the food

Standard FSVP Requirements

7. Recordkeeping – Document compliance status reviews, hazard analysis, verification activities, investigations and corrective actions, and FSVP reassessments
   - FDA would have access to these records under section 301(a) of FSMA (section 805(d) of the FFDCA)
   - FDA would likely view records access as extending to on-site audit reports
   - FDA proposes to give itself remote access to records
     - If requested in writing by FDA, importer would be required to send records to agency electronically
   - Records must be kept in English
   - Some records must be kept for 2 years; others for longer

Control of Hazards – What Verification Activities are Required?

- Key is identifying verification activities adequate to control the hazard
- In determining appropriate verification activities and frequency, importer would need to consider:
  - Risk presented by the hazard
  - Probability that exposure to the hazard would result in serious harm
  - Food and foreign supplier's compliance status

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Potential Exemption for Multinational Corporations

- FDA questions whether FSVP should apply to a multinational corporation where a U.S. company imports food from entities under the same corporate ownership
  - e.g., Company ABC U.S. imports from Company ABC Canada
- FDA requests comment on whether such companies should be exempt from FSVP or subject to different FSVP requirements

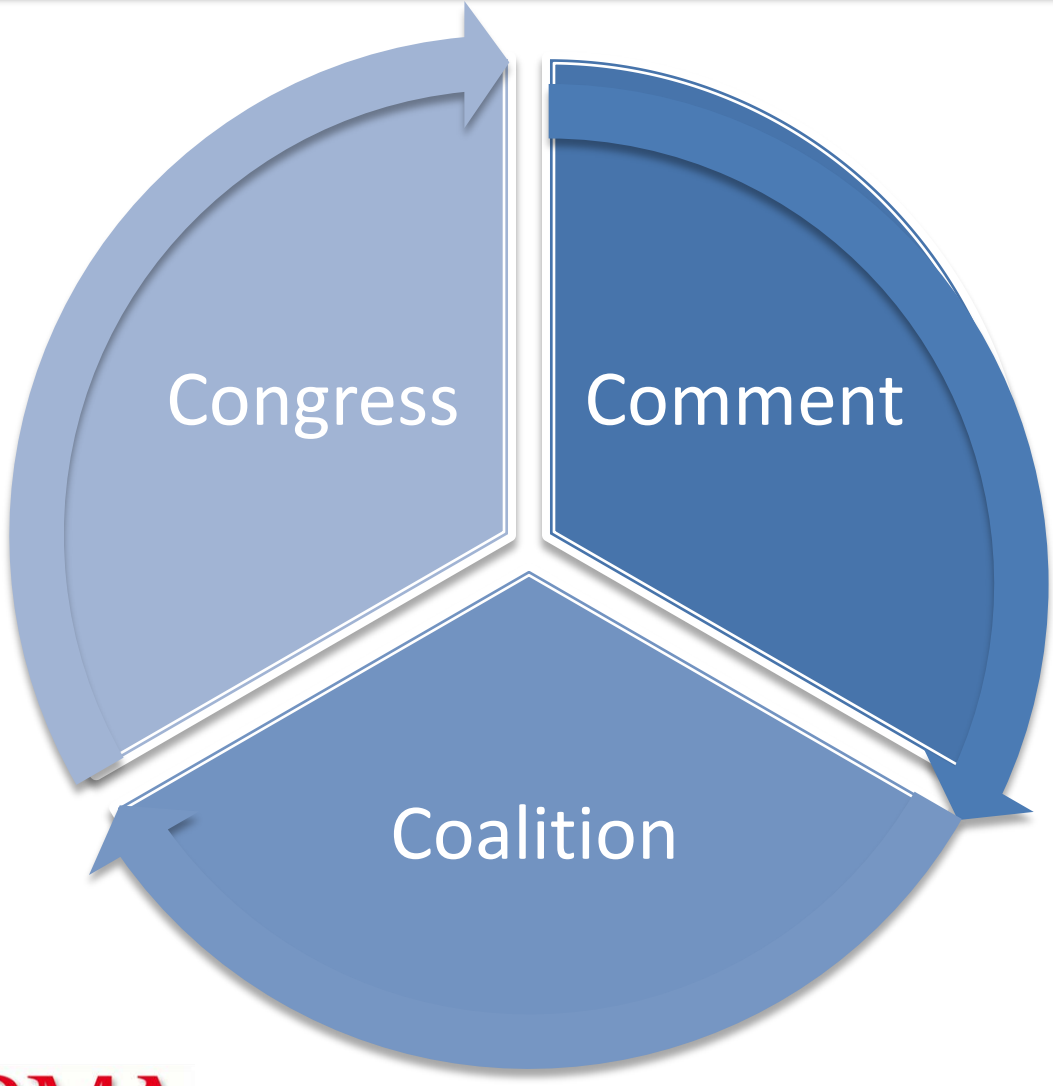
Modified Requirements

- FDA proposes to apply modified FSVP requirements for:
  1. Importation of a dietary supplement or dietary supplement component
  2. Importation of food by a very small importer or from a very small foreign supplier with annual sales of less than $500,000
  3. Importation of food from a foreign supplier in good compliance standing with a food safety system that FDA has officially recognized as comparable/equivalent to that of the U.S.

Next Steps

- Review preventive controls proposal in light of new proposals and submit comments to FDA by November 15, 2013
- Review both new proposed rules and submit comments to FDA by November 26, 2013
  - Consult with third party accreditation community in conducting these reviews
- FDA under court order to issue final rules by June 30, 2015 with compliance dates anticipated to be June 30, 2016 for large manufacturers

The Three Cs of Influence



FSMA Strategy:
Three Components

1) Written Comments and direct influence with FDA

2) Alliances with other organizations via Coalition

3) Government affairs outreach to Congress

Economic Impact Analysis

- Objective:
  - Review and assess the Preliminary Regulatory Impact Assessment (PRIA)
- Strategy:
  - Scientific/technical members analyzing PRIA and drafting comments showing the added costs to the industry to implement FSMA based on proposed regulations
  - Comments will recommend FDA adopt the proposed language as presented by GMA in its comments to the new regulations. This would make the final rule align more with the PRIA and the FSMA statute.

Post-Rulemaking Focus: Effective Implementation

- Focus on the following are needed to promote consistent and appropriate enforcement post-rulemaking:
  - Training FDA inspectors
  - Reconsideration of general inspectional approach
  - Consistency of implementation
  - Effective and transparent appeals process
  - Consistency among state and federal inspectors
- Collaboration on development of guidance documents will be essential

Upcoming Proposed Rules

- To be Published by Nov 30, 2013
  - Preventive Controls for Animal Feed
  - Intentional Adulteration

- To be Published by Jan 30, 2014
  - Sanitary Transportation of Food

Final Rules to be Published by June 30, 2015 with Implementation Dates Specified

Industry Food Safety Practices: Informing the FDA FSMA Rule Making Process

GMA has been working closely with the FDA to develop the rules and guidance that will be used to implement the provisions of the FDA Food Safety Modernization Act. This manual is a compilation of the technical information, industry practices, and recommendations that GMA members and the industry provided FDA through public dockets, testimony and meetings.

This publication provides a logical approach for introducing food safety Hazard Analysis and Preventive Controls, and includes information necessary for developing a model Food Safety and Food Defense plan.

Part one of the publication will present an introduction to foundational food safety programs with a separate chapter devoted to sanitation, and will feature subsequent chapters focused on identifying biological, chemical and physical hazards.

Part two is a unique companion publication that provides a combination of industry and regulatory resources all in one place, and focuses on the principles and methods for development of a Food Defense plan.

“This two-part manual contains thoughtful contributions from over 30 food safety, quality, legal and regulatory experts with the fundamental and practical knowledge that food companies will find essential in developing food safety and food defense plans that have been mandated by FSMA.

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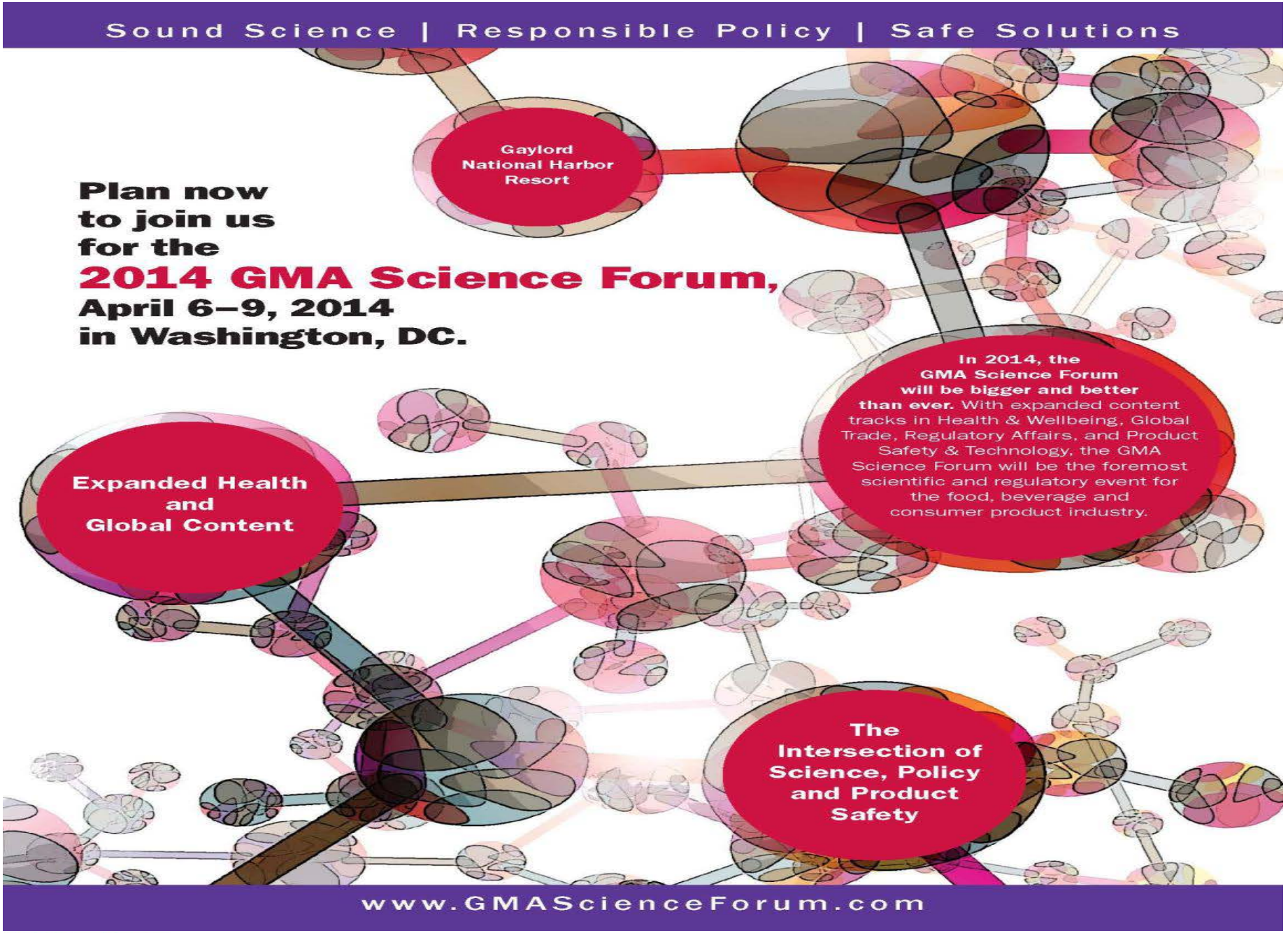
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Thank you for your time!

Contact Information:
Shannon Cooksey, MS, PMP
Senior Director, Science Program Management
Grocery Manufacturers Association
(202) 639-5979
scooksey@gmaonline.org