GMA

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

FSMA – Domestic and Foreign Supplier Verification

IFTPS Annual Meeting
03/12/2014

FDA FOOD SAFETY MODERNIZATION ACT

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www.gmaonline.org

Agenda

- List of Proposed Rules to date
- Preventive Control Rule Takeaways
- Proposed Rule on Foreign Supplier Verification Programs
- Proposed Rule on Accreditation of Third Party Auditors
- GMA Member Concerns with Proposed Rules

Current List of Proposed Rules

- Preventive Controls for Human Food (PCFH)
- Produce Safety Standards
- Foreign Supplier Verification Program (FSVP)
- Accreditation of 3rd Party Auditors (3PAC)
- Preventive Controls for Animal Food (March)
- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (March)
- Sanitary Transportation (May)

Analytical Philosophy is Changing

- Reactive Approach
  - Regulatory testing
  - “Compliance” testing
- Preventive Approach
  - Environmental Testing
  - Supplier Verification

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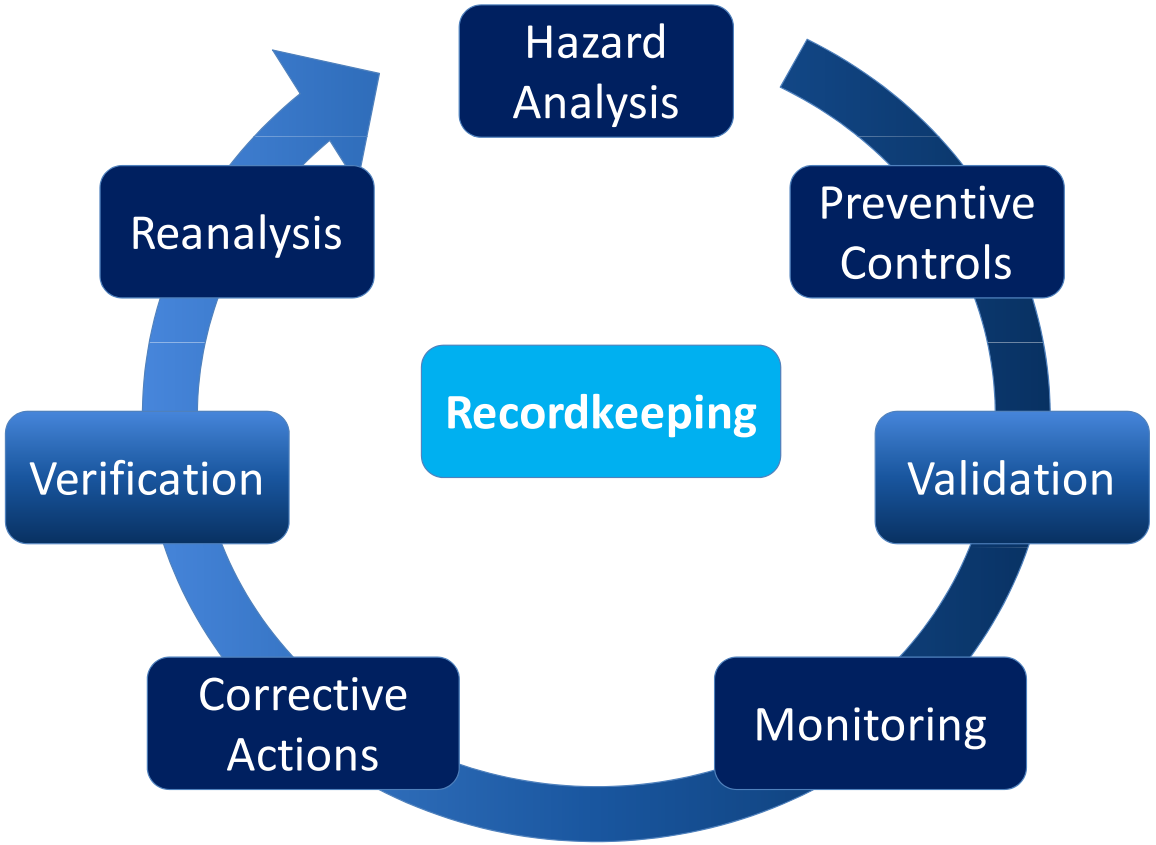
Preventive Controls Rule Takeaways

1. **Proposed rule generally tracks the statute**



Takeaways (cont'd)

2. **FDA generally provides industry flexibility**
   - Each facility to tailor food safety plan
3. **FDA generally aligned proposal with HACCP**
4. **Testing/supplier verification not required initially**
   - Cost implications and Economic analysis assumptions
   - Comments requested on inclusion in final rule

Takeaways (cont'd)

5. Validation of preventive controls key issue

- FDA expects high level of scientific justification

6. High emphasis on recordkeeping/FDA access

- Food safety plan on-site at least 6 months
- Electronic records (Part 11)

7. Updates to cGMPs

- Outgrowth of cGMP Modernization Initiative
- Replaces Part 110 entirely

Takeaways (cont'd)

8. **Defines small and very small businesses**
9. **Compliance dates**
   - 1 year / 2 year / 3 year – Based on size
10. **Warehouse exemption**
   - Non-refrigerated warehouses – exempt
   - Refrigerated & Frozen warehouses – modified controls

***** All from date of publication of Final regulation***

Food Safety Plan

- Would need to include:
  1. Hazard analysis
  2. Preventive controls (Process/Sanitation/Allergen)
  3. Monitoring (including frequency),
  4. Corrective actions
  5. Verification (and validation)
  6. Recall plan
- Written – Hard copy…..

Food Safety Plan

- Prepared (or preparation approved) by "**Qualified Individual**"
  - Recognized training (FDA)
  - **OR** Qualified thru Experience
  - Could be a Team
  - FSPCA developing curriculum
  - Follows HACCP training

- Plan to be Signed and dated by owner, operator, or agent in charge initially and each time modified

Remember – Low Acid Foods

- Foods Regulated under 21 *CFR* 113:
  - **Exempt from Biological Hazards**
  - Food Safety Plan for Chemical & Physical required

- All other Foods are subject to the new requirements:
  - Including Acidified Foods (at this point)
  - Acid, Water Activity Controlled, etc.

Side Note on Package Materials

- Expect **Food Packaging** – the noun (i.e. food contact surfaces) to be handled like foods and ingredients from the standpoint of potential adulteration:
  - New emphasis on GMP's and prevention of insanitary conditions
  - Focus on sterilization in finished product
  - Verification may apply
  - Exemptions for Packing on Farms shipping RAC's

FSVP Proposed Rule:

- FDA proposes to require that all importers establish and follow an FSVP, unless exempted
- Importers would need to verify that their suppliers are meeting the same U.S. safety standards

- FDA intends to apply the **same rules domestically** under the supplier verification requirements

FSVP – Foreign Supplier Verification

- FSMA requires compliance with international agreements:
  - “Nothing in this Act (or an amendment made by this Act) shall be construed in a manner **inconsistent with** the agreement establishing the World Trade Organization or any other treaty or international **agreement** to which the United States is a party.” (FSMA § 404)

Who is Subject to FSVP?

- U.S. Owner: person/company in the U.S. who has purchased an article of food for entry
- U.S. Consignee: if article not sold at the time of entry, the person in the U.S. to whom the article has been consigned
- U.S. Agent/Representative: if there is no U.S. owner or consignee, the U.S. agent or representative of foreign owner at the time of entry

Legal Standard for FSVP

- For each food, an importer must develop, maintain, and follow an FSVP that provides "adequate assurances" that its foreign supplier is producing food in compliance with FDA standards
- Equivalent standards: proposed rule contemplates that other standards **might** provide the same level of public health protection with **NO** explanation

- Applies to both packaged food and fresh produce

FSVP Requirements

1. Compliance status review of foods and suppliers
2. Hazard analysis
3. Supplier verification activities
4. Corrective actions (if necessary)
5. Importer identification at entry
6. Periodic reassessment of the FSVP
7. Recordkeeping

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

Standard FSVP Requirements

2. Hazard Analysis for each food
   - Identify hazards “reasonably likely to occur”
   - Identify the severity of the illness or injury if each hazard were to occur
   - Document the hazard analysis

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

Standard FSVP Requirements

4. Corrective Actions – As necessary - documented
5. Importer Identification – as discussed above
   - All importers would need to:
     - Obtain a DUNS number for company
     - Provide name and DUNS number electronically to Customs and Border Patrol when filing for entry of food

DUNS – Dun and Bradstreet Data Universal Numbering System

Standard FSVP Requirements

6. Reassessment –FSVP must be reassessed at least **every 3 years**; or anytime you are aware of new information about potential hazards
7. Recordkeeping – Document :
   a) compliance status reviews
   b) hazard analysis
   c) verification activities
   d) Investigations
   e) corrective actions
   f) FSVP reassessments, etc.

FSVP Recordkeeping

- FDA would have access to FSVP records
- FDA would likely view records access as extending to **on-site audit reports**
- FDA proposes to give itself remote access to records - **electronic**
- Records must be kept in English

Control of Hazards

1. Hazards Controlled by Importer
   - Documented at least annually
2. Hazard Controlled by Importer's Customer
   - Importer to obtain written assurance, annually, from customer

- If either of these criteria are met, importer would not need to conduct verification activities

Control of Hazards

3. Hazards Controlled or Verified by the Foreign Supplier
   - 2 alternative co-proposals for verification activities
     - Option 1: Different requirements by hazard (Risk)
     - Option 2: Same requirements for all hazards

Control of Hazards

Option 1 – *different* requirements depending on hazard

- Mandatory initial and annual audit for hazards presenting the highest risks
- For *other* hazards, a "menu" of verification options

Option 2 – *same* requirements for all hazards

- For *all* hazards, a "menu" of verification options

Control of Hazards

- For Importer choosing from a "menu" of specified verification activities (Option 2):
  - Periodic on-site auditing (no frequency specified)
  - Periodic sampling and testing
  - Review of foreign supplier's food safety records

Control of Hazards

- On-site Audits
  - Could be conducted by importer or a third party
  - Either option, importer may rely on the results of a governmental inspection by FDA or the food safety authority of a country determined to be equivalent to that of the U.S.
    - Within 1 year of date required

Equivalent Countries

- FDA proposes to apply modified FSVP requirements for countries with food safety programs comparable/equivalent to that of the U.S.
  - Currently, only **New Zealand** has received this designation
  - Enforcement action for fraud

Compliance Date

- Normally 60 days after Final Rule
- FDA would provide additional time before importers must come into compliance
  - No compliance dates less than **18 months** after publication of final FSVP rule

Accreditation of 3rd Party Auditors

- Program for accrediting third-party auditors to conduct food safety audits of foreign facilities/foods
- FDA would recognize accreditation bodies
  - **Could be** foreign governments
- Accreditation bodies would accredit auditors/certification bodies
- Auditors/certification bodies would audit and certify foreign facilities or foreign foods at least **once a year**

Regulatory Audits

- Determine compliance with FDA regulations
- Determine whether food is certified for import to US
- Direct Reporting to FDA will apply

Will only be required for Mandatory Import Certification and Voluntary Qualified Importer Program

Direct Reporting to FDA

- Audit Reports: **Regulatory audit reports** sent to FDA within **45 days**
- Immediate Reporting: Auditors required to report to FDA immediately any conditions that present a *"serious risk to public health"*
  - Class I and Class II level recall risks
- Lab Results: Laboratory results taken during an accredited audit would be **automatically** sent to FDA **by accredited laboratories**

Consultative Audits

- Audit to evaluate compliance with FDA requirements and industry standards
  - **For internal purposes only (by Company)**
- Consultative audit reports would **not** be automatically filed with FDA, *but* would still trigger proposed reporting requirements of serious health risks and of all sample testing results

Impact on Related Programs

- FSVP
  - FDA proposes to require adherence to **third-party audit rules** whenever an accredited auditor is chosen to conduct the on-site FSVP audit
  - FDA has suggested it might make use of accredited auditors mandatory for FSVP third party audit purposes

Impact on Related Programs

- Domestic Supplier Verification
  - FDA has strongly suggested it will align FSVP and **domestic supplier verification**
  - If accredited certification bodies are required for on-site audits under FSVP, that could signal FDA's intention to include them in domestic supplier verification

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Key Concerns for PC Rule

- "Reasonably likely to occur" –phrase is defined in the HACCP regulations to mean CCPs, but preventive controls are broader
- Level of oversight required for hazards – not all controls should be managed the same way
- Product & Environmental Testing –
  - Likely to be in Final Rule – opportunity for comment?
  - Should be a Verification Activity, not a Control
  - Requires flexibility and purpose
  - Impossible to prescribe specific testing for all cases

Key Concerns for PC Rule

- Supplier Verification in general
  - Should encourage appropriate behavior
  - Does not control hazards
  - Should be based on holistic assessment of Risk
- Records Issues
  - 6 months on-site requirement should be flexible
  - Part 11 electronic requirements should be optional
  - Facility profiles & Remote records access should not be required
  - Records should be reviewed on-site (context)

Key Concerns for PC Rule Overall

1. System based
   - Looking at all controls
2. Risk based and tailored
   - HA should address Risk based food safety needs
   - Not a prescriptive list that carries equal weight
3. Implemented properly
   - Trained investigators
   - Proper oversight

Key Concerns for FSVP

- Regulation needs to be broader, simpler and more flexible, yet provide adequate assurance of food safety
- Option 1 for supplier verification is very prescriptive and not aligned with current leading industry practices
- Supplier verification should be risk based and **NOT** hazard based
  - Evaluation of supplier's entire food safety system
  - i.e. Performance history

Key Concerns for FSVP

- Consultative Audit reports need to remain confidential and not subject to FDA inspection and direct reporting
- FDA should allow use of qualified third party auditors to meet supplier verification responsibilities
  - **Outside** of the formal third party accreditation process and reporting requirements

Key Concerns for Third Party Accreditation

- Third party accreditation reporting requirements should **ONLY** apply to Mandatory Import Certification (MIC) and Voluntary Qualified Importer Program (VQIP)
- Should **NOT** apply to FSVP, Domestic SV or Consultative & Continuous Improvement Audits
  - FSVP should leverage the existing third party auditing systems and their governance programs

Key Concerns for Third Party Accreditation

- FSMA's "serious risk to public health" standard for immediate reporting should be applied consistent with the existing Reportable Food Registry (RFR) requirements and Class I definition
  - SAHCODHA "significant adverse health consequence or death to humans or animals" (FDA definition for Class I recalls)
  - The RFR reporting program is well known
- Immediate notification trigger for reporting should **ONLY** apply to Class I recalls and **not** Class II

Requirements for Effective Implementation

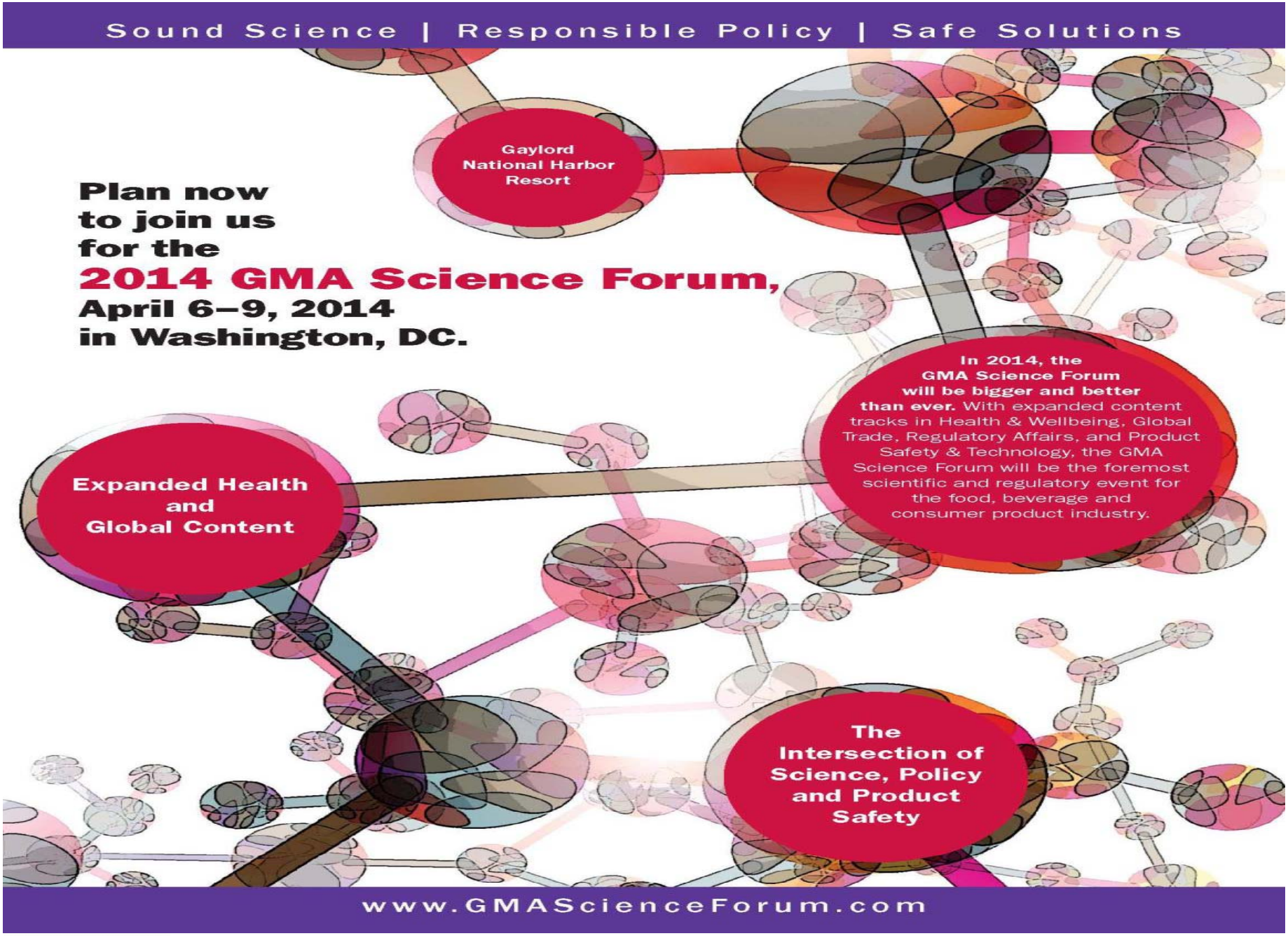
- Focus on the following:
  - **Training FDA inspectors**
  - **Reconsideration of general inspectional approach**
  - **Consistency of implementation**
  - **Effective and transparent appeals process**
  - **Consistency among state and federal inspectors**

- Collaboration on development of guidance will be essential

FSMA Final Rule Dates*

- Preventive Controls for Human Food **Aug. 30, 2015**
- Preventive Controls for Animal Food **Aug. 30, 2015**
- Foreign Supplier Verification Program **Oct. 31, 2015**
- Produce Safety Standards : **Oct. 31, 2015**
- Accreditation of Third Party Auditors **Oct. 31, 2015**
- Sanitary Transport of Food and Feed **March 31, 2016**
- Intentional Contamination : **May 31, 2016**

* Current dates given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