FSMA’s Foreign Supplier Verification Program and its Implications for Importers of Food Contact Materials into the U.S.

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Became law in January 2011

Improving safety and security of U.S. food supply through prevention rather than response

“Importer accountability” is a key component

Pressure on FDA to get regulations in place

Pressure on Congress to properly fund
Highlights

- Biennial Facility Re-Registration (on even years)
- Hazard Analysis and Risk-Based Preventive Controls (human + animal)
- Foreign Supplier Verification Program
  - Voluntary Qualified Importer Program
  - 3rd Party Accreditation
- Produce Safety Rule
- Sanitary Transportation
- Intentional Adulteration
- Mandatory Recall
- Inspection Mandate
# FSMA Implementation

<table>
<thead>
<tr>
<th>FSMA Component</th>
<th>Current Status</th>
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<tr>
<td>Biennial Re-Registration</td>
<td>Next registration period begins October 2016</td>
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<tr>
<td>HARPC – Human Food and Animal Food</td>
<td>Final rules published September 17, 2015, effective Nov. 16, 2015</td>
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<tr>
<td>FSVP, 3rd Party Accreditation, Produce Safety</td>
<td>Final rules published November 27, 2015, effective January 26, 2016</td>
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<td>VQIP</td>
<td>Draft guidance published June 2015</td>
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<td>Sanitary Transportation</td>
<td>Final rule expected March 31, 2016</td>
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<tr>
<td>Mandatory Recall</td>
<td>Already effective</td>
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<tr>
<td>Intentional Adulteration</td>
<td>Final rule expected May 31, 2016</td>
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FSVP

- Requires importers to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards
- Applies to “food”

FOOD
§ 201(f) of the FFDCA

Articles used for food or drink for man or other animals

Chewing gum

Articles used for components of any such article
Applicability to “Food”

§ 201(s) “Food additive”
Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (unless GRAS or Prior Sanctioned)
Categories of Food Additive

1) Direct Additives – Food Ingredients

2) Secondary Direct Additives
   - Technical effect during processing, not in finished food
   - Reasonably expected to migrate to food?
   - Boiler water additives, ion exchange resins, some antimicrobials (kill surface microorganisms on food, but have no continuing effect on food)

3) Indirect Additives – Food Packaging and Other Food-Contact Materials
Importer Considerations

FSVP
- Imposes burden on importers to “self-police” the supply chain
- Evaluate food and supplier risk through hazard analysis
- Conduct verification activities

VQIP
- Expedited import procedures for trusted importers

Sanitary Transportation
- Applies to shippers, receivers, carriers who transport food in the U.S. by motor or rail vehicle; shippers by sea or air are covered if involved with the transfer of the food to a motor or rail vehicle
- Requirements for equipment, operations, training, and recordkeeping
Who?

- **Importers**
  - The U.S. owner or consignee
  - If none, U.S. agent or representative of the foreign owner or consignee

- **Exemptions**
  - For certain foods already subject to other regulatory programs
  - Food for consumption, transshipment, import for export, returned U.S. food
  - “Very small importer” – Averaging <$1 million in sales over the prior 3 years (including value of unsold food)
What’s an FSVP?

- Develop (written), maintain, and follow an FSVP for …
  - Each imported food
    - Hazard analysis
    - Risk posed by each hazard and need for controls
  - Each foreign supplier of that food
    - Evaluate supplier’s performance
      - Procedures, processes and practices
      - Food safety history
      - Compliance with FDA regulations (i.e., import alerts, recalls, etc.)
    - Determine and conduct appropriate supplier verification activities
      - Use only approved suppliers
      - On-going verification of compliance (audits, testing, records review)
- Take corrective actions when supplier is out of compliance
HARPC Final Rule

- Written food safety plan
  - Hazard analysis
  - Preventive controls
  - Oversight and management of preventive controls

- Supply chain program
  - Designed to cover similar ground as the FSVP
  - Importers that are manufacturers/processors automatically comply with most FSVP requirements with a compliant supply-chain program

- Does not apply to food contact substances
HARPC Food Safety Plan

- Importer may rely upon another entity to conduct the HA, but must review and assess
- Importer must evaluate the entity minimizing or preventing controls
- Importer must review supplier’s procedures, processes and practices related to food safety
- Importer may rely on another entity (not supplier) to do risk evaluation, but must review and assess
When Does My FSVP Have to Be In Place?

- The later of…
  - 18 months after publication of the final rule
  - If supplier is subject to the HARPC rules, six months after the supplier must be in compliance with HARPC
  - If importer is a manufacturer or processor subject to the HARPC supply-chain program, FSVP compliance date is the same as the HARPC compliance date
Final Thoughts

- A food safety plan can conclude there are no hazards that need preventive controls
- Can use existing documentation and procedures as part of the plan
- Merely a recordkeeping issue for food contact materials?
- Will FDA recognize foreign systems (e.g. EU) as equivalent?
- Is VQIP worth it?