FDA Food Safety Modernization Act

Five Years to Safer Imports

Carbonine Smith DeWaal
Center for Science in the Public Interest
July 20, 2011
- The Center for Science in the Public Interest (CSPI) is a bi-national NGO representing over 850,000 consumers in both the U.S. and Canada.

- Safe Food International (SFI), a CSPI project, partners with consumer organizations in other regions of the world on food safety issues.

- The International Association of Consumer Food Organizations provides representation in Codex for consumer organizations on five continents.
FDA Food Safety Modernization Act

- Foreign facilities:
  - Register biennially
  - May be suspended
  - Prevention programs
- Inspection mandate
- Foreign offices
- Foreign Supplier Verification Program
- Voluntary Qualified Importer Program
- Capacity building programs
- Certification of high-risk foods

President Obama signs FSMA Jan. 4, 2011
Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Registration</th>
<th>Inspections</th>
<th>Foreign Offices</th>
<th>Prevention</th>
<th>FSVP</th>
<th>VQIP</th>
<th>Capacity Bldg</th>
<th>Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td></td>
<td></td>
<td>600</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td></td>
<td></td>
<td>1,200</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td></td>
<td></td>
<td></td>
<td>2,400</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4,800</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Registration: 1st Re-registration, 2nd Re-registration
Inspections: Small, Very Small
Foreign Offices
Prevention
FSVP
VQIP
Capacity Bldg
Certification: Authority, Accreditation, 3rd Party Auditors
Year 1: Registration (and Suspension)

21 Countries with 3,000 or more Registered Facilities

- 20,000-29,999
- 10,000-19,999
- 5,000-9,999
- 3,000-4,999

166,000

191,000 of 252,000 Foreign Facilities (70 percent) are located in these 21 countries.
Year 1: Foreign Facility Inspection

New mandate to inspect foreign facilities

- Double foreign facility inspections every year for five years
- Can refuse products from facilities that refuse inspection
- Interagency agreements on inspection of seafood
Year 1: Border Inspection

- Changes to border inspections
  - Interagency agreements on inspection of seafood
  - Risk-based border inspection
18 Months: Prevention

- Foreign and domestic facilities must implement a food safety plan that includes:
  - Hazard analysis
  - Preventive controls
    - Sanitation
    - Food allergen control
    - GMPs
    - Environmental monitoring
  - Employee training
  - Supplier Verification
  - Recall plan
  - Monitoring and records
  - Verification steps
  - Corrective action plan
  - Records of corrective actions
  - Recall plan
Year 2: Foreign Supplier Verification Program

- Importers must implement FSVP that includes:
  - Assurance that foreign supplier has risk-based preventive controls.
  - Verification steps such as --
    - Monitoring records for shipments,
    - Lot-by-lot certification,
    - Annual on-sight inspection,
    - Checking foreign supplier’s HACCP plan, or
    - Verification testing.
  - Records that must be accessible for inspection.
FSVP Introduces “Look-Back” to Enhance Import Safety

- Importer is accountable for product’s safety.
- FSVP required regardless of risk.
Importers may obtain expedited review
- Application (notice of intent to participate in VQIP)
- Certified facility is source for food
- FDA reviews application for risk factors
VQIP Lets Importers Jump to Head of Line

- Contribution to safety
  - Assesses safety before product reaches border.
  - Reduces number of import lines needing review, improving risk-based targeting of border inspections.

CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Foreign Governments can be “trusted partners” for ensuring import safety

- Mutual recognition of foreign inspection reports,
- Training of foreign governments and producers,
- Acceptance of lab methods/testing.
Certification assures
- High-risk imported food meets U.S. requirements
- Food is eligible for VQIP.

Certification may be from government or qualified 3rd party auditor.

3rd party auditors -- accredited by recognized accrediting bodies – may be:
- Foreign governments,
- Foreign cooperatives, or
- Private parties
FDA may require certifications of high-risk foods if there are:

- Known safety risks associated with the food
- Known safety risks associated with the place food originates from
- A finding by Secretary that foreign food safety system is inadequate
- A finding by Secretary that certification would assist border inspections
Certification: Final Check for High-Risk Food

1. Secretary designates food or region as high-risk and requires certification.

2. Foreign government or accredited 3rd party audits facility for compliance with U.S. requirements.

3A. Importer’s FSVP includes check for certification.

3B. Certification is communicated to FDA with shipment or by other specified method.

Based on findings, auditor issues certification.
Voluntary Qualified Importer Program
Thank you!

Caroline Smith DeWaal  
Food Safety Director  
Center for Science in the Public Interest  
1220 L Street, NW, Suite 300  
Washington, DC 20005

Phone: (202) 777-8366  Fax: (202) 265-4954  
E-mail: cdewaal@cspinet.org  
On the internet: www.cspinet.org  and  
www.safefoodinternational.org