FDA Food Safety Modernization Act

Export Certificates and Other Assurances of Food Safety

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Agenda

• Why are assurances important?
• What kinds of assurances do we have at our disposal?
• How do these different kinds of assurances work together?
Foodborne Illness Burden

• Foodborne illness is a significant burden in the United States
  – About 48 million (1 in 6 Americans) get sick each year
  – 128,000 are hospitalized
  – 3,000 die

• Immune-compromised individuals more susceptible
  – Infants and children, pregnant women, older individuals, those on chemotherapy

• Foodborne illness is not just a stomach ache—it can cause life-long chronic disease
  – Arthritis, kidney failure
Changes in the Food Supply

- **Globalization**
  - 15 percent of U.S. food supply is imported
    - 60 percent of fresh fruits and vegetables and 80 percent of seafood
- **Food supply more high-tech and complex**
  - More foods in the marketplace
  - New hazards in foods not previously seen
- **Shifting demographics**
  - Growing population in US (about 30%) of individuals are especially "at risk" for foodborne illness
US Response: FSMA

- Creation of a new food safety framework
  - Broad prevention mandate and accountability
  - New system of import oversight
  - Emphasizes partnerships and collaboration
  - Emphasizes farm-to-table responsibility
Four Cornerstones of the FMSA Framework

- Prevention
- Enhanced Partnerships
- Inspections, Compliance, and Response
- Import Safety
Prevention: The First Cornerstone of FSMA

- Comprehensive preventive controls for food facilities
  - Congress has given FDA explicit authority to use the tool more broadly
  - Strengthens industry accountability for prevention
- Produce safety standards
Inspection, Compliance, and Response: The Second Cornerstone of FSMA

- Mandated inspection frequency
  - Considering new ways to inspect
- New tools
  - Biennial registration
  - Suspension of registration
  - Mandatory recall
  - Expanded records access
  - Expanded administrative detention
  - Enhanced product tracing
  - Third party laboratory testing
Import Safety: The Third Cornerstone of FSMA

- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- FDA and food firms can rely on third parties to certify that foreign food facilities meet U.S. requirements
- Mandatory certification for high-risk foods
- Voluntary qualified importer program—expedited review
Enhanced Partnerships: The Fourth Cornerstone of FSMA

- Reliance on inspections by other US agencies
- State and local capacity building
- Improve foodborne illness surveillance
- Consortium of laboratory networks
- Capacity building
- Accreditation of Third Party Recognition Bodies (Imports)
- Comparability
Starting Point for Assurances: Food Safety Standards

- FSMA's Emphasis is on prevention
- New requirements for:
  - Mandatory preventive controls for facilities
  - Produce safety standards
Assurances: Government Inspections

- Inspection is an important means of holding industry accountable for their responsibility to produce safe product.
  - Applying its inspection resources in a risk-based manner
  - Innovating in its inspection approaches to be the most efficient and effective with existing resources
Assurances: Better Information

- Information about Industry
  - Registration
- Information Sharing with regulatory partners
  - MOUs
  - Other agreements
- PREDICT
Assurances: Imports

- Importer Verification
  - New requirement for importers to perform supplier verification activities to ensure imported food is safe.

- Mandatory Certification
  - Authorizes FDA to require certification, based on risk criteria, that the imported food is in compliance with food safety requirements

- Importer Incentives
  - Provides an incentive for importers to take additional food safety measures by directing FDA to establish a voluntary program for expedited review of their shipments
Assurances: Regulatory Partnerships

• Comparability
  – Comprehensive assessment of a country’s food safety system
  – Determine where we can leverage work being done
  – Create regulatory partnerships to enhance food safety

• Capacity Building
  – Developing a proactive plan
    • Evidence based, leveraged through partnerships and designed for effectiveness
Assurances: Third Party Certification

- FSMA incorporates accredited third party certification
  - central example of FSMA’s focus on public-private collaboration
  - recognition of the role being played in supply chain management by third party audits and certifications
- FDA will recognize accrediting bodies and set standards for accreditation of third-party certification bodies and auditors.
- Will provide assurances about the safety of food moving in international trade in a more efficient way.
- Third-party audits are not a replacement for direct regulatory oversight.
Summary of Assurances

**Food Industry:**
- Implement Food safety standards
- First party verification
- Supply chain knowledge and verification (e.g. supplier/importer controls)
- Third party audits and testing by recognized bodies

**Governments:**
- Regulatory Partnerships
  - Comparability
  - Capacity Building
- Information Sharing
- Harmonization
- Inspections
- “Border” Activities
- Enforcement
Thank you!

For more information:

- [www.fda.gov/fsma](http://www.fda.gov/fsma)
- [www.foodsafety.gov](http://www.foodsafety.gov)