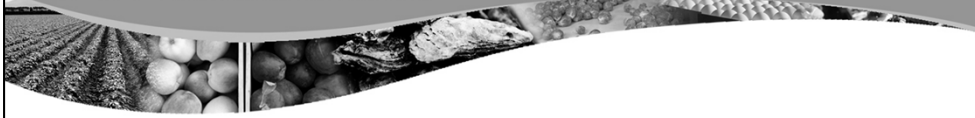




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Protecting and Promoting Public Health

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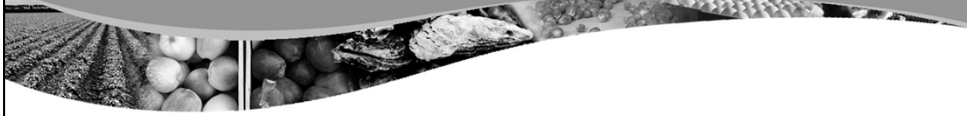


FDA Food Safety Modernization Act

Export Certificates and Other Assurances of Food Safety

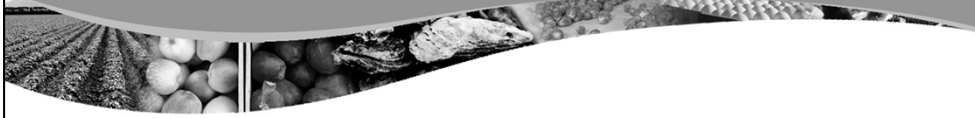
25 April 2012

Leslie Kux
Assistant Commissioner for Policy
U.S. Food and Drug Administration



Agenda

- Why are assurances important?
- What kinds of assurances do we have at our disposal?
- How do these different kinds of assurances work together?

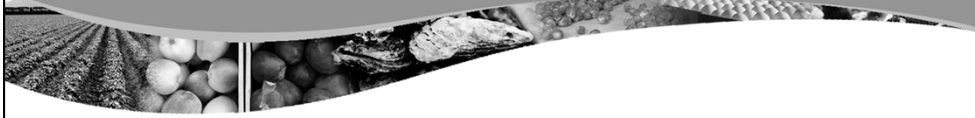


Foodborne Illness Burden

- 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

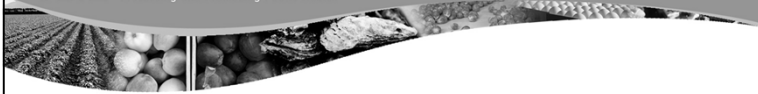
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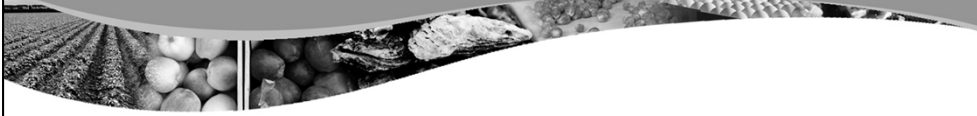
Changes in the Food Supply

- 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





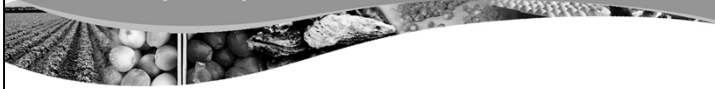
Prevention: The First Cornerstone of FSMA

- 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



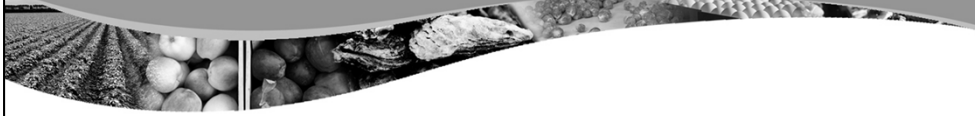
Import Safety: The Third Cornerstone of FSMA

- 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



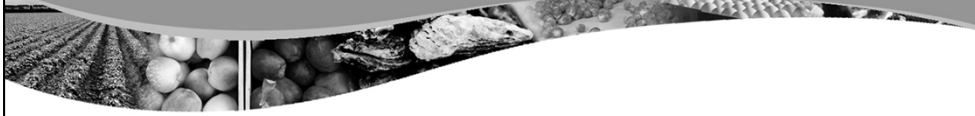
Enhanced Partnerships: The Fourth Cornerstone of FSMA

- 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



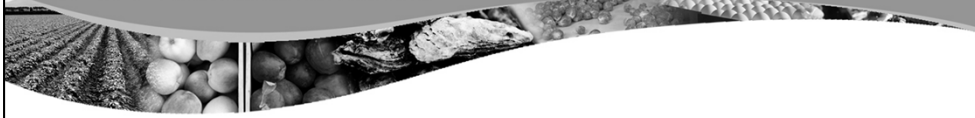
Starting Point for Assurances: Food Safety Standards

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



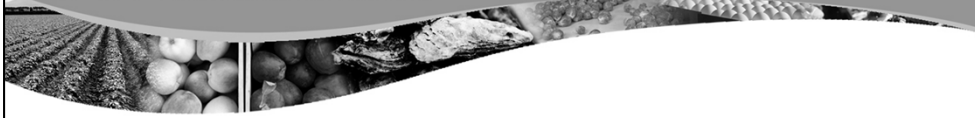
Assurances: Government Inspections

- 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



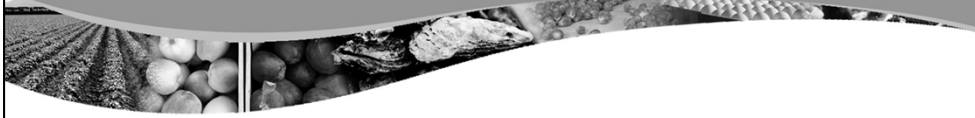
Assurances: Better Information

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



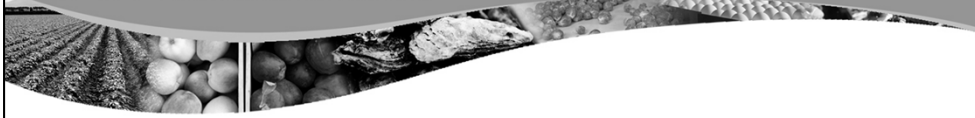
Assurances: Imports

- **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



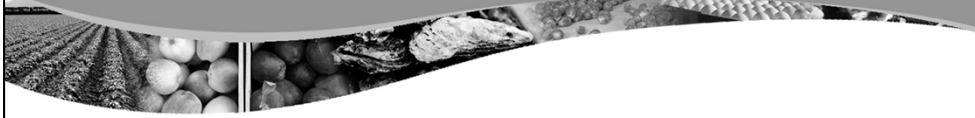
Assurances: Regulatory Partnerships

- **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
- www.foodsafety.gov