

2011 World Seafood Congress



FDA: Food Safety

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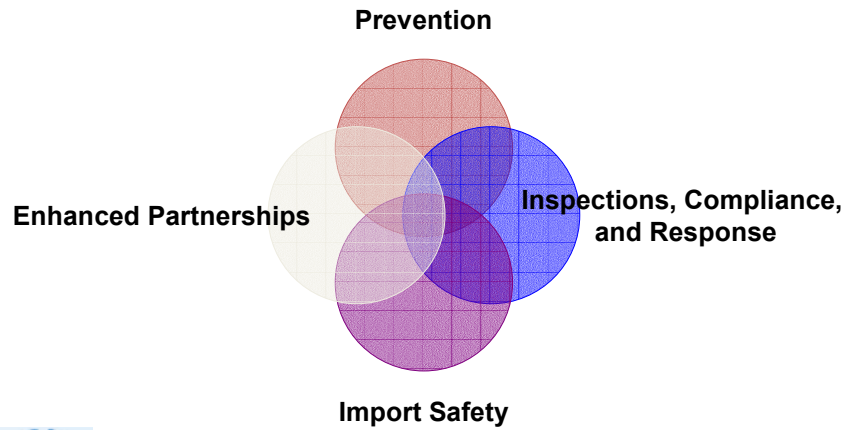
Food Safety Modernization Act

- **Signed January 4, 2011**
 - Most significant update to FDA food authorities since 1938
- **New, prevention-oriented system**
 - Broad prevention mandate and accountability;
 - New system of import oversight
 - Built on partnerships



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FSMA Themes



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Prevention

- **New preventive controls provision**
 - Seafood HACCP firms expressly exempted
- **Produce safety standards**
- **Intentional adulteration**
- **Sanitary transportation**
- **Performance standards**



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Inspections, Compliance, Response

- **Mandated inspection frequency**
 - Domestic: frequency based on risk
 - Foreign: 600/yr doubling each yr/5 yrs (19K)
- **New tools**
 - Mandatory recall, traceability pilots
 - Expanded records access, detention authority
 - Suspension of registration
 - Accredited laboratory testing



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Imports

- **Foreign supplier verification**
 - Importer must verify supplier preventive controls
- **Third-party certification**
 - FDA-Recognized accreditation bodies
 - Accredited “auditors” (certification bodies)
 - Food safety audits of eligible foreign firms
 - Certifications of food, facilities



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Imports

- **Voluntary qualified importer program**
 - In addition to mandatory FSVP requirements
 - Participants must have foreign facility certification
 - Expedited review and entry
- **Mandatory certification**
 - Risk-related determination: food, area of origin
 - Certification required for certain imported food



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Imports

- **Capacity building**
 - Plan required
 - Seeking to leverage efforts
- **Comparability**
 - Public hearing in March 2011
 - Assesses comparability of foreign food regulatory systems



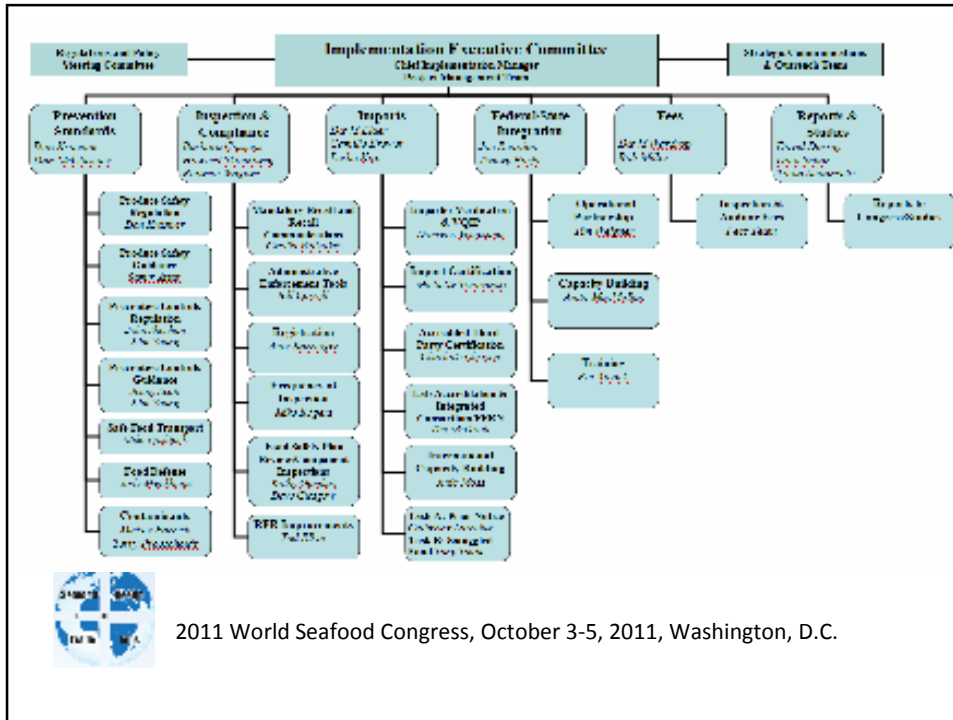
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Partnerships

- Reliance on other regulators' inspections
- State/local/foreign capacity building
- Improved food borne illness surveillance
- Consortium of laboratory networks
- National ag and food defense strategy



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FSMA: Challenges and Opportunities

- 50 rules/guidance/reports in 3 years
- Tight statutory deadlines
- Stakeholder input, transparency are key
- Changes will take long-term effort
- Resources



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For more information



- www.fda.gov
 - FSMA link on home page
 - Subscribe to FSMA updates by email
- www.foodsafety.gov



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