U.S. Food Safety Capacity Building: APEC and FSMA Plan

Julie Moss, PhD, RD

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APEC Food Safety Initiatives

• APEC Food Safety Cooperation Forum (FSCF)
  – Food safety regulators
  – Build food safety regulatory systems consistent with internationally recognized food standards
  – Exchange technical information to identify and address food safety capacity needs

• Partnership Training Institute Network (PTIN)
  – Public-private partnership of industry, academia, and government
  – Resources and expertise to address food safety capacity building priorities in the APEC region
PTIN Strategic Goals

To facilitate trade and improve public health by

– Better assuring the safety of the food supply chain in the APEC region

– Building capacity in the use of international standards and best practices in food safety
PTIN In Practice

• Creates a network of food safety experts from industry, academia, and government

• Builds on existing food safety training in the region and globally

• Standing curricula and reproducible training modules address key food safety challenges

• Outcomes, further work, and consensus building carry over to international fora such as Codex & WTO
Priority Capacity Building Areas

• Supply Chain Management
• Incident Management
• Risk Management
• Laboratory Competency
• Food Safety Regulatory Systems
Progress: Capacity Building

- 6 PTIN workshops held
  - Expert Working Group
  - Risk Analysis
  - Export Certificates
  - Supply Chain Management
  - Incident Management
  - Laboratory Capacity Building

- Next
  - Export Certificate, Lab Capacity

- 2 PTIN training modules in development
- Review of existing training resources in APEC region
Future: Bringing Regional Food Safety Capacity Building Efforts Global
A Global Model

• After the signing of an MOU between the World Bank and APEC Food Safety Cooperation Forum in May 2011, work began on developing a Global Food Safety Partnership

• Eventually, the public-private partnership model will address food safety capacity building needs on a sustainable basis worldwide
The Global Food Safety Partnership would:

• Establish **Public-Private Partnership** for capacity building including **new food safety multi-donor trust fund (MDTF)**.

• Address critical **capacity building** gaps in food safety through open source “Food Safety Academy”

• Deliver 5-year **work program** of demand-driven food safety projects and advisory services. An initial pilot series of training programs are being developed in partnership with APEC.
Progress to Date

• USAID, Mars, and Waters have made initial donations of $1 million

• Announcement of creation of Global Food Safety Partnership at APEC Leader’s Meeting in Honolulu, Hawaii November 2011

• Outreach to additional donors and participants is continuing

• Currently developing a three and five year plan
Upcoming Activities

• Pilot training on first supply chain training modules scheduled for June in Beijing

• Series of 3 regional Lab Capacity Building workshops focused on analytical methods/fit for purpose scheduled for June-August 2012 in Peru, Malaysia, and Vietnam

• Plans to develop e-learning platform with new and existing material underway
For more information please visit:

www.fscf-ptin.apec.org

Questions?

Transition to 2\textsuperscript{nd} topic:
FSMA Capacity Building Plan
Food Safety Modernization Act (FSMA)

• January 2011
• Main Elements
  • Title I – Improving Prevention Capacity
  • Title II – Improving Detection and Response Capacity
  • Title III – Improving Imported Food Safety
  • Title IV – Miscellaneous Provisions including Jurisdictions and WTO Compliance
Title III – Improving Imported Food Safety

• Groundbreaking shift…
  – Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place (i.e., Foreign Supplier Verification Program)
  – FDA can rely on third parties to certify that foreign food facilities meet U.S. requirements
  – Can require mandatory certification for high-risk foods
  – Voluntary qualified importer program—expedited review
  – Can deny entry if FDA access for inspection is denied
  – Requires food from abroad to be as safe as domestic
  – Develop a capacity building plan

• Comparability
FSMA: Section 305

• Charge: FDA shall develop a comprehensive plan to expand the technical, scientific and regulatory food safety capacity of foreign governments and their respective food industries that export foods to US

• Due: within 2 years, 1/04/13

• In developing the plan, FDA shall consult with:
  – USDA, DOS, DOT, DOC, DHS, USTR
  – Food industry representatives
  – Foreign government officials
  – Non-governmental organizations representing consumers,
  – Other stakeholders

• Supports Sec 308: Foreign Office of the FDA
The plan shall include, *as appropriate*:

1. Recommendations for agreements, including exporter responsibility
2. Provisions for secure electronic data sharing
3. Provisions for *mutual recognition* of inspection reports
4. Training of U.S. requirements
5. Recommendations on whether/how to harmonize requirements with Codex
6. Provisions for *mutilateral acceptance* of lab methods and testing/detection techniques
1. Recommendations for agreements, including ensuring exporter responsibility

- Non-binding, driven by need
- Enable confidential information sharing
- Support CB with other countries

Question: What do you envision for cooperation and information sharing?
2. Provisions for secure electronic data sharing

- Follow existing FDA policy
- Utilize FDA wide IT mechanisms under consideration in FSMA implementation
- Inspection reports, outbreak data, etc.

Question: what are your considerations or limitations for IT use? What kinds of information would you like to share?
3. Provisions for *mutual recognition* of inspection reports

- Via comparability and third party accreditation
- Consider models from other FDA regulated product areas

**Question:** Are there models in other countries?
4. Training of U.S. requirements

• Focus on web based training, more translation of materials, use post presence and regional bodies/harmonization bodies
• Prioritize based on risk and self assessment

Questions: How best to engage developing countries? What are effective modalities? What are potential obstacles?
5. Recommendations on whether and how to harmonize requirements with Codex

- Support science based standard setting within the Codex process
- Support Codex Trust Fund principles
- Support draft strategic plan on capacity building

Question: What are your thoughts on Codex engagement (e.g., mentoring) and how U.S. Codex with FDA participation can help other countries?
6. Provisions for *multilateral acceptance* of lab methods and testing and detection techniques

- Focus on performance characteristics of the method based on the intended purpose
- Validate for the intended purpose

Question: What do you envision or need?
Other considerations…
CB historically reactive, shift to proactive approach

• Measuring and evaluating the impact of capacity building programs to public health outcomes (see next slides)

• Partnerships

• Identification of country needs through self assessment
  • Not what FDA thinks is an issue, show country rigor and ownership, direct CB priorities
Protect Public from Unsafe Imported Foods*

- Entry of Unsafe Food Reduced
  - Improved Targeting of Import Entries for Inspection
  - More Effective and Efficient Post-Detection Follow-Up
- More Effective Detection of Adulterated & Contaminated Food (including smuggled food products)
- Increased Public Awareness of Unsafe Foods in Market
- Better Able to Locate Unsafe Food
- More Effective & Efficient Post-Identification Follow-Up

Result 1: Increased Use of Best Practices by Industry in Priority Countries and Commodities
  - R 1.1: Increased Knowledge of Improved Practices
  - R 1.2: Increased Acceptance by Host Country Industry of their Role in Food Safety
  - R 1.3: Expanded Market Incentives to Use Best Practices

Result 2: More Effective FDA Compliance Actions
  - R 2.1: Better Targeting of High Risk Situations
  - R 2.2: Increased Understanding of Host Country's Food System
  - R 2.3: Increased Skills & Knowledge of FDA Food Inspectors/Investigators

Result 3: More Effective Host Country Compliance Actions
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More Effective and Efficient Post-Detection Follow-Up
- Improved Coordinating and Information Sharing with External Partners
- Improved Coordinating and Information Sharing Between FDA Offices

Foundational Results
- Expanded Coordination and Information Sharing with External Partners
- Improved Coordinating and Information Sharing Between FDA Offices
- Expanded Development of New/Rapid Detection Tools
- Improved Knowledge and Skills of Food Inspectors/Investigators

Increased Public Awareness of Unsafe Foods in Market
- Increased Use of Improved Detection Methods
- Increased Capacity of Testing Labs
- Increased Information Sharing with Foreign Partner Agencies

Additional Domestic Tracking and Recall Actions

FDA Capacity Building Activities (e.g. Training, Int'l Visitors Program, Harmonization)
- Effective Leveraging of Bi-lateral and Multi-lateral Orgs (e.g. IICA, APEC, Bi-lateral agreements)

*Imported foods refers to those regulated by FDA
Better Prevention of Food Safety Problems in the Foreign Supply Chain

Result 1: Increased Use of Best Practices by Industry in Priority Countries and Commodities

R 1.1: Increased Knowledge of Improved Practices
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R 1.3: Expanded Market Incentives to Use Best Practices

Result 2: Increased Use of Practices in Compliance with Regulated Standards by Industry in Priority Countries and Commodities

Result 3: Better Execution of Compliance Activities by FDA

R 3.1: Better Targeting of High Risk Situations
R 3.2: Increased Skills & Knowledge of FDA Food Inspectors/Investigators
R 3.3 Increased Understanding of Host Country's Food System
R 3.4 Improved Tools and Procedures for Effective Compliance

Result 4: Better Execution of Compliance Activities by Host Country and Non-FDA Actors

R 4.1: Better Targeting of High Risk Situations
R 4.2: Increased Skills & Knowledge of Host Country Food Inspectors/Investigators

Effective Leveraging of Bilateral and Multilateral Orgs (e.g., IICA, APEC, Bilateral agreements)

Foundational Results

More Effective Cooperation & Information Sharing with Host Country Regulatory and Enforcement Agencies

Improved Policy and Regulatory Framework for Food Safety in Host Country

Improved Capability of Host Country Food Safety Regulatory Organizations & Industry Groups

Increased Understanding of Problems & Risks in Global Supply Chain

Affected Stakeholders
Private Industry
Host Country Govt
FDA

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## Illustrative Metrics

### Result 1: Increased Use of Best Practices by Industry in Priority Countries and Commodities

#### R 1.1: Increased Knowledge of Improved Practices

<table>
<thead>
<tr>
<th>Illustrative Performance Indicator</th>
<th>Definition/Unit of Measure</th>
<th>Data Source/Collection Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of industry groups that provide information and training to their members about food safety and preventive control practices.</td>
<td>Percentage of industry groups</td>
<td>TBD in pilots</td>
</tr>
<tr>
<td>Number/percentage of trade associations’ members aware of good practices for improved food safety</td>
<td>Number or Percentage of trade associate members</td>
<td>TBD in pilots</td>
</tr>
<tr>
<td>Hit rates/downloads of information related to food safety on the websites of industry groups</td>
<td>Number of hits and downloads</td>
<td>TBD in pilots</td>
</tr>
</tbody>
</table>
Pilot

• Each framework is a 5-year plan

• Opportunity to practice

• Two countries on produce and seafood within the next year

• Success
Thank you

Welcome all input/comments on the plan:
--experiences/lessons learned?
--data?
--suggestions?

Email: Julie.Moss@fda.hhs.gov
(future docket when public meeting announced)