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

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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<sup>nd</sup> 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 sharp
- 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 *multilateral acceptance* of 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?

## 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

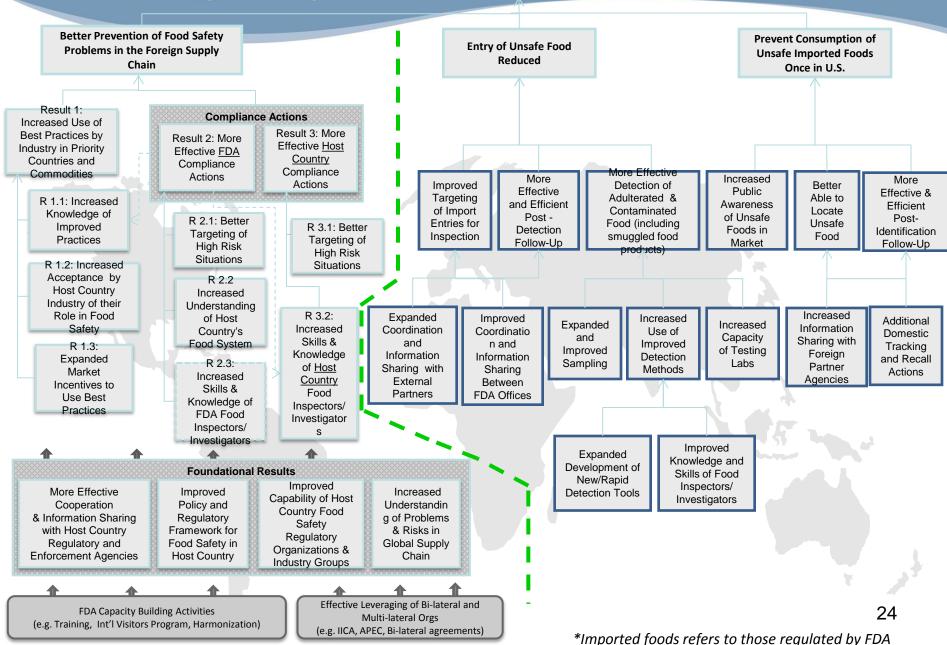
Question: What do you envision or need?

#### 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





## Affected Stakeholders Private Industry Host Country Govt

**FDA** 

Food and Deting and Pro

Better Prevention of Food Safety Problems in the Foreign Supply Chain

#### Imports Prevention Results Framework

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

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

R 1.1: Increased Knowledge of Improved Practices

Result 3: Better Execution of Compliance Activities by FDA

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Result 4: Better Execution of Compliance Activities by

Host Country and NonFDA Actors

R 1.2: Increased Acceptance by Host Country Industry of Their Role in Food Safety

R 3.1: Better Targeting of High Risk Situations

R 4.1: Better Targeting of High Risk Situations

R 1.3: Expanded Market Incentives to Use Best Practices 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

R 4.2: Increased Skills
& Knowledge of Host
Country Food
Inspectors/
Investigators

#### **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

**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)

# **Illustrative Metrics**

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

R 1.1: Increased Knowledge of Improved Practices

R 1.1 Increased Knowledge of Improved Practices		
Illustrative Performance Indicator	Definition/Unit of Measure	Data Source/Collection Method
Percentage of industry groups that provide Information and training to their members about food safety and preventive control practices.	Percentage of industry groups	TBD in pilots
Number/percentage of trade associations' members aware of good practices for improved food safety	Number or Percentage of trade associate members	TBD in pilots
Hit rates/downloads of information related to food safety on the websites of industry groups	Number of hits and downloads	TBD in pilots

### **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)