Southeast Region Food Safety Seminar
FDA Update

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- **Southeast Regional Office**
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- Laurie Farmer, Director, State Cooperative Programs
FDA Food Facts

- Products under Jurisdiction: Seafood, Dairy, Fruits, Vegetables, Juices, Beverages
- 80% of Nation’s Food Supply
- 150,000 Registered Domestic Food Processing Facilities
- 230,000 Registered Foreign Facilities
- One Million Restaurants/Other Retail Food Establishments
- Two Million Farms
- Workplan Targets, Performance Goals
- Shared Responsibility with State and Local Agencies in conducting food plant inspections/investigations/retail
FDA Facts

- FDA is responsible for overseeing the safety and quality of imported foods, drugs, devices, biologics, cosmetics and radiation emitting devices.

- FDA faces enormous challenges from globalization because of the dramatic increase in the volume of imported FDA-regulated products and the increasing complexity of the global supply chain.
Globalization of Production

- FDA-regulated products now account for approximately 10% of all imports to the U.S.

- Over the last 7 years importation of FDA regulated products has dramatically risen:
  - Food products have grown by an average of 10% per year
  - Pharmaceutical products have increased at nearly 13% per year
  - Medical Devices have grown at over 20% per year

- Projected import growth rates range from low estimates of 5-8% to high of 15%, meaning that imports of FDA-regulated products would triple between 2007 and 2015.

- Products entering the U.S. come from new and different markets, flow through long, multi-step processes to convert globally sourced materials into finished products.
Changing Nature of Risk in Global Supply Chains

Products often traverse complex global supply chains to reach U.S. consumers.
Supply chain for canned tuna

FSMA & Nationally Integrated Food Safety System

- Building an integrated national food safety system has been a foundational element of FDA’s strategy for carrying out an effective & efficient food safety program; one of key mandates of FSMA

- System is premised on building full strategic & operational partnerships with state & local food safety agencies – FDA has engaged in this effort for last decade through the Partnership for Food Protection & other initiatives

- Now more important than ever as a result of external drivers, including:
  - FSMA mandates to work in full partnership with the states
  - Calls by state/local officials to strengthen partnerships, establish more seamless operations, create an atmosphere of mutual reliance & respect
  - Budget-driven - make most efficient possible use of all available food safety resources
National Integrated Food Safety System

Integration Task Force

- Commissioner has charged: high-level Integration Task Force to oversee the development & implementation of new strategies & action plans to achieve full partnership with state/local agencies

- Co-chaired by Joe Reardon, ORA & Jeff Farrar, OF
  - Members: senior officials from FDA’s ORA, CFSAN, CVM & state/local agencies involved in the Partnership for Food Protection
Nationally Integrated Food Safety System

Elevating Leadership and Management

- Organizational Changes
  - ORA has initiated process of creating an Office of Partnerships & moving DFSR to that new office to ensure that the need to work with state & local officials & other critical partners is fully recognized & addressed by ORA

- Senior Advisor for Federal-State Relations
  - ORA is creating the new position of Senior Advisor for Federal-State Relations, which will report to the ACRA; Joe Reardon, who will work with the ACRA to provide the leadership & strategic direction necessary for achieving a national integrated food safety system

- Director of Intergovernmental Affairs and Partnerships
  - OF is creating the new senior position of Director of Intergovernmental Affairs and Partnerships, reporting to the Deputy Commissioner for Foods, with a charge that includes collaborating closely with ORA leadership to enhance the federal-state partnership; Dr. Jeff Farrar will play this leadership role
Recently Posted FSMA Items

- [www.fda.gov/food/foodsafety/fsma](http://www.fda.gov/food/foodsafety/fsma)
- Preventative Controls for Registered Human and Animal Food/Feed Facilities: 11/1/2011
- Foreign Facility Reinspections, Recall, and Importer Reinspection User Fee Rates for Fiscal Year 2012: 10/1/2011
Recently Posted FSMA Items

- Burden of FSMA Fee Amounts on Small Business 10/18/2011
- Proposed Rule: Foreign Supplier Verification Program.
Cantaloupe

- September, 2011 - 7 listeria cases reported to CDC from Colorado.
- September, 2011 - after inspections, trace-back investigations, voluntary recall issued.
- Deadliest food borne outbreak in the United States in 25 years.
- 139 cases, 28 states, 29 deaths
Arsenic and Apple Juice

- Establish levels for inorganic arsenic
Strategic Priorities

The Commissioner has selected five cross-cutting areas to serve as strategic priorities over the next five years.

1) Advance Regulatory Science and Innovation
2) Strengthen the Safety and Integrity of the Global Supply Chain
3) Strengthen Compliance and Enforcement Activities to Support Public Health
4) Address the Unmet Public Health Needs of Special Populations
5) Advance Medical Countermeasures and Emergency Preparedness
Budget 2012

- House Version: significant cuts overall.
- Senate Version: slight increase in area of foods.
- President’s Version: slight increase overall.
- Decrease in Staffing: 1) natural attrition 2) limited hiring, mostly internal.
Questions?