



Local Implications of a Global Food Supply

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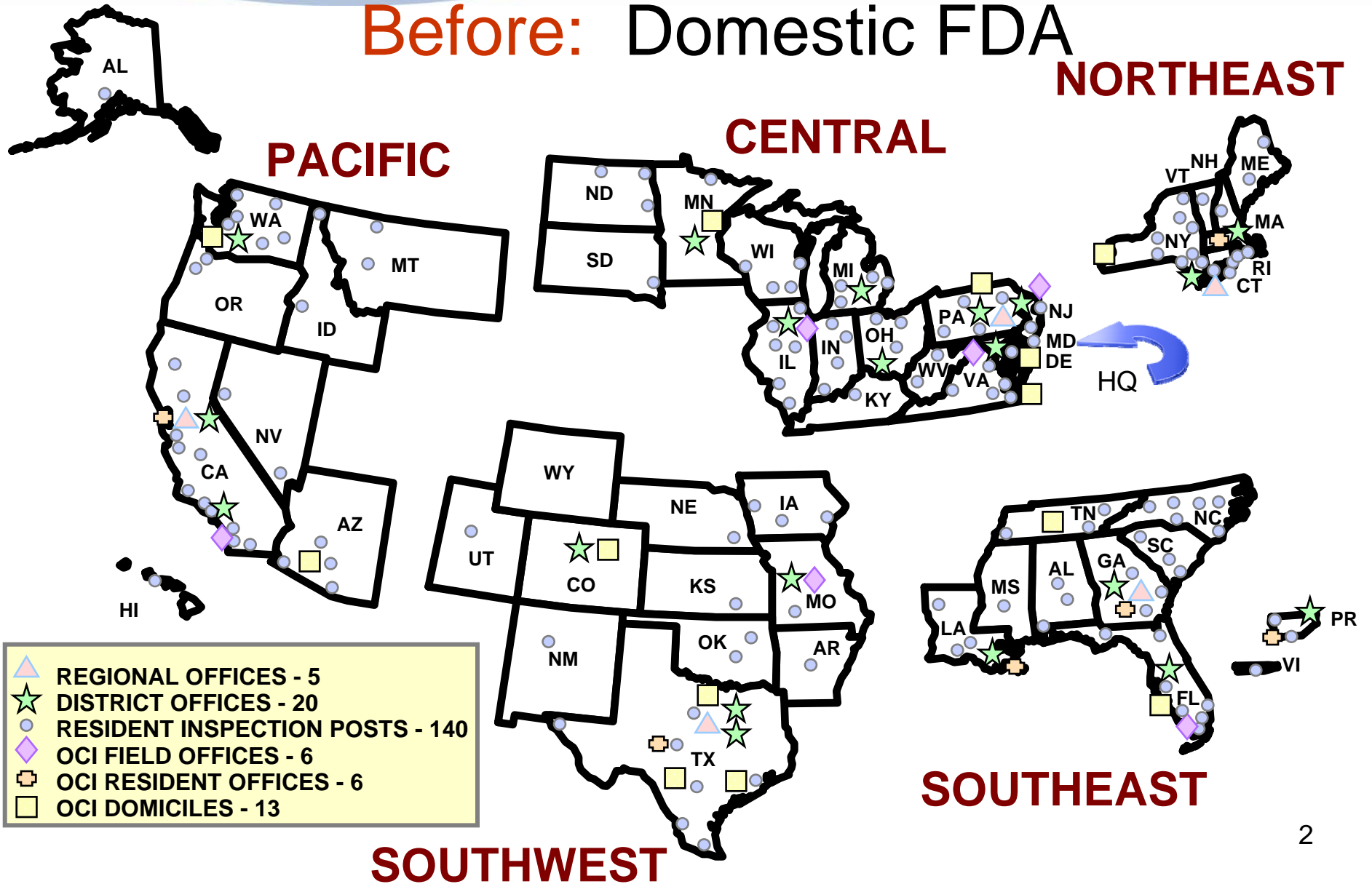
U.S. Department of Health and Human Services

Rocky Mountain Food Safety Conference

May 5, 2009



Before: Domestic FDA

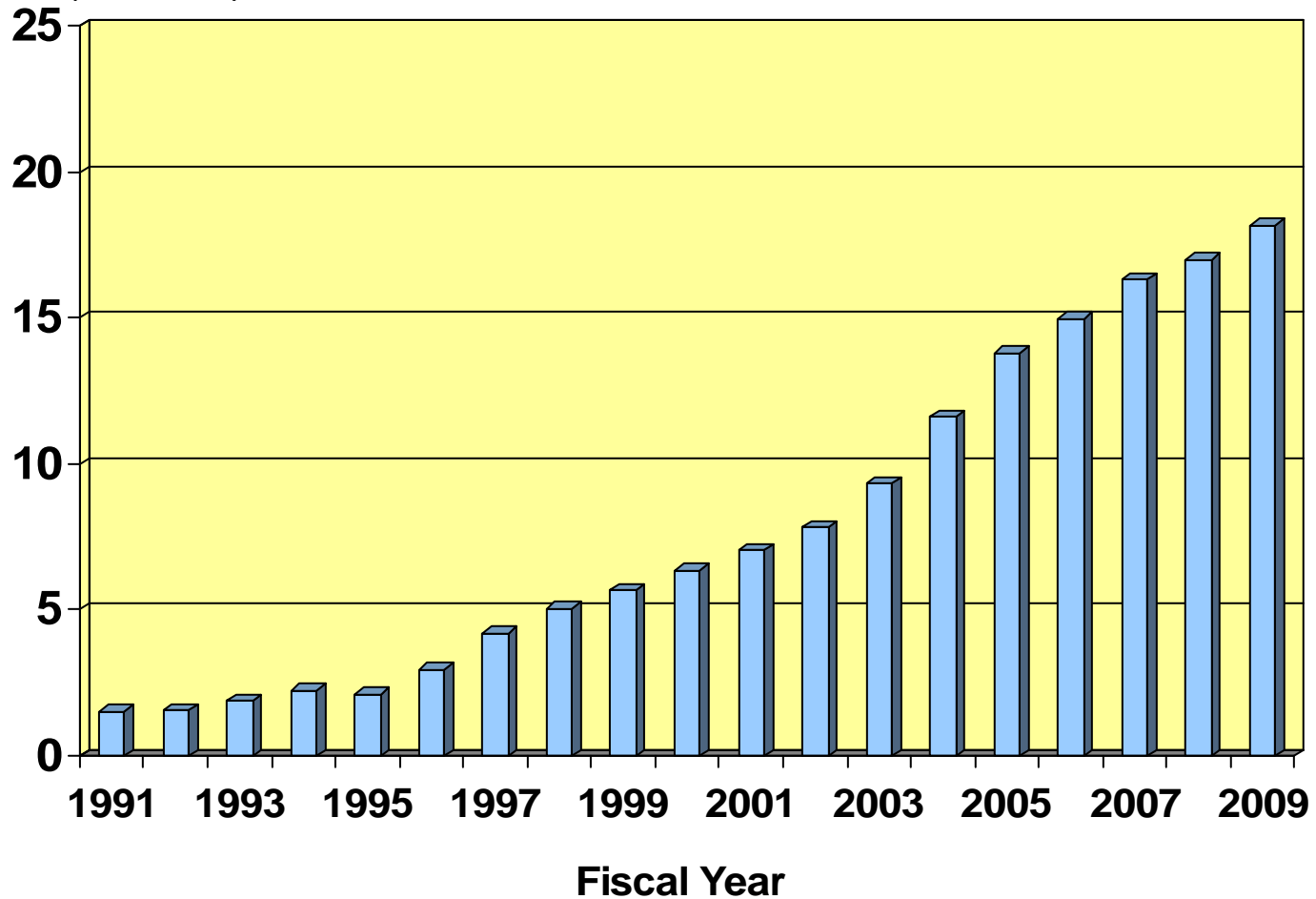




Import Volume History

18.2M Lines Estimated for FY2009

Import Lines (millions)





Challenges of Globalization

Globalization has fundamentally changed the environment for regulating food and medical products and has created unique regulatory challenges for FDA

- More foreign facilities supplying the United States
- Increasing volume of imported products
- More outsourcing of manufacturing and clinical trials
- Greater complexity in supply chains
- Growing complexity of products and manufacturing methods
- Imports coming from countries with less well-developed regulatory systems
- Greater opportunities for economic fraud



21st Century Reality

- Now our borders are **boundaries** to our jurisdiction
- Borders are **not barriers** to
 - disease
 - information flow
 - product acquisition
 - challenges of globalization
- And borders cannot be barriers to FDA's realm of activities



21st Century Reality

- Borders can no longer be the first line of defense
- We cannot “inspect out” non-compliant products at the border
- Borders must be places where we “audit” that quality and safety have been built-in at the point of manufacture

conclusion

- FDA must engage more effectively abroad to be more effective at home

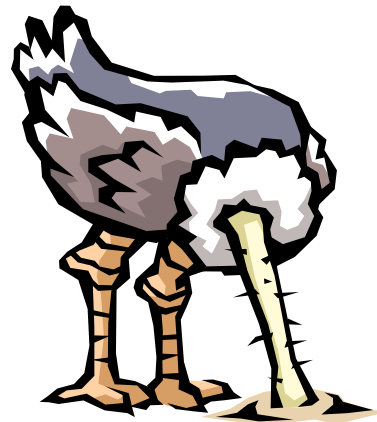


Problems for Protection

- Some products come from countries with governments that pose a security threat
- Some come from countries with less stringent regulatory oversight of food safety
- Thus this could present opportunities for contamination, counterfeiting, or economic adulteration

Problems for Protection

- Food, cosmetics, and medical products could be unintentionally or intentionally adulterated to harm the U.S. or any other country's population
- Our 20th century approach to defending against these possible threats is
 - outdated
 - ineffective
 - irresponsible
 - dangerous





FDA's Food Safety Strategy

- Develop an integrated strategy consisting of components that cover three areas
 - Prevention
 - Intervention
 - Response



International Strategy

- Establish FDA global presence
- Regulatory capacity-building
- International standards development and harmonization
- Increase timely foreign inspections
- Receive and use inspection reports from foreign competent authorities
- Third-party certification
- Enhance information technology tools



Beyond Our Borders Initiative

- Reflects growth of the global market in the past decade
- Establishes continuous FDA presence in strategic international areas based on
 - Volume and riskiness of imports
 - Opportunity for benefit of bilateral capacity building or resource leveraging activities
 - Potential for fostering relationships with FDA's counterparts



Desired Outcomes

- Engage more proactively and consistently abroad to enhance FDA's ability to build safety, quality, and security into FDA-regulated products exported to the United States
 - Increase our knowledge about product manufacturing and shipping
 - Respond to requests of foreign regulatory counterparts to help build their capacity to assure product safety
 - Provide information about our regulations and expectations to the industry exporting to the United States
 - Engage with sister agencies to better coordinate USG approaches to achieve synergy and leverage resources



Improve Product Safety Inspections

- Increasing capacity to perform more FDA overseas inspections in a more timely manner in certain locations, especially of high risk products
- Auditing third party certifiers
- Helping efficient movement of quality products
- Combating counterfeiting



Global Presence

- By the end of FY 2010, engage and post in-country 43 US nationals and 20 locally employed staff
- In 5 regions of the world
 - China, India, Europe, Latin America, Middle East
- Congress awarded \$20M supplemental in FY08 to initiate program (personnel, start-up costs, capacity building)





China

- *Purpose: improve product safety, implement MoAs, conduct certain inspections in more timely manner*
- 8 FTEs
 - Country Director, Chris Hickey
 - 4 inspectors; 3 senior tech experts in foods, medicines, and devices
- Beijing (HQ), Guangzhou, Shanghai
- Secretary opened HQ November 19, 2008



Reasons for a China Office

- October 2006: at least 46 deaths in Panama due to cough syrup from China tainted with diethylene glycol (DEG)
- March/April 2007: melamine in pet food from China kills ~4,150 pets in United States
- May/June 2007: DEG-laced toothpaste from China in Panama and Europe
- June 2007: FDA country-wide Import Alert against Chinese aquaculture
- July 2007: former head of SFDA executed for accepting bribes from pharmaceutical firms



Reasons for a China Office

- July 2007: Mattel and other toy manufacturers issue massive recall of children's toys made in China
- December 2007: HHS signs product safety agreements with SFDA, AQSIQ
- March 2008: 81 deaths, 785 other adverse events from tainted heparin from China
- September-December 2008: six infant deaths, 296,000 Chinese infants sickened from infant formula tainted with melamine from China
- November 2008: FDA imposes Import Alert against Chinese products that contain dairy



Import Alert against Imported Chinese Vegetable Protein

- Imposed May 2007
- Due to presence of melamine, from wide variety of producers
- Implicated ingredients
 - wheat, corn, soy and rice gluten
 - rice, mung bean and soy protein
 - rice protein concentrate
 - corn gluten and soy meal
 - corn by-products



Import Alert against Aquacultured Seafood Imports from China

- China is largest producer of aquacultured seafood (70% of global production, 55% of global value)
- Imposed in June 2007
- Due to widespread presence of unapproved antibiotics or chemicals (malachite green, nitrofurans, fluoroquinolones, and gentian violet)
- Implicated products
 - catfish
 - basa
 - shrimp
 - dace
 - eel



Import Alert against Dairy and Dairy-Containing Products from China

- Issued November 2008
- Due to melamine as protein substitute in supply chain for Chinese dairy products
- Implicated products
 - Wide range of products, including baked goods, snack foods, soft drinks, cereals, candies, baby foods, casein





India

- *Purpose: help develop food and medical product regulations and agencies, improve product safety, conduct certain inspections in more timely manner*
- 12 FTEs
 - Country Director, Bruce Ross
 - Acting Country Director, Beverly Corey
 - 5 inspectors, 6 sr tech experts in medicines, devices and foods
- New Delhi (HQ), Mumbai
- Secretary opened HQ January 14, 2009



India Office Portfolio

- Provide information portal and capacity building for new government agencies and industry
 - New food safety agency
 - Create medical devices inspectorate
 - Improve pharmaceutical GMPs
- Food safety import alerts on spice, rice and seafood





Europe

- *Purpose: Improve product safety by further enhancing coordination and leveraging resources of counterpart authorities*
- 3 FTEs
- Brussels (HQ), Belgium -- Regional Director, Linda Tollefson
 - Secretary opened HQ December 4, 2008
- European Medicines Agency (EMA) in London, United Kingdom (Senior Technical Expert)
- European Food Safety Agency (EFSA) in Parma, Italy (Senior Technical Expert)



Europe Office Portfolio

- Serve as an expert source of and portal to information about FDA for counterpart agencies and industry
- Coordinate FDA and US initiatives involving collaboration with EU agencies, EU members and non-members
- Learn about the European industry exporting to the United States
- Exchange scientific information and collaborate on joint science and trade programs





Latin America

- *Purpose: Improve product safety, implement new agreements*
- 8 FTEs
- San Jose, Costa Rica (HQ)
 - Regional Director, Paul Seligman
 - Secretary opened in December
 - 3 Senior Tech Experts
- Mexico
 - recruiting 2 Senior Tech Experts
- Chile
 - Senior Tech Expert
- Honduras (local staff)
- Guatemala (local staff)



Produce Associated Outbreaks Traced to Latin America

1996-2008

Mexico	14
Peru	4
Guatemala	4
Chile	2
Brazil	1
Honduras	1



Outbreaks Caused by Mexican Produce Imports

1997 Cantaloupe

1998 Parsley, Green Onions

1999 Basil

2000 Cantaloupe, Green Onions

2001 Cantaloupe

2002 Cantaloupe

2002 Tomatoes

2003 Green Onions

2008 Peppers, Tomatoes

2008 Raspberries, Blueberries





Outbreaks Caused by the Rest of Latin American Produce Imports

1996 Mesclun	Peru
1996 Raspberries	Guatemala
1997 Raspberries	Guatemala
1997 Mesclun	Peru
1999 Mango	Brazil
2000 Berries	Chile
2000 Raspberries	Guatemala
2001 Raspberries	Chile
2004 Snowpeas	Guatemala
2005 Basil	Peru
2005 Basil	Peru
2008 Cantaloupe	Honduras

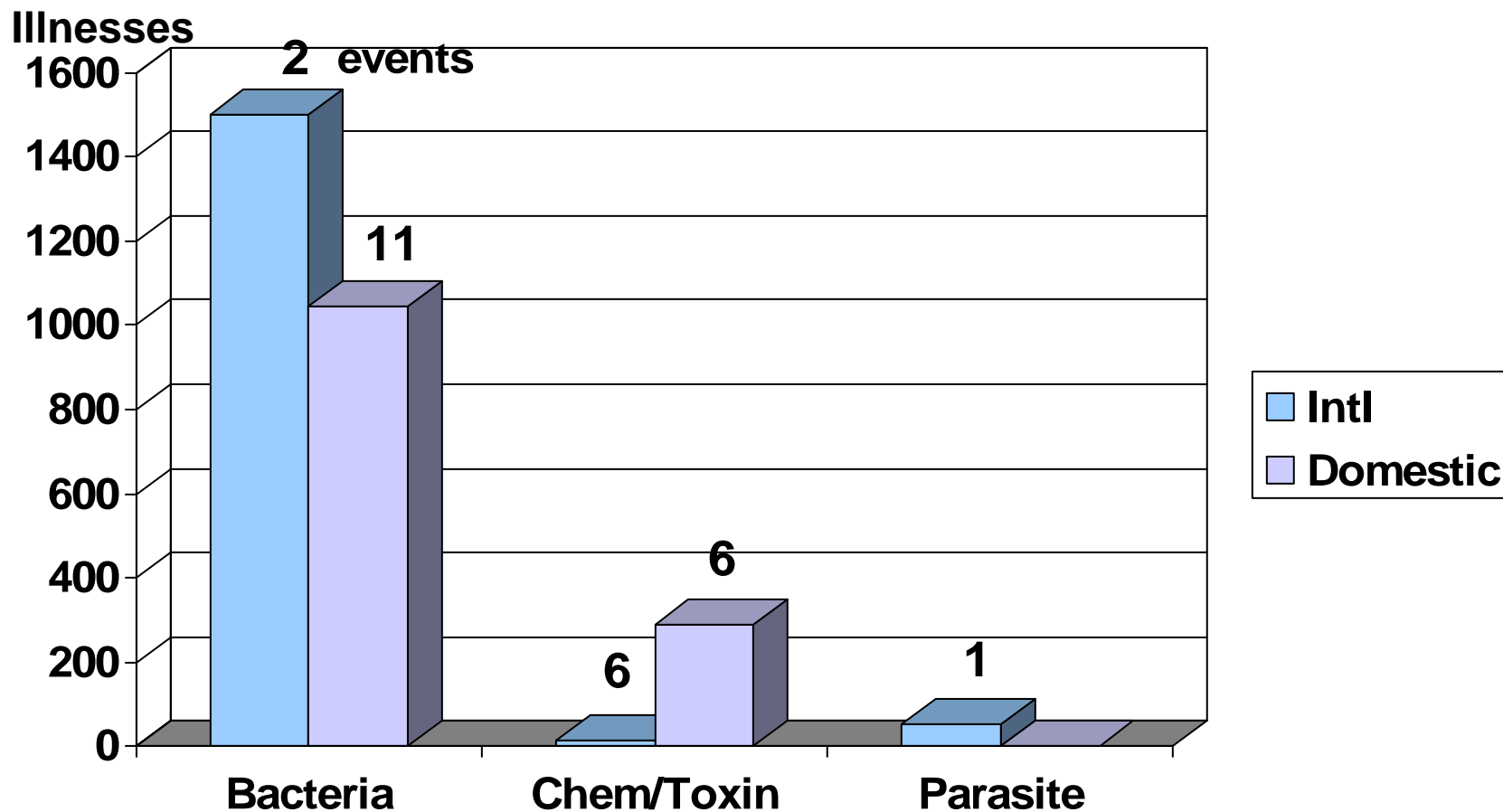


2008 Foodborne Illness Outbreak Data

- 26 outbreaks
- 2,900 reported illnesses, 477 hospitalizations, 9 deaths
- Illnesses caused by bacteria (87.6%), chemicals/toxins (10.6%), parasites (1.6%)



Sources of 2008 Foodborne Outbreaks







Middle East

- *Purpose: improve product safety and security, conduct inspections in timely manner, help develop food and medical product regulatory agencies in region*
- 4 FTEs
- Jordan
- Israel



Breakdown of New FDA Hires

- 43 US National FTEs
 - 5 Regional/Country Directors
 - 21 Senior Technical Experts in foods, medicines, or devices
 - 9 inspectors with expertise in food/feed or medical products
 - 8 support personnel at Headquarters
- 20 Locally employed staff



Office of International Programs Responsibilities

- Provides leadership for all international matters in all program areas
 - interactions with foreign counterpart regulatory authorities and multilateral organizations
 - capacity building
 - managing FDA's foreign offices
 - making formal international arrangements
 - exchanging non-public information
 - trade issues

OFFICE OF INTERNATIONAL PROGRAMS

Deputy Commissioner – Murray Lumpkin, M.D.
Associate Commissioner - Mary Lou Valdez
Deputy Director - Walter Batts
Assistant Director for International Communications – Vashti Klein
Capacity Building Coordination – Beverly Corey
Agreements and Trade Coordination – Matthew Eckel
Travel Team
International Visitors Program
Administrative Team

Africa and Asia
Office
Director
Beverly Corey

India Office
Director
Bruce Ross

China Office
Director
Chris Hickey

Latin America
Office
Director
Paul Seligman

Europe Office
Director
Linda Tollefson

Middle East
Office
Director
Vacant

Harmonization and Multilateral
Relations Office
Director
Michelle Limoli

Quads and Trilateral
Office
Director
Matthew Eckel

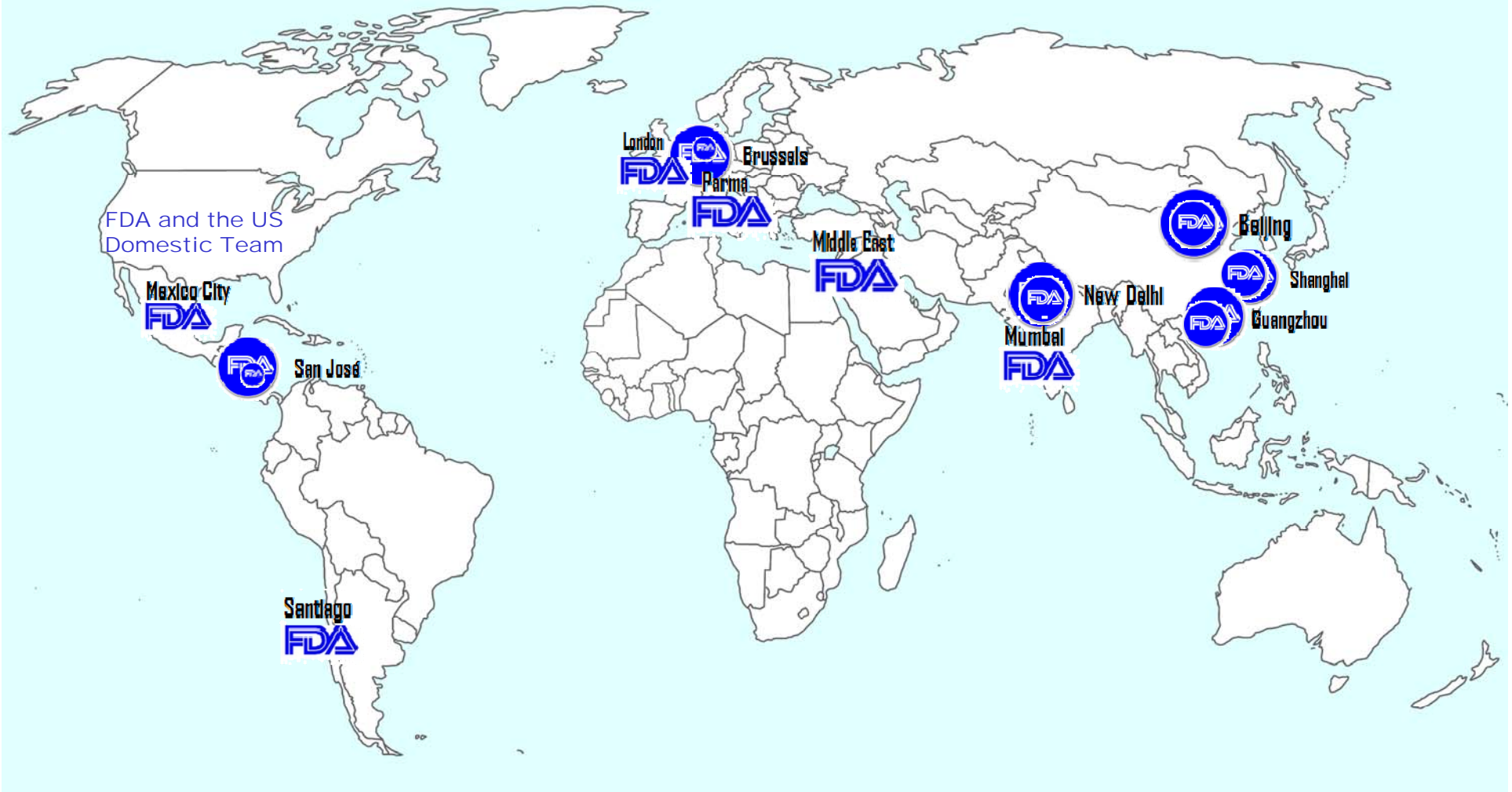


FDA's International Working Group

- Center for Food Safety and Applied Nutrition (CFSAN) – Office of the Center Director, International Affairs Staff
- International Offices at the
 - Center for Veterinary Medicine (CVM)
 - Center for Biological Evaluation and Research (CBER)
 - Center for Drug Evaluation and Research (CDER)
 - Center for Device and Radiological Health (CDRH)
 - Office of Regulatory Affairs (ORA)



After: Global FDA Inaugurated International Offices





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