U.S. Food and Drug Administration
Office of International Programs

FDA's China Office: Focus on Food Safety

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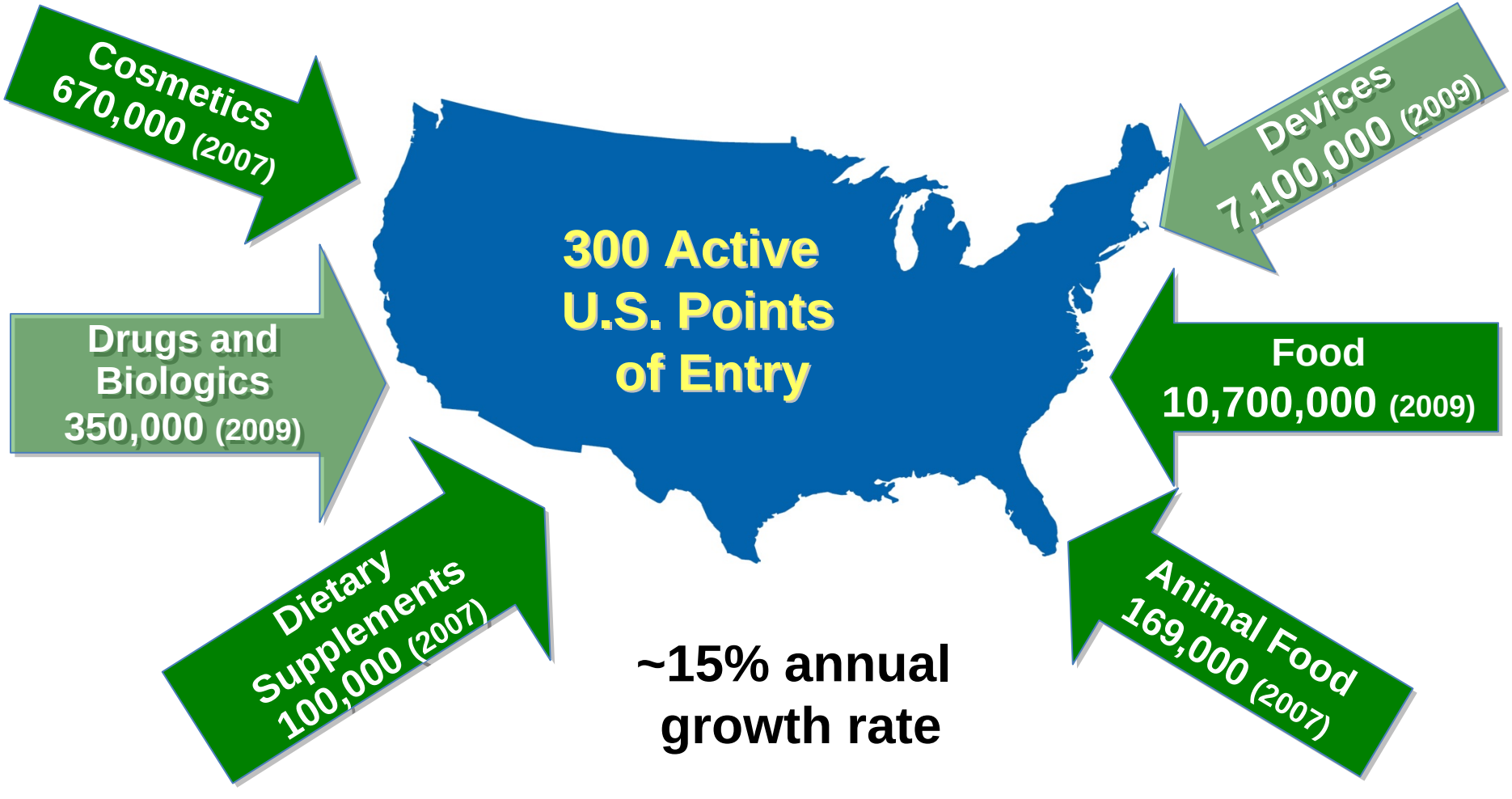
Volume of FDA Regulated Imports



~15% annual growth rate

FDA Overseas Presence: Current Locations

- China
  - Beijing, Shanghai, Guangzhou
- India
  - New Delhi, Mumbai
- Latin America
  - San Jose (CR), Mexico City, Santiago
- Europe
  - Brussels, Parma
- Middle East
  - Amman
- South Africa
  - Pretoria

FDA Overseas Efforts Long-Term Goal

- Products meet safety and quality standards before they enter the U.S.
- Strengthened relationships with regulatory counterparts
- Support responsible supply chain management at:
  - point of manufacture
  - point of export
  - and when presented for importation

FDA China Office

China: opened Nov 2008

- Beijing
  - Director
  - Assistant Directors in Foods, Drugs, and Medical Devices
- Guangzhou
  - 2 Food Inspectors
- Shanghai
  - 2 Medical Product Inspectors
- Local Hires in all 3 Posts

Key Activities

- Further relationships with counterpart agencies
- Engage with regulated industry to support production of safe and high quality foods
- Conduct inspections
- Monitor and report on conditions and events that might affect the safety and quality of FDA-regulated products
- Collaborate with other U.S. government agencies, academia, multilateral organizations

Key Initiatives

- **Better Process Control Schools (BPCS)**
  - Training for production of thermally processed low acid and acidified foods
  - FDA requirement of U.S. operators
  - Collaborated with Ocean University to launch first BPCS – China in 2011
  - 2nd training scheduled for May 2012
  - Goal to branch out to other universities in 2013 and beyond

Key Initiatives

Inspection

- Low Acid Canned Food (LACF) production
- Seafood
- Dietary supplements
- Other

Training

- LACF facility inspection
- Food Defense
- Good Aquaculture Practices

President Obama – FY2013 Budget
Calls for $10 million to expand FDA presence in China
Ultimate goal to enhance mutual collaboration and enable FDA to increasingly rely on info and actions of its regulatory counterparts

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The Food Safety Modernization Act (FSMA) and IMPORTS

Why is the law needed?

Globalization

- 15 percent of U.S. food supply is imported

Food supply more high-tech and complex

- More foods in the marketplace
- New hazards in foods not previously seen

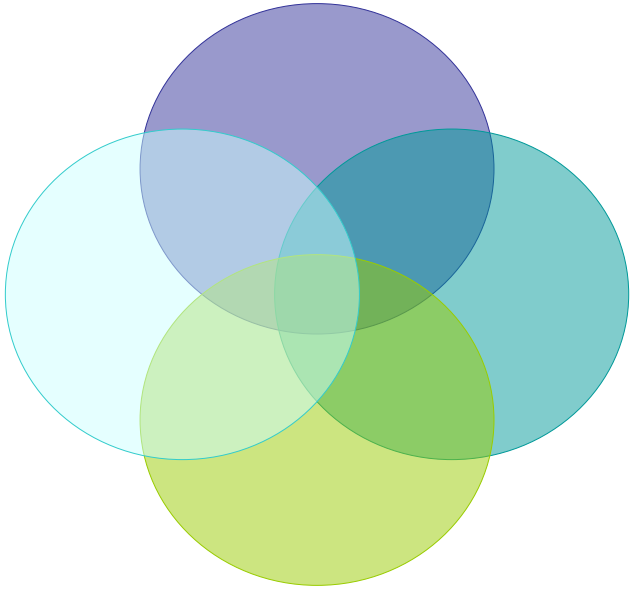
Shifting demographics

- Growing population (about 30%) of individuals are especially “at risk” for foodborne illness

Main Themes of the Legislation

Prevention

Enhanced Partnerships



Inspections, Compliance, and Response

Import Safety

Import Safety: Most Groundbreaking Shift

- Current reliance on port-of-entry inspection cannot handle increase in imported food
- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- Requires food from abroad to be as safe as domestic

Import Safety Mandates

Sec. 301. Foreign supplier verification program

- Requires importers to verify their suppliers use risk-based preventive controls that provide same level of protection as U.S. requirements

Sec. 302. Voluntary qualified importer program

- Allows for expedited review and entry; facility certification required

Sec. 303. Certification for high-risk food imports

- FDA has discretionary authority to require assurances of compliance for high-risk foods

Import Safety Mandates

Sec. 304. Prior notice of imported food shipments ☑

- Requires information on prior refusals to be added to prior notice submission

Sec. 305. Capacity building

- FDA mandate to work with foreign governments to build food safety capacity

Sec. 306. Inspection of foreign food facilities

- Can deny entry if FDA access for inspection is denied

Sec. 201. Targeting of inspection resources

- Increased inspection of foreign as well as domestic facilities

Import Safety Mandates

Sec. 307. Accreditation of third-party auditors

- FDA can rely on accredited third parties to certify that foreign food facilities meet U.S. requirements

Sec. 308. Foreign Offices of the FDA

- Establish offices in foreign countries to provide assistance on food safety measures for food exported to the U.S.

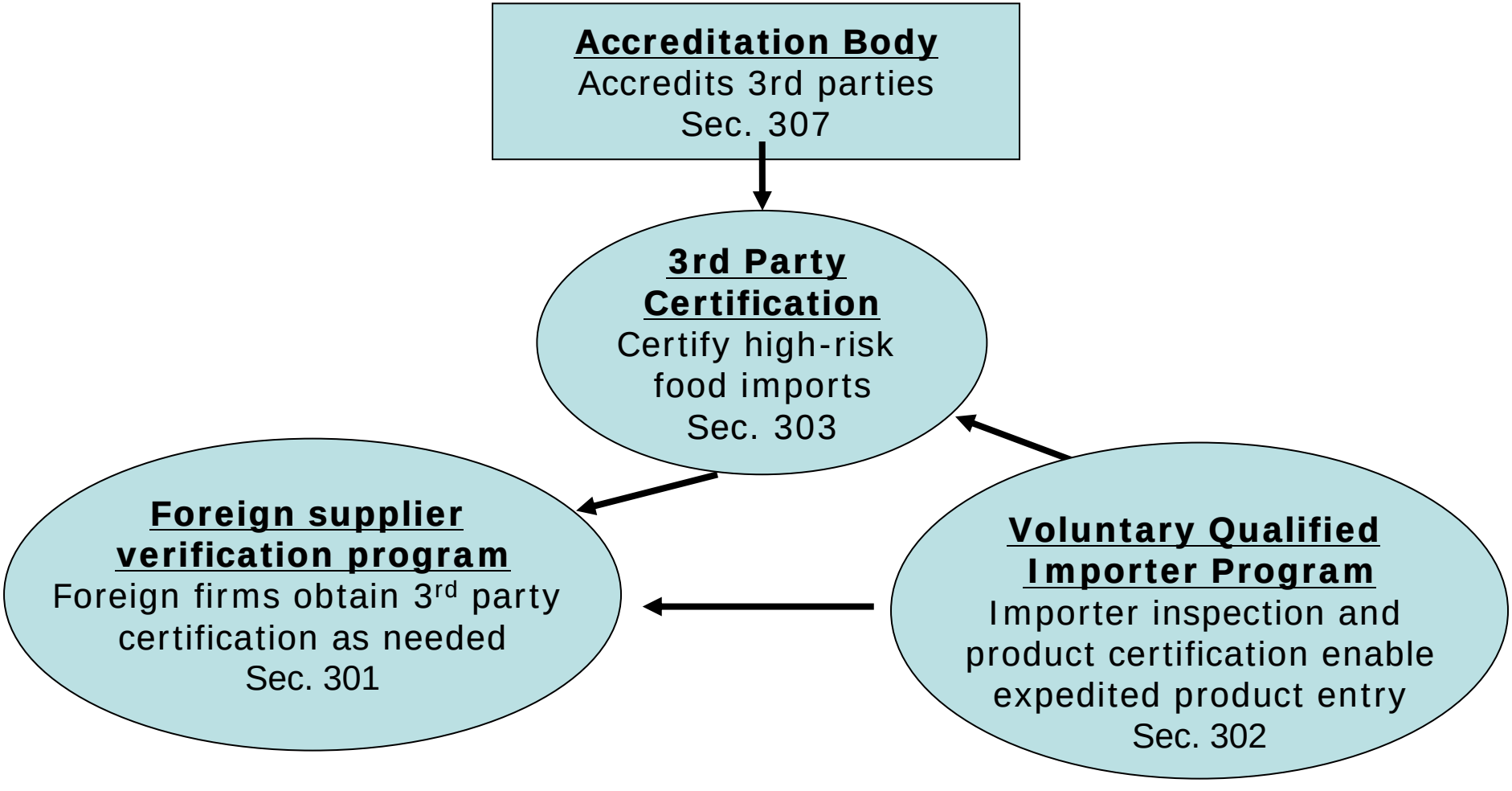
Sec. 309. Smuggled Food

- In coordination with DHS, better identify and prevent entry of smuggled food ☑

Role of Third-Party Certification Programs

- Tool for importers to obtain needed assurances to meet their obligations for the foreign supplier verification program (sec. 301)
- A way for importers to participate in the voluntary qualified importer program to expedite movement of food through the import process (sec. 302)
- Can be required by FDA to accompany high-risk foods (sec. 303)

Import Provisions Work as a Whole



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FSMA - Prevention: The Cornerstone of Food Safety

Prevention: The Cornerstone

- Prevention is not new, but Congress has given FDA explicit authority to use the tool more broadly
  - **Comprehensive preventive controls**
    - Human food facilities
    - Animal food facilities
  - **Produce safety standards**
  - Intentional adulteration standards
  - Transportation

General Approach to Preventive Controls

5 Preliminary Steps

1. Assemble a HACCP team
2. Describe the food and its distribution
3. Identify the intended use and consumers of the food
4. Develop a flow diagram
5. Verify the flow diagram

7 Principles of HACCP

1. Conduct a hazard analysis
2. Determine the CCPs
3. Establish the critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish recordkeeping and documentation procedures

Prevention Standards Mandates

Sec. 103. Hazard analysis and risk-based preventive controls

- Requires human and animal food facilities to:
  - Evaluate hazards that could affect food safety
  - Identify and implement preventive controls to prevent hazards
  - Monitor controls and maintain monitoring records
  - Conduct verification activities

Prevention Standards Mandates

Examples of compliance with prevention standards:

- Sanitation
- Training for supervisors and employees
- Environmental controls and monitoring
- Food allergen controls
- Recall contingency plan
- Good Manufacturing Practices (GMPs)
- Supplier verification activities

Prevention Standards Mandates

Sec. 105. Standards for Produce Safety

- Establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables
- Applies to raw agricultural commodities (RAC) for which FDA determines that such standards minimize the risk of serious adverse health consequences or death

Intentional Adulteration

Sec. 106. Protection against Intentional Adulteration

- Conduct vulnerability assessments of the food supply and determine mitigation strategies
- Issue final rule and guidance to protect against the intentional adulteration of food

Prevention Standards Mandates

Sec. 111. Sanitary Transportation of Food

- Addresses implementation of the Sanitary Food Transportation Act of 2005, which requires persons engaged in food transportation to use sanitary transportation practices to ensure that food is not transported under conditions that may render it adulterated

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FSMA:
The Process

Implementation Approach

- Implementation already underway
- Coalition needed
- Transparency a priority
- Focus on public health protection
- Engage with stakeholders to help determine reasonable and practical ways to implement provisions

Trade Agreements

- Section 404, Compliance with International Agreements, explicitly notes that FSMA must be consistent with our agreement with the World Trade Organization (WTO) and any other treaty or international agreement

- At each stage of the implementation process, we will make every effort to ensure that our proposed activities, policies, and measures are consistent with the WTO

Enhanced Partnerships: Vital to Success

International capacity building

- FDA has mandate to work with foreign governments to build their food safety capacity
- Allows FDA to rely more heavily on foreign government oversight
- Capacity building helps to prevent problems before products reach the U.S. port of entry

Rulemaking Process

- Rulemaking is open and public
- Draft rules are published on http://www.regulations.gov
- Time is allowed for public comment, and FDA is required to consider significant comments during the rulemaking process
- Check http://www.fda.gov/fsma to find out what is open for comment

Top Priorities

Proposed Regulations

1. Preventive Controls – Human Food
2. Preventive Controls – Animal Food
3. Foreign Supplier Verification Program
4. Produce Safety
5. Third Party Certification

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