

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



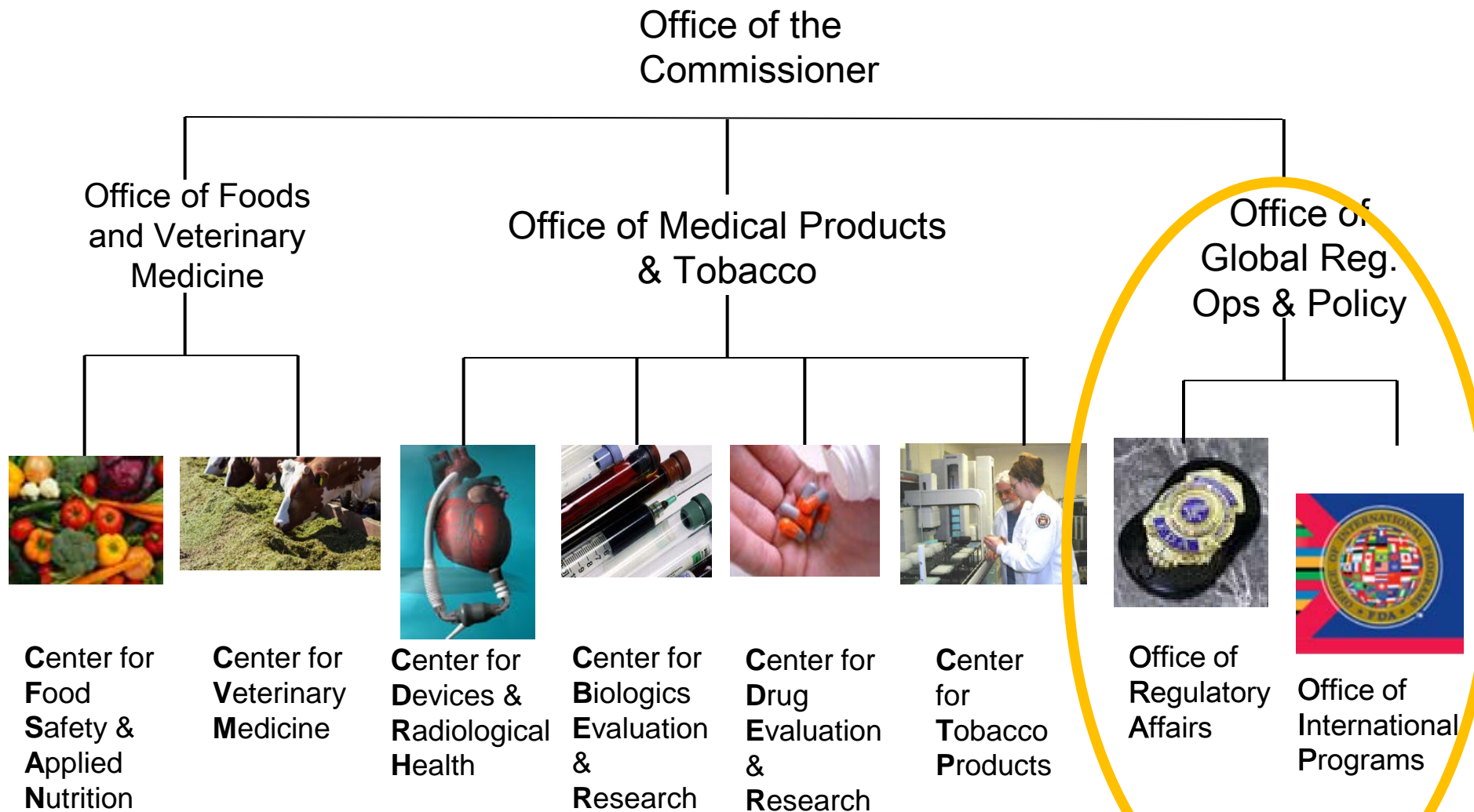
## ***U.S. - Mexico Regulatory Partnerships***

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# FDA Organogram





# ***Challenges of Globalization***

**Globalization has fundamentally changed the environment for regulating food and medical products**

**Created unique regulatory challenges for FDA:**

- **More foreign facilities supplying the U.S.;**
- **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; and**
- **Greater opportunities for economic fraud.**



# ***Globalization...By The Numbers***

- **Foreign production of FDA-regulated goods and materials has exploded over the last decade.**
- **Number of FDA-regulated shipments at 300 U.S. ports has more than quadrupled during the last ten years.**
  - In 2004, 6 million shipments of imported food and medical products crossed our borders. In 2014, that number was over 28 million – almost a fivefold increase.
- **Food**
  - About 15% of food consumed by U.S. households is imported.
  - Approx. 50% of fresh fruits and 20% of fresh vegetables consumed by U.S. households are imported.
  - Approx. 80% of seafood eaten domestically comes from outside the U.S.

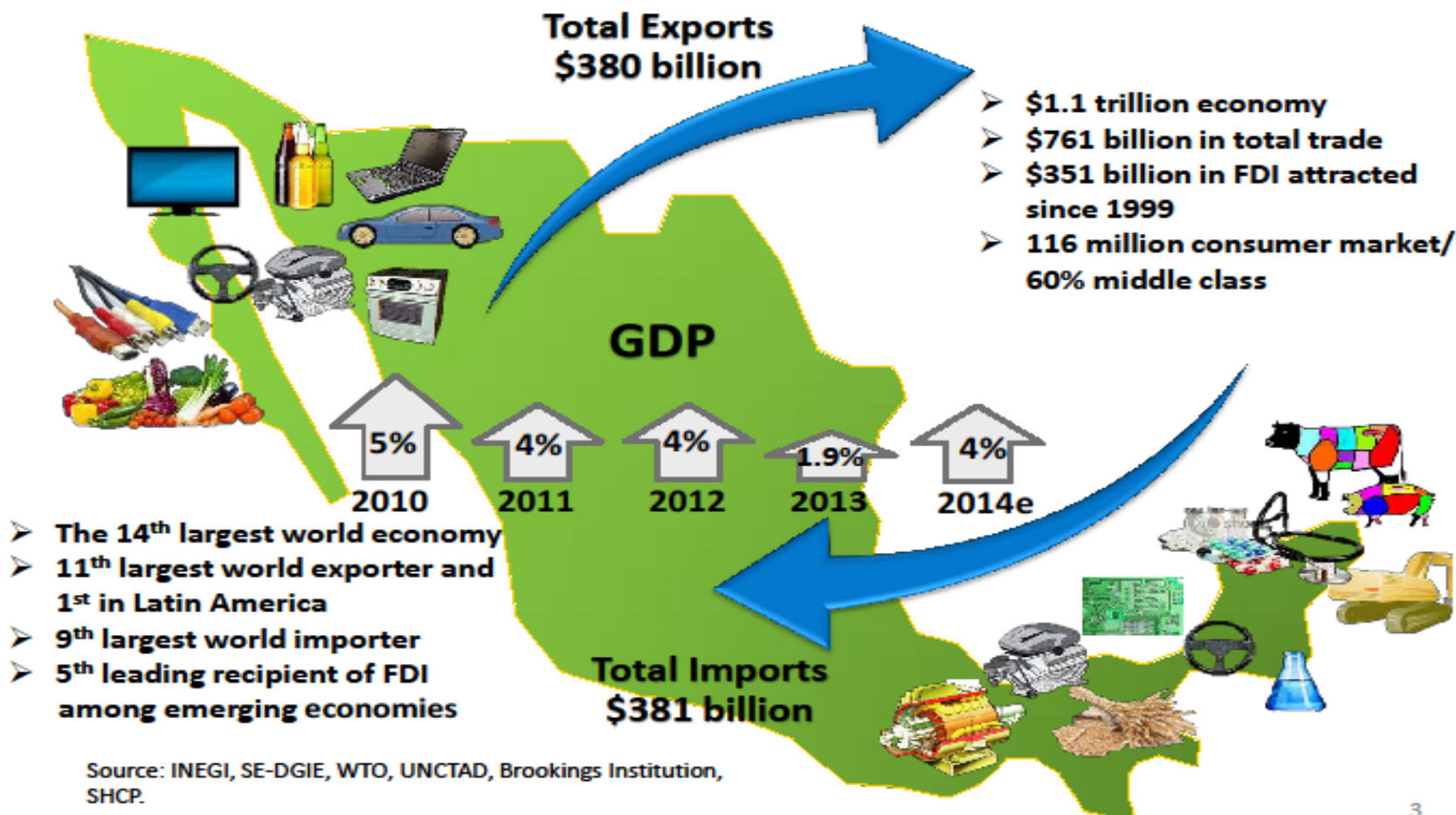


# **Mexico: significant import source**

- **Almost one quarter of all import lines;**
- **>30 percent of human foods (#1);**
- **> 25 percent of medical devices (#2);**
- **10 percent of drugs and biologics (#3);**



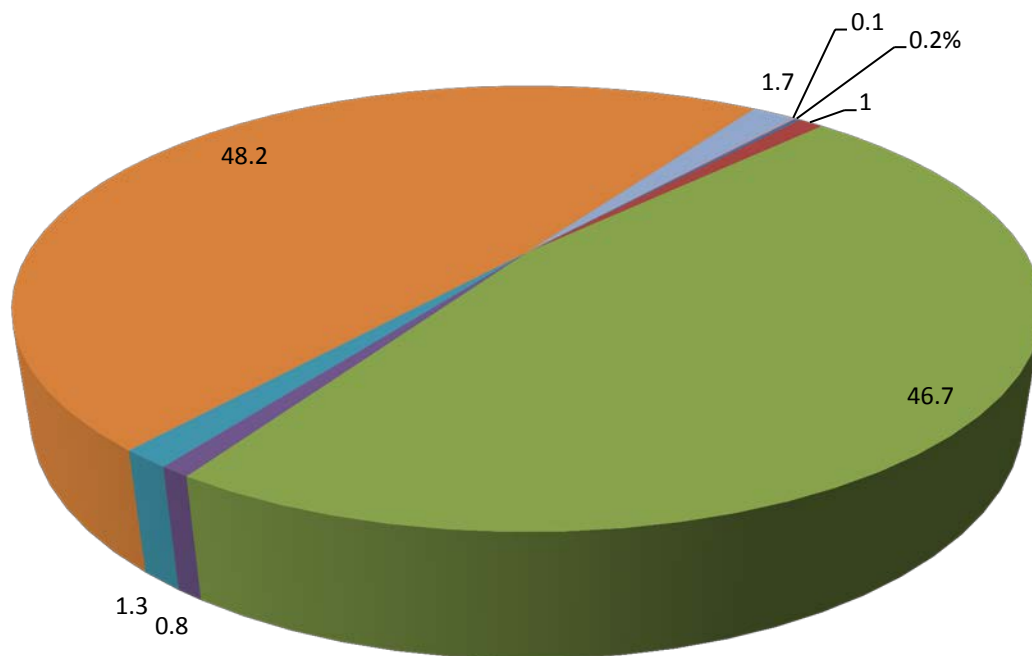
# U.S. – Mexico Trade flows



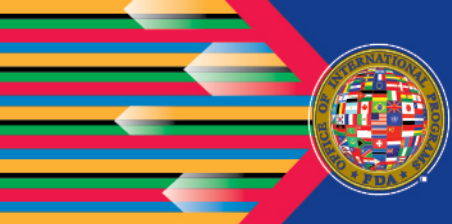


# Products Imported from Mexico

- Animal foods
- Cosmetics
- Devices
- Drugs and Biologics
- Housewares and food-related
- Human Foods
- Radiation-Emitting Devices
- Tobacco Products





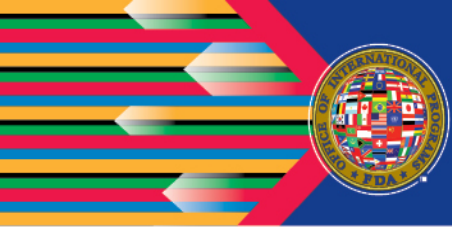


# ***Enhanced Partnerships: Vital to Success***

## **Global Coalition of Regulators**

- **Enables FDA to rely more heavily on other foreign regulators;**
  - Mutual reliance
  - Familiarity, understanding,
- **Help prevent problems before products reach U.S. ports of entry;**
- **More common approaches to regulation ensuring quality, safety**
  - International Coalition of Medicines Regulatory Authorities (ICMRA);
  - International Medical Device Regulators Forum (IMDRF);
  - Pharmaceutical Inspection Co-operation Scheme (PIC/S)
- **International capacity building**
  - FSMA gives FDA the mandate to work with foreign governments to build their food safety capacity





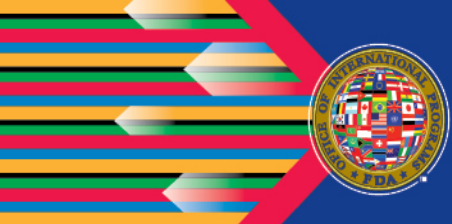
# ***Enhanced Partnerships: Vital to Success***

## **Produce Safety Partnership**

- Based on a long history of collaboration
- Recognition of the volume of produce originating from Mexico

## **Purpose**

- work in partnership to implement preventive practices and verification measures that will support high rates of compliance with produce safety standards, guidelines and best practices and therefore reduce risk of illness or death associated with the consumption of fresh and/or minimally processed produce.



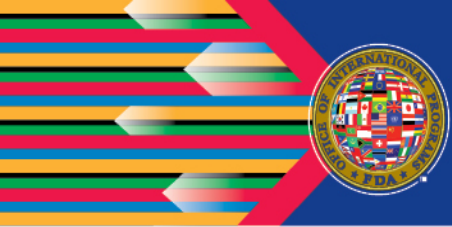
# Signing Ceremony





# ***Particular Objectives***

- 1. Exchange information to better understand each other's produce safety systems;**
- 2. Develop effective, specific education and outreach materials that support industry compliance with produce safety standards;**
- 3. Identify common approaches for training of auditors who will verify compliance with produce safety standards**
- 4. Expand collaboration on regulatory lab activities**
- 5. Expand collaboration on outbreak response and traceback activities**
- 6. Expand collaboration on consumer education outreach**



# ***Mexico – U.S. food safety cooperation***

- **1995 FDA training introducing Good Agricultural Practices (GAPs) guidance in Mexico**
  - **10 training programs on GAPs held in Mexico from 2002 through 2013 (and two additional regional trainings in Latin America with Mexico's participation).**
- **Cooperation on traceback investigations and in building lab capacity for produce microbial testing.**
- **SENASICA and COFEPRIS officials routinely accompany FDA during routine surveillance inspections of Mexican food firms, including produce firms.**
- **FDA has also accompanied SENASICA and COFEPRIS during routine inspections of U.S. produce firms.**
- **FDA has participated in several industry sponsored visits to growing areas as well as to observe supply chain management.**
- **Mexican technical staff has participated in FDA headquarters training alongside FDA staff, including Farm Investigations training in 2014.**
- **Several joint outreach meetings held with industry on new regulatory efforts and existing requirements.**



# Questions?



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