Supply & Safety: Monitoring Imported Food

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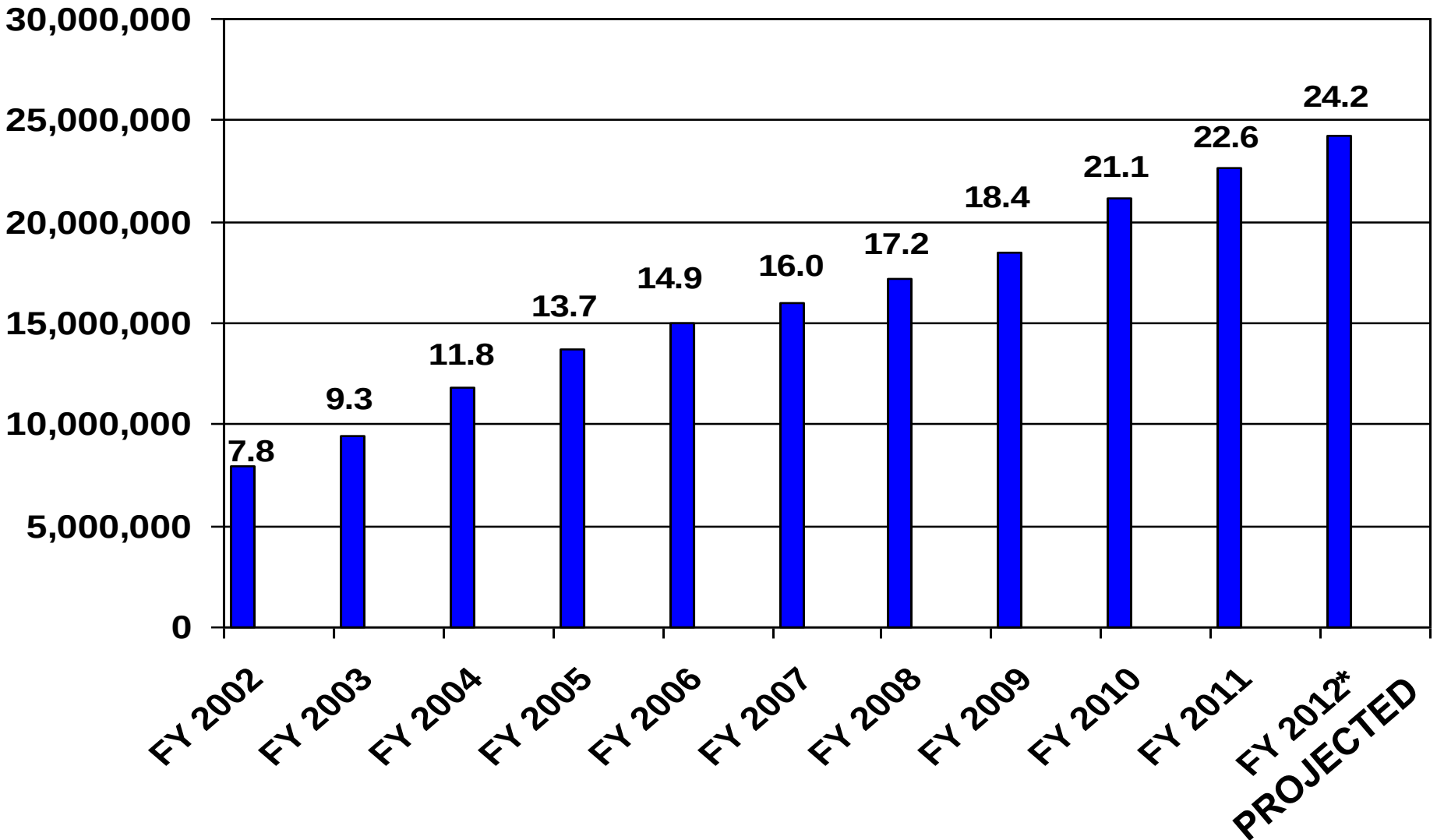
U.S. Department of Health and Human Services
FDA Food and Drug Administration

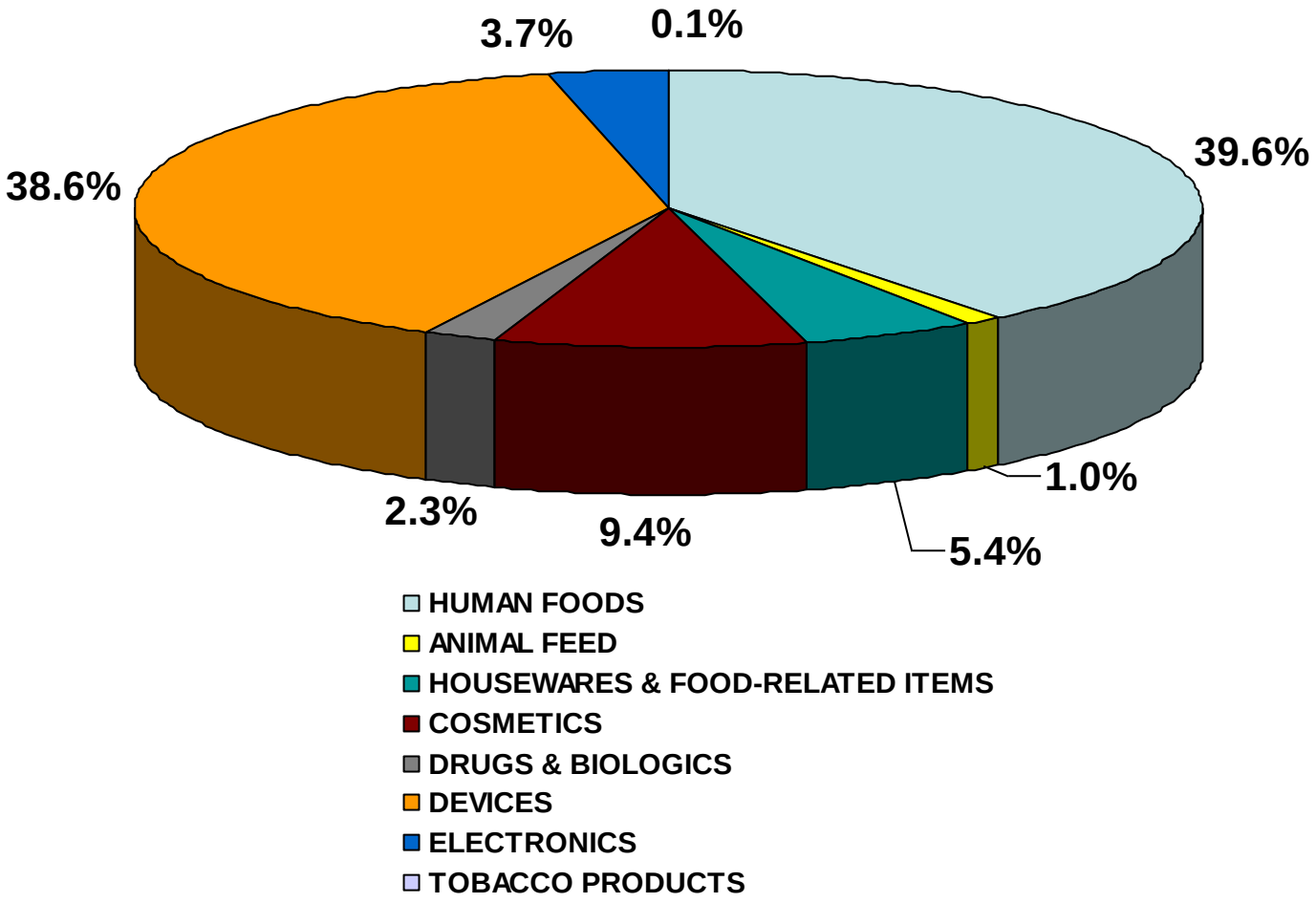
➢FDA responsibility

- ✓Ensuring that food is safe, wholesome and sanitary;
- ✓Human & veterinary drugs, medical devices &human biologics are safe and effective;
- ✓Cosmetics and electronic products that emit radiation are safe;
- ✓Tobacco product comply with regulations; and
- ✓Labeling of these products honestly represent them to the users and their instructions for use are adequate

FY 2002 – 2012*
TOTAL IMPORT LINES



FY 2011 LINES BY CATEGORIES



GLOBALIZATION

- ✓ 15 – 20% of U.S. foods consumed originate from other countries
  - ✓ 80% of seafood
  - ✓ 35% of produce
  - ✓ 60% of spices
- ✓ 228 countries/areas export foods to the U.S.
- ✓ Over 9.2 million lines of food products in FY-2011
- ✓ Over 10,000 lines of food were refused admission

Five Proposed Rules Establish Food Safety Framework

- Produce Safety Standards - Published Jan. 2013
- Preventive Controls for Human Food - Published Jan. 2013
- Foreign Supplier Verification Program
- Preventive Controls for Animal Food
- Accredited Third Party Certification

Key Aspects of Proposals

- Confirm industry's primary role on food safety
- Risk-based and flexible
- Address small business issues
- Extensive government, stakeholder Input

Produce Rule - Key Principles

- ✓ Considers risk posed by practices, commodities
- ✓ Science- and Risk-based
  - ✓ Focus on identified routes of microbial contamination
  - ✓ Excludes certain produce rarely consumed raw
  - ✓ Excludes produce to be commercially processed (documentation required)
- ✓ Flexible
  - ✓ Additional time for small farms to comply
  - ✓ Variances
  - ✓ Alternatives for some provisions

Standards for Produce Safety

Focus on identified routes of microbial contamination

- Domesticated and wild animals
- Equipment, tools, buildings and sanitation
- Worker health and hygiene
- Agricultural water
- Growing, harvesting, packing and holding activities
- Biological soil amendments of animal origin
- Specific requirements for sprouts

Covered Produce

- “Produce” defined as fruits and vegetables
- Produce includes mushrooms, sprouts, herbs and tree nuts
- Produce does not include grains
- Some limitations on covered produce

Preventive Controls for Human Food - Key Principles

- ✓ Confirms industry's primary role on food safety
- ✓ Prevention of hazards
- ✓ Risk-based

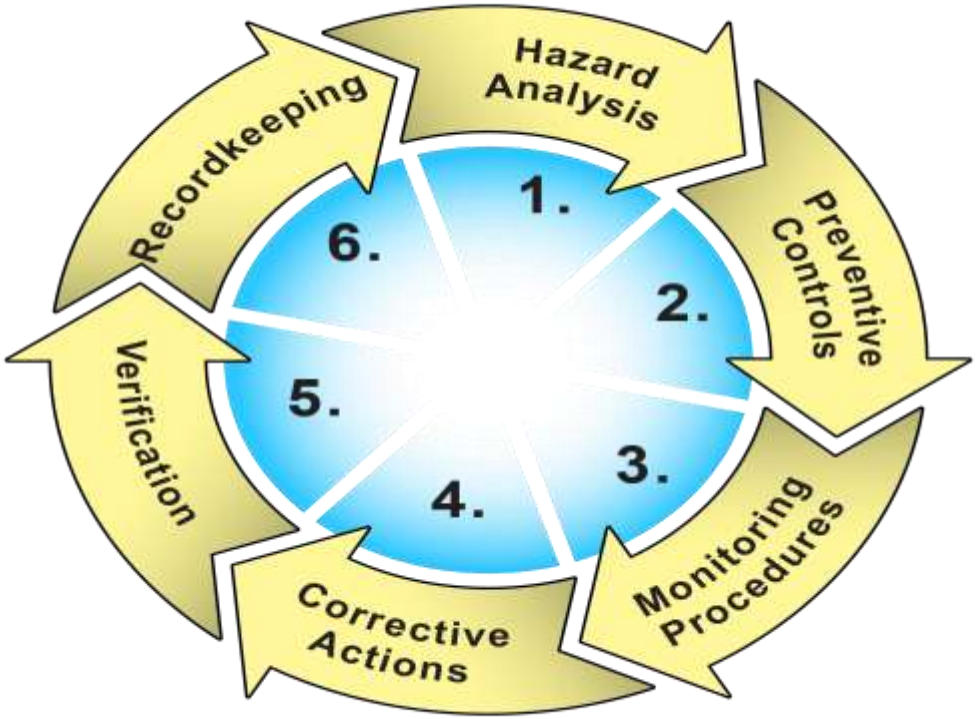
Summary of Requirements

- ✓ Hazard Analysis and Risk-Based Preventive Controls
  - ✓ Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
- ✓ Updated Good Manufacturing Practices

Who is Covered?

- ✓ Facilities that manufacture, process, pack or hold human food
- ✓ In general, facilities required to register with FDA under sec. 415 of the FD&C Act
- ✓ Applies to domestic and imported food
- ✓ Some exemptions and modified requirements are being proposed

Hazard Analysis and Risk-Based Preventive Controls



Preventive Controls Required

- Process controls
- Food allergen controls
- Sanitation controls
- Recall plan
- In addition, seeking comment on supplier approval and verification program

How to Comment on the Proposed Rules

- http://www.regulations.gov
- Link to rules on http://www.fda.gov/fsma
- Comment period is 120 days; exact due date will be in the Federal Register
- Comment periods on major FSMA proposals will be coordinated to enable comment on how the rules can best work together.

FMSA Public Meeting

- ✓ **Proposed Rules to Establish Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption and for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**

- ✓ February 28, 2013
  8:30 am - 5:00 pm

- ✓ March 1, 2013
  8:30 am - 12:00 pm

- ✓ Jefferson Auditorium
  U.S. Department of Agriculture
  14th and Independence Avenue, SW, Wing 5 Entrance
  Washington, DC 20250

Foreign supplier verification program (FSVP)

- ✓ Each importer must perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer is:
  - ✓ Produced in compliance with Section 418 (Preventive Controls) or 419 (Produce Rule)

And

- ✓ Not adulterated under section 402 or misbranded under 403(w) (undeclared allergens)

Foreign supplier verification program (FSVP)

- ✓ Agency shall, as appropriate, take into account:
  - ✓ Differences among importers
  - ✓ Types of imported foods
  - ✓ Risk of the food

- ✓ Verification activities may include (but are not limited to):
  - ✓ Monitoring records for shipments
  - ✓ Lot-by-lot certification of compliance
  - ✓ Annual on-site inspections
  - ✓ Checking the Food Safety Plan of the foreign supplier
  - ✓ Periodically testing and sampling shipments

Foreign supplier verification program (FSVP)

- ✓ FDA is required to take action to flesh out the foreign supplier verification program
  - ✓ FDA will promulgate regulations
  - ✓ FDA will issue guidance documents to assist importers in developing their foreign supplier verification programs
- ✓ Statutory effective date: January 4, 2013
  - ✓ Proposed rule currently undergoing review by OMB
- ✓ Records must be maintained for at least 2 years and made available to FDA upon request

Voluntary Qualified Importer Program

- **Who can apply:** Importer means the person in the United States or foreign agent (Importer of Record) who brings food, or causes food article of food to be brought from a foreign country into the U.S.

- **Stages & Benefits:**
  - **Stage 1 Benefits-**
    - ✓ adjusted risk score for the applicant/FSVP importer/supplier combination resulting in a reduction in the probability that the product would be sampled under FDA's surveillance program.
    - ✓ expedited treatment at an FDA laboratory, being prioritized over other similar samples

Voluntary Qualified Importer Program

- **Stage 2 Benefits-**
  - ✓Once an inspection confirmed, adjusted risk score for the applicant/FSVP importer/supplier
  - ✓Samples would generally only be collected for cause
  - ✓sample would receive expedited lab analysis by FDA as described for the gold tier.

VQIP - Eligibility Criteria:

- ✓ Applicant must be an Importer of Record w/ an Importer ID
- ✓ must be in good standing with CBP
- ✓ Tier 2 status in Customs' voluntary C-TPAT program
- ✓ Applicant must be using a paperless Filer/Broker
- ✓ The FSVP importer must be in full compliance with all provisions of FSVP
- ✓ Applicant/entities cannot be subject to an FDA action
- ✓ one year's history of importing food into U.S. commerce
- ✓ import documents through ITACS
- ✓ must be in good standing with other voluntary Federal agency programs in which they participant.

VQIP

Revocation:

- ✓ FSVP Importer is not fully Compliant with FSVP and their corrective action plan is unacceptable and/or not received within established time frames.
- ✓ Applicant is no longer a C-TPAT member at the Tier 2 level.
- ✓ Applicable Fees are not paid within 60 days
- ✓ Falsified Application/Entry information
- ✓ Applicant or other entities identified in the application are debarred or has other documented significant violations, i.e., smuggling, civil money penalties or failure to hold
- ✓ Self Revocation or Out of Business
- ✓ Broker/filer failure linked to the importer

VQIP

- **User fees:** Working with the User Fee Workgroup to establish the appropriate user fee schedule, model, and policies.

  - ✓ Develop a user fee schedule based on the number of individual products for each application and the maximum number of applications that will be reviewed each year.
  - ✓ Identify timeframes for when fees must be paid.
  - ✓ Develop the notification mechanism for verifying that the applicant's user fee has been paid.
  - ✓ If an applicant is refused participation in VQIP, the FDA will not refund the applicant's user fee.

QUESTIONS?