LEAVITT PARTNERS

The Food Safety Modernization Act and Other Important Factors

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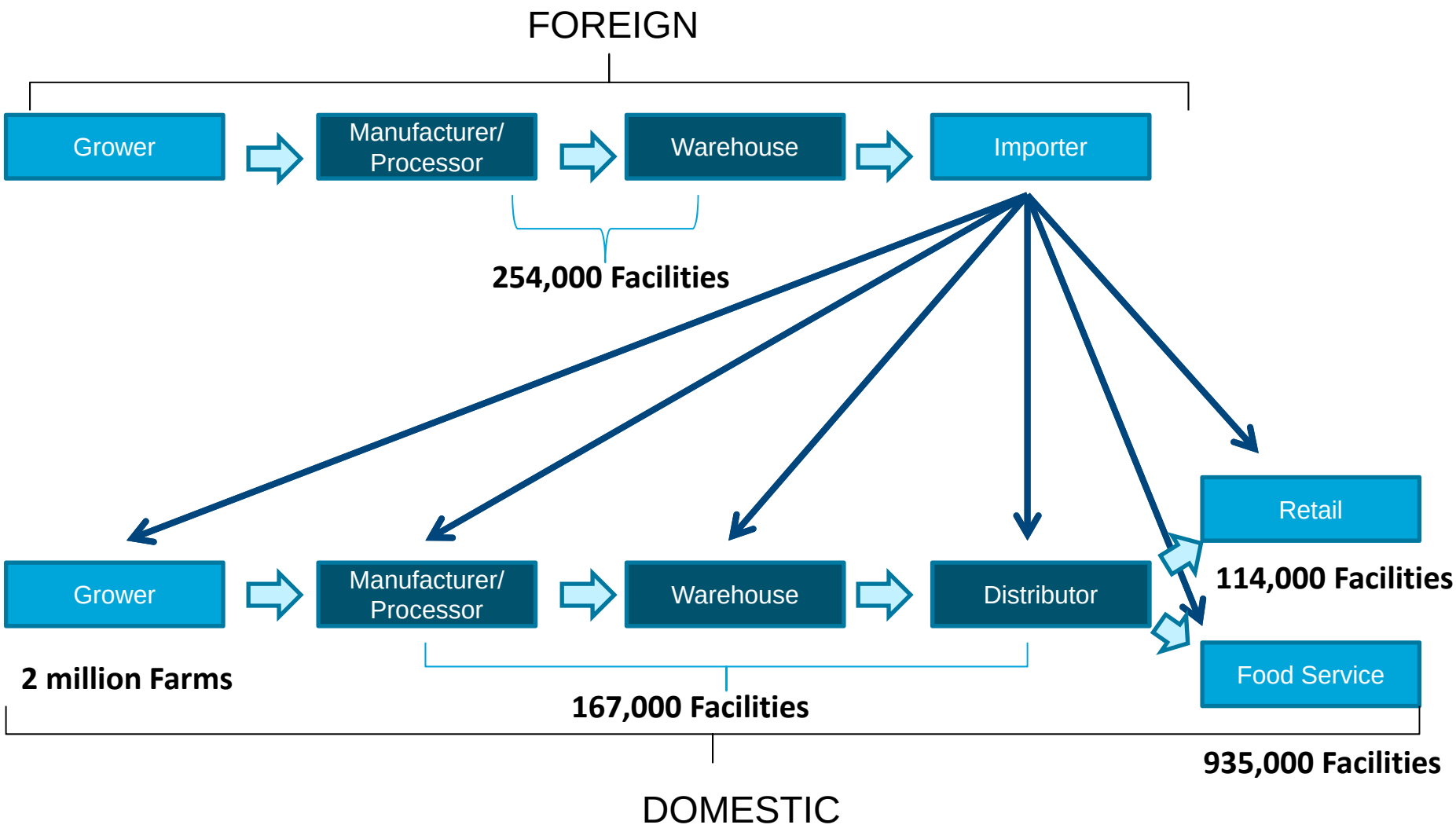
Outline

- Factors Driving Change
- Food Safety Modernization Act
- Looking to the Future

The Changing Food-Safety Landscape

- Global food supply
- Changing science
- Media influence
- New Threats
- Consumer expectations
- New Regulations

The Global U.S. Food Supply



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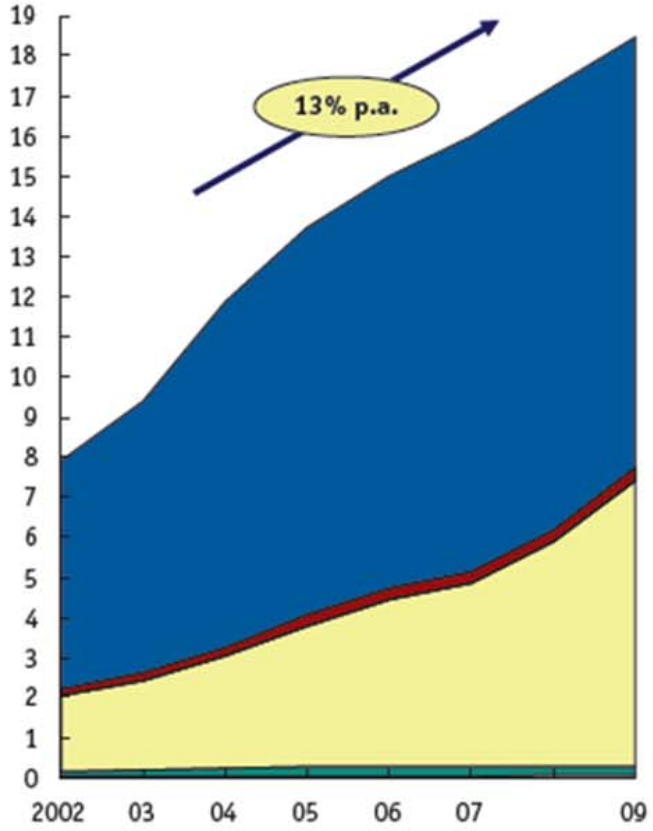
Import shipments of FDA-regulated products have been growing at 13 percent per year.

Imported lines[1] (millions)

Total = 7.9 MM in 2002; total = 18.5 MM in 2009



	CAGR 2002-09	Explanation of center's products
Foods	9.5%	• Food products for human, animal, pet use, except meat and poultry • Articles for cleansing, beautifying, promoting attractiveness of body
Drugs	12.9%	• Prescription and OTC drugs for human
Devices	20.8%	• Medical devices for human use • Products that emit radiation (e.g., microwaves, lasers, x-ray machines)
Veterinary products	6.7%	• Drugs, devices, and food additives for animals and pets
Biologics	15.8%	• Blood products, vaccines, and tissues for transplantation

1 An import line represents the portion of a shipment listed as a separate item on an entry document. The number of units can vary.

Source: FDA

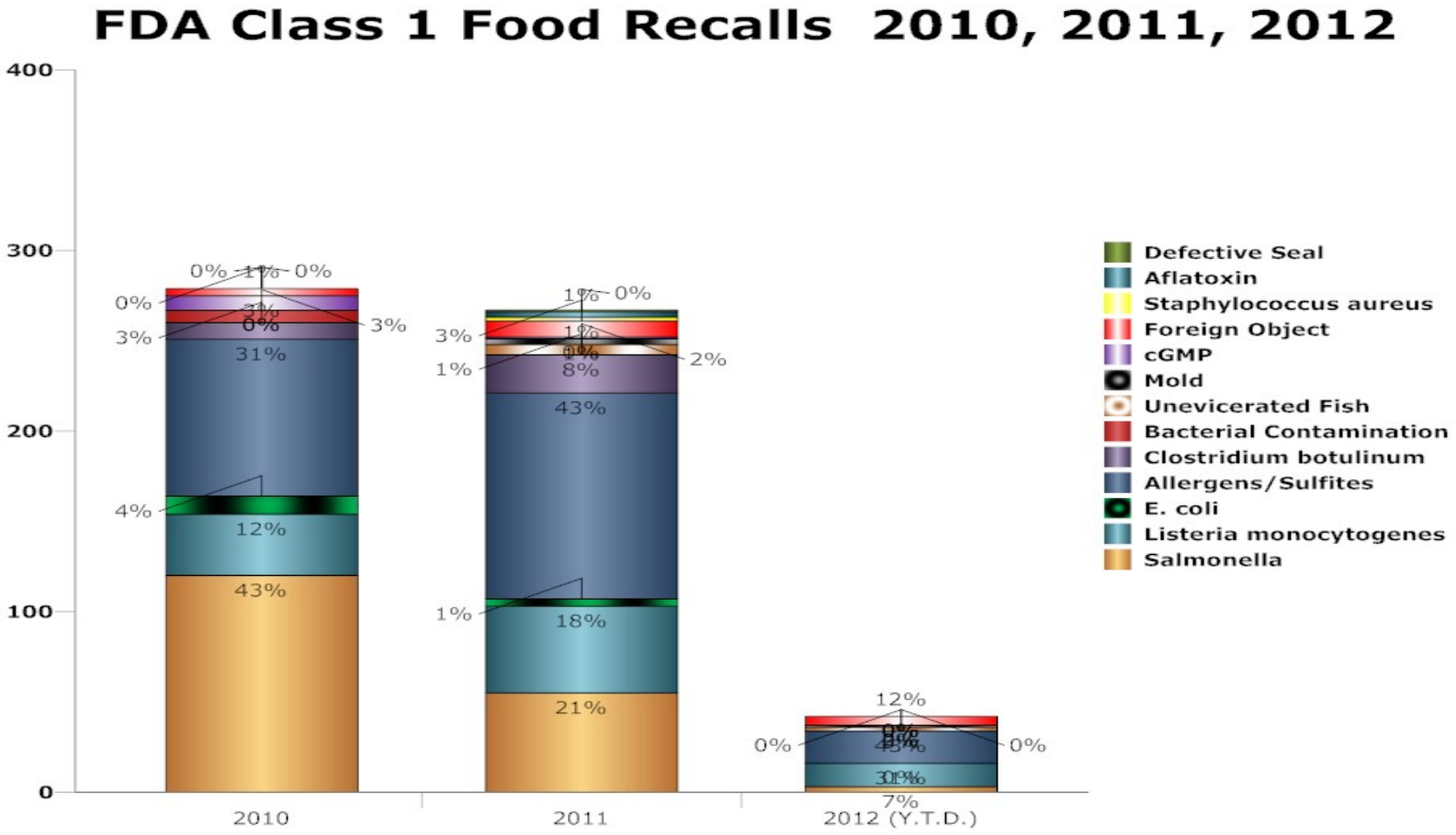
Changing Science of Food Safety

- New risks identified with foods (peanut butter, cookie dough)
- Greater capacity to link food with illness
- Ability to measure lower levels of chemicals
- Greater fidelity of epidemiology
- Improvements in genetic testing

13 Foods Linked to New Outbreaks of Foodborne Illness in the United States Since 2006

Bagged spinach	Carrot juice	Peanut butter	Canned chili sauce	
Broccoli powder on snack food		Hazelnuts	Pot pies	Dog food
Hot peppers	Papayas	White pepper	Raw cookie dough	Pine Nuts

Trends in Food Recalls



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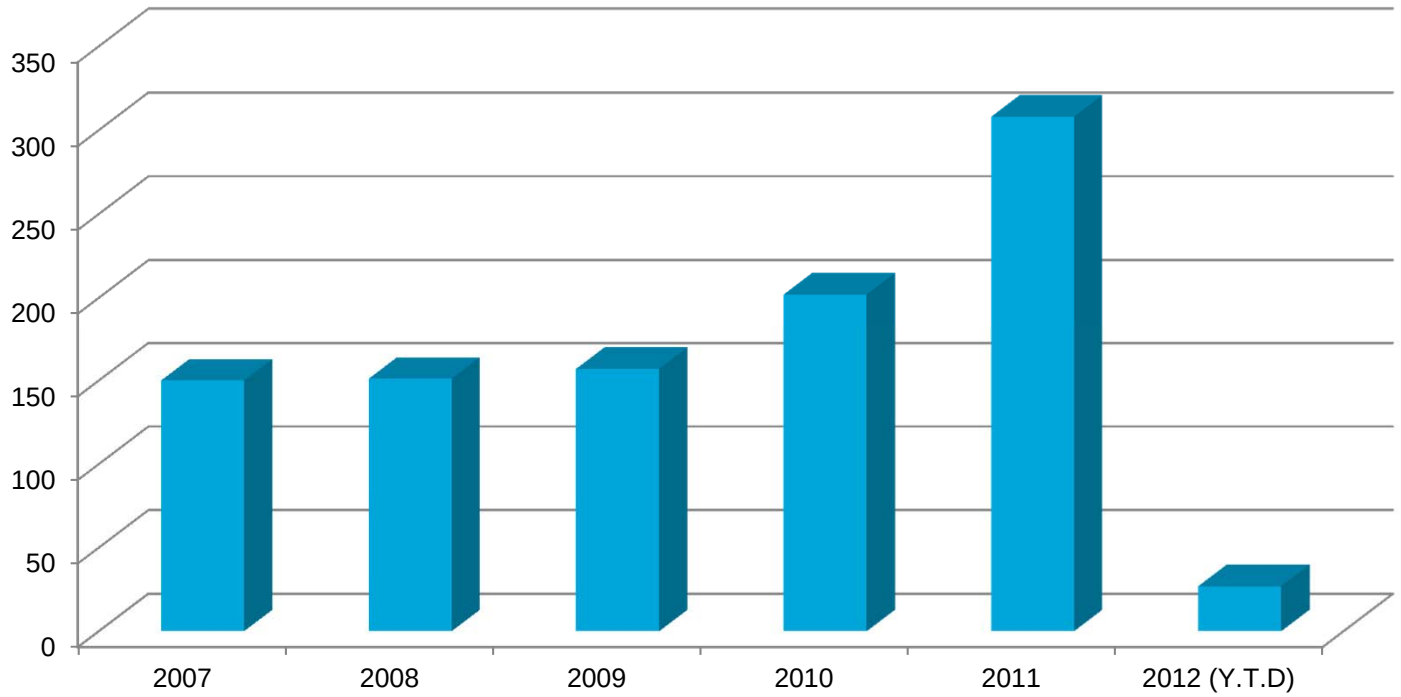
Increasing Numbers Of Warning Letters



Consumer Expectations Have Shifted in the United States

- Americans expect all types of food will be available all the time
- Zero tolerance for unsafe food
- Consumers place responsibility for safe food on the producer
- Increased desire for local and unprocessed food
- “Chemophobia”
- Consumers ability to damage a brand

Influence of the Media on Food Safety in the U.S.

- The U.S. media, especially television, has changed:
  - Faster
  - 2-hour news cycle
  - Focused on health and food
  - Looks to blame

- Social media has exploded gives individual citizens a mechanism to broadly report food-related illness and destroy a brand.

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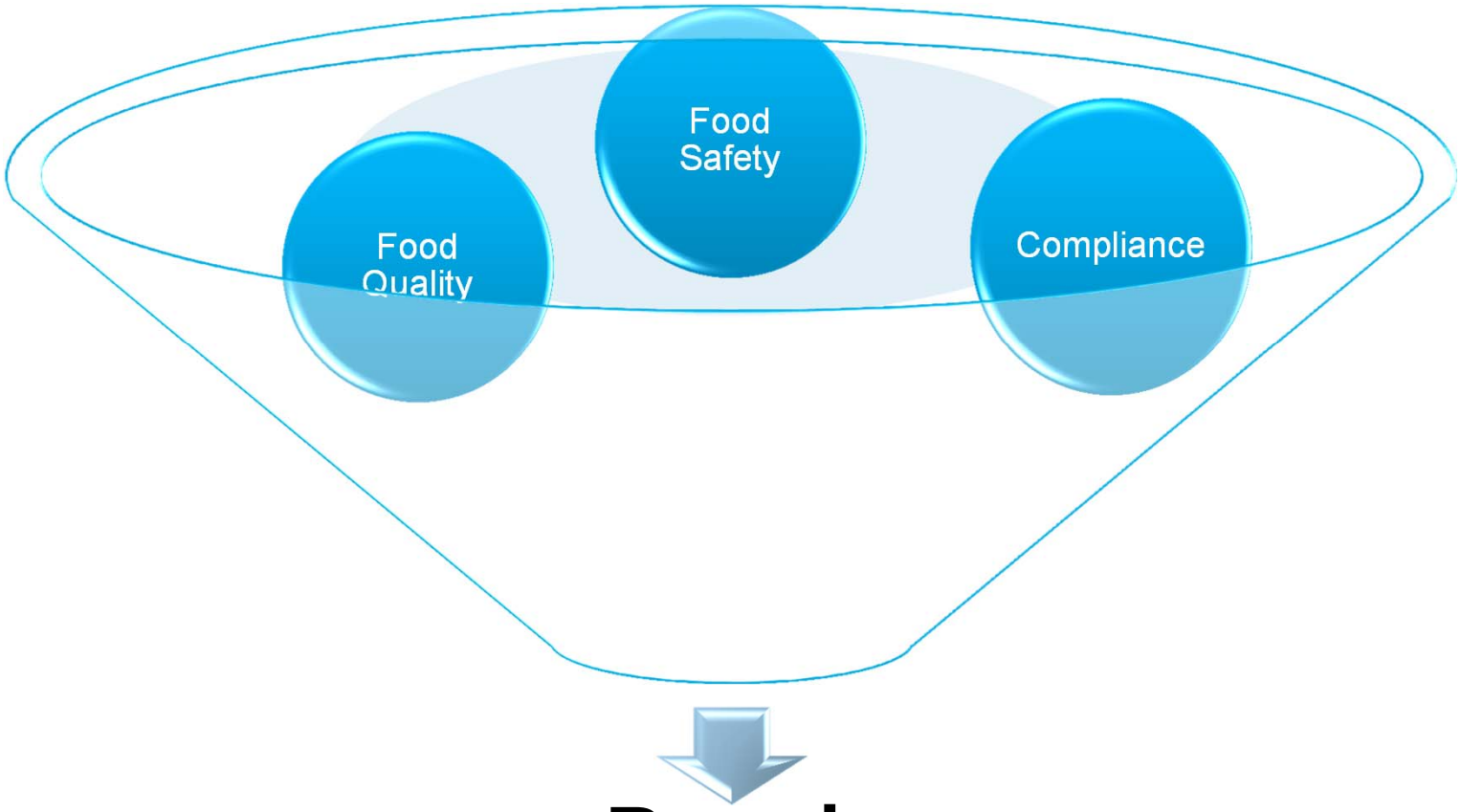
Consequences for Industry

- Damage to Brands
- Greater focus on prevention
- Additional regulatory oversight and authority
    - Food Safety Modernization Act
- Looking for cost effective solutions

Protecting Your Brand



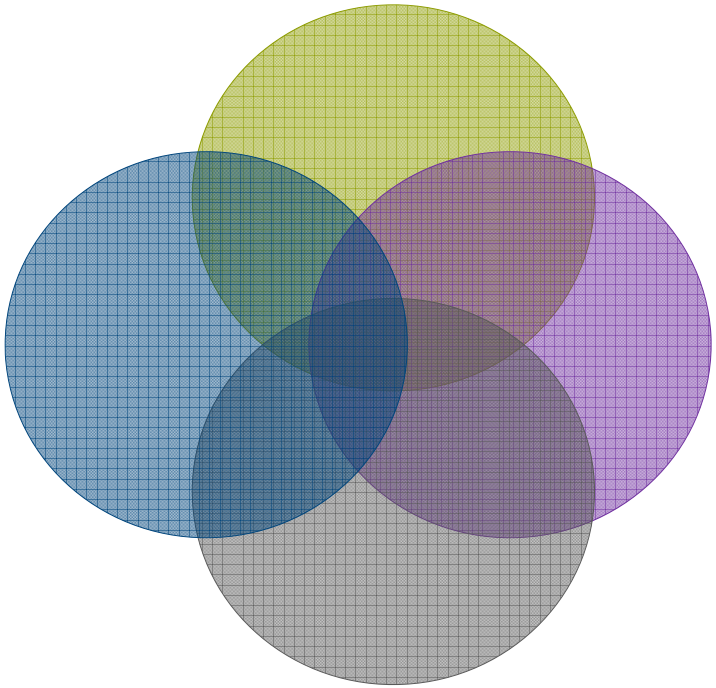
Food Safety Modernization Act

- Signed into law on January 4, 2011
- Most sweeping overhaul of the food safety system since 1938
- Law reflects risk-based integrated global systems approach

Food Safety Modernization Act

Prevention

Enhanced Partnerships



Increased Inspections
Enhanced Response

Import Safety
Apply Domestic Standards to Imported Foods

Whom does the new law affect?

- Manufacturers and processors
- Farmers and growers
- Transporters
- Retailers
- Importers
- Laboratories
- Third-party certification bodies
- Foreign Governments

FDA Implementation Activities 2011

Upon Enactment

- Inspection of records
- Mandatory recall authority
- Authority to require import certificates

May 2011

- Interim Final Rule on Prior Notice of Imported Food
- Interim Final Rule on Criteria for Administrative Detention

July 2011

- FDA/DHS Joint Anti-smuggling Strategy
- Authority to Suspend the Registration of Food Facilities
- Administrative Detention of Foods becomes Effective
- Food Defense Mitigation Strategies Database

Inspection of Records

- Greater access to records
- Need reasonable probability that food will cause a serious adverse health consequence
- Records relating to manufacturing, processing, packing, receipt, holding or importation
- All records relating to an article of food AND
- All records relating to any food that is likely to be affected in a similar manner
- Access to facility food safety plans and related records documenting implementation of their plans.

Examples of Records FDA can Examine

- Manufacturing records
- Raw materials (ingredients and packaging) receipt records
- Product distribution records
- Product inventory records
- Test records
- Recall records
- Reportable food records
- Customer distribution lists
- Complaint and adverse event records

Suspension of Registration

- If food manufactured, processed, packed, received, or held by a facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals
- Impact of suspension:
  - No import or export of food into the U.S.
  - No offering of food for interstate or intrastate commerce in the U.S.
- Effectively shuts down the facility

Mandatory Recall

- Offer opportunity for voluntary recall
- Mandate if a reasonable probability of serious adverse health consequence or death
- Opportunities for appeal

Administrative Detention

- “Credible evidence that food presents a serious adverse health consequence” CHANGED TO “Reasonable belief food is adulterated or misbranded”
- Lowers the bar to hold food
- FDA has already used this new authority

Product Tracking

- Pilot programs underway
- Report to Congress in July 2012
- Current law (one up one back) has not changed
- More data required for high risk foods
- Door is open for more product tracking requirements

FDA Implementation Activities 2012

Preventive Controls

- Publish proposed rule on preventive controls (effective July 2012)
  - Human foods
  - Animal foods
- Issue regulation on intentional contamination
- Issue regulation on sanitary transportation of food
- Publish list of high risk food for record keeping purposes

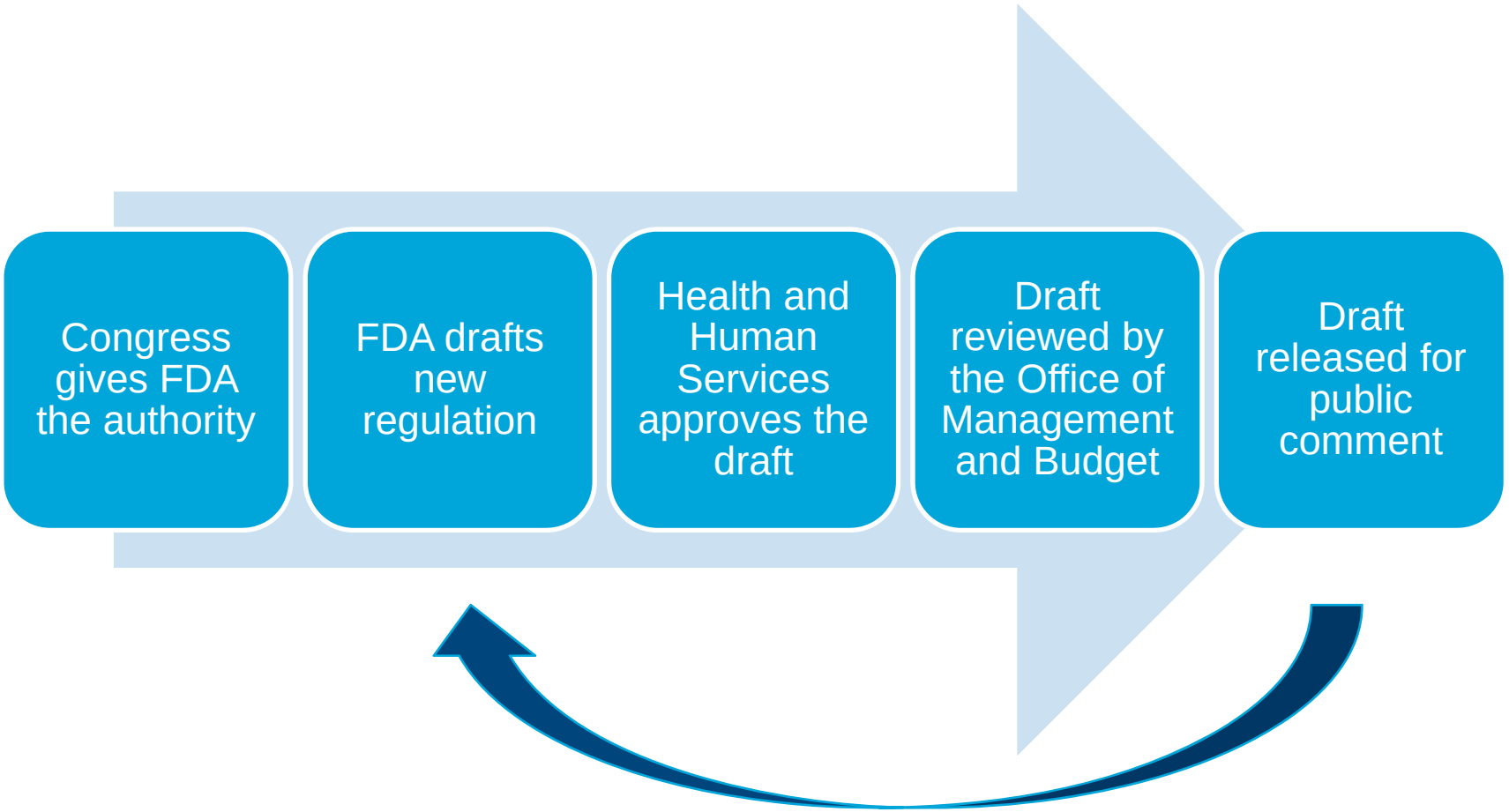
Import requirements

- Publish guidance and regulation for Foreign Supplier Verification Program
- Publish guidance on Voluntary Qualified Importer Program (effective July)
- Develop model standards for third party auditors
- Issue regulations for third party auditors around conflicts of interest

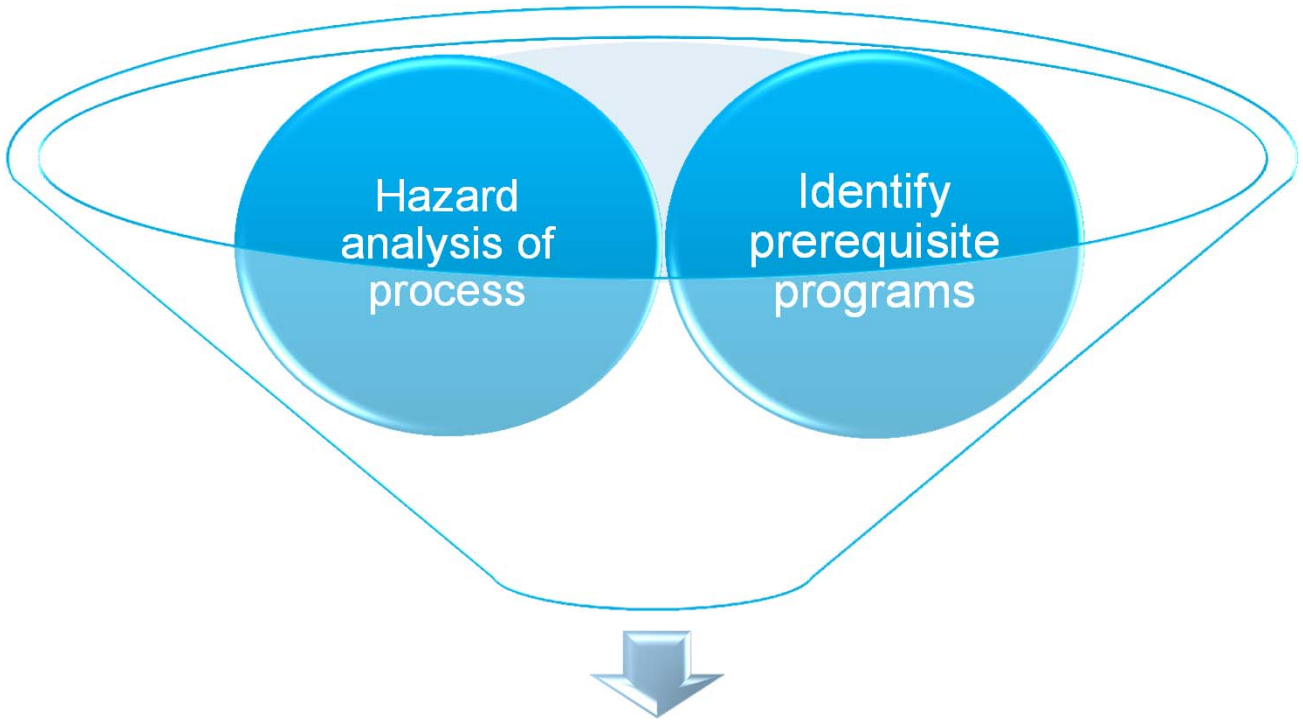
Produce Controls

- Issue proposed rule on standards for produce safety
- Publish updated good agriculture practices

Rule Making Process



Preventive Controls and the Food Safety Plan



Food Safety Plan

Implementation

The Food Safety Plan

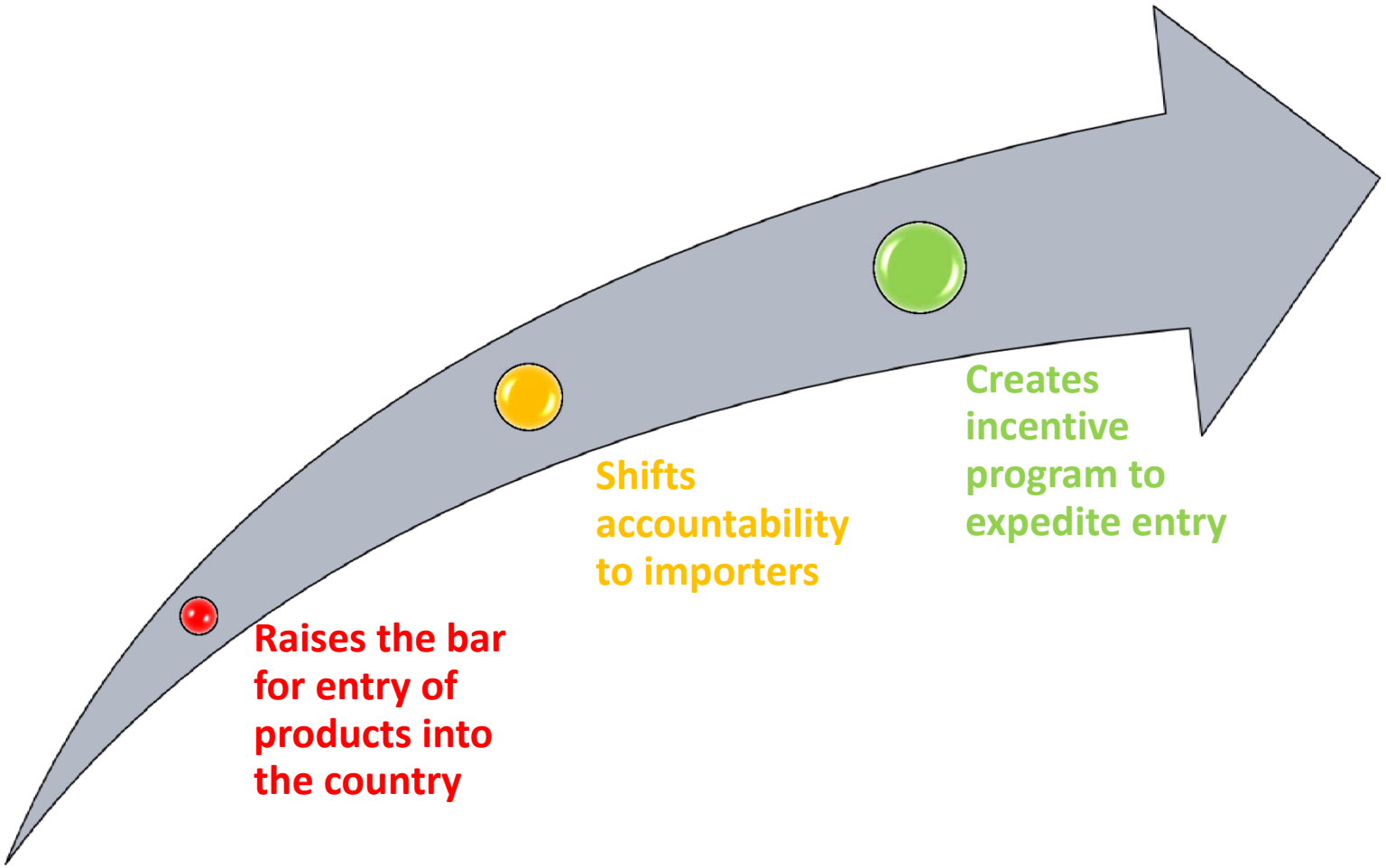
Intentional Contamination

Hazard Analysis	Prerequisite Programs
• Biological • Chemical • Physical • Radiological • Natural toxins • Pesticides • Drug residues • Decomposition • Parasites • Allergens • Unapproved food or color additives	• Personnel • Plant and Grounds • Sanitary Operations (SSOPs) • Sanitary Facilities and Controls • Equipment • Production and process controls • Warehousing and distribution • Allergen controls • Environmental monitoring • Product recalls • Supplier control • Product tracking • Customer Complaint System

Food Safety Plan

Implementing The Food Safety Plan

Importation



Focus on Imports

- Certification for high risk foods
- Foreign supplier verification program
- Voluntary qualified importer program
- Third party certification
- Authority to deny entry

Certification for High Risk Foods

Impact

FDA has the authority to require that high-risk imported foods be accompanied by a credible third party certification or other assurance of compliance as a condition of entry into the U.S.

Entry of product into the United States may be delayed until certification is obtained.

Timeline

Upon enactment

Foreign Supplier Verification Program

Who is Impacted

- Importers – as defined:
  - The U.S. owner or consignee of the article of food at the time of entry of such article into the United States; or
  - In the case when there is no U.S. owner or consignee:
  - The U.S. agent or representative of a foreign owner or consignee at the time of entry into the U.S.

- Foreign suppliers
  - Registered firms
  - Growers subject to the new produce regulations

Timeline

Regulation with Guidance – January 2012

Effective Date January 2013

Foreign Supplier Verification Program

How are importers Impacted

- Provide assurances that each foreign supplier produces food in compliance with current and new regulatory requirements
  - 418 (Risk based preventive controls)
  - 419 (Standards for produce safety)
  - 402 (Adulterated food)
  - 403w (Misbranded food)
- Verify that food imported into the U.S. is as safe as food produced and sold domestically.
- Lot by lot certification of compliance
- Annual on site inspections
- Checking of HACCP and risk based preventive control plan
- Periodically sampling and testing shipment

Third Party Certification

Impact

- FDA must establish a program to recognize accreditation bodies and third-party auditors.
- Third-parties can be a foreign government or a private entity.
- Third-party audit certifications will be used to ensure that the product offered for import is in compliance with U.S. laws and regulations and to determine if a facility is eligible to offer food for import under the voluntary qualified importer program (VQIP)
- FDA will have to develop a program to recognize accreditation bodies

Timeline

- Develop model standards – July 2012
- Issue Regulations around conflicts of interest – July 2012
- Recognize accreditation bodies - January 2013

Working with Foreign Governments

Impact

- FDA established foreign offices
  - China
  - India
  - Middle East
  - Europe
  - South/central America
- Build capacity with foreign governments – expand technical, scientific and regulatory capacity of foreign governments
- Determine how and which foreign governments can provide third party certificates

Timeline

- Building Capacity – January 2013

Voluntary Qualified Importer Program

Impact

- Provide importers who are “doing things right” to have an expedited entry process for imported foods.
- FDA is required to establish a program that would provide expedited review of food from importers who participate in the voluntary program and import food from facilities that have been certified by a third party auditor.
- Specific requirements for participation will be outlined in a FDA guidance document.
- To be eligible for expedited entry, importers will need to apply to the program and pay a fee to cover the administrative costs of participation.
- Importers can use third-party auditors to verify the facilities are producing food are in compliance with U.S. laws and regulations. At a minimum, the combination of a qualified importer and product from a certified facility will be necessary to expedite entry.

Timeline

- Publish guidance – January 2012
- Establish program – July 2012

Authority to Deny Entry

Impact

- Refuse entry to the U.S. if there is a refusal to allow entry of U.S. inspectors
  - Factory
  - Warehouse
  - Other establishment

Timeline

Upon enactment

Laboratory Accreditation for Regulatory Testing

Impact

- FDA must develop a program for laboratory accreditation.
- The program will have model standards that include sampling and analytical procedures, internal quality systems and training for individuals conducting sampling and analysis.
- Both domestic and foreign laboratories are eligible for participation and both must meet the model standards.
- importers will be required to disclose to FDA if the food offered for import was refused by any other county as part of the prior notice requirements.

Timeline

- Establish a program for accredited laboratories – January 2012
- Implementation – July 2013

Inspection and Compliance

- **Increased Frequency of Mandatory Inspections by U.S. FDA** *[Upon Enactment]*
  - U.S. FDA must target inspection resources based on risk
  - High Risk
    - Within 5 yrs
    - Every 3 yrs after that
  - Low Risk (non high risk
    - Within 7 yrs
    - Every 5 yrs after that
  - U.S. FDA may use other federal agencies, private third-party certification bodies and agreements with foreign governments to perform inspections
  - Firms that refuse inspection may be denied authority to import into the United States

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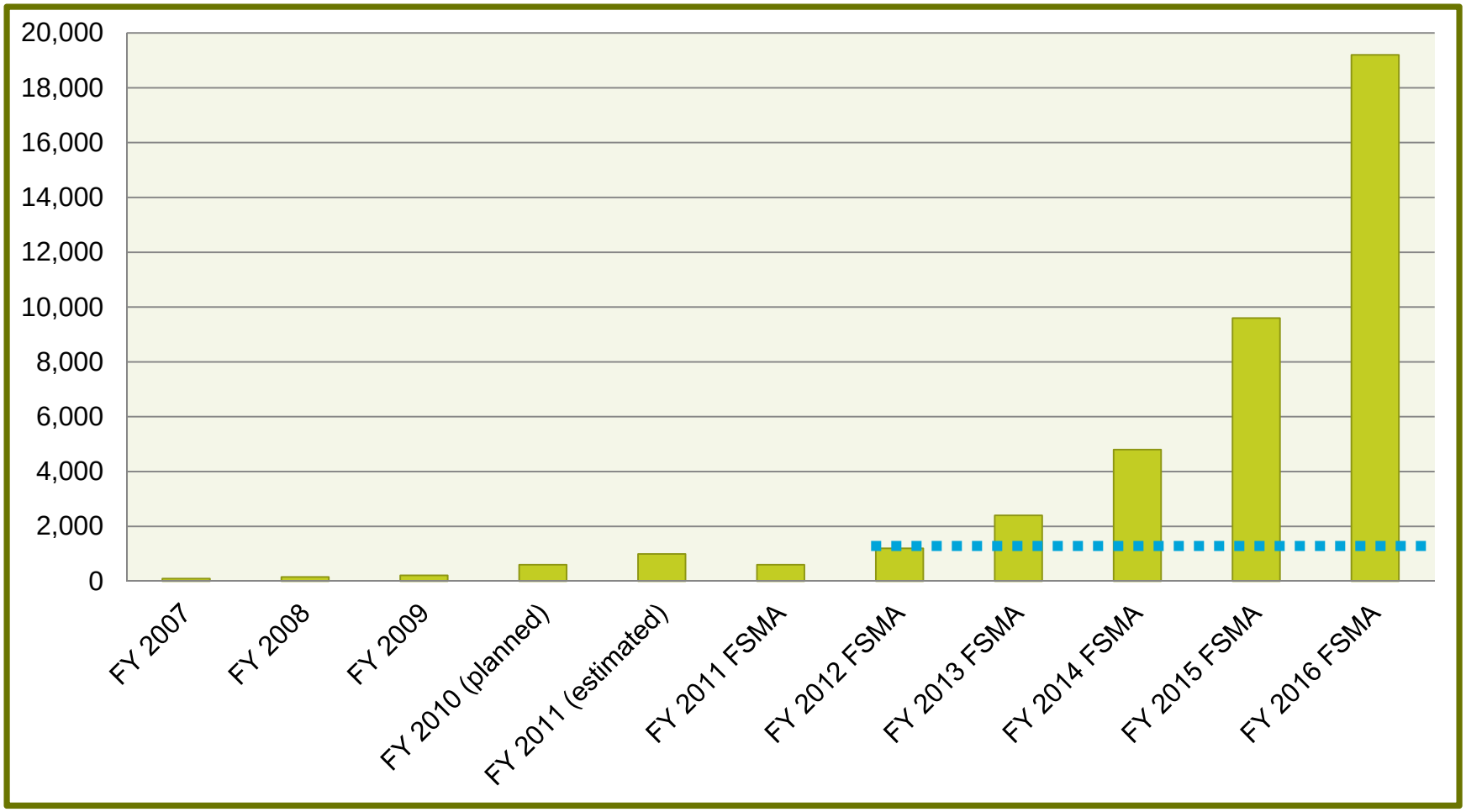
Increase in Inspections of Foreign Food Producers by U.S. FDA



Funding

•Implementation costs for FSMA estimated $1.2-1.5b

• 2012 - Small increase for FDA ($50m)

• 2013 – President request for FDA foods - $253m

- $240m from user fees
- $220m from registration fees

FSMA User Fees: The Cost of Non-Compliance

- **Reinspection**

  The party that receives the recall order (responsible party for a domestic facility or an importer).

- **Recalls**

  The party that receives the recall order (responsible party for a domestic facility or an importer).

- **Import Reinspection/Examination**

  The fee will depend on the number of hours spent directly on the import reinspection or examination, which includes reviewing documentation submitted by the importer.

$224	**$335**
FSMA Fee hourly rate if no foreign travel is required	FSMA Fee hourly rate if foreign travel is required

Three Critical Elements

Summary

- Greater focus on prevention
- Increased responsibility on importers to assure compliance
- More enforcement actions
- New concerns that impact brand
  - Media
  - Consumers
- FSMA big changes coming

Staying In Front

- Stay informed
- Take advantage of what we know today
- Prepare
- Plan and Prioritize

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