

Changes, Risks, and Trends in the Food Marketplace: *Focus on Food Safety*

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Outline

- A New Era of Food Safety
- Consequences
- Food Safety Legislation
- Product Tracking



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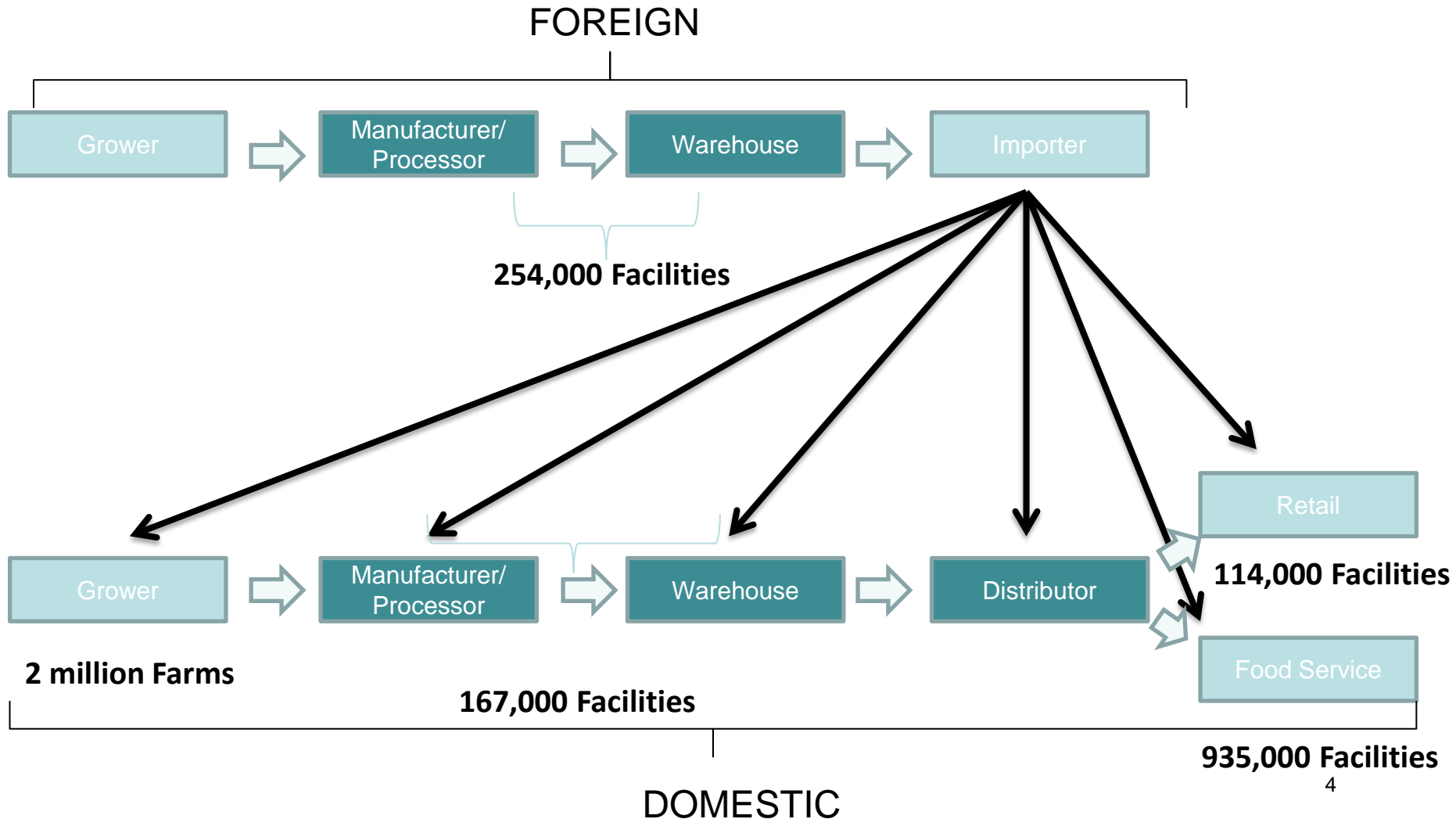
The Changing Food-Safety Landscape in the U.S.

- Global food supply
- Changing science
- Consumer expectations
- Media influence



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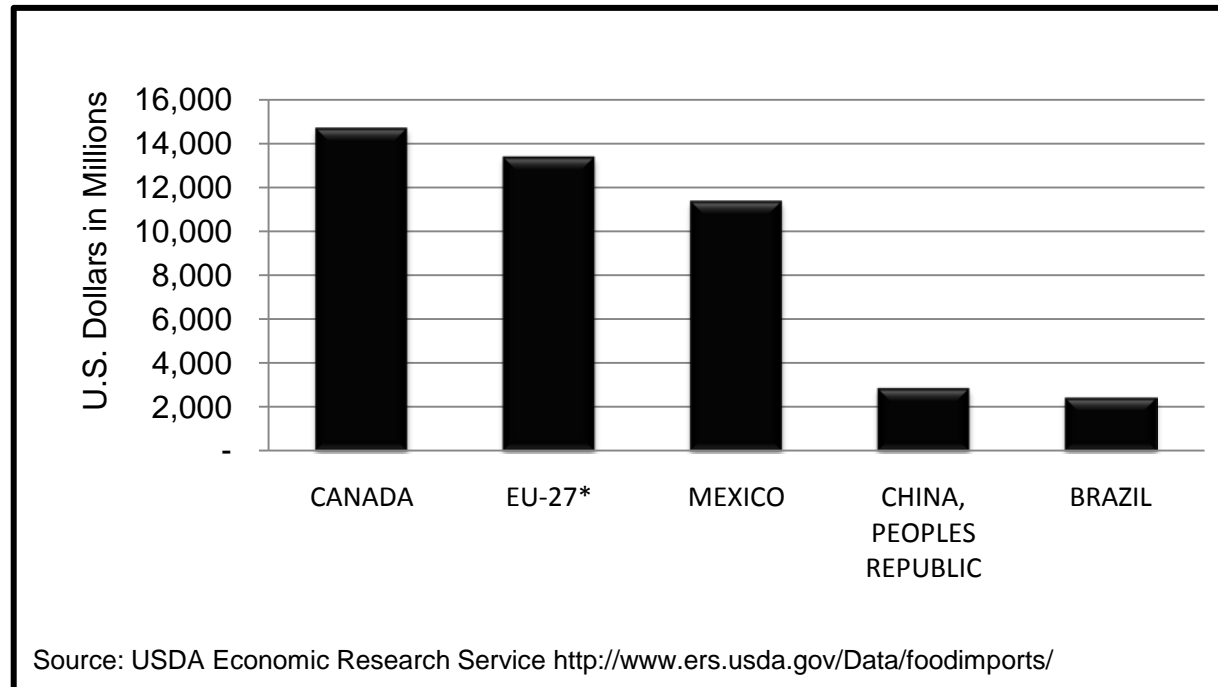
The Global U.S. Food Supply



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The Global United States Food Supply

- Global sourcing of foods and ingredients
- Imports account for 15% of U.S. food supply
 - Over 75% of seafood
 - Over 60% fresh produce
- Volume of imported food has increased dramatically over the last 10 years and will continue to rise



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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



10 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

Pot pies

Dog Food

Hot peppers

White pepper

Raw cookie dough

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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
- European-style “Chemophobia”
- Consumers have the ability to damage a brand



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

- The U.S. media, especially television, has changed:
 - Faster
 - 24-hour news cycle
 - Focused on health and food
 - Looks to blame
 - Variation in bias and selective reporting
- Social media gives individual citizens a mechanism to broadly report food-related illness and destroy a brand.



- Yet, American media still retains a vast capacity to educate.

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Aggressive and Swift Enforcement Actions by U.S. Government

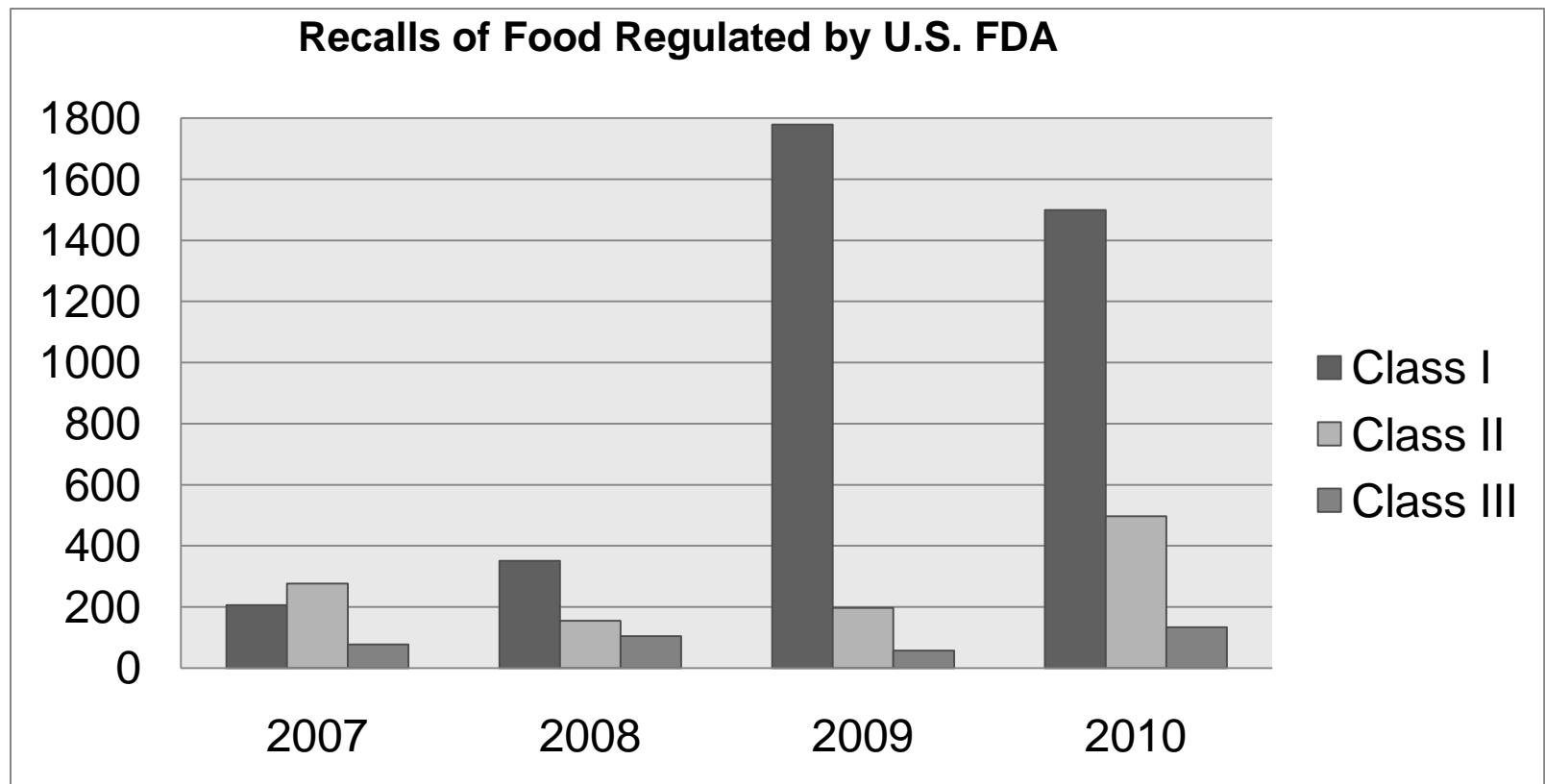
- U.S. regulatory agencies are cracking down on unsafe food and fraudulent claims (Federal Trade Commission, Occupational Safety and Health Administration, United States Department of Agriculture).
- August 2009: U.S. FDA announced significant changes to enforcement posture.
- These changes will result in faster, more frequent enforcement actions.

“Companies must have a realistic expectation that if they are crossing the line, they will be caught, and that if they fail to act, we will”

- U.S. FDA Commissioner Margaret Hamburg (8/6/09)

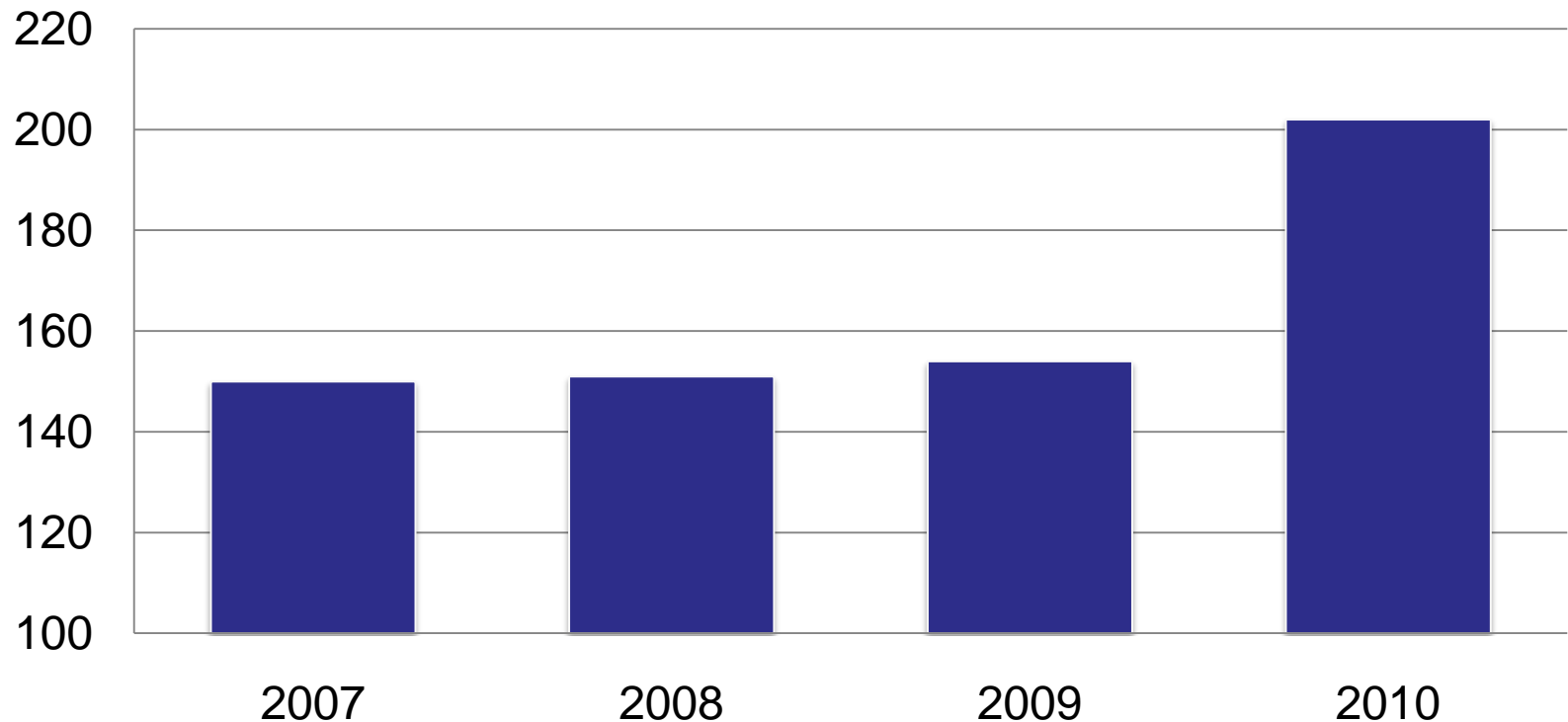
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More Recalls of Food in the United States



Increased Number of Warning Letters

Warning Letters Issued by U.S. FDA



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
- Provisions covering:
 - Prevention
 - Inspection and Compliance
 - Response
 - Imports
 - Enhanced Partnerships

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Whom does the new law affect?

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

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New Requirements: Prevention

- ▶ **Mandatory Preventive Controls for Registered Food Facilities** *[Final Rule July 2012]*
 - Hazard Analysis and Critical Control Points (HACCP or “HACCP like”)**
 - Focus on biological, chemical, physical, and radiological hazards
 - Hazards can occur naturally, be unintentionally introduced, or be intentionally introduced
 - Producers must identify specific preventive controls for critical control points
 - **Other Prevention Elements/Prerequisite Programs (SSOPs, GMPs, etc.)**
 - Sanitation procedures
 - Training in hygiene for supervisors, managers, and employees
 - Environmental monitoring
 - Allergen control
 - GMPs
 - Recall plans
 - Supplier-verification activities
- ▶ **Mandatory Produce Safety Standards (GAPs)** *[ANPR January 2012; Final Rule target early 2013]*
- ▶ **Authority to Prevent Intentional Contamination** *[Final Rule July 2012]*
 - Mitigation strategies at specific vulnerable points in the food supply chain

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New Requirements: Inspection and Compliance

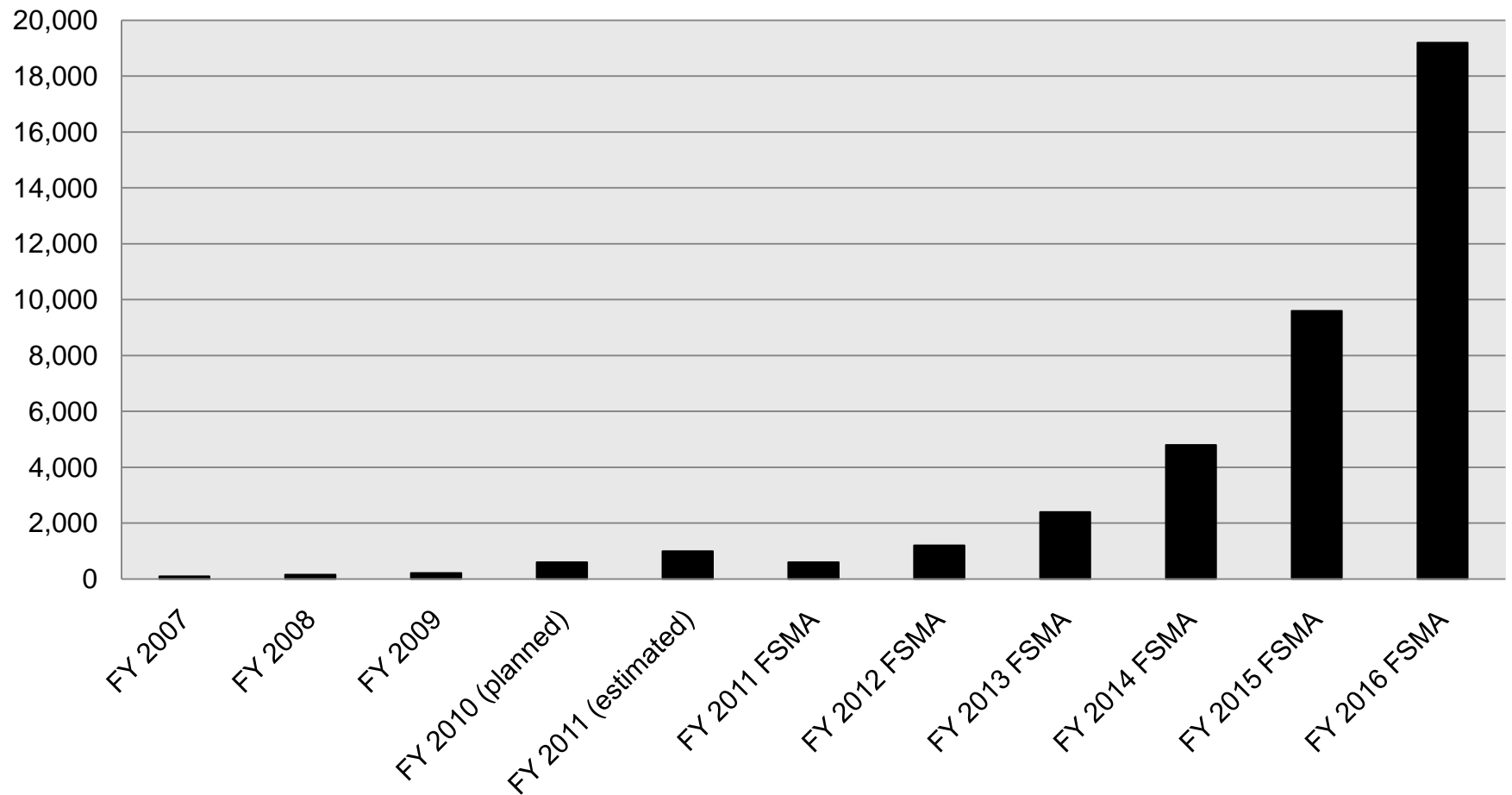
- ▶ **Increased Frequency of Mandatory Inspections by U.S. FDA** [*Frequency to Increase Immediately*]
 - U.S. FDA must target inspection resources based on risk;
 - U.S. FDA may use other federal agencies, private third-party certification bodies and agreements with foreign governments to perform inspections;
 - Firms that refuse inspection may be denied authority to import into the United States.

- ▶ **Records Access** [*Upon Enactment*]
 - If U.S. FDA has a reasonable belief an article of food will cause severe adverse health consequences, a facility must provide U.S. FDA access to all records: 1) Relating to that article of food; and 2) Relating to any other article of food that might have been affected in a similar manner.
 - Under preventive controls provision: Upon request, FDA to promptly have access to facility food safety plans and related records documenting implementation of their plans.

- ▶ **Testing by Accredited Laboratories** [*Establish Accreditation Program by January 2013*]
 - Certain food testing must be carried out by accredited labs. Law directs FDA to establish a program for laboratory accreditation to ensure laboratories meet high quality standards.

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



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New Requirements: Response

- ▶ **Mandatory Recall** [*Upon Enactment*]
 - Provides FDA with authority to issue a mandatory recall when company fails to voluntarily recall unsafe food after being asked to by FDA.
- ▶ **Expanded Administrative Detention** [*Interim Final Rule July 2011*]
 - Provides FDA with a more flexible standard for detaining products at the border.
- ▶ **Suspension of Registration** [*Effective July 2011*]
 - FDA can suspend registration at a facility if determination is made that the food poses a reasonable probability of serious adverse health consequences or death.
 - While on suspension, facility is prohibited from distributing food.

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New Requirements: Importers

- ▶ **Foreign Supplier Verification Program** *[Final Rule January 2012]*
 - Importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe (not adulterated or misbranded, and have been produced in accordance with U.S. laws and regulations).
- ▶ **Third Party Certification** *[Program to Recognize Accreditation Bodies by January 2013]*
 - Qualified public and private third parties can certify that foreign food facilities comply with U.S. food safety standards.
- ▶ **Certification for High Risk Foods** *[Upon Enactment]*
 - 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.
- ▶ **Voluntary Qualified Importer Program** *[Program Implementation Due by July 2012]*
 - FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities.
- ▶ **Authority to Deny Entry** *[Upon Enactment]*
 - FDA can deny entry into the U.S. of food from a foreign facility if FDA is denied access by the facility or the country in which the facility is located.

New Requirements: Enhanced Partnerships

- ▶ **State and Local Capacity Building** *[By January 2012 Conduct Review]*
 - FDA to develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies.
 - ▶ **Foreign Capacity Building** *[By January 2013 Comprehensive Plan]*
 - FDA to develop a comprehensive plan to expand the capacity of foreign governments and their industries.
 - ▶ **Reliance of Inspections by Other Agencies** *[Upon Enactment]*
 - The Agency is authorized to rely on inspections of other Federal, State, and local agencies to meet its increased inspection mandate for domestic facilities. FSMA also allows interagency agreements to leverage inspectional resources with respect to inspection of seafood facilities domestic or foreign as well as seafood imports.
- Additional partnerships are required to develop and implement a national agriculture and food defense strategy, to establish and integrated consortium of laboratory networks and improve food borne illness surveillance.

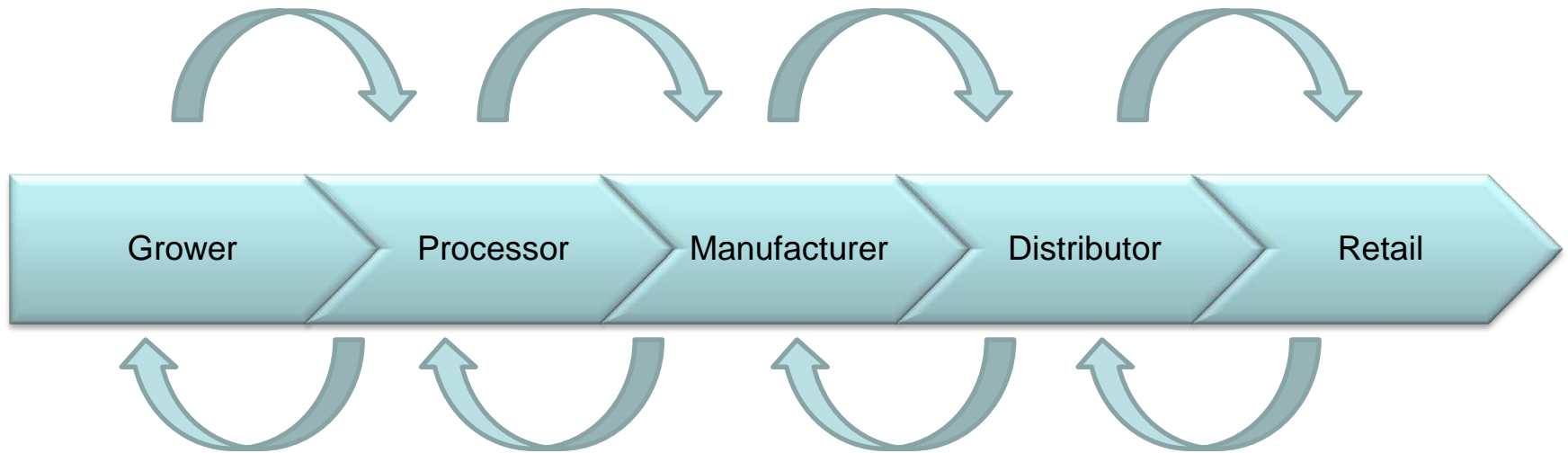
New Requirements: Traceability

- What are the challenges
- What are the drivers for new requirements
- What is required in the legislation
- What do regulators want
- How to stay ahead of new requirements

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The Supply Chain

Trace Forward



Trace Back

Challenges

- The complexity
 - Distribution systems – broad and fast
- Supply chain unknowns
 - Suppliers - suppliers
 - Brokers sources
- Inconsistent record keeping
 - Extent of records
 - Electronic v paper
- Changing names of products
- Different systems of tracking
- Repacking of products

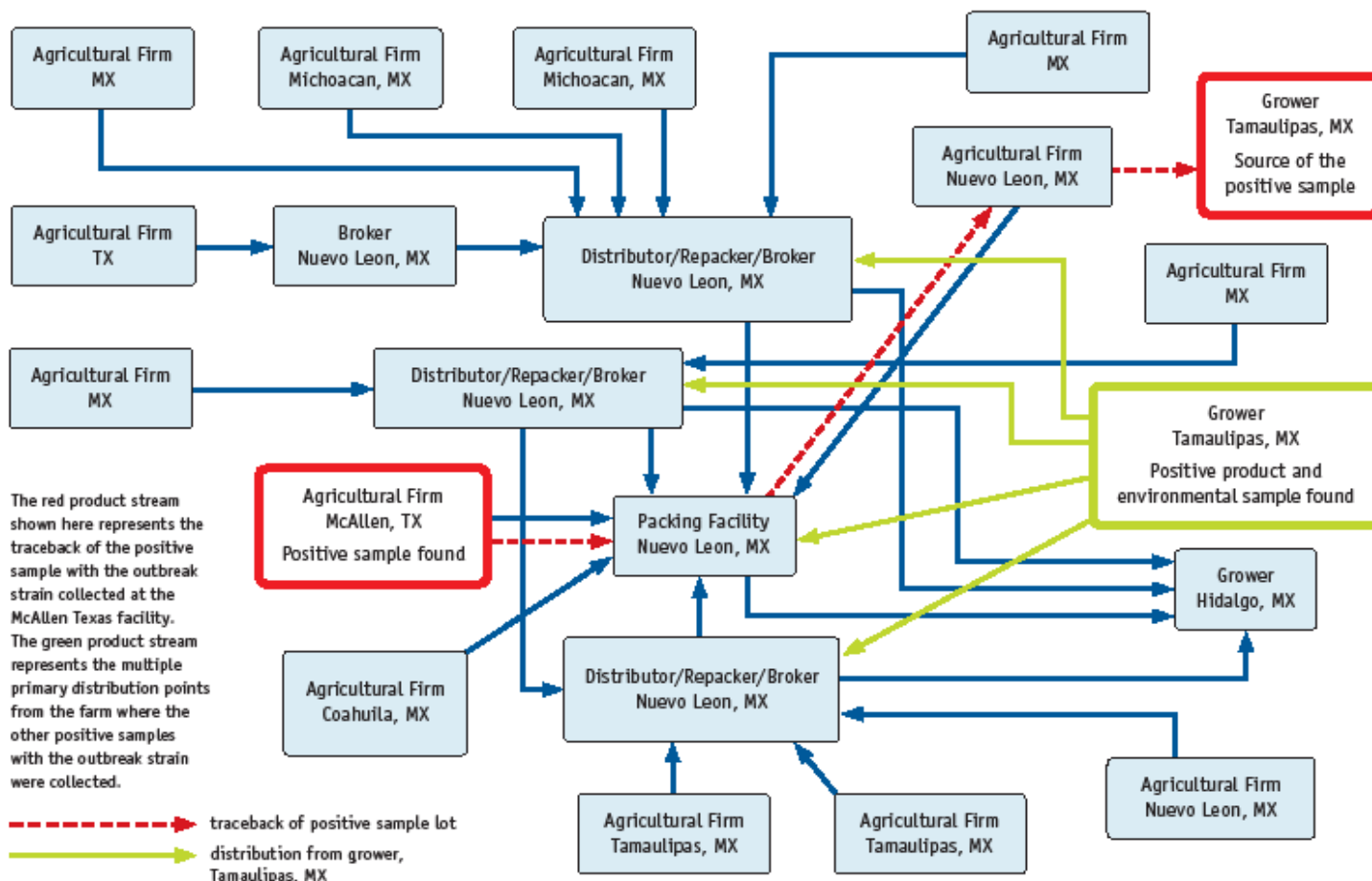
Drivers for Change

- Inability for regulators to determine where food is moving in the supply chain
 - Salmonella Saintpaul 2008
 - Peanut products 2009
 - Melamine in Wheat gluten 2007
- Not able to narrow the scope quickly
 - Consumer exposure continues
 - Industry “damage” remains broad
- Industry unhappy about breadth of message

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Salmonella Saintpaul Outbreak Traceback & Distribution

Partial view of the traceback & distribution of peppers from Mexico: July 16 – July 22, 2008



What does the new law require?

- Pilot Programs:
 - Within 9 months, FDA must develop pilots with the processed food sector and produce industry
 - Demonstrate how track and trace would work for small businesses
 - Demonstrate technologies to inform promulgation of regulations
 - Within 18 months, FDA must provide a report to Congress on recommendations for establishing more effective product tracing, including consideration of:
 - Costs and benefits
 - Feasibility of technologies for different sectors
 - Existing practices and international efforts

What does the new law require?

- Establishment of a product tracing system
- Prior notice of rule making within 2 years to establish recordkeeping requirements for high-risk foods
- Requirements for Regulation:
 - Relate only to information that is reasonably available
 - Consider cost and public health benefit
 - Be scale-appropriate and similar across commodities
 - Should not prescribe specific technologies, require a full pedigree, require a record of recipient of food beyond the immediate subsequent recipient, or product tracking to the case level

What does the new law require?

- FDA to define high-risk products within 1 year based on:
 - Known safety risks of a particular food;
 - Likelihood of microbiological or chemical contamination;
 - Point in manufacturing process where contamination is likely to occur and steps taken to reduce the possibility of contamination;
 - Likelihood consuming the food will result in foodborne illness; and
 - Likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food

What do the Regulators Want?

- Consistency
- Speed
- Full supply chain coverage
- Electronic records
- Interoperable systems
 - Can be multiple so long as they “talk to each other”
- Coverage of imports and domestic
- Industry to develop the tools
- Industry to pay for it

How to be an industry leader

- Start with higher risk foods
- Focus on speed and interoperability
- Develop systems that can clear brands, products or food categories
 - Early query of the system when multiple possible sources
 - During outbreaks to exclude sections of the supply chain
- Avoid “rolling recalls”
- Systems that directly inform consumers

Conclusions

- Requirements for product tracking will change
- Opportunities to provide input to FDA
- New regulations will likely emerge
- Regulators and Congress will not accept the status quo
- Product tracking should be viewed as a food safety tool
- Tracking systems need work
 - Determine the ROI
 - Develop cost effective tools
- Engage with the regulators

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Strategies

- Stay in front of the shifting landscape:
 - Understand the dynamics of the U.S.-specific and global food-safety landscape;
 - Understand and address your own risks and vulnerabilities;
 - Assess your own internal system for continual process improvement.
- Respond to the needs of regulators:
 - Understand the U.S. regulatory system and strategy
 - Anticipate and respond to new regulations and guidance
 - Engage with regulators proactively in the event of a problem

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Thank You

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