The Food Safety Modernization Act

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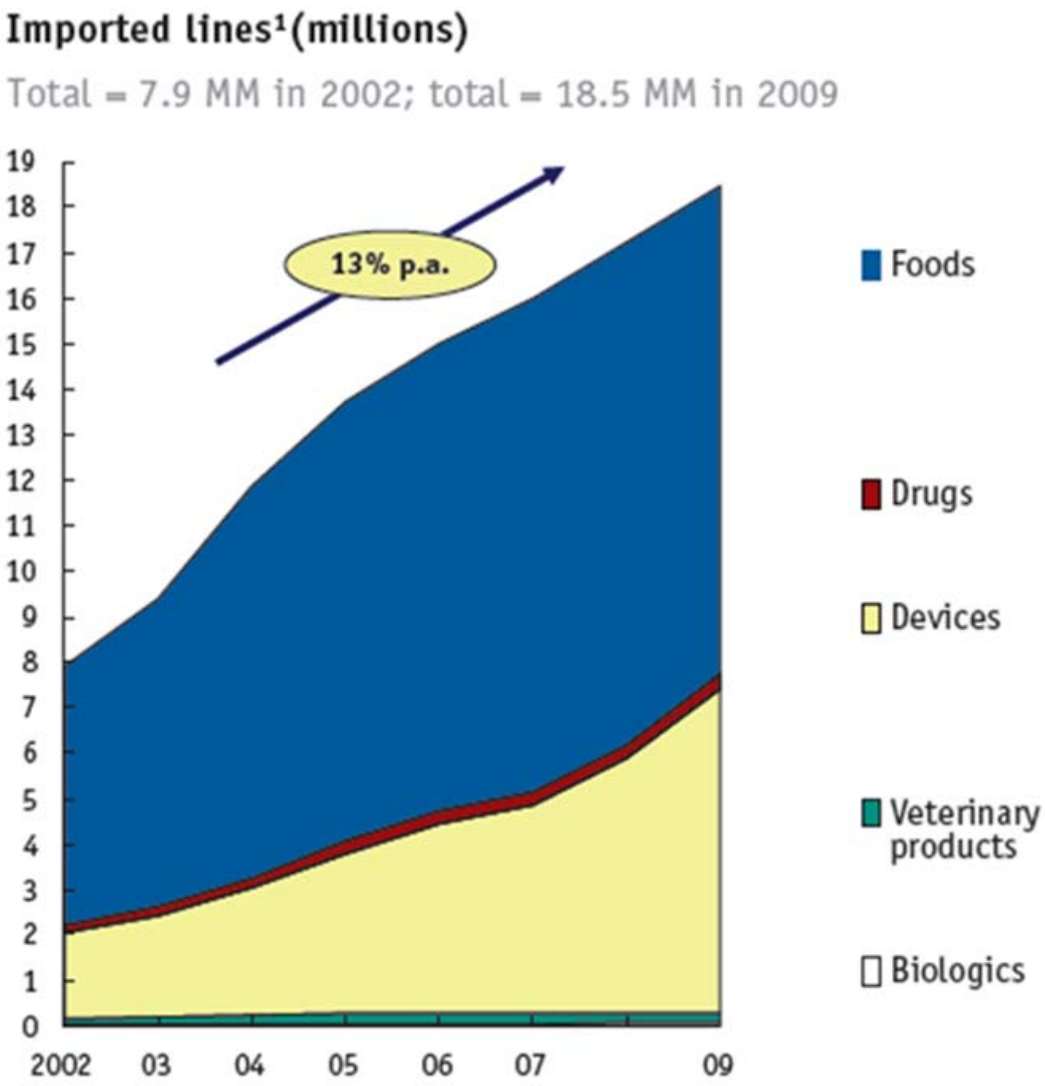
Outline

- Changing landscape
- Key provisions
- Impacts on the food industry
- How to prepare

The Changing Food-Safety Landscape

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

Import shipments of FDA-regulated products continue to rise



Consequences for Industry

- Damage to Brands
- Additional regulatory oversight:
  - More Recalls
  - More Warning Letters
  - Greater Use of Import Alerts
- Additional regulatory oversight and authority
  - Food Safety Modernization Act

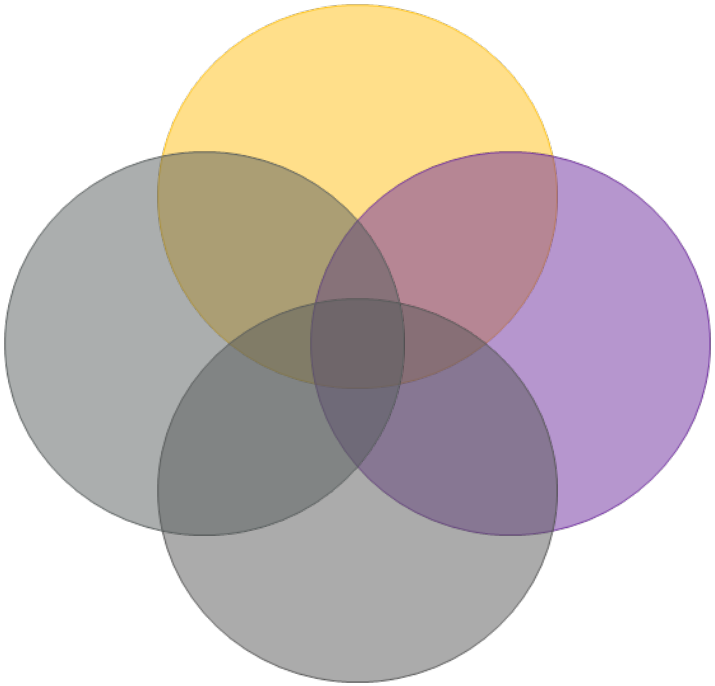
Food Safety Modernization Act

- Signed into law on January 4, 2011
- Biggest changes since 1938
- Law reflects risk-based global systems approach

Food Safety Modernization Act

Prevention

Enhanced Partnerships



Inspections, Compliance, and Response

Import Safety

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
- Effectively shuts down the facility

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

Proposed Preventive Control Rules

- **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
- **Compliance**: 1-3 years after final rule is published

Who is Covered

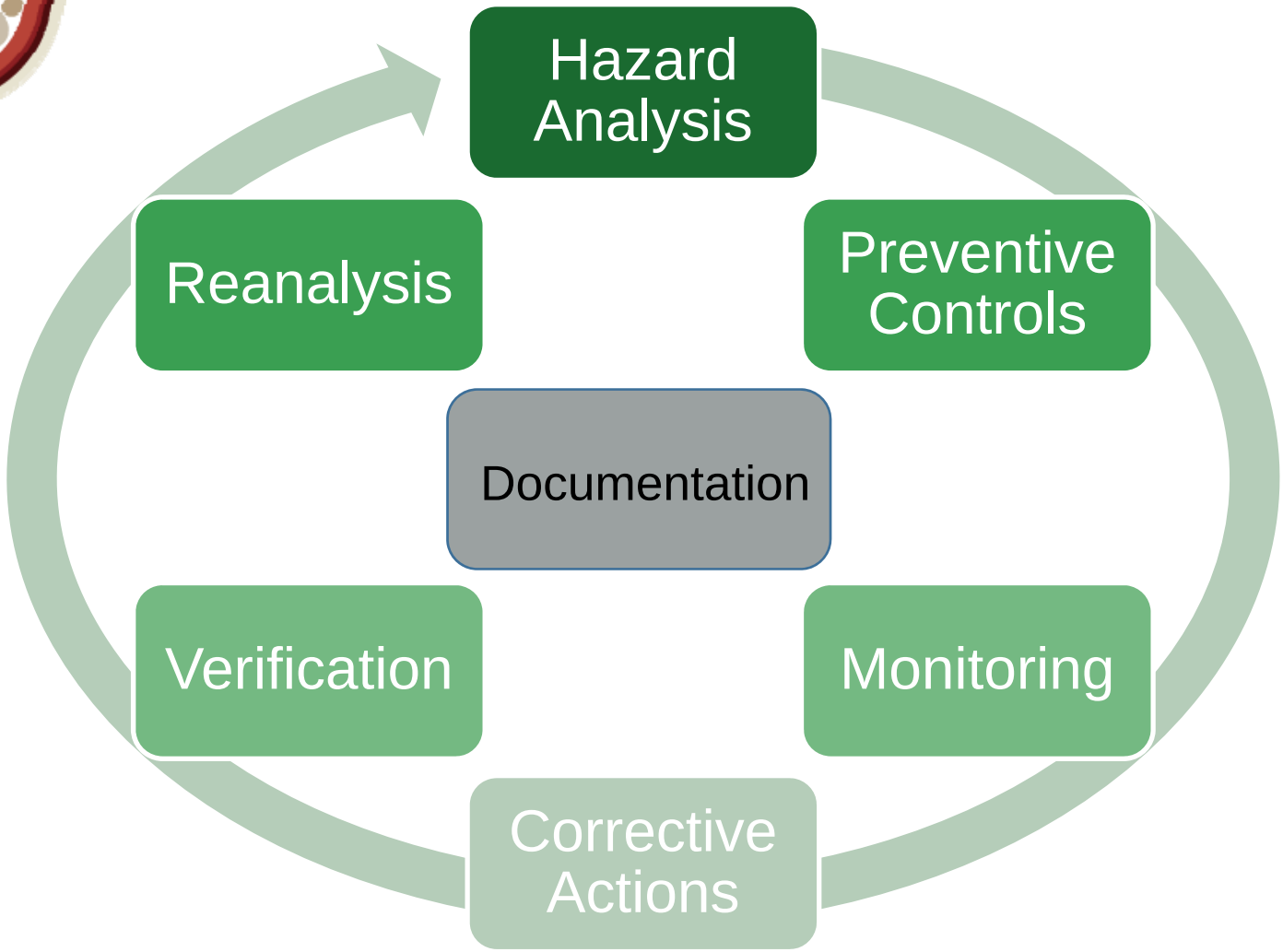
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act

- Facilities that manufacture, process, pack or hold human food
- Applies to domestic and imported food
- Various exemptions

Exemptions

- Juice and Seafood HACCP programs
- Farms
- Low acid canned food for Botulism
- Dietary supplement manufactures
- Warehouses UNLESS they store fruits and vegetables or other foods that require time/temperature control to control microbial growth
- Related to size of business

The Food Safety Plan



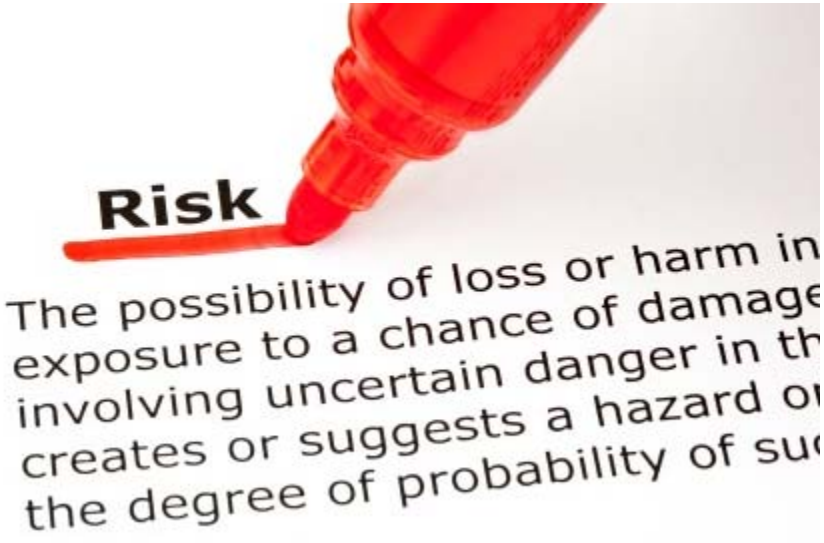
13

Preventive Controls - Hazard Analysis

- Identify all potential hazards associated with each type of food manufactured
- Must consider biological, chemical, physical and radiological
- Does not include intentional
- Determine if each hazard is reasonably likely to occur including
  - Severity of the illness
  - Foreseeable use of the food
- If hazard is reasonably likely
  - Identify and implement preventive controls
    - Process controls
    - Environmental controls
    - Allergen controls
  - Must be sufficient to assure food is not adulterated under the FD&C Act

Preventive Controls - Hazard Analysis

- Identify parameters needed to control hazard – this is not necessarily the same as a CCP
- Controls must be proven effective
  - Published studies
  - Independent scientifically valid study
- Recall plan may be a necessary preventive control



Monitoring

- Establish and implement written procedures to monitor each preventive control
  - To provide an early warning
  - Correct a deviation before it becomes problem
  - Allows for corrective actions
- Frequent enough to provide assurances that the preventive control is being consistently performed (may be continuous monitoring)
- Must keep written record of monitoring activity
  - Observations and specific measurements
  - Not just a checklist
- If there is no verification the preventive control did not happen

Corrective Action Requirements

- Establish and implement written corrective action procedures
- When monitoring activity detects a deviation the facility must take corrective action and document
- Corrective action must ensure all food affected by the deviation has been evaluated for safety
- All food affected by the deviation is assumed adulterated or misbranded until proved otherwise

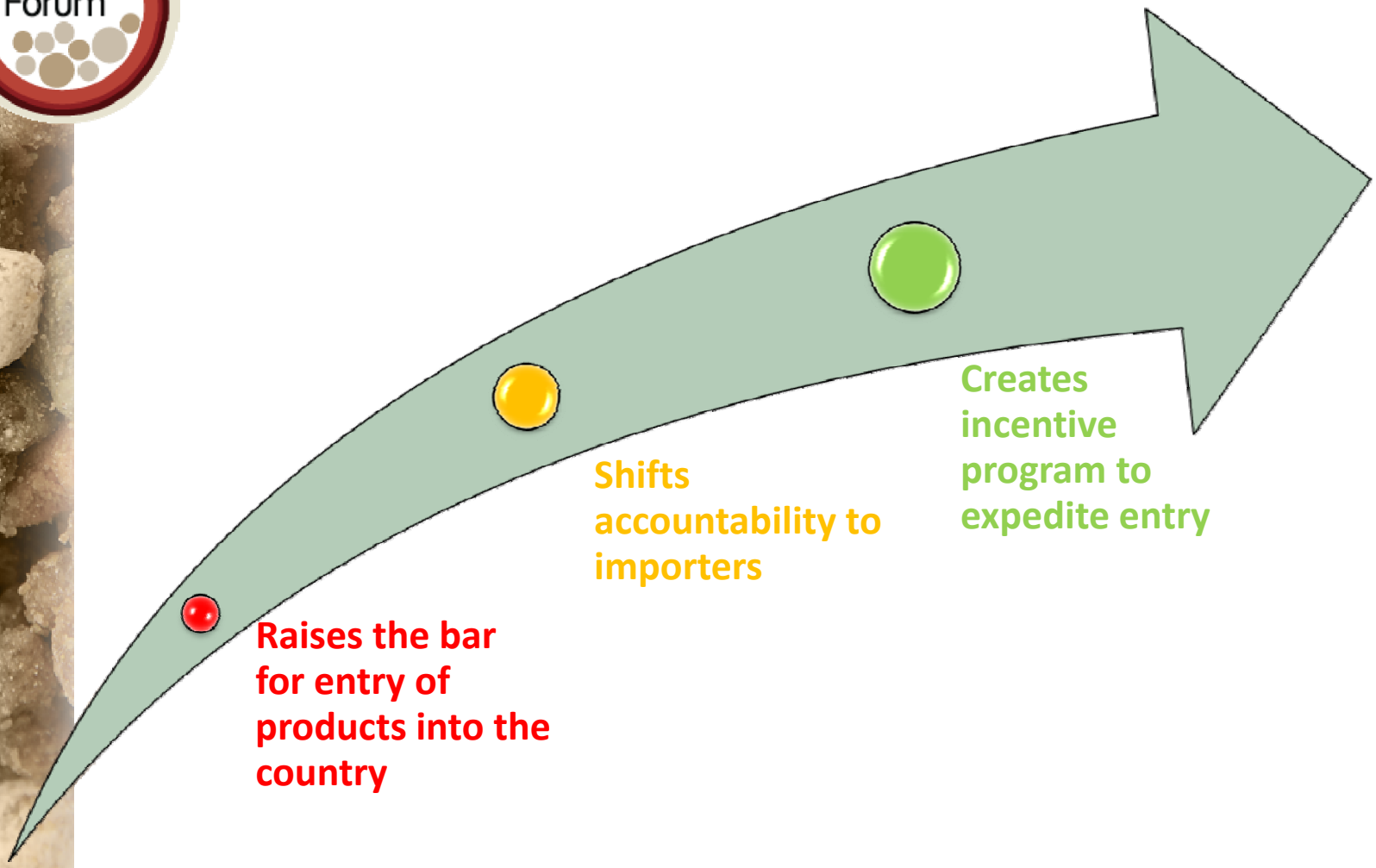
Verification Requirements

- Validation of the adequacy of preventive controls
- Verification of the implementation of the controls
- Preventive controls must be validated by a qualified individual
- Verification must include ensuring monitoring records are completed, deviations recorded and corrective actions undertaken
- All verification activity must be documented

Record Keeping Requirements

- Must be made concurrently with the activity
- Must contain the actual values and observations
- May be paper or electronic (subject to 21 CFR Part 11)
- Must be maintained for 2 years
- Six months worth of records must be available on site
- All records must be made available to FDA upon request

Stricter Import Requirements



Certification for High Risk Foods

- 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.
  - May be for whole country
  - May be for specific commodities

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 Supplier Verification Program

- **How are importers Impacted**
- Provide assurances that each foreign supplier produces food in compliance with current and new regulatory requirements
  - 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

Voluntary Qualified Importer Program

- 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 VQIP
- There will be “extras” on top of basic requirements
  - Testing
  - Tracking
  - Record keeping
  - Supplier controls
- Third parties will provide certificates to FDA
  - Foreign governments
  - Private third party auditors

Leverage The VQIP System

- Speed of entry is business survival and success
- Understand and use the system
- Take advantage of VQIP
  - Faster entry
  - If stopped expedited testing

Third-party Auditors

- Who
  - Foreign government
  - Agency of a foreign government
  - Any other third party, as the Secretary determines appropriate
  - May be a single individual
  - A third-party auditor may employ or use audit agents to help conduct consultative and regulatory audits

How to Prepare

- Create a FSMA team – per facility approach
- Spend time understanding how the new regulations apply to you
  - Do you qualify for any exemptions
- Assess how far you are from being compliant
  - Gap analysis
  - Review of risk control through HACCP and SOPs
  - Examine environmental program
  - Examine allergen control program
  - Do you have a recall plan

How to Prepare

- Look at your record keeping system
  - Are you capturing the key data to document process control
  - Are you capturing the data in an appropriate way
  - Can technology help to reduce errors, simplify and save cost
- Look at your training program
- Look at how you address corrective actions

The ROI from FSMA Implementation

- Your brand is your biggest asset and your gre risk
- Prevention and preparedness is the best way protect your brand
- Data capture and trending is the key to stayin out in front
- Preventive control of risk
  - Brand protection
  - FSMA Compliance

Summary

- FSMA rules are complex
- Heavy focus on risk
- Broad thinking for preventive controls
- Establish a program in your facility to address FSMA
- Major shift toward documentation

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- Co-sponsored by Leavitt Partners and SafetyChain Software
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32