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FSMA Behind the Scenes

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Outline

- Who are we?
- Changing Landscape
- Food Safety Modernization Act
- Top 5- FSMA for retailers
- FDA Trends
- Discussion

- These slides will be available from FMI

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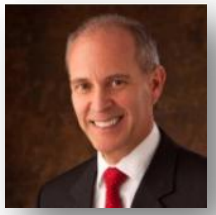
Who are you?

- Retailer, Wholesaler, Other?
- Big, small?
- Manufacturer? Private label?
- Importer?

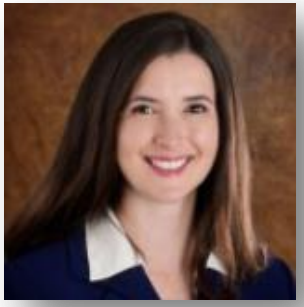
Who am I?

David Acheson, M.D.



- Former Chief Medical Officer, FDA
- Former Associate Commissioner for Foods at FDA; published 2007 Food Safety Plan
- Extensively published, and internationally recognized
- Uses his regulatory insight, food safety knowledge and expertise in crisis response to advise clients around the globe

Jennifer McEntire, Ph.D.



- BS, PhD Food Science (U Delaware and Rutgers)
  - Interned at NFPA (GMA) and FDA CFSAN
- Former Director and Senior Staff Scientist, Institute of Food Technologists (IFT), directed FDA contract work
- Led the FDA Food Safety Modernization Act (FSMA) traceability pilots
- Subcontractor to Deloitte for FDA Preventive Control guidance document contract
- Spokesperson on issues related to food protection, particularly product tracing

Melanie Neumann, JD, MS, Food Safety

- Former in-house and outside food law counsel for multi-national food companies
- Former VP, Crisis Management & General Counsel for RQA, Inc., a global recall consulting firm
- Published author and frequent speaker on recall/crisis management, traceability and food defense

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
- 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 snacks	Hazelnuts	Pot pies	Dog food
Hot peppers	Papayas	White pepper	Raw cookie dough
Pine Nuts			

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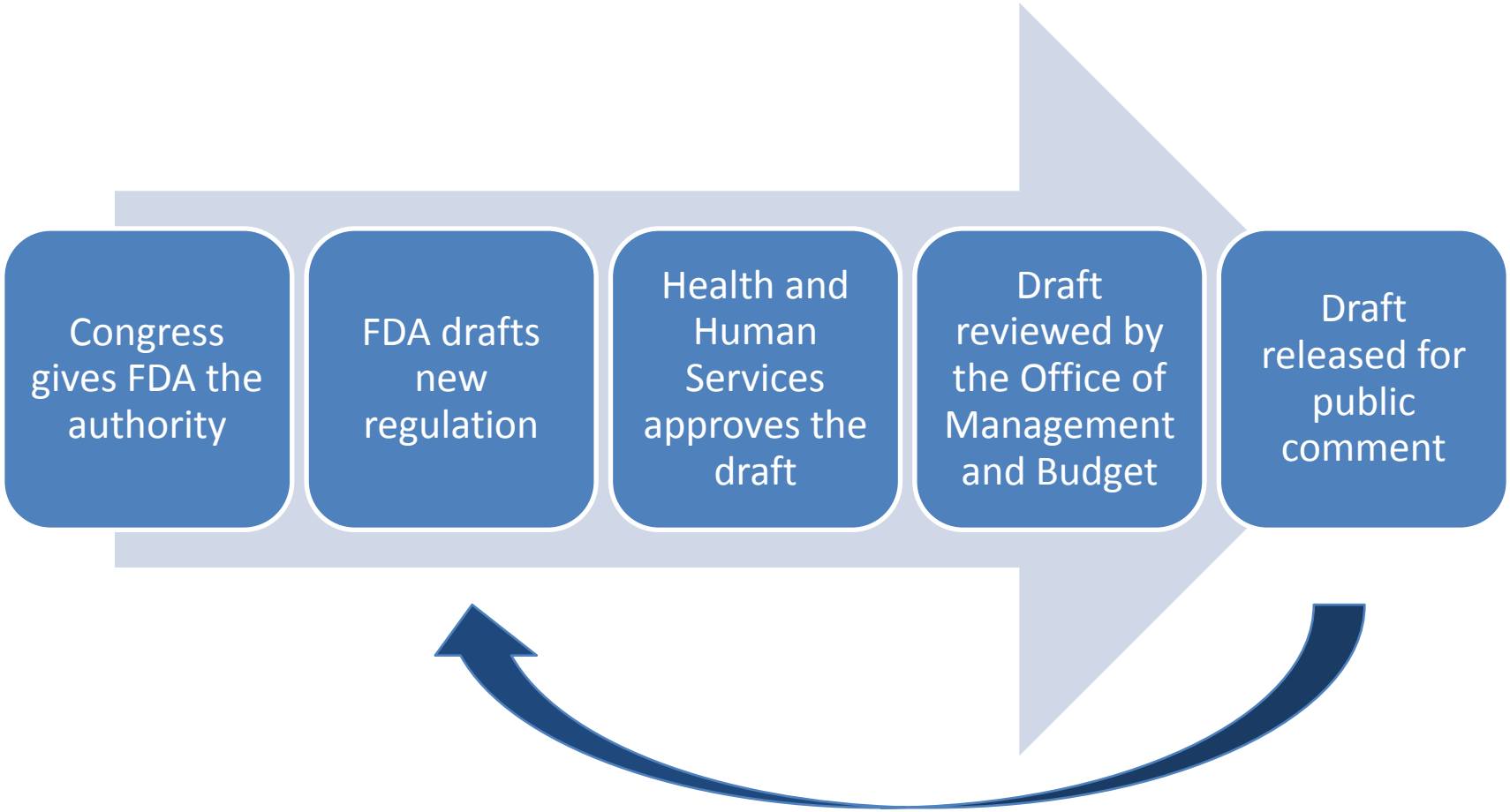
Food Safety Modernization Act

Signed into law on January 4, 2011

Most sweeping overhaul of the food safety system since 1938

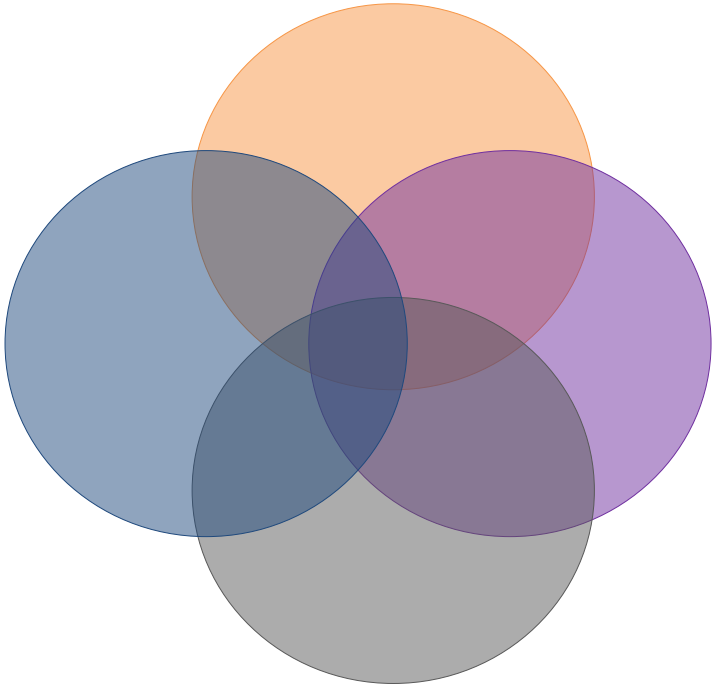
Rule Making Process



Food Safety Modernization Act

Prevention

Enhanced Partnerships



Increased Inspections
Enhanced Response

Import Safety
Apply Domestic Standards to Imported Foods

FSMA Status Summary

- Mandatory recall authority
- Records access
- Administrative detention
- Preventive Controls – human 5/16
- Produce Safety 5/16
- Traceability 7/3
- Preventive Controls-Animal TBD
- FSVP TBD
- 3rd party accreditation TBD
- VQIP- long time

Top 5 FMSA Impacts for Retailers

1. Standardized recall notices
    1. Side note on mandatory recall authority
2. Preventive controls (for manufacturing facilities)
3. Produce safety rule (esp the modified requirements for “local”)
4. Foreign Supplier Verification Program
5. Traceability

Details

1. RECALL

Recall notices

- Only FSMA requirement that speaks directly to retail locations
- Post standardized notice in a conspicuous location

Mandatory Recall

- Offers opportunity for voluntary recall
- FDA can mandate if "a reasonable probability of serious adverse health consequence or death"
- Opportunities for oral hearing/appeal

- Impact on retailers:
  - –Who pays for this?

Details

2. PREVENTIVE CONTROLS- HUMAN

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 Current Good Manufacturing Practices

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
  - Includes private label
  - Includes co-mans
  - Includes DCs*

- Applies to domestic and imported food
- Various exemptions

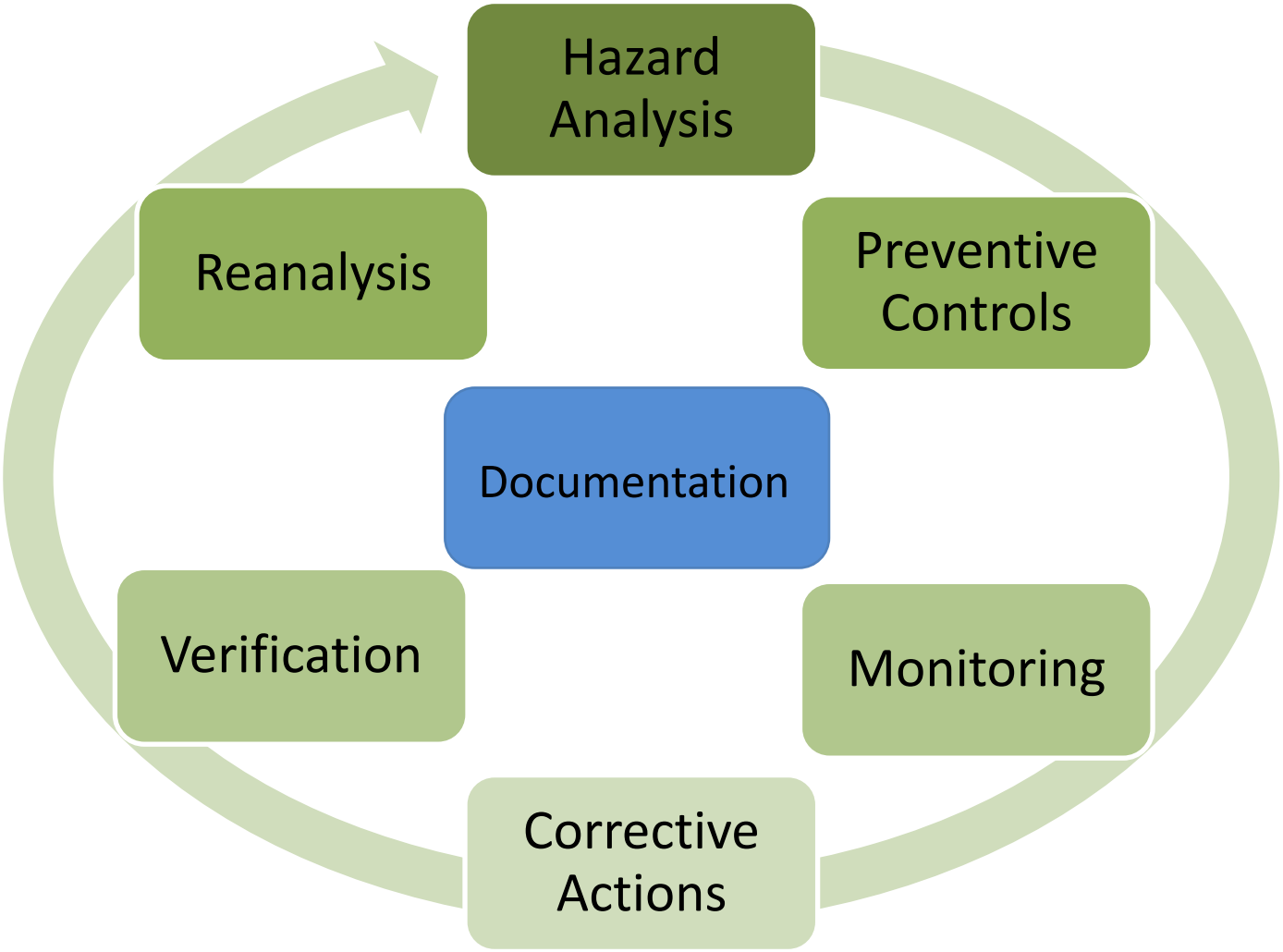
Exemptions

- Juice and Seafood HACCP programs
- Activities within the definition of “farm”
- Low acid canned food for microbiological risk
- Facilities registered with the Treasury Department regarding alcoholic beverages
- Facilities that manufacture, process, hold or pack dietary supplements
- Facilities that store raw agricultural products other than fruits and vegetables
- Modified requirements for Small (<500 employees) and very small businesses (TBD but < $250k, $500k, $1m)

Exemptions

- Facilities solely engaged in the storage of unexposed packaged food unless the food requires time/temperature control to control microbial growth
  - “solely engaged”
  - “unexposed packaged food”
  - “time/temp control” modified requirements

The Food Safety Plan



Importance of a Qualified Individual

"Qualified Individual" to oversee

- The preparation of the food safety plan
- Validation of preventive controls
- Review of records for implementation and effectiveness of preventive controls
- Appropriateness of corrective actions
- Reanalysis of a food safety plan

What is Required

- Hazard Analysis
- Preventive Controls
  - Process controls (like HACCP CCPs)
  - Food allergen controls
  - Sanitation controls
  - Recall plan (odd inclusion)
- Monitoring
- Corrective Actions
- Verification
  - Validation
  - Calibration
  - Review of records

Hazard Analysis

- Identify all potential hazards associated with each type of food manufactured
  - Must consider biological, chemical, physical and radiological
- 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
    - Others as needed

Allergen Management

- FDA acknowledges the importance of allergen controls in the Preventive Controls Rule.
  - One of the main updates to cGMPS is the inclusion of preventing cross contact with allergens.
- FDA leaves it up to the facility to determine the specific allergen control procedures

Environmental Monitoring

- FDA is not currently requiring monitoring, but has authority to in the final rule
  - Doesn't mean it can't be a component to sanitation control

- Facility / Pathogen specific references in proposed rule
  - LM: called out as a reasonably foreseeable hazard in refrigerated or frozen RTE food products (such as dairy products, prepared foods such as sandwiches, and frozen foods).
  - Salmonella: called out as a reasonably foreseeable hazard in low-moisture RTE food (e.g. nut and seeds)
    - Environmental monitoring seen as important to verify sanitation controls
  - FDA requests comment on whether a final rule based on this proposed rule should include requirements for environmental monitoring

Controlling Supply Chain Risk

- FDA has authority to require control of supply chain risk
- Not in the proposed rule
- Likely in the final rule
- What does this mean
  - Responsibility to identify and to the extent possible control upstream supply chain risk

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
- Root cause analysis
- Occurrence of unanticipated problems should trigger a reanalysis of the food safety plan

Verification Requirements

- Facility must verify essential elements of its food safety plan
  - Validation of the adequacy of preventive controls
  - Verification of the implementation of the controls
  - Reanalysis of the preventive controls
- Verification must include ensuring monitoring records are completed, deviations recorded and corrective actions undertaken
- All verification activity must be documented

Recall Plan- required

- Preventative Programs
- Corporate Quality Policy
- Leadership
- Organization
- Roles & Responsibilities
- Incident Evaluation Process
- Additional Resources (Internal and external)
- Records Maintenance
- Communications Capabilities
- Systems Support
- Periodic Review, Testing and Training
- Customer Knowledge
- Recall Plan and Procedures

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

Updated cGMPs

- The Proposed Preventive Controls Rule also updated current Good Manufacturing Practices

- Change Section 110 to section 117 and add a variety of updates

- Modernizing and updating the regulatory language (e.g., by replacing the word “shall” with “must” and by using certain terms consistently).

Updated cGMPs

- Clarifying that certain cGMP provisions requiring protection against contamination require protection against cross-contact of food in order to address allergens;
  - adding the term “cross contact” to the cGMP regulations.
  - defines “cross-contact” as “the unintentional incorporation of a food allergen into a food.”

- Proposes that provisions directed to preventing contamination of food and food contact surfaces also be directed to preventing contamination of food packaging materials

Details

PRODUCE SAFETY RULE

Proposed Produce Rules

- **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

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Standards for Produce Safety

- 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

Produce Safety: Who is Covered?

- Farms that grow, harvest, pack or hold most produce in raw or natural state (raw agricultural commodities)
- Farms and "farm" portions of mixed-type facilities
- Domestic and imported produce
- Farms with annual sales > $25,000 per year

What is Exempt?

- Produce for personal or on-farm consumption
- Produce that is not a Raw Agricultural Commodity (RAC)
- Certain produce rarely consumed raw
- Produce that will receive commercial processing (with documentation)
- Farms with sales of $25,000 or less per year
- Qualified exemption and modified requirements (<$500,000 in prev. 3yrs and majority sold to qualified end users)

Qualified Exemption

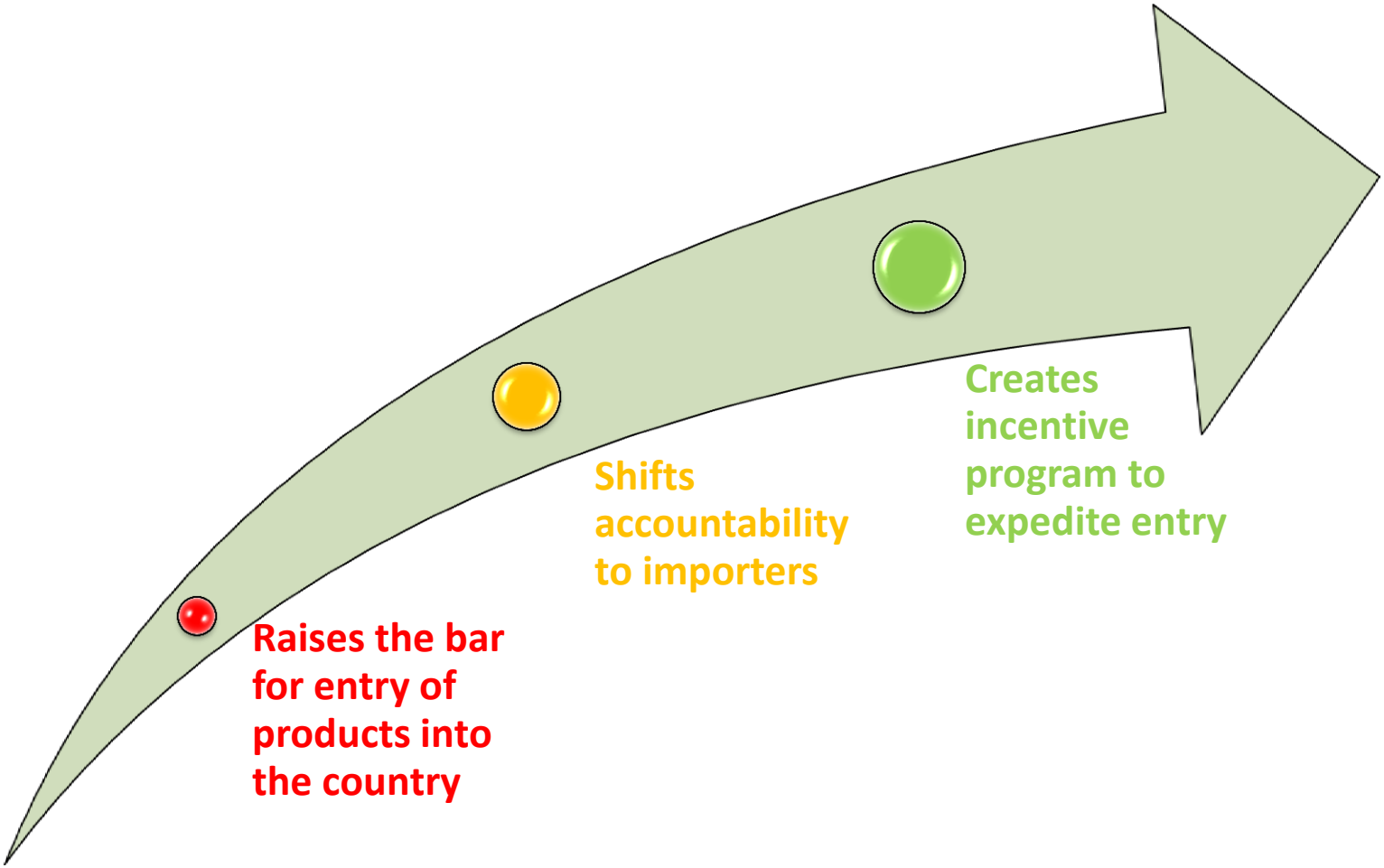
- "Tester Amendment"
  - "local"
  - Sales less than $500K/yr; same state or 275 miles; sales to retail/foodservice
- Farm name and business address displayed at POS

Foreign Supplier Verification Program (FSVP)

Voluntary Qualified Importer Program (VQIP)

IMPORT SAFETY

Stricter Import Requirements



Shift from port of entry focus to supply chain focus

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Focus on Imports

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

Foreign Supplier Verification Program

- **How are importers impacted?**
  - Must provide assurances that each foreign supplier produces food in compliance with current and new regulatory requirements
  - Must 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

WHERE ARE WE?
WHAT'S NEXT?

Future FDA Implementation Activities

- **Preventive Controls**
  - Publish proposed rule on preventive controls for 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
  - Develop model standards for third party auditors
  - Issue regulations for third party auditors around conflicts of interest

- **Produce Controls**
  - Publish updated good agriculture practices

Agency Insights

- Current priorities
  - Domestic
  - Global
- Timelines
- Inspections
  - Number
  - Depth
- Funding

The ROI from FSMA Implementation

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

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Staying In Front

- FSMA rules complicated, overlapping and intersecting
- Submit comments
- Risk based approach
- Heavy focus on process control and prevention
- Most reflects best practices

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Questions?

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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
  - Consumer complaints
  - Testing
- Can expand to other parts of your business

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
- Sunland Inc. peanut butter facility first to be shut d

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

Who Can Do Them?

What Products Need Them?

The Role of GFSI

THIRD PARTY AUDITS

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

SEC 307 – Accreditation of 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

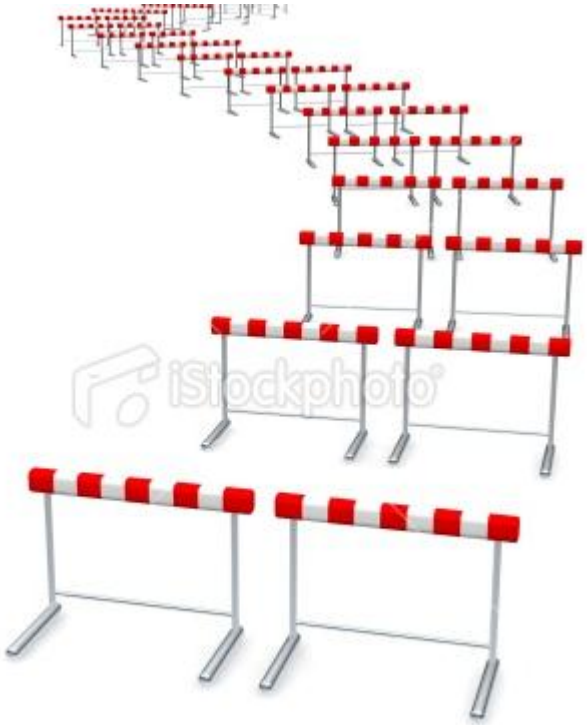
SEC 307 – Accreditation of Third-party Auditors

- What will the information be used for?
  - Eligibility for importation if deemed in need of a certificate (high risk foods)
  - Determine if food can be imported under VQIP
  - Consider audits to determine risk based inspections and risk based entry inspections and testing

Hurdles for FDA

- No infrastructure for third party audits
- Need to establish rules and a program
- Need to generate an accreditation process
- Three main steps
  - Set the standards
  - Establish accreditation process
  - Use the information

- GAO Report November 2012



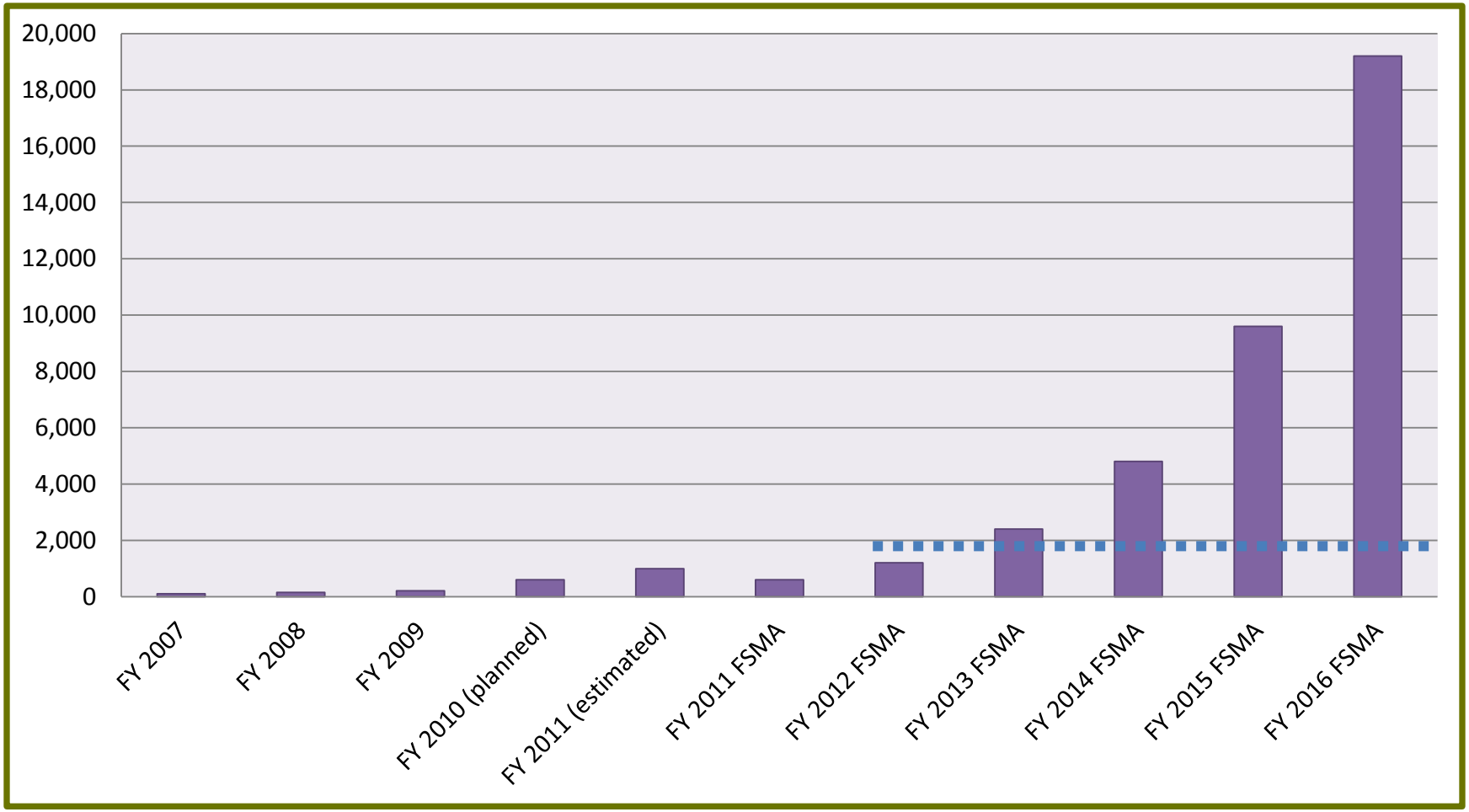
Role of GFSI Audits

- GFSI won't "match" exactly
  - Schemes will adapt
- Oversight of schemes will become increasingly critical
  - e.g. training, delivery, conflicts of interests
    - Walls between regulatory v. consultative audits

Inspection and Compliance

- **Increased Frequency of Mandatory Inspections by U.S. FDA**
  - 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

Increase In Inspections Of Foreign Food Producers By U.S. FDA



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