WHAT YOU NEED TO KNOW ABOUT
THE FOOD SAFETY MODERNIZATION ACT

December 2015
Time Sensitive Material
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1. What is FSMA?
   • Food Safety Modernization Act
   • Biggest change in food regulations since the Food Drug and Cosmetic Act (FD&C Act) was established in 1938
     o FSMA is an amendment to the FD&C Act
   • Includes requirements for industry
   • Includes requirements for the FDA that do not directly apply to industry
     o Work cooperatively with other agencies in the US and in foreign countries
     o Generate progress reports for Congress
   • There are four segments to FSMA
     o Title I: Preventing Food Safety Problems (Sections 101-116)
     o Title II: Detecting and Responding to Food Safety Problems (Sections 201-211)
     o Title III: Improving Food Safety in Imported Foods (Sections 301-309)
     o Title IV: Miscellaneous Provisions (Sections 401-405)

2. Why is FSMA needed?
   • Significant failures in food safety in recent years
     o Major recalls
     o Major outbreaks
   • Increased risks
     o Increased issues with food allergens
     o More resilient and more virulent microorganisms

3. Who does FSMA apply to?
   • FSMA is an amendment to the FD&C Act, therefore it applies to sites that fall under the FD&C Act.
   • It applies to sites and products that are under FDA jurisdiction, including foreign facilities that export to the USA.
   • It does not apply to USDA-regulated products.
   • Within FSMA there are some requirements that are food category specific:
     o Part 112, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
     o Section 113, New Dietary Ingredients
     o Section 114, Guidance Relating to Post Harvest Processing of Raw Oysters
     o Section 116, Alcohol-Related Facilities
   • Specific exemptions are included within the sections
     o Examples of food sector categories that are included in some of the exemptions are packaging manufacturers, manufacturers of dietary supplements, and manufacturers of low-acid canned foods
4. When did FSMA go into effect?

- FSMA was signed into law by President Obama on January 4, 2011
- At that time all sections of the Act became law and were considered enforceable.
  - Some sections did not require any further regulation and were readily understood and enforced.
  - Some sections, while currently enforceable as written, are subject to further rulemaking in which additional, more prescriptive requirements will be added.
  - The rules that are not yet finalized are:
    - Section 106 - Focused Mitigation Strategies
      - Proposed rule published December 2013
    - Section 111 – Sanitary Transport of Food
      - Proposed rule published January 2014
      - Final rule expected March 2016
    - Section 302 – Voluntary Qualified Importer Program
    - Section 303 – Authority to Require Import Certifications for Food
    - Section 307 – Accreditation of Third-Party Auditors
      - Proposed rule published July 2013
      - Proposed and supplemental rules represent FDA’s current thinking on an issue and are not law nor regulation until final publication in the Federal Register.

What is the Rulemaking Process?

1. Bill is passed by the House/Senate
2. President signs the Act
3. The Act is ENFORCEABLE by the FDA
4. Proposed rules are written to further describe requirements
5. Proposed rules are published and comment is sought from the public
6. Final rules are published, including compliance timelines
7. Final rules are ENFORCED by the FDA
5. What sections apply directly to the food industry?

Title I – Preventing Food Safety Problems
- Section 101 – Inspection of Records
- Section 102 – Registration of Food Facilities
- Section 103 – Hazard Analysis and Risk-Based Preventive Controls
- Section 105 – Standards for Produce Safety
- Section 107 – Authority to Collect Fees
- Section 111 – Sanitary Transportation of Food
- Section 112 – Food Allergy and Anaphylaxis Management
- Section 113 – New Dietary Ingredients
- Section 114 – Requirements for Guidance Relating to Post-Harvest Processing of Raw Oysters
- Section 116 – Alcohol-Related Facilities

Title II – Detecting and Responding to Food Safety Problems
- Section 201 – Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry
- Section 202 – Laboratory Accreditation for Analyses of Foods
- Section 204 – Enhancing Tracking and Tracing of Food and Recordkeeping
- Section 206 – Mandatory Recall Authority
- Section 207 – Administrative Detention of Food
- Section 211 – Improving the Reportable Food Registry

Title III – Improving the Safety of Imported Foods
- Section 301 – Foreign Supplier Verification Program
- Section 302 – Voluntary Qualified Importer Program
- Section 303 – Authority to Require Import Certifications for Food
- Section 304 – Prior Notice of Imported Food Shipments
- Section 306 – Inspection of Foreign Food Facilities
- Section 307 – Accreditation of Third-Party Auditors

Title IV - Miscellaneous
- Section 402 – Employee Protections

6. What does industry need to know about Section 101 – Inspection of Records?

• Records access that was in place prior to FSMA and is still in effect includes:
  - The authority to inspect records of interstate shipment, proof of FDA registration, and records in plain sight
  - The authority to inspect HACCP records for seafood and juice
  - The authority to inspect thermal processing records for LACF (low-acid canned foods)

• What has changed?
  - Under the Bioterrorism Act of 2002, the FDA also gained the authority to inspect records if there is credible evidence that the product will cause serious adverse health consequences or death to humans or animals (known as the SAHCODHA threshold). Under FSMA, the threshold has been lowered. Rather than having to obtain credible evidence, the FDA simply needs reasonable belief that the product will cause SACHODHA, in order to have authority to inspect records.
    - Reasonable belief is a much lower threshold.
    - It means that once suspect products are identified, “similar products” will meet the reasonable belief criteria.
    - Reasonable belief may come from gaps or errors in documentation.
  - Records associated with Foreign Supplier Verification and Preventive Controls are expected to be part of the readily available records once those corresponding rules are published and enforced.
The company’s procedures for handling regulatory inspections should be updated to reflect this new authority and lower threshold. Responsible personnel should be trained to the new standard.

As part of the Bioterrorism Act of 2002, food facilities were required to register with the FDA and provide updates to the registration when there were changes. The purpose of the registration is to provide information to the FDA to facilitate with inspections and investigations in the event of an outbreak and/or recall.

The industry often failed to keep site information current with the registry, so under FSMA, re-registration requirements have been added.

Facilities are still required to register any new sites and re-register when there are updates.

In addition, sites are required to re-register every 2 years. The re-registration period is from October 1 – December 31 in even numbered years.

Sites that are not registered or re-registered may be required to recall foods processed and distributed without registration. Unregistered sites are also subject to fines.

Food facility registration is no longer referred to as Bioterrorism registration.

Under FSMA, the FDA has the right to suspend a facility’s registration. This right was first exercised in November 2012.

Final rule published September 10, 2015
Rule will become effective November 16, 2015 with most businesses compliant in one year (November 16, 2016)
The preventive controls and the cGMP revisions have been codified in a new section of Title 21 of the Code of Federal Regulations, Part 117
Part 110 will be removed and reserved effective September 17, 2018
The rule contains the following sections
Subpart A - General Provisions
Subpart B - Current Good Manufacturing Practice
Subpart C - Hazard Analysis and Risk-Based Preventive Controls (HARPC)
Subpart D - Modified Requirements
Subpart E - Withdrawal of Qualified Facility Exemption
Subpart F – Requirements Applying to Records That Must Be Established and Maintained
Subpart G – Supply-Chain Program
General Provisions You Must Know
New definitions and terminology to understand and apply to the rule
Different levels of qualifications for personnel engaged in manufacturing, processing, packing, or holding of food depending on the position
Qualified employees
Supervisors of qualified employees
Preventive Controls Qualified Individual (PCQI) is responsible for:
Preparing the food safety plan (HARPC plan)
Validating the preventive controls
Reviewing records for implementation and effectiveness
Reviewing corrective actions
Performing the required reanalysis
How does someone become a PCQI?
Completes training under a recognized curriculum
• Is otherwise qualified through a combination of education, training, or experience
  ◊ Qualified auditor

• Key modifications to current GMPs
  o Non-binding provisions contained in Part 110 have been deleted or made binding in Part 117
  o Allergen cross-contact prevention is a requirement for major food allergens
  o All employees involved in manufacturing, processing, packing, or holding of food will have to be trained to be Qualified Individuals for their respective positions

• What is HARPC?
  o Is it HACCP?
    ◊ No. It is very similar to HACCP, but it includes additional elements.
  o Do I need to modify my HACCP plan to comply with HARPC or do I need both HACCP and HARPC?
    ◊ The FDA requires either HACCP (juice and seafood) or HARPC depending on product type. They do not require both.
    ◊ Customers and foreign governments may require a HACCP program and may not accept a HARPC program. In these cases, it may be in a company’s best interest to maintain both.
  o What are the additional elements in a HARPC program that are not in HACCP?
    ◊ Hazards
      » The Act has outlined 12 hazard categories. HACCP has identified three hazard categories. Upon closer look, most of the 12 hazard categories fall into the HACCP three category approach:

<table>
<thead>
<tr>
<th>HARPC</th>
<th>HACCP</th>
</tr>
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<tbody>
<tr>
<td>Biological</td>
<td>Biological</td>
</tr>
<tr>
<td>Chemical</td>
<td>Chemical</td>
</tr>
<tr>
<td>Physical</td>
<td>Physical</td>
</tr>
<tr>
<td>Radiological*</td>
<td>No equivalent category</td>
</tr>
<tr>
<td>Natural toxins</td>
<td>Chemical</td>
</tr>
<tr>
<td>Pesticides</td>
<td>Chemical</td>
</tr>
<tr>
<td>Drug residues</td>
<td>Chemical</td>
</tr>
<tr>
<td>Decomposition</td>
<td>Chemical</td>
</tr>
<tr>
<td>Parasites</td>
<td>Biological</td>
</tr>
<tr>
<td>Allergens</td>
<td>Chemical</td>
</tr>
<tr>
<td>Unapproved food and color additives</td>
<td>Chemical</td>
</tr>
<tr>
<td>Economically motivated adulteration**</td>
<td>No equivalent category</td>
</tr>
</tbody>
</table>

* The examples of sources of radiological hazards that are listed in the proposed rule are water and nuclear accident.

**Economically motivated adulteration (EMA), only concerned with food safety hazards, not those that affect value or quality. Should focus on situations where there has been a pattern of EMA in the past. (Example: melamine)

• Hazard Evaluation and Risk-Based Preventive Controls
  o “Known or reasonably foreseeable hazards” are evaluated (risk analysis) to identify hazards requiring preventive controls associated with raw materials, ingredients, process, and environment.
  o The risk analysis is an assessment of severity of the illness or injury if the hazard were to occur and the likelihood that the hazard will occur in the absence of preventive controls
The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:
- The formulation of the food
- The condition, function, and design of the facility and equipment
- Raw materials and other ingredients
- Transportation practices
- Manufacturing/processing procedures
- Packaging activities and labeling activities
- Storage and distribution
- Intended or reasonably foreseeable use
- Sanitation, including employee hygiene
- Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins)

Decide what entity or entities in the food supply chain will control hazards needing preventive controls (i.e., direct supplier, supplier to the direct supplier, receiving facility, customer, or customer to the customer)
- Hazards controlled prior to the receiving facility must have a supply chain program, including supplier verification activities, such as audits, sampling/testing, review of supplier’s food safety records, and supplier’s compliance history
- Suppliers not controlling hazards must provide written notification to customers that the “product is not controlled for the [name of the hazard]”

Preventive Controls
- A PC is an appropriate procedure, practice, and process that “significantly minimizes or prevents” an identified hazard.
- Examples of preventive controls listed in the Act are:
  - Process controls
  - Sanitation of food-contact surfaces
  - Environmental monitoring for ready-to-eat (RTE) products
  - Food allergen controls, including labeling
  - cGMPs to prevent unsanitary conditions
  - Supply chain controls
  - Recall Plan
- In addition, any other control that significantly minimizes or prevents a specific hazard would be considered a preventive control
- Identified PCs must be validated as effective with four exceptions
- All preventive controls must have monitoring, corrective action, verification, and recordkeeping.

Reanalysis
- The rule requires a reanalysis of the food safety plan or parts of it under the following conditions.
  - Food Safety Plan every three years
  - Whenever significant change occurs at your facility
  - Whenever you become aware of new information about potential hazards associated with the food
  - Whenever an unanticipated food safety problem
  - Whenever you find a preventive control or combination of controls is ineffective
  - Whenever changes are made they must be validated as effective

Food Safety Plan
- The results of the HARPC evaluation must be documented in a written food safety plan regardless of the results
  - Hazard analysis
  - Preventive controls
  - Supply chain program
Recall plan
- Procedures for monitoring the implementation of preventive controls
- Corrective action procedures
- Verification procedures including validation as appropriate

Records (evidence of effective food safety plan)
- The Rule requires a facility to establish and maintain the following records:
  - Written food safety plan
  - Documentation for not establishing a preventive control for an identified hazard
  - Monitoring, corrective action, verification, supply chain program, and training records
  - Verification records include: validation, verification of monitoring, verification of corrective actions, calibration of process monitoring and verification instruments, product testing, environmental monitoring, records review, and reanalysis of the food safety plan
  - Supply chain program records applicable to a plant’s food safety plan when the hazard is controlled prior to receipt, i.e. the supplier

Exemptions and Modifications
- Products excluded from HARPC and supply chain program in the Act:
  - Seafood (already falls under regulated HACCP)
  - Juice (already falls under regulated HACCP)
  - There is a partial exclusion in the Act for thermally processed low-acid foods packaged in hermetically sealed containers
    - Microbiological hazards do not need to be assessed with these products as requirements for microbial control are covered under existing legislation.
  - Dietary supplements
  - Activities subject to the produce rule
  - Alcoholic beverages
  - Facilities solely engaged in the storage of packaged food not exposed to the environment
    - The rule excludes warehouses in which the product is fully enclosed in packaging and does not require temperature controls.
    - The proposed rule has modified requirements for warehouses that have product that is fully enclosed, but requires refrigeration for food safety.
    - Hazard analysis would not be required, but temperature monitoring would be.
- Qualified facility
- Farms, and activities within the “farm” definition conducted on “farm mixed-type facilities”
- Specific low risk, on farm activities performed by a small/very small business
- “Includes, but is not limited to” is replaced with “includes”
  - “Adulteration within the meaning of the Act” is replaced with “adulteration”

Packaging Material Considerations
- Domestic packaging material plants are exempt from registering with the FDA and are exempt from complying with subpart C, Hazard Analysis and Risk-Based Preventive Controls
However, in subpart B, Current Good Manufacturing Practices, registered plants must comply with 117.180 Processes and controls, a)(2) “Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food packaging materials are safe and suitable.”

9. What does industry need to know about Part 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Food (HARPC)?

- Final rule published on September 17, 2015
- Companies generally must comply with the Current Good Manufacturing Practice (cGMP) requirements by September 19, 2016, and with the HARPC requirements by September 18, 2017.
- The rule provides later compliance dates for small and very small businesses for certain types of facilities (e.g., qualified facilities, facilities subject to the Pasteurized Milk Ordinance [for human HARPC rule], and for certain provisions [e.g., the supply-chain program]).
- The rule contains the following sections
  - Subpart A - General Provisions
  - Subpart B - Current Good Manufacturing Practice
  - Subpart C - Hazard Analysis and Risk-Based Preventive Controls (HARPC)
  - Subpart D - Withdrawal of a Qualified Facility Exemption
  - Subpart E - Supply Chain Program
  - Subpart F - Requirements Applying to Records That Must Be Established and Maintained
- General Provisions You Must Know
  - New definitions and terminology to understand and apply the rule
  - Different levels of qualifications for personnel engaged in manufacturing, processing, packing, or holding of food depending on their position
    - Qualified employees
    - Supervisors of qualified employees
    - Preventive Controls Qualified Individual
      - Responsible for developing, implementing, managing, and updating food safety plan(s)
    - Qualified auditor
- Key modifications to current GMPs
  - Human food by-products destined for animal food must
    - Be held and shipped under sanitary conditions to prevent contamination
    - Be labeled with common name
    - Have containers and bulk vehicle inspections prior to use
  - FDA has finalized baseline cGMP standards for producing safe animal food that takes into consideration the unique aspect for the animal food industry and provides flexibility for the diverse types of processors
  - Further process of a by-product (e.g. drying, pelletizing, heat treatment, etc.) will require compliance with human or animal food cGMP
    - Unless the process is a qualified facility a hazard analysis and preventive control evaluation will be required even if preventive controls would not need to be established
  - All employees involved in manufacturing, processing, packing, or holding of food will have to be trained to be qualified Individuals for their respective positions
- HARPC
  - Covered facilities must establish a food safety system that includes analysis of hazards and risk-based preventive controls. A food safety plan includes:

9. What does industry need to know about Part 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Food (HARPC)?
10. What does industry need to know about Section 105 (Part 112) - Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

- The final rule for produce safety was published November 27, 2015
- The rule applies to domestic and imported produce
- It does not apply to:
  - Produce that is seldom eaten raw
  - Produce for on-farm or personal use
  - FDA-exempt produce that will receive commercial processing that adequately reduces pathogens of public health concern
- The rule provides a qualified exemption and modified requirements for eligible farms
- FDA focuses on six routes of contamination:

1. Agricultural water
- Two sets of criteria for microbial water quality based on the presence of generic E. coli, which can indicate the presence of fecal contamination
  - Applies to:
    ◦ Water used for handwashing and water directly touching product during or after harvest
1. Water used on food contact surfaces
   - Water used for ice in contact with produce
   - Must discontinue use and complete corrective action before reuse if generic E. coli is detected
   - Prohibits use of untreated surface water for any of above uses
   - Establish a second numerical criteria for agricultural water used for growing produce other than spouts
   - Establishes generic E. coli water testing protocol for surface and ground water sources

2. Biological soil amendments
   - FDA risk assessment will establish minimum number of days raw manure as a soil amendment that can be applied prior to harvesting to minimize the risk of contamination
   - Current practices under the US Department of Agriculture’s (USDA) National Organic Program Standards are acceptable pending FDA risk assessment
   - USDA requires 120 days if crops contact the soil and 90 days if crops do not contact the soil
   - Requires that untreated biological soil amendments of animal origin be applied in a manner that does not contaminate covered or uncovered produce

3. Domesticated and wild animals
   - Raw manure:
     - Requires covered farms to visually examine the growing area and all covered produce to be harvested, regardless of the harvest method
     - Requires farms to perform additional assessments during the growing season to identify significant areas of potential contamination and voluntarily apply a waiting period between grazing and harvest depending on type of produce/commodity being produced
   - Stabilized compost:
     - Microbial standards that set limits on detectable amounts of bacteria (including Listeria monocytogenes, Salmonella spp., fecal coliforms, and E. coli 0157:H7) have been established for processes used to treat biological soil amendments, including manure
     - Two examples of scientifically valid composting methods that meet those standards are included in the rule
     - Stabilized compost prepared using one of these methods must be applied in a manner that minimizes the potential for contact with produce during and after application

4. Sprouts
   - Prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting
   - Testing irrigation water from each batch of in-process sprouts for certain pathogens which cannot enter commerce until these required tests are completed with negative results
   - Testing the growing, harvesting, packing, and holding environment for the presence of Listeria species or Listeria monocytogenes
   - Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive
   - Sprout operations will have less time to come into compliance with the rule than farms growing other produce (one to three years to comply based on the size of the operation with no additional time to meet the water requirements)
5. Worker training, health, and hygiene

- Prevent ill or infected persons from contaminating produce and food contact surfaces
- Use hygienic practices (hand washing) when touching covered produce and food contact surfaces
- Farm workers and supervisors must be trained on the importance of health and hygiene
- Farm workers who handle covered produce and food contact surfaces and their supervisors, must have the required combination of training, education and experience necessary to perform their assigned responsibilities

6. Equipment, tools, and buildings

- Establish standards and sanitation requirements for equipment, tools, and buildings to prevent produce contamination
- Adequate toilet and handwashing facilities
- Required measures to prevent contamination of covered product and food contact surfaces including storage, maintenance, and cleaning of equipment and tools

11. What does industry need to know about Section 107 – Authority to Collect Fees?

- Although the Act allows the FDA to collect fees for inspection, the approach has been to focus on collecting fees only for re-inspection
- 2015 re-inspection fees
  - Domestic sites: $217/hour/inspector
  - Foreign sites: $305/hour/inspector
- These fees can apply to multiple inspectors at a single site.
- These fees also apply to travel time to the facility.
- So far, the FDA has not acted on their ability to collect fees.

12. What does industry need to know about Section 111 – Sanitary Transportation of Food?

- Currently, Section 416 of FD&C Act requires sanitary transportation practices. Under FSMA, the FDA is tasked with writing regulations that define these sanitary practices.
- The proposed rule was published January 2014.
- There are five key elements of the proposed rule:
  - Vehicles and Transportation Equipment: The design and maintenance of vehicles and transportation equipment does not cause contamination.
  - Transportation Operations: Measures are taken during transportation to prevent contamination, such as temperature control and separation of food from nonfood.
  - Information Exchange: Procedures exist for exchange of information between shipper, carrier, and receiver. Procedures cover prior cargos, cleaning of equipment, and temperature control.
  - Training: Documented training of carrier personnel in sanitary transportation practices is maintained.
  - Records: Procedures and records related to cleaning, prior cargo, and temperature control are maintained”.
- Shelf-stable foods in completely sealed packaging are exempt.
- The regulation extends to FDA and USDA products.
13. What does industry need to know about Section 112 – Food Allergy and Anaphylaxis Management?

- This section applies to schools and educational institutions
- FDA is to provide food allergy management guidelines
- Note: Allergen control measures for manufacturers and distribution centers are being covered under the revision to the cGMPs, as well as HARPC under Section 103.

14. What does industry need to know about Section 113 – New Dietary Ingredients?

- Within FSMA, the FDA was tasked with publishing a guidance document to clarify when a manufacturer or distributor of a dietary ingredient or a dietary supplement should provide evidence to the FDA that the supplement is safe
- Draft guidance was published July 2011

15. What does industry need to know about Section 114 – Requirements for Guidance Relating to Post Harvest Processing of Raw Oysters?

- The FDA is to conduct a study and publish a report on post-harvest processing of raw oysters.
- The report is expected to influence changes in the Seafood HACCP Requirements outlined in 21 CFR Part 123.

16. What does industry need to know about Section 116 – Alcohol-related Facilities?

- The section outlines which parts of FSMA are applicable to alcohol-related facilities.
- An alcohol-related facility is defined by the Federal Alcohol Administration Act and includes distilled spirits, wine, and malt beverages.
- The sections of FSMA applicable to alcohol-related facilities are:
  o Section 102 – Food Facility Registration
  o Section 206 – Mandatory Recall Authority
  o Section 207 – Administrative Detention
  o Section 302 – Voluntary Qualified Importer
  o Section 304 – Prior Notice of Imported Food Shipments
  o Section 402 – Employee Protections
  o Section 403 – Jurisdiction/Authorities
    ◊ Nothing in FSMA alters the jurisdiction and authorities of the Alcohol and Tobacco Tax and Trade Bureau
  o Section 404 – Compliance with International Agreements
    ◊ Nothing in FSMA will be inconsistent with the World Trade Organization
17. What does industry need to know about Section 201 – Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry?

- FDA is to identify high-risk and non high-risk facilities in order to prioritize facilities for inspection.
- High-risk facilities are targeted for inspection at least every three years.
- Non high-risk facilities are targeted for inspection at least every seven years.
- Risk factors are:
  - The type of food has been associated with a Class I recall
  - The type of food has been associated with outbreaks
  - The facility has a history of OAI violations
  - The facility has a history of VAI non-compliance
  - The rigor and effectiveness of the facility’s HARPC program
  - Years since last inspection at the facility
- The most frequent type of Class I recall is undeclared allergen. Types of foods associated with allergen recalls include: bakery, chocolate/candy/confections, ice cream, and snack foods. These foods have not been previously viewed as high-risk using traditional criteria, such as water activity and pH. However, with these new criteria, additional foods will fall under the high-risk category.
- Section 201 also requires doubling the number of foreign facility inspections each year with a minimum of 600 inspections in the year 2011.

18. What does industry need to know about Section 202 – Laboratory Accreditation for Analyses of Foods?

- The FDA is tasked with identifying a list of accredited labs
- The list was to be published no later than January 4, 2013, but this date has passed.
- These labs are the ones approved to do testing on behalf of the FDA.
- Manufacturers are not required to use these labs for routine testing. However, these labs are to be used when dealing with a suspected food safety problem that involves the FDA.

19. What does industry need to know about Section 204 – Enhancing Tracking and Tracing of Food and Recordkeeping?

- The IFT (Institute of Food Technology) was appointed to conduct pilot trace programs
- Three traces were done:
  - Tomatoes
  - Frozen Kung-Pao Style Dish
  - Jarred peanut butter and dry, packaged peanuts
- Based on the study, IFT has made recommendations to improve traceability.
- The FDA is expected to make rules for high-risk facilities regarding traceability. If product tracing plans are a requirement of the rule, facilities will be required to share their plans during a routine FDA inspection.

20. What does industry need to know about Section 206 – Mandatory Recall Authority?

- Prior to FSMA recalls were voluntary.
- Under FSMA, if a facility refuses to voluntarily recall suspect product, the FDA can mandate the recall.
  - The facility will be subject to civil penalties.
  - If the recall involves alcohol, the FDA must first give the Alcohol and Tobacco Tax Trade Bureau the opportunity to cease distribution first.
- New authority was used for the first time in February 2013.
The FDA has maintained the authority to detain (hold) food since the implementation of the Bioterrorism Act of 2002.

What has changed under FSMA?
- The threshold required to hold the food has been lowered. Previously, the FDA had the authority to detain food if there was credible evidence that the food would cause SAHCODHA. The new threshold is that there is reasonable belief that the food will cause SAHCODHA.
- The FDA has the right to detain product for 30 days.

The Reportable Food Registry (RFR) was established in September 2009.
- Additional requirements were added to the RFR under FSMA.
- When reporting a reportable food, additional information must be provided:
  - Description of the food
  - Affected product identification codes
  - Contact information for the responsible party
- Grocery stores are required to post consumer notifications for reportable foods that they sold.

The final rule for foreign supplier verification was published on November 27, 2015.
- Generally, importers will have to come into compliance 18 months after the publication date.
- The rule entails a fundamental shift in oversight of imported foods from one relying on inspection/examination of imported foods at the port of entry, and reaction to market failures to a system that places the responsibility of preventing food safety failures on the importers and their foreign suppliers.
- **Importer** means the US owner or consignee of an article of food that is being offered for import into the United States. If there is no US owner or consignee of an article of food at the time of US entry, the importer is the US agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.
  - For each line entry of food product offered for importation into the United States, the importer’s name, email address, and unique facility identifier recognized as acceptable by FDA and identifying the importer of the food must be provided electronically when filing entry with US Customs and Border Protection.
- **Foreign supplier** means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.
- A **qualified individual** must develop the FSVP and perform the activities required by the program. A qualified individual must have the education, training, or experience (or a combination thereof) necessary to perform their assigned activities and must be able to read and understand the language of any records that must be reviewed in performing an activity.
- All importers of food for human and animals, unless specifically exempt or subject to modified requirements, will be required to develop, maintain, and follow a standard risk-based FSVP to ensure that the food they import is produced in a manner that “provides the same level of public health
protection as the preventive controls or produce regulations, and to ensure that the supplier’s food is not adulterated and is not misbranded with respect to allergen labeling”. These requirements are:

- For each food imported and supplier of such food, undertake a risk evaluation to approve/disapprove the supplier, including:
  ◦ Determining known or reasonably foreseeable hazard for each food.
  ◦ Evaluating the risk posed by a food, based on the hazard analysis of the food (probability x severity) and the foreign supplier’s compliance performance history. The risk evaluation can be done by another entity, as long as the importer reviews and assesses the relevant documentation.
  ◦ For approved suppliers, determining appropriate verification activities and frequencies based on the specific results of the product risk analysis and the supplier’s performance review. These include onsite audits, sampling and testing, effectiveness of corrective actions, and review of supplier’s relevant food safety records and compliance history.
- Conducting supplier verification activities.
  ◦ Verification activities can be carried out by another entity than the importer (but not the foreign supplier, except sampling and testing), as long as the importer reviews and assesses the relevant documentation.
- An initial and future annual audits to the supplier’s facility is required if “there is a reasonable probability that exposure to the hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans and animals (SAHCODHA).”
  ◦ Such audit must be carried out by a qualified auditor.
  ◦ The audit can be carried out by another entity than the importer (but not the foreign supplier), as long as the importer reviews and assesses the relevant documentation.
  ◦ The importer can choose not to carry out an annual onsite audit, as long as the importer documents how such alternative choice is appropriate and provides the adequate assurances that the foreign supplier is producing the food in accordance with applicable US standards.
- Conducting corrective actions. Reviews of complaints, instances of adulteration, or misbranding and carrying out appropriate corrective actions, which could include discontinuing the use of a foreign supplier.
- Establishing and following written procedures to ensure that the importer is importing foods from approved foreign suppliers, or when necessary on a temporary basis, from an unapproved supplier whose food is subjected to adequate verification activities prior to being imported.

- The rule contains certain modified requirements for the following situations:
  - Dietary supplements and dietary supplement components subject to existing dietary supplement cGMP regulations.
  - Very small importers and importers of food from certain small foreign suppliers.
  - A foreign supplier in a country whose food safety system has been recognized as comparable or determined to be equivalent of the US system.
- The rule contains exemptions for the following situations:
  - If it is determined and documented that the type of food (e.g., raw agricultural commodities such as cocoa beans and coffee beans) could not be consumed without application of an appropriate control.
  - If the importer relies on its customer to ensure that the identified hazard will be significantly minimized or prevented and the importer and complies with certain documentation requirements.
• Food categories not covered by the FSVP, include:
  o Juice and fishery products, subject to and in compliance with their respective HACCP rules
  o Food for research and evaluation
  o Food for personal consumption
  o Alcoholic beverages
  o Food imported for further processing and subsequent export
  o LACF, with respect to microbiological hazards, covered under different regulation
  o Meat, poultry and egg products regulated by the USDA

• The FSVP or a specific component must be promptly reevaluated and such activity documented when the importer becomes aware of compliance problems with his foreign suppliers. The complete FSVP must be reevaluated no less than every 3 years. Periodic or complete reevaluations of the FSVP and its components can be carried out by an entity (other than the foreign supplier), as long as the importer reviews and assesses the results, including that the activity was carried out by a qualified individual.

• The FSVP records must be retained for at least two years; these records must be made available to the FDA upon request.

24. What does industry need to know about Section 302 – Voluntary Qualified Importer Program?

25. What does industry need to know about Section 303 – Authority to Require Import Certifications for Food?

26. What does industry need to know about Section 304 – Prior Notice of Imported Food Shipments?

• The requirement to provide advance notice to the FDA before importing a food went into effect under the Bioterrorism Act of 2002.
• The new addition under FSMA is the requirement to list any country to which the food has been refused entry before being shipped to the US.

• The FDA has the authority to inspect foreign establishments, including factories and warehouses.
• If a foreign facility refuses an FDA inspection, its product will be refused entry into the US.

• The proposed rule for accreditation of third-party auditors was published in July 2013.
• The proposed rule establishes a program for accreditation of third-party auditors (certification bodies), to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce.
• The Rule does not provide specific accreditation standards to be imposed on auditors/certification bodies. These standards are expected in a separate rule or guidance document.
• The Rule distinguishes between regulatory audits and consultative audits.
  o Regulatory audit
27. What does industry need to know about Section 306 – Inspection of Foreign Food Facilities?

- Determine whether eligible entity complies with FDA regulations;
- Used to determine whether food can be certified for import to the US.
- Unannounced audit
- May include sampling (product and environmental)
- Report would have to be made available in English to FDA within 45 days with immediate reporting of issues that could result in serious health risk

- Consultative audit
  - Evaluate compliance to FDA and industry standards
  - Internal purposes only
  - Not available to FDA except under “special records access” or if the audit is used as part of foreign supplier verification

- A third-party auditor/certification body would be prohibited from using an audit agent to conduct a regulatory audit if the agent has been in the facility within the past 13 months for either a consultative or regulatory audit. The requirement could be waived under certain conditions.

- This is whistleblower protection.
- An employee cannot be discriminated against for reporting FSMA violations.
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