



Food Safety Modernization Act

**It's impact on Wholesalers and
their service to Retailers**

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FSMA Overview

- FSMA aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.
- Key Sections:
 - CGMP updates (including Allergen Control)
 - Preventive Controls
 - Inspection and Compliance
 - Traceability and Registration
 - Imported Food Safety
 - Response (recalls)
 - Sanitary Transporting of Food
 - Intentional Adulteration
 - Produce Safety





Key Sections Applicable to Wholesalers/Retailers

- CGMP updates
- Access to Records (Section 101)
- Hazard Analysis & Risk-Based Preventative Controls (Section 103)
- Standards for Produce Safety (Section 105)
- Food Defense / Intentional Adulteration (Section 106)
- Sanitary Transportation of Food (Section 111)
- Mandatory Recall Authority (Section 206)
- Import of Food:
 - **Foreign Supplier Verification Program (Section 301)**
 - **Voluntary Qualified Importer Program (Section 302)**
 - **Prior Notice of Imported Food Shipments (Section 304)**
 - **Inspection of Foreign Food Facilities (Section 306)**
 - **Accreditation of Third-Party Auditors (Section 307)**



FSMA: Mandatory Recall Authority

- Pre-FSMA
 - Recalls historically up to 2011 were voluntary for the manufacturer to execute
 - Unfortunately, necessary recalls either didn't occur on potentially adulterated product or occurred too late in the life-cycle of the product and thus potentially injured or killed people
- Post-FSMA
 - FDA has the ability to immediately initiate a product recall if they feel that conditions exist to cause health effects to humans
 - FDA can charge the vendor fees associated with the pre and post recall and subsequent inspections under the vendor is in compliance with the law

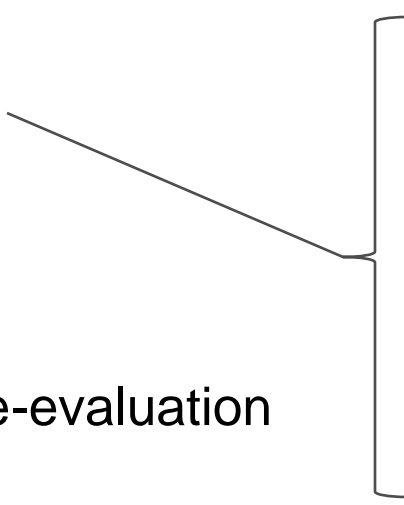


FSMA: Access to Records

- Pre-FSMA
 - Access to records involving interstate shipments, HACCP (as defined by FDA), as examples
 - Depending on company, release of records was broad from “provide them anything” to “not without a court order”
- Post-FSMA
 - FDA has expanded their access to those company records related to any article of potentially adulterated food
 - Assume all records maintained to be accessible to FDA therefore, clearly review what information you document



FSMA: Hazard Analysis & Preventive Controls Rule

- Each covered facility is required to prepare and implement a written food safety plan by a “qualified individual” which includes:
 1. Hazard Analysis
 2. Preventive controls
 3. Monitoring
 4. Corrective actions
 5. Verification activities
 6. Recordkeeping & Re-evaluation
 7. Recall Plan
 - Food Defense
 - Food Handling
 - CGMPs
 - HACCP
 - Recall
 - Pest Control
 - Sanitation
 - Cold Chain Mgmt.
 - Preventative Mntce.
- “Qualified Individual” – trained in the development/application of risk-based preventative controls and deemed “adequate” by FDA or through job experience



FSMA: Standards for Produce Safety

- Produce suppliers will need to meet these new standards depending on the size of their business
- New Standards:
 - **Personnel Qualifications, Training, and Health and Hygiene**
 - **Agricultural Water Quality and Safety**
 - **Biological Soil Amendment (BSA) Quality and Safety**
 - **Domesticated and Wild Animal use of Farmland**
 - **Equipment, Tools, and Buildings (Design, Use, and Cleanability)**
 - **Sprout Food Safety**



FSMA: Intentional Adulteration

- Rule addresses acts intended to cause massive public harm, including acts of terrorism
- **All facilities that hold food are exempt from this rule**
- Facilities who manufacture food must comply with this rule
- Utilize HACCP principles (Hazard Analysis) to identify those possible areas where intentional adulteration could occur along with actionable processes and mitigation strategies to eliminate the hazard
- Monitoring, corrective actions, and verification procedures must be part of your plan



FSMA: Sanitary Transportation of Food

- Retailers and Wholesalers can be a *Shipper, Carrier, and a Receiver* or any combination
- Requirement of both trailer pre-cooling and in-transit temperature monitoring for both TCS and non-TCS foods at risk for microbial spoilage
- Carrier must present in-transit temperature records to Carrier or Agreement
- Carrier food safety awareness and basic sanitary transportation practices training required
- Availability of “convenient” hand-washing facilities for Carriers



FSMA: Import of Food

- *Importer* to verify that products are being produced overseas in compliance with FSMA Preventative Controls and Produce Safety rules *and* are not adulterated or misbranded
- The *Importer* is required to develop, maintain, and follow an FSVP for *each food* it imports (Use of a “Qualified Individual” or 3rd Party Accredited Auditor required) and reassess within 3 years for effectiveness
- Compliance Status of the food AND the foreign supplier must be reviewed
- Audits to be completed either annually or periodically depending on hazards (SAHCODA or non-SAHCODA)