

Retail Food Industry: Import and Distribution and the Impact of FSMA

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FMI

What I hear...

- Does FMISA apply to my company?
- Which FSMA rules do I need to follow?
- When do I need to comply?
- What training do I need?
- What records does the FDA require?
- Does this really go into effect [insert date]?



Where FSMA Impacts Retail Businesses

- Procurement
- Produce
- Imports
- Suppliers
- Recordkeeping, retention, policies
- Training
 - Qualified Individual
- Information Management/IT



Review of the 7 Major Rules

Seven Major FSMA Regulations	Publication Date or Expected Date	Expected Compliance Deadline**
1. Preventive Controls – Human food	September 17, 2015	September 17, 2016
2. Preventive Controls – Animal food	September 17, 2015	September 17, 2016 cGMP September 19, 2017 PC
3. Produce Safety	November 27, 2015	November 27, 2017
4. Foreign Supplier Verification Program	November 27, 2015	May 31, 2017
5. Accreditation of Third Party Auditors	November 27, 2015	May 31, 2017
6. Sanitary Transportation	April 6, 2016	April 6, 2017
7. Food Defense	May 2016	May 2019

** Compliance deadlines depend on several variables so check the rules for details

FSMA Compliance at a Glance

	Produce Grower/ Farm	Manufacturing or Processing	All Importers (retail, wholesale, production)	Retail Distribution Center or Warehouse	Transportation: Shippers, Loaders, Carriers, Receivers
Preventive Control Plan					
Produce Safety					
Foreign Supplier Verification					
Sanitary Transportation					
Food Defense					

Foreign Supplier Verification (FSVP)

Definition of a FSVP Importer:

The US **owner** or consignee of an article of food that is being offered for import into the US. 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.

FSVP

- Intent – Imported foods must be produced in compliance with the preventive controls and produce safety rules, not be adulterated or mislabeled
- Importers must develop, maintain and follow a FSVP
- Importer definition different than Customs and Border Patrol (CBP) importer definition



FSVP: Required Records

- Hazard Analysis
 - Known or reasonably foreseeable hazards
- Verification activities
 - Use of approved foreign suppliers
 - On-site audits
 - Food safety records
 - Sampling and testing



Key Considerations for FSVP

- A **Qualified Individual** must now develop the FSVP and perform FSVP activities
 - Different than PCQI
- Records can be original, copies or electronic
 - Must be signed and dated
 - Other languages are acceptable, but must be translated upon request

Sanitary Transportation



Key Considerations for Sanitary Transportation

Based on the Proposed Rule:

- Applies to shippers, carriers and receivers
- Covers food transported Interstate as well as Intrastate
- Valid for human or animal food shipped via rail or road
- Focuses on temperature control and avoiding contamination of products

Intent of Rule



- FDA was required to issue regulations for shippers and carriers by motor and rail to use sanitary transportation processes to avoid creating food safety risks
- History of the regulation goes back to 2005 with the FDA and 1990 with Sanitary Transportation of Food Act (1990) assigned to DOT



Who has to comply?

- Shippers
- Loaders
- Receivers
- Carriers

Engaged in transportation operations of food

Applies to intrastate and interstate transportation

Scope

Applies to:

- Temperature controlled for safety (TCS) Foods
- Food not completely enclosed by a container
- Animal food (includes pet, animal feed, raw materials and ingredients)

Exempt:

- Foods regulated exclusively by USDA
- Food that is completely enclosed by a container that is not TCS
- Compressed food gases
- Food contact substances as defined in section 409(h)(6) of the FDCA
- Human food byproducts for use as animal food w/o further processing
- Live food animals except molluscan shellfish

Definitions



- **Shipper** – a person (manufacturer or freight broker) who arranges for the transportation of food in the US by a carrier or multiple carriers sequentially



- **Carrier** – person who physically moves food by rail or motor vehicle in commerce within the US. Does not include any person who transports food while operating as a parcel delivery service.

Definitions



- **Loader** – person that loads food onto a motor or rail vehicle during transportation operations
- **Receiver** – any person who receives food at a point in the US after transportation, whether or not that person represents the final point of receipt for the food



What is required?

- Vehicles and equipment must be cleanable and suitable to prevent food from becoming unsafe during transportation ops
 - Maintained in sanitary condition
 - Designed, maintained and equipped to provide adequate temperature control
 - Store in a manner to prevent pests

Vehicle Operations

- Rules apply to all parties and roles might be combined
- Responsibilities may be reassigned through written agreements and contracts
 - Subject to records requirements

Vehicle Operations (continued)

- Goal is to prevent food from becoming unsafe during transportation (examples)
 - Prevent cross contamination of raw foods and non-foods by segregation, isolation, and packaging
 - Handwashing to protect food in bulk vehicles or open containers
 - Temperature control of TCS products
 - Conditions depend on type of food – animal feed, pet food, human food and product stage

Intra-Company Shipments

- “Common integrated written procedures” may be used for shippers, receivers, loaders and carriers under the ownership or operational control of a single legal entity.
 - Written procedures are subject to the records requirements

Additional Provision

- Requirement to stop sale or distribution of food if shipper, loader, receiver or carrier becomes aware of “of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation”
 - Take appropriate action
 - Communicate with other parties
 - Determination by a qualified individual





Shippers

- Specify in writing to the carrier and if appropriate the loader, the conditions for the sanitary specifications of the vehicle and equipment.
 - This includes design specs, cleaning procedures, sanitary conditions, temperature requirements including pre-cooling
 - Can be a one time written notification if the information does not change
 - Subject to records requirements

Loaders

- Determine specific requirements for containers not completely enclosed to avoid contamination and evaluate condition (pests)
- Verify temperature requirements and condition of refrigerated storage



Receivers



- Upon receiving TCS food, the receiver must *“take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food’s temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, e.g., for off-odors.”*



Carriers

- Depending on the written agreement*, the carrier is responsible for:
 - Equipment meets specs to prevent the food from becoming unsafe during transportation
 - If requested provide operating temperature and demonstrate temperature conditions were maintained (by agreed upon means)
 - Identify previous cargo for bulk containers, and information on most recent cleaning
 - Written procedures on sanitary condition of vehicles and equipment, transportation control, and bulk vehicle requirements

*only applies when a written agreement is in place between shipper and carrier identifying the carrier as responsible for these activities

Training

- Carrier must provide “adequate” training to personnel engaged in transportation operations
 - Potential food safety problems that can occur
 - Basic sanitary transportation practices
 - Responsibilities of the carrier
- Training required upon hiring and as needed
- Training records – date, type of training, and name of person trained



Records

- Shippers and Carriers
 - Specific records requirements
 - Written agreements
- Intra-Company (single legal entity)
 - written procedures
- All records must be **kept for 12 months beyond when the procedures are in use**
- All records are required to be available to an duly authorized individual promptly upon oral or written request
- Carrier's written procedures must be onsite but offsite storage is permitted for all other records if accessible in 24 hours.
- Electronic records are onsite if accessible onsite



Waivers



- PMO
 - Transportation of Grade A milk and milk products
- Retail Stores
 - As receiver (facility is under jurisdiction of the Food Code)
 - Direct to consumer transportation

FDA is planning to issue a final rule on waivers

Compliance Dates

- One year compliance date
 - April 6, 2017
- Small Businesses
 - April 6, 2018
 - Non-motor carriers <500 FTE
 - Motor carriers <\$27.5 million in annual receipts



At a Glance

	Produce Farm	Manufacturing /Processing	Shippers, Carriers, Receivers of Transported Foods	Ret/Wholesaler	Any Facility Importing Products
Preventive Control		✓		✓	
Produce Safety	✓				
FSVP		✓		✓	✓
Sanitary Transportation			✓		
Food Defense Plan		✓			
Training	✓	✓	✓	✓	
Recordkeeping	✓	✓	✓	✓	✓
Facility Registration		✓		✓	

Getting Started with FSMA Compliance

1. Check that **Facility Registration** is complete
2. Learn about FSMA and the rules that apply to your company
3. Obtain training through the FSPCA for the **Preventive Control Qualified Individual(s)**
4. Form your “**FSMA Team**”
5. **Implement compliance programs** for each FSMA rule that applies to your company
6. Determine **recordkeeping system**
7. **Train** all employees
8. **Monitor and test** system
9. **Retrain**



For Help

- **FDA Technical Assistance Network**
 - <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>
- **FDA FSMA Email updates**
 - https://public.govdelivery.com/accounts/USFDA/subscribe/new?topic_id=USFDA_206

Thank You!

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