



Welcome

OnTrak with FSMA: A Webinar Series

Hosted by: ReposiTrak[®]

FSMA Ready?

Here's Your List of To-dos

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FMI Antitrust Statement

FMI believes strongly in competition. Our antitrust laws are the rules under which our competitive system operates. It is FMI's policy to comply in all respects with the antitrust laws.

Association meetings or workshops by their very nature bring competitors together. It is expected that all member representatives involved in FMI activities, as well as FMI consultants and other participants, will be sensitive to the legal issues and act in compliance with applicable antitrust and competition laws both at FMI meetings and FMI-sponsored events.

Accordingly, it is necessary to avoid discussions of sensitive topics that can create antitrust concerns. Agreements to fix prices, allocate markets, engage in product boycotts and to refuse to deal with third parties are illegal under the antitrust laws. At any association meeting discussions of prices (including elements of prices such as allowances and credit terms), quality ratings of suppliers, and discussions that may cause a competitor to cease purchasing from a particular supplier, or selling to a particular customer, should be avoided. Also, there should be no discussion that might be interpreted as a dividing up of territories.

An antitrust violation does not require proof of a formal agreement. A discussion of a sensitive topic, such as price, followed by action by those involved or present at the discussion is enough to show a price fixing conspiracy. As a result, those attending an association-sponsored meeting should remember the importance of avoiding not only unlawful activities, but even the appearance of unlawful activity.

As a practical matter violations of these rules can have serious consequences for a company and its employees. Antitrust investigations and litigation are lengthy, complex and disruptive. The Sherman Act is a criminal statute, and may even result in penalties punishable by steep fines and imprisonment. The Justice Department, state attorneys general and any person or company injured by a violation of the antitrust laws may bring an action for three times the amount of the damages, plus attorney's fees.

What I hear...



- Does FSMA 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]?

What does it mean to be FSMA Ready?

- You know what rules apply to you
- You have executed a gap analysis and know what you need to correct and document
- Your preventive controls and corrective actions are in place and are documentable
- You can access your records easily and quickly
- You are ready for an inspection at any time



What regulations apply to which facilities?



- **FSMA – FDA Registered Food Facilities**
 - Distribution Centers
 - Manufacturing/Central Kitchens
 - Transportation
 - Store to consumer recall notification (pending)



- **FDA Food Code**
 - Retail Stores
 - Home Delivery

Where FSMA Impacts Your Business

- Procurement
- Produce
- Imports
- Recordkeeping, retention, policies
 - Record content
- Training
 - Qualified Individual
 - Driver training
- Information Management/IT



FDA Authorities Now in Effect

- Increased Inspection Authority
 - Depends on appropriations
- Increased Records Access
- Mandatory Recall Authority
- Import Certification Authority
- Fees for Re-inspection
- Administration Detention
- Facility Registration and Suspension of Registration



FSMA Expands Access to Records

- FSMA greatly expands FDA's **access to records**, allowing FDA to review many food-safety-related records **at any time**
- Five main records-related changes or requirements:
 - Food Safety Plan records
 - Foreign Supplier Verification Program records
 - Food Defense Plan records
 - Sanitary transportation records
 - Expanded FDA access to records during an emergency (written request)
- “If it isn't documented, it didn't happen”

24 hours



Time allotted for records requested by the FDA

2 years



Retention period for required records under FSMA



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	March 31, 2016	March 31, 2017 ?
7. Food Defense	May 31, 2016	May 31, 2017 ?

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

FSMA Compliance at a Glance

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

Breakdown of Impact by Rule

- Preventive Controls
- Produce Safety
- Foreign Supplier Verification Program
- Sanitary Transportation
- Intentional Adulteration





Impact

PREVENTIVE CONTROLS

Impact: Preventive Controls

Who does it impact?

- FDA-registered facilities that manufacture, process, pack or hold food
 - Examples: DCs, Manufacturing & Processing

Requirements?

- cGMPs (good manufacturing practices)
- Hazard Analysis
- Food Safety Plan
- Training

Preventive Controls Qualified Individual

Who is this?

...a “qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.”

- This is the person deemed qualified to write the food safety plan, oversee verification/validation, etc.
- Training and documentation is critical
- Look for training from the FSPCA



FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Qualified Individual



And... who is this?

- All employees engaged in cGMPs or Preventive Controls must be a “Qualified Individual”
 - a person who has the education, training, or experience or combination of same, to properly manufacture, process, pack, or hold clean and safe food as according to their job description
 - All, including supervisors, **must receive training** in in principles of food hygiene and food safety, including employee health and personal hygiene
 - **Records of same to be kept**, frequency of training is up to the facility
- Training is now required for the first time by regulation
 - **documentation becomes critical**

Preventive Controls: Required Records

- Hazard Analysis
- Food Safety Plan
 - Process Preventive Controls, Food Allergen Preventive Controls, Supply Chain Preventive Controls, Sanitation Preventive Controls



You should know:

- Records must document corrective actions, monitoring, verification/validation of process preventive controls, and training
- No special format is required; must be accessible in 24 hours; can be stored 'off-site' except food safety plan
- Electronic records (like those managed in ReposiTrak) are considered on-site

Supply Chain Program

- Documentation for hazards requiring a supply chain applied control
- Depends on who controls the hazard in the supply chain
- Verification activities
 - Onsite audit
 - Sampling/testing
 - Records
 - Certificates of conformance
 - Continuing guarantees

Preventive Controls: Your To-do List

Task	Retail DC	Wholesaler	Manufacturer
Follow cGMPs	✓	✓	✓
Document your PC Qualified Individual	✓	✓	✓
Complete a Hazard Analysis	✓	✓	✓
Create a Food Safety Plan	✓	✓	✓
Train all Qualified Individuals	✓	✓	✓
Maintain Records	✓	✓	✓

Do these apply?

Yes, if your facilities are required to be registered by FDA and they manufacture, process, pack or hold food



Impact

PRODUCE SAFETY

Impact: Produce Safety

Does the Produce Safety Rule apply?



Impact: Produce Safety

Who does it impact?

- Is this a farm?

Requirements?

- Agricultural water
- Biological soil amendments
- Domesticated & wild animals
- Growing, harvesting, packing & holding
- Worker training, health & hygiene
- Equipment, tools & buildings
- Sprouts



Produce Safety: Required Records

For Farms:

- Name and location of farm
- Actual values and observations obtained during monitoring
- Description of covered produce applicable to the record
- Location of growing area
- Date and time of activity documented
- Dated signed or initialed by the person who documented the activity
- Some are required to be documented by a supervisor

Records kept on:

- Qualified exemption
- Training
- Water
- Soil amendments
- Cleaning and sanitizing equipment
- Sprouts



Produce Safety: Your To-do List

Task	Retailer	Wholesaler	Produce Grower
Ensure agricultural water safety			✓
Document biological soil amendments			✓
Record domestic or wild animal interactions			✓
Detail growing, harvesting, packing & holding data			✓
Maintain worker training, health and hygiene records			✓
Maintain records on equipment, tools & buildings			✓
Sprouts records			✓
Labeling for exempt products – from the grower	✓	✓	✓

Do these apply?

Yes, if you are a primary production or secondary activities farm and meet requirements



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.

Impact

FOREIGN SUPPLIER VERIFICATION (FSVP)

Impact: 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
 - Opportunity for GFSI
 - Food safety records
 - Sampling and testing



Key Considerations for FSVP

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



FSVP: Your To-do List

Task	Retailer	Wholesaler	Manufacturer
Determine for which of your suppliers, you are the FSVP Importer	✓	✓	✓
Verify foreign supplier facilities meet FDA FSMA Preventive Controls & Produce Safety Rules	✓	✓	✓
Verify food safety activities and maintain records	✓	✓	✓

Do these apply?

Yes, if it is determined you are the 'FSVP importer'



Impact

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



Sanitary Transportation: Your To-do List

Coming soon!

Task	Retailer	Wholesaler	Manufacturer

FSMA Finalizes Sanitary Transportation: Impact of Key Changes

Tuesday, April 26, 1:00 pm – 2:00 pm eastern

Register here:

<http://repositrak.com/events/>



Impact

FOOD DEFENSE

Key Considerations for Food Defense

Based on the Proposed Rule:

- Applies to manufacturing, processing and bulk liquid holding facilities
 - bulk liquid receiving and loading
 - liquid storage and handling
 - secondary ingredient handling (the step where ingredients other than the primary ingredient of the food are handled before being combined with the primary ingredient)
 - mixing and similar activities
- Written food defense plan based on vulnerability assessment



Food Defense: Your To-do List

Coming soon!

Task	Retailer	Wholesaler	Manufacturer

FSMA Finalizes Food Defense: How You're Expected to Prevent Intentional Adulteration

Tuesday, June 28, 1:00 pm – 2:00 pm eastern

Register here:

<http://repositrak.com/events/>



KEY IMPACT SUMMARY

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

- Check that **Facility Registration** is complete
- Learn about FSMA and the rules that apply to your company
- Obtain training through the FSPCA for the **Preventive Control Qualified Individual(s)**
- Form your “**FSMA Team**”
- **Implement compliance programs** for each FSMA rule that applies to your company
- Determine **recordkeeping system**
- **Train** all employees
- **Monitor and test** system
- **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
- **ReposiTrak**
 - <http://repositrak.com/>

Thank You!

- **Interest in food safety**
 - Compliance with FSMA requirements
 - Preventive risk management
- **ReposiTrak supporting SQF user experience**
 - Easier registration
 - Faster audit results
- **Have asked ReposiTrak to go deeper into food safety**
 - Food Safety Plan management
 - Quality assurance



Industry Standard Food Safety Platform



ReposiTrak

Trusted Brand Protection

Co-founders



Two Components



**Compliance
Management**

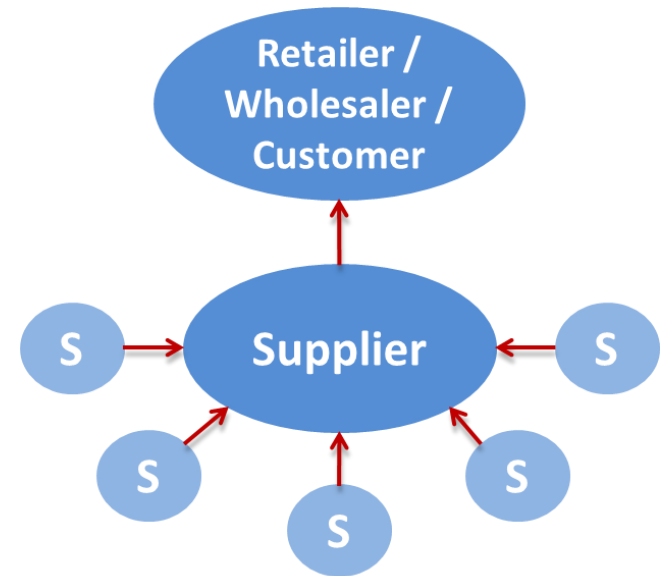


Track & Trace



1-Stop System for All Compliance Records

- Supplier & corporate records
- Dashboards and automated, proactive exception-based alerts
- Incredibly flexible
 - Choose/create supplier classifications
 - Customize document requirements
- A rapidly growing community



For your entire supply chain



Our Active Approach? A Dedicated Team



- We provide a dedicated staff
- We clean AND build your supplier contact list as part of ReposiTrak's implementation
- We reach out to every supplier and follow up until implementation is complete
- We **ACTIVELY** follow up with suppliers to correct non-compliance

70%

**Average decline in
Non-Compliance
among new users
on ReposiTrak**

