



FSMA's Sanitary Transportation Rule is Here: How to Stay on the Right Track

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Today's Speakers



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Today's Discussion

- Rule objectives and key changes
- Requirements for shippers, loaders, carriers, and receivers
- Training and recordkeeping requirements
- Training and reinforcement: keys to compliance
- Q&A



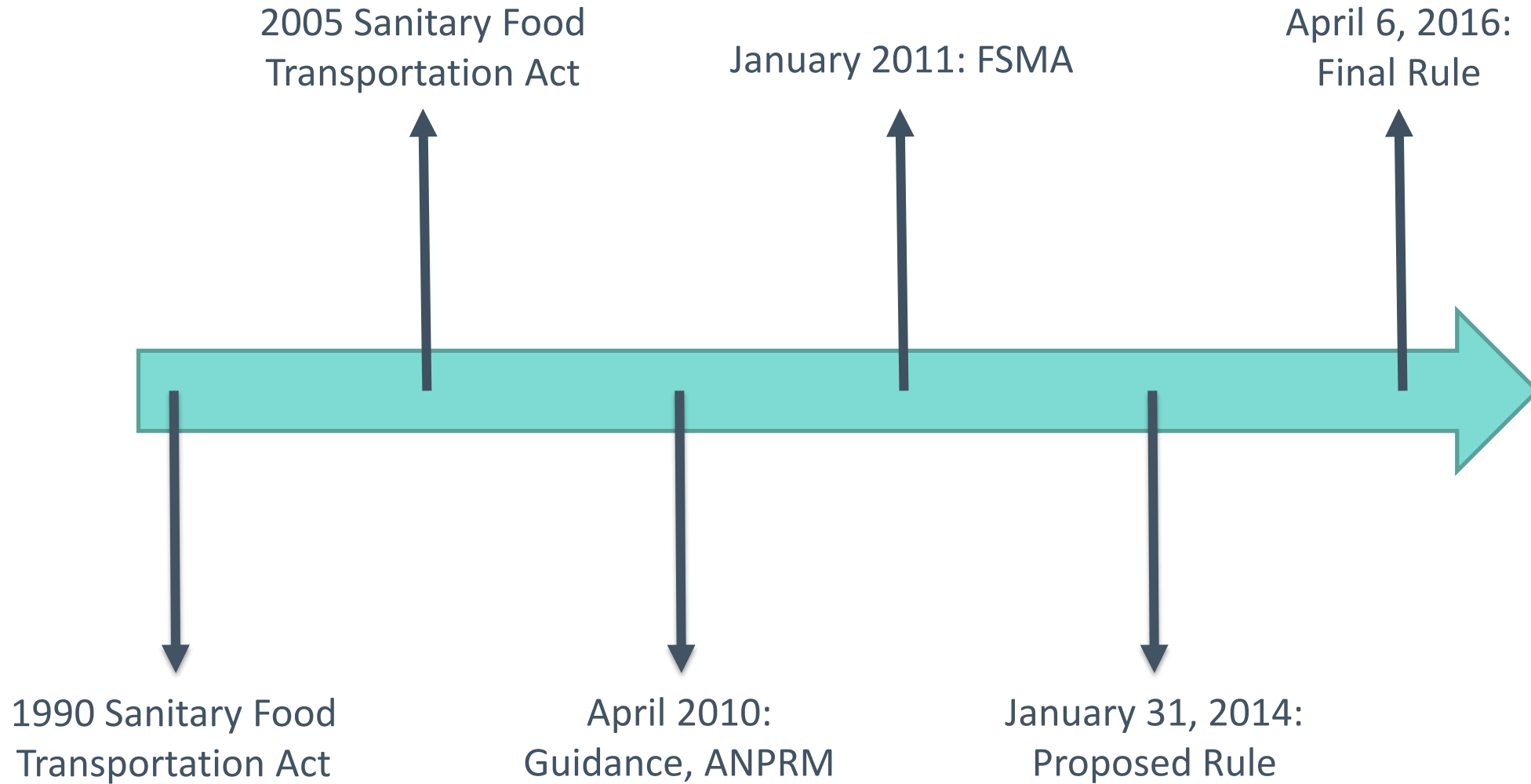
POLL

Under the Sanitary Transportation Rule,
are you a:

- Shipper
- Receiver
- Loader
- Carrier
- Multiple Roles/Other



How We Got Here



Rule Objective

- Prevent practices during transportation that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food



Key Takeaways

- FDA does not intend for companies that follow industry best practices to significantly alter their approach to sanitary food transportation
- Flexibility



Key Changes from the Proposed Rule

- Overall the regulation is less prescriptive and more GMP-like
- **Focus is on food safety**—the agency has removed references and requirements that address quality or deterioration or spoilage issues
- Exemption for food completely enclosed by a container, unless it requires temperature control for safety
- Primary responsibility placed on the shipper to determine what is needed for food safety and then make sure the necessary controls/practices are carried out
- Requirements for the use of a temperature indicating or recording device during transport have been replaced with a more flexible approach

Who is Subject to the Rule?



Shipper



Loader



Carrier



Receiver

Who is Not Subject to this Rule?

- Shippers, loaders, receivers, or carriers:
 - With less than \$500,000 in average annual revenues over a 3 year period
 - When engaged in operations of food transshipped through the United States to another country
 - When engaged in operations of food imported for future export
 - When engaged in operations of food when it is located in a facility that is regulated exclusively throughout the entire facility by USDA
- Farms performing transportation operations

What Foods Are Not Covered?

- Foods that are completely enclosed by a container (except foods that require temperature control for safety)
- Compressed food gases
- Food contact substances
- Human food byproducts transported for use as animal food that will not be subject to further processing
- Live food animals (except molluscan shellfish)



Requirements for Vehicles & Transportation Equipment

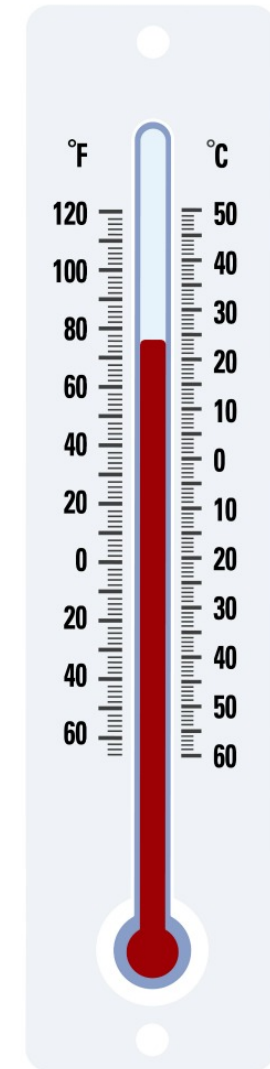
- Vehicles and transportation equipment must be:
 - Designed and of such a material and workmanship to be suitable and adequately cleanable for the intended use to **prevent the food from becoming adulterated**
 - Maintained in such a sanitary condition for their intended use as to **prevent the food from becoming unsafe during transportation** operations
 - Stored in a manner to **prevent harborage of pests or contamination** that could result in food becoming unsafe during transportation operations
 - If food needs to be refrigerated for safety, vehicles must be **designed, maintained, and equipped as necessary to provide adequate temperature control** to prevent the food from becoming unsafe during transportation operations

General Requirements for Transportation Operations

- Responsibility for ensuring that transportation operations are carried out in compliance with the regulation must be assigned to competent supervisory personnel
- All transportation operations must be conducted under appropriate conditions and controls to prevent the food from becoming unsafe during transportation operations.
 - Contamination by raw foods and nonfood items in the same load
 - Contamination and cross-contact in bulk vehicles or food not completely enclosed by a container
 - Adequate temperature control for food that requires temperature control for safety
- The type of food and its production stage must be considered in determining the necessary conditions and controls for the transportation operation

General Requirements, Continued

- If a shipper, loader, receiver, or carrier becomes aware of a possible material failure of temperature control or other conditions that may render the food unsafe, the food cannot be sold or otherwise distributed unless a **determination is made by a qualified individual** that the temperature deviation or other condition did not render the food unsafe



Requirements for Shippers



- The shipper must specify to the carrier and, when necessary, the loader, in writing:
 - Sanitary specifications for the carrier's vehicle and transportation equipment
 - An operating temperature for the transportation operation including, if necessary, the pre-cooling phase

Requirements for Shippers, Continued

- The shipper must develop and implement written procedures adequate to ensure that:
 1. Vehicles and equipment used in transportation operations are in appropriate sanitary condition to prevent the food from becoming unsafe during transportation
 2. A previous cargo does not make the food unsafe if food is transported in bulk
 3. Food that requires temperature control for safety is transported under adequate temperature control

- Flexibility here!



Requirements for Loaders

- Before loading:
 - Food not completely enclosed by a container, must determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food
 - Food that requires temperature control for safety, must verify that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, if necessary



Requirements for Carriers

- When the carrier and the shipper have a **written agreement**:
 1. Ensuring that vehicles and transportation equipment meet the shipper's specifications and prevent the food from becoming unsafe during transportation
 2. If requested, provide information to the shipper that identifies the previous cargo transported in the vehicle and/or the most recent cleaning of the bulk vehicle
 3. If requested by the receiver, providing the operating temperature specified by the shipper
 4. If requested by the receiver or shipper, demonstrating that the carrier has maintained temperature conditions consistent with the operating temperature specified by the shipper
 5. If requested by the shipper for food that requires temperature control for safety, pre-cool each mechanically refrigerated cold storage compartment
 6. Develop and implement written procedures

Requirements for Receivers

- Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse



Intra-Company Transportation Activities

- Shippers, carriers, loaders, and receivers, which are under the ownership or operational control of a single legal entity can rely on compliance with common, integrated written procedures for transportation activities
- Loaders must continue to :
 - Determine that the vehicle and transportation equipment is in appropriate sanitary condition
 - Verify that refrigerated transportation vehicles and equipment are adequately prepared for the transportation of food that requires refrigeration for safety



Less Than Load Shipments

- The loader is responsible for making sure that the vehicle is in a sanitary condition and is appropriate for transporting the food
 - Adequate physical condition
 - Free of visible evidence of pest infestation
 - Previous cargo that could cause the food to become unsafe
- FDA expects that the shipper would generally instruct the loader on what to inspect the vehicle for



Transportation of Food with or Subsequent to Non-Food

- The law mandates FDA establish a list of nonfood products that may render food simultaneously or subsequently transported in the same vehicle to be adulterated
 - FDA decided not to develop such a list
 - Packaging, segregation, and isolation can be effective means of protecting food from contamination by non-food items
 - FDA intends to develop guidance on this issue



International Shipments



Training Requirements for Carriers

- When the carrier and shipper have a written agreement that the carrier will be responsible for sanitary conditions during transportation operations, **the carrier must provide training to personnel that covers:**
 - Awareness of potential food safety problems
 - Basic sanitary practices to address those problems
 - The responsibilities of the carrier under the rule
- Training must be provided upon hiring and as needed



Recordkeeping Generally

- Retained for 12 months after their use has been discontinued
- Made available promptly to a duly authorized individual upon oral or written request
- Electronic records are exempt from compliance with Part 11
- Offsite storage is permitted if records can be retrieved and provided onsite within 24 hours of a request
 - Exception: carriers' written procedures for cleaning, sanitizing, and inspecting vehicles and transportation equipment must remain onsite
- Standard FOIA exemptions from disclosure apply

Records that Must be Retained

- Shippers must retain records:
 - That demonstrate that they provide sanitary specifications for vehicles and equipment and operating temperatures to carriers
 - Of the written procedures:
 - To ensure that vehicles and transportation equipment are in appropriate sanitary condition
 - For food transported in bulk, to ensure that a previous cargo does not make the food unsafe
 - For food that requires temperature control for safety, to ensure the food is transported under adequate temperature control
 - Of written agreements to have another party implement the written procedures
- Shippers, loaders, carriers and receivers that operate under the ownership or control of a single legal entity must retain records of written procedures for transportation activities

Records that Must be Retained



- Carriers must retain records:
 - Of the written procedures for:
 - Cleaning, sanitizing, and inspecting vehicles and transportation equipment
 - Providing the operating temperature specified by the shipper to the receiver if requested
 - Demonstrating that it has maintained temperature conditions
 - Providing information on previous cargo transported in a bulk vehicle and the most recent cleaning of the bulk vehicle
 - Of employee training (date, type of training, person trained) when the carrier has agreed in writing to assume responsibility for sanitary conditions during transportation
- Shippers, loaders, carriers and receivers must retain records of agreements that assign tasks under the rule

Waivers



Businesses that hold valid permits and are inspected under the National Conference on Interstate Milk Shipments' Grade "A" Milk Safety Program



Food Code "Food Establishments" that provide food directly to consumers, in certain circumstances



Businesses operating under the Interstate Shellfish Sanitation Conference's National Shellfish Sanitation Program (NSSP)

Compliance Dates

- **Large businesses:** April 6, 2017
- **Small businesses:** April 6, 2018





POLL

Under the Sanitary Transportation Rule, are you considered a:

- Large Business
- Small Business
- Unknown at this time



Enforcement

- Compliance encompasses all of the requirements in the regulations, but FDA will consider all circumstances surrounding a deviation before initiating enforcement action
- When responsibility is assigned by contract, FDA will consider the terms of the contract in determining who is responsible for compliance
 - If a task is assigned via contract to a party not covered by the rule, FDA will hold the party covered by the rule ultimately responsible for compliance
- DOT has the authority to conduct inspections, but FDA will likely take lead on enforcement when violations arise

Training & Reinforcement: Keys to Compliance



Challenges with Drivers!

- They can fly under the radar
- Not included as part of your food safety culture
- May lack understanding of food safety risks
- There can be challenges with accountability
- It can be tough managing their irregular schedules



Compliance Training: What is the best approach?

- A **blended learning** strategy is correlated to best outcomes
 - Leverage training to introduce/reinforce knowledge of new FSMA regulations
 - Reinforce critical food safety procedures with coordinated coaching, digital signage, and posters



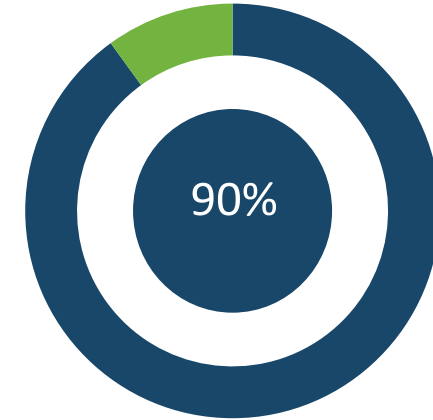
Training Alone is Not Enough



<15% of learners successfully apply what they learn



80% of content is forgotten within 30 days



90% of content is forgotten after one year



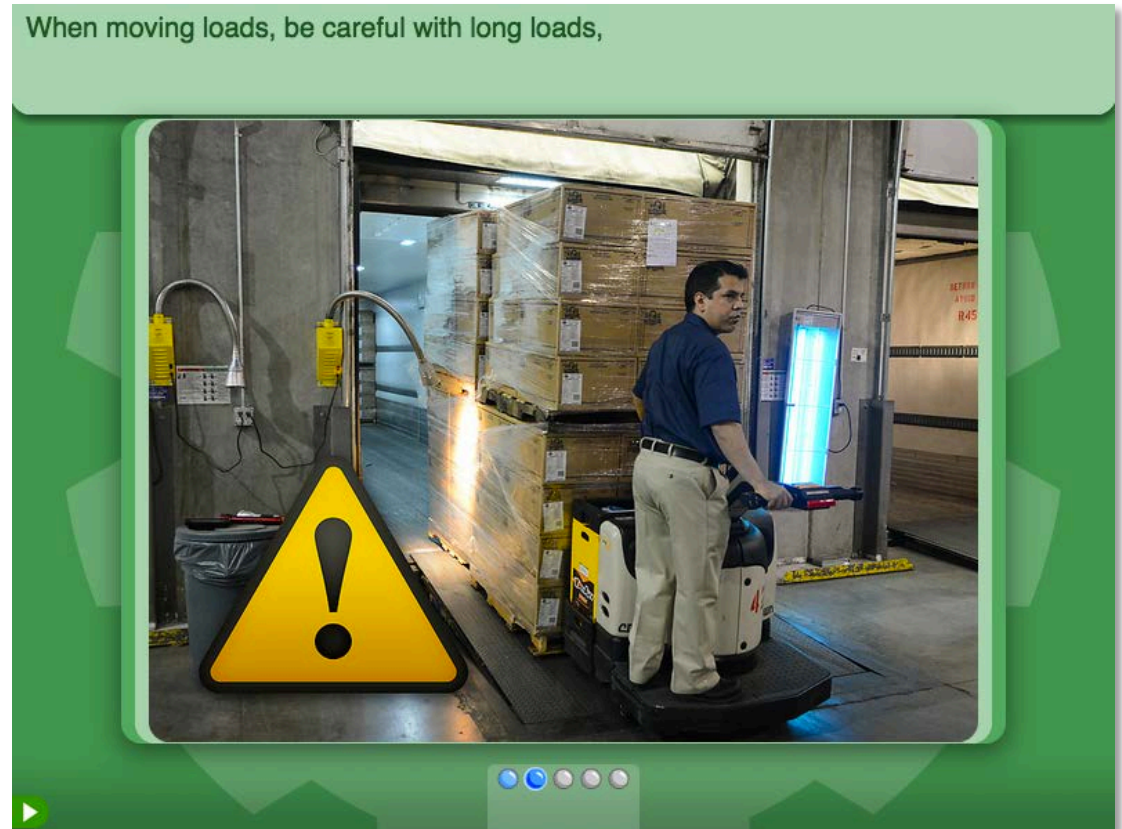
Compliance Training: What is the best approach?

- Communicate food safety 'wins' with drivers
- Introduce drivers to 'upstream' team members for big picture role in food safety
- Use posters/signs proactively to sustain food safety awareness, compliance and performance
- Recognize drivers for completed training efforts



Design the Training for Drivers

- Make it concise
- Tailor the learning objectives to drivers
- Create the training at the appropriate educational level
- Use words and images to convey key points



Help is Available Now

Alchemy has 7 specific driver courses available so you can start training now!

- Introduction to FSMA
- Driver Food Safety: SOPs Trailer Maintenance
- Driver Food Safety: SOPs Pre-Chilling Procedures
- Driver Food Safety: SOPs Maintaining Proper Temperature
- Driver Food Safety: SOPs Less Than Load (LTL) Delivery Stops
- Basic Food Defense for Drivers
- Effective Record Keeping Practices

Share the Why

- Contractual obligations between shippers and carriers
- Regulatory FSMA compliance
- Public health



- Course title: Introduction to FSMA
- Estimated course time = 13 minutes
- Learning objectives:
 - Describe some of the powers that FSMA gives the FDA
 - Understand the primary requirements of the seven main FSMA rules
 - Explain how FSMA has changed recordkeeping requirements

Planning for the Moments of Truth

Ensure your training incorporates the ‘what if’



- Course title: Driver Food Safety SOPs – Maintaining Proper Temperature
- Estimated course time = 2 minutes
- Learning objective:
 - Describe temperature monitoring procedures during transit
 - Procedures in case of a breakdown

Integrate the Cold Chain Team

Selectors and Loaders



Drivers



Receivers

- Loading Food Safety SOPs – Overview
- Food Safety SOPs – Pre-Load Temperature Checks
- Food Safety for Selectors – Overview
- Food Safety for Selectors – Safe Pallet Building Practices



- Receiving Food Safety SOPs – Overview
- Receiving Food Safety SOPs – Can Inspection

Alchemy Preventive Controls Qualified Individual Training Options



On-site classroom
across the country



On-site at
your facility



eLearning on
your terms

- Register Here: <http://www.alchemysystems.com/food-production/events/preventive-control/>

Compliance is Attainable!

- Understand the Sanitary Transportation Rule and it's application to you
- Obtain consulting advice on compliance early as needed
- Identify current gaps in food safety protocols by drivers
- Embrace drivers as part of your extended food safety culture

Q & A



THANK YOU

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