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FSMA Sanitary Transportation of Human and Animal Food

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Food Safety Modernization Act (FSMA)

Background

- FDA had mandate to regulate transportation since 1990 FDA never acted
- Sanitary Transportation of Food Act - 2005
- FSMA signed into law in 2011
  - Required FDA to regulate in 7 areas (**including transportation**)
- Proposed Sanitary Transportation Rule in 2014
  - Focused primarily on motor carriers
  - Did not under rail transportation
- Final Rule in 2016
  - Compliance required for most by ***April 6, 2017***

Sanitary Transportation Rules

What is Covered

- **Rail & Motor Carrier Transportation**
  - Food transported by any rail or motor vehicle
  - Any place in the United States
  - Including import/export but excluding food that is transshipped through US

- **Food**
  - Anything intended for consumption by humans or animals
  - Including ingredients
  - Food does not include:
    - Food fully enclosed by a container that does not require temperature control
    - Live animals, except molluscan shellfish (shrimp, lobster, etc.)
    - Compressed gasses and food contract substances
    - Human food byproducts used for animal food without further processing

Sanitary Transportation Rules

Who is Covered

Defined Roles

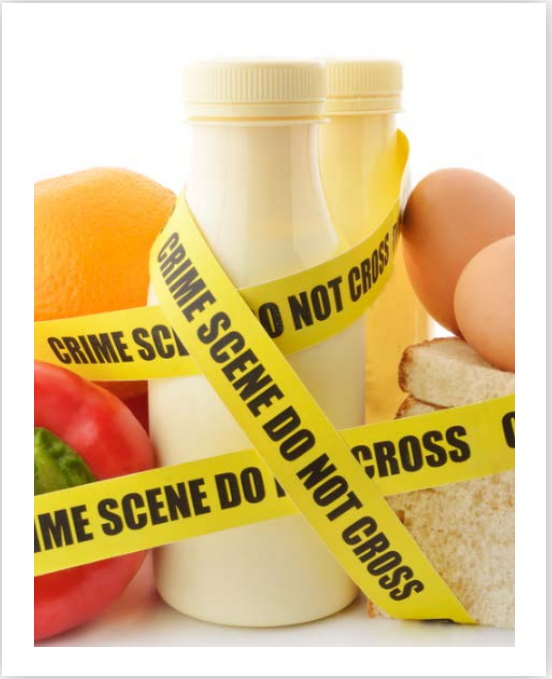
- **Shipper**
  - Person who arranges for the transportation of food
  - Can be ‘traditional shipper’, broker, 3PL, IMC, etc.
- **Loader**
  - Person who loads food onto a vehicle
- **Receiver**
  - Person who receives food after transportation.
- **Carrier**
  - Person who physically moves food by rail or motor vehicle
- **Roles are not discrete**
  - One person can have multiple roles
  - Multiple people can have same role

General Responsibilities

All Covered Persons

- Conduct transportation operations under conditions that prevent food from becoming unsafe, including:
  - Take effective measures such as segregation, isolation, or others to…
    - Protect food from contamination
    - Protect food transported from cross-contact
  - Ensure that food requiring temperature control is transported under adequate temperature control

- Take appropriate action to ensure food is safe if aware of a possible material failure of temperature control or other condition that may render food unsafe, including:
  - Communicate with other parties
  - Determination by qualified individual before food is sold or consumed



General Responsibilities
Equipment

- Equipment includes anything used to transport food
  - Rail cars, intermodal containers, pallets, conveyors/loading systems, etc.
- To prevent food from becoming unsafe, equipment must be…
  - Designed to be suitable and adequately cleanable for intended use
  - Maintained in a condition for intended use
  - Stored in a manner to prevent it from harboring pests or becoming contaminated in any way
- Refrigerated equipment must be able to maintain appropriate temperature

General Responsibilities
Additional Considerations

- What is ***Adequate?***
  - What's needed to accomplish the intended purpose in keeping with good public health practice
  - If food is rendered unsafe, something was not adequate
  - Will likely be determined after the fact

- Type of food must be considered in determining adequacy
  - Human food v. pet food v. live stock feed
  - Raw material v. ingredient v. finished food

Adequate for ***safety****, not quality*

Shipper Responsibilities

- Ensure equipment is in appropriate sanitary condition
- Inform carrier of specifications for equipment
- Specify operating temperature to carrier for food requiring temperature control
- Develop and implement written procedures:
  - For food transported in bulk, to ensure previous cargo does not make food unsafe
  - For food requiring temperature control, to ensure temperature control is maintained
  - For all food, to ensure transportation is conducted in a sanitary manner
- Shipper can assign compliance responsibility to others **by agreement only**
  - Shipper cannot require UP to be responsible without affirmative agreement

*Shipper has **primary responsibility** to ensure sanitary transportation*

Carrier Responsibilities

- Carrier only has responsibilities if it agrees, in writing, to be responsible for sanitary conditions during transportation
- If agreed to, Carrier may be responsible for:
  - Ensuring equipment meets shipper's specifications
  - Demonstrate that carrier maintained temperature conditions
  - Pre-cool refrigerated equipment
  - Identify one previous cargo for bulk equipment
  - Identify most recent cleaning for bulk equipment
- If agreed to, develop and implement written procedures that:
  - Specify practices for cleaning, sanitizing (if necessary), and inspecting equipment
  - Describe how carrier will demonstrate it maintained temperature control
  - Describe how carrier will provide previous cargo and cleaning information

Carrier Responsibilities (cont.)

- Carrier only has responsibilities if it agrees, in writing, to be responsible for sanitary conditions during transportation
- Adequate training that provides:
  - Awareness of potential food safety problems that may occur during transportation
  - Basic sanitary transportation practices
  - Carrier responsibilities under the rules
- Record keeping
  - Agreements
  - Procedures
  - Training

Loader & Receiver Responsibilities

- **Loaders**
  - Ensure shipper’s specifications are met before loading food, including inspecting equipment
  - Ensure refrigerated equipment is pre-cooled, if necessary, and otherwise suitable
- **Receivers**
  - For food that requires temperature control, assess that the food was not subjected to significant temperature abuse.