Proposed Rule for Sanitary Transportation of Human and Animal Food

http://www.fda.gov/fsma
Proposed Regulations for Sanitary Transportation
Summary of Requirements

• Shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, and food subject to USDA/FSIS requirements must use sanitary transportation practices to ensure the safety of the food they transport.
Significance of Proposal

• Part of FDA’s larger effort to focus on prevention of food safety problems throughout the food chain and is part of our implementation of the Sanitary Food Transportation Act (SFTA) of 2005 and the FDA Food Safety Modernization Act of 2011
History of Sanitary Food Transportation Regulation

- **1990 SFTA** – Transport of food in bulk
- **FDA/USDA ANPRM** – 1996, Transport of potentially hazardous foods
- **2005 SFTA** – Sanitary transportation practices for all food transportation
- **FDA ANPRM** – 2010, SFTA rulemaking
- **FSMA** – 2011, Timeframe for SFTA regs
2005 SFTA

• Food deemed adulterated if transported by motor vehicle or rail contrary to conditions (sanitary transportation practices) to be prescribed in new regulations

• Other transportation modes, e.g., ship, air, not addressed in SFTA
2005 SFTA Provisions

• Applicable to shippers, carriers, receivers, other persons engaged in food transport
• FDA to establish regulations for sanitary transportation practices addressing:
  – sanitation
  – vehicle use limitations
  – packaging isolation and other protective measures

– Information disclosure, e.g., between carriers and shippers
– Records
• Waivers
• Preemption
Key Elements of FDA’s Proposal

- Activities/entities covered/not covered
- Definitions
- Good transportation practices
  - Vehicles/equipment/operations/info exchange
- Training
- Records
- Waiver procedures
Covered by Proposal

- Transportation* operations of shippers, receivers and carriers
- Transportation of food in intrastate commerce

* Transportation means any movement of food in commerce by motor vehicle or rail vehicle
Not Covered by Proposal

- Trans-shipments of food through the U.S.
- Food not consumed in the U.S. (import for export)
- Transportation of raw agricultural commodities (RACs) by a farm
- Shippers, receivers and carriers with transportation operations with less than $500,000 in total annual sales
Not Covered by Proposal

• Transportation of:
  – Shelf stable food fully enclosed by a container
  – Live food animals
  – Compressed food gases
Examples of Types of Food Subject to Proposal

- Foods transported in bulk, e.g., juice, animal feed
- Packaged foods not fully enclosed by a container, e.g., fresh produce
- Foods that require temperature control for safety (TCS food) or to prevent spoilage
Provisions of Proposal

• Good transportation practices:
  – Provisions for vehicle and equipment design, storage and maintenance
  – Ensure temperature control where necessary to ensure safety and prevent spoilage
  – Ensure that transportation operations are conducted in a way that prevents contamination and cross contact
Provisions of Proposal

• Good transportation practices:
  – Shipper specifies all necessary sanitary requirements for vehicle, including conditions necessary for a temperature-controlled food
  – Carrier must supply a vehicle that meets the shipper’s specifications, including precooling
  – Shipper verifies vehicle precooling and sanitary condition, as appropriate
Provisions of Proposal

• Good transportation practices
  – Carriers must be able to demonstrate to shippers (and upon request, receivers) that appropriate temperature conditions were maintained during transport, as appropriate
  • Flexible and consistent with current practices
Provisions of Proposal

• Good transportation practices (bulk transport)
  – For bulk vehicles, carriers must provide to shippers information that:
    • Identifies of up to 3 previous cargoes for the vehicle
    • Describes the most recent cleaning of the vehicle
  – Flexible and consistent with current practices
Provisions of Proposal

• Required records for shippers
  – Records that demonstrate that the shipper provides information to carriers about the necessary sanitary requirements for a vehicle, and the necessary temperature conditions for a temperature-controlled food as appropriate
Provisions of Proposal

• Required records for carriers
  – Carriers must develop written procedures (SOPs) for cleaning and inspection of vehicles, and that describe how it will meet requirements to provide information to shippers about temperature conditions and bulk cargo protection, as appropriate
  – Training records
Provisions of Proposal

• Required training for carriers
  – Carrier personnel engaged in transportation operations must have training that provides an awareness of the food safety problems that may occur during transport, proper sanitary practices, and their responsibilities under the rule
Waiver Procedures

• Proposed rule includes process for FDA to grant waivers either on its initiative or via petition
• Preamble discusses tentative conclusions on potential waivers
Potential Waivers

- Shippers, carriers and receivers holding valid permits under the NCIMS Grade A Milk program, when transporting Grade A milk and products.
- Food establishments, e.g., retail stores and restaurants, holding valid permits, when acting as a receiver or as a carrier delivering food to consumers.
Effective and Compliance Dates

• Effective date:
  – 60 days after the final rule is published

• Compliance dates
  – 2 years after publication of the final rule for small businesses
  – 1 year after the date of publication of the final rule for businesses other than small businesses
Proposed Small Business Definition

• A business subject to this rule employing fewer than 500 persons except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to this rule having less than $25,500,000 in annual receipts.
How to Comment on the Proposed Rules

• http://www.regulations.gov
• Link to rules on http://www.fda.gov/fsma
• Comment period closes on May 31, 2014
• Comment periods on major FSMA proposals will be coordinated to enable comment on how the rules can best work together
Outreach and Technical Assistance Will Continue

- Public meetings
- Presentations
- Listening sessions
- Guidance documents

Partnerships will be essential
More Information Available

- Web site: http://www.fda.gov/fsma
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov