

## ALERTS

### Food, Drug And Device Law Alert - FDA Issues Final Rule On Sanitary Transportation Of Food

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Food and Drug Administration (FDA) recently [issued the sixth of the seven major final rules](#) required by the Food Safety Modernization Act (FSMA), one governing the safe transportation of food that actually has its origins in the Sanitary Food Transportation Act of 2005. According to FDA's summary, the rule will help maintain the safety of human and animal food during transportation by establishing conditions, practices, tracking, and record-keeping governing the sanitary transportation of food.

The highlights of the rule include establishing requirements for:

- **Vehicles and transportation equipment:** The design and maintenance of vehicles and transportation equipment to ensure they do not contaminate the food they transport.
- **Transportation operations:** The measures taken during transportation to ensure food is not contaminated, such as adequate temperature controls and separation of food from non-food items in the same load.
- **Information exchange:** Procedures for exchange of information about prior cargos, cleaning of transportation equipment, and temperature control between the shipper, carrier, and receiver, as appropriate to the situation. For example, a carrier transporting bulk liquid non-dairy foods would want to ensure vehicles that have previously hauled milk will not introduce allergens into non-dairy foods through cross contact.
- **Training:** Training of carrier personnel in sanitary transportation practices and documentation of the training.
- **Records:** Maintenance of written procedures and records by carriers and shippers related to transportation equipment cleaning, prior cargos, and temperature control.
- **Waivers:** Procedures by which the FDA will waive any of these requirements if it determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and that it is in the public interest.

FDA issued the proposed version of this rule more than two years ago in February, 2014. Based on the feedback received, FDA made a number of changes in the final rule. Some of the more important changes include:

- The definition of "transportation operations" has been changed to exclude:

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- Transport of foods completely enclosed by a container (except for food that requires temperature control)
  - All transportation activities performed by a farm. The diversity of farms and their transportation operations make it difficult to develop regulations that would be broadly suitable. Instead, the FDA is considering providing guidance on good farm transportation practices
  - Transport of human food by-products for use as animal food without further processing, i.e., those sold directly to farmers to be fed to livestock. These do not include by-products that are transported to facilities to be manufactured into feed or pet food
  - Transport of food contact substances, which include coatings, plastics, paper, adhesives, as well as colorants, antimicrobials, and antioxidants found in packaging
  - Transport of live food animals, except for molluscan shellfish, such as oysters, clams, mussels and scallops
- Another change is particularly important to rail carriers. According to comments, the shipper or loader, and not the rail carrier, has generally assumed responsibilities, such as inspecting a railcar, to ensure that it is suitable. Shippers will continue to hold primary responsibility for sanitary conditions of transport under the rule unless the carrier has entered into a written agreement with the shipper to assume this responsibility. By contrast, motor carriers generally own their vehicles and are directly involved with sanitation during transportation operations.
  - “Loaders” have been added as a covered party. A loader is a person who physically loads food onto a motor or rail vehicle.
    - Before loading a food not completely enclosed by a container, the loader must determine that the transportation equipment is in appropriate sanitary condition.
    - Before loading a food requiring temperature control, the loader must determine that each mechanically refrigerated cold storage compartment is adequately prepared for refrigerated transportation, including precooling, if necessary.
  - The final rule clarifies that the intended use of the vehicle or equipment (e.g., transporting animal feed versus human food) and the production stage of the food being transported (e.g., raw materials versus finished products) are relevant in determining the applicable sanitary transportation requirements.
  - Requirements for the use of a temperature indicating or recording device during transport have been replaced with a more flexible approach. The shipper and carrier can agree to a temperature monitoring mechanism for foods that require temperature control for safety. The original proposal specified that a compartment must be equipped with a thermometer, temperature measuring device, or temperature recording device.

- FDA agreed with commenters that carriers need to demonstrate they maintained requested temperature conditions only upon request, rather than as a requirement for every shipment, as previously proposed.
- Primary responsibility for determining appropriate transportation operations now rests with the shipper, who may rely on contractual agreements to assign some of these responsibilities to other parties.
- Shippers must develop and implement written procedures to ensure that equipment and vehicles are in appropriate sanitary condition.
- Shippers of food transported in bulk must develop and implement written procedures to ensure that a previous cargo does not make food unsafe.
- Shippers of food that require temperature control for safety must also develop and implement written procedures to ensure that food is transported under adequate temperature control. If a covered person or company at any point in the transportation chain becomes aware of a possible failure of temperature control or any other condition that may render a food unsafe, that food must not be sold or distributed until a determination of safety is made

The rule provides the general date for compliance is one year after its publication. Small businesses other than motor carriers, who are not also shippers and/or receivers employing fewer than 500 persons and motor carriers having less than \$25.5 million in annual receipts, would have to comply within two years after the publication of the final rule.

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