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# Legal Requirements and Liabilities under FDA Food Safety Modernization Act of 2011

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# NEW USFDA REGULATIONS

**On February 5, 2014, the USFDA published proposed regulations under the Sanitary Food Transportation Act of 2005 and Food Modernization Act of 2011.**



# NEW USFDA REGULATIONS



- Title: Sanitary Transportation of Human and Animal Food, 21 C.F.R §1.900, *et seq.*
- Establishes requirements for shippers and receivers, and carriers by motor vehicle and rail.
- Significant and substantial change for sanitary food transportation practices.

## NEW USFDA REGULATION | EFFECTIVE DATE

- The new regulations took effect June 6, 2016: 21 CFR Part 1, Subpart O, Sections 1.900 – 1.934.
- Compliance dates will be staggered: two years for “small businesses,” and one year for all others.

## PROPOSED USFDA RULES | EFFECTIVE DATE

- “Small business”:
  - For shippers and receivers, is a firm employing fewer than 500 employees.
  - For carriers which are not also shippers and receivers, is a company having less than \$25 million in annual receipts.
- Therefore, most businesses will have two years.

## DOES THIS APPLY TO SHIPPERS OF INTERMODAL EXPORT AND IMPORT SHIPPERS?

- The regulation does not apply to ocean carriers, but may apply to intermediaries which arrange the inland transportation of a through intermodal move, as they may be considered “shippers.”
- Because shippers in an intermodal move into the U.S. are subject to the regulation, insurance coverage of cargo will be impacted, as they may suffer losses caused simply by technical violations of the regulations.

## NEW USFDA RULES | SCOPE OF CHANGE

- Food transported or offered for transport by a shipper, carrier, or receiver engaged in transportation operations not in compliance with the regulations could render the food to be considered “adulterated” within the meaning of the Food, Drug and Cosmetic Act, 21 U.S.C. §321 (21 C.F.R. §1.902).
- The food could be unfit for human or animal consumption, with little salvage value beyond fertilizer or compost.

# NEW USFDA RULES | SCOPE OF CHANGE

- The regulations require shippers, carriers and receivers to use sanitary transportation practices to ensure the food being transported to market is fit for human and animal consumption.
- The regulations seek to curtail practices that create or allow food safety risks, including:
  - Failure to properly refrigerate food by maintaining temperatures
  - Inadequate cleaning of vehicles between loads
  - Failure to protect during transportation



# SHIPPER REQUIREMENTS

- Shippers are required to provide written sanitary requirement to carriers regarding the carrier's vehicles and equipment.
- This includes design requirements and cleaning procedures.
- The shipper and carrier must maintain, for at least twelve months, records of providing and receiving these requirements.



- Before loading, the shipper is required to visually inspect the transportation equipment if loading food not completely enclosed by a container.
- The shipper must determine that the equipment is in appropriate sanitary condition.
- Shippers of food that can support rapid growth of undesirable microorganism in the absence of temperature control must:
  - Specify in writing to the carrier the temperature conditions necessary during transportation.
  - Before loading, verify that each freezer and mechanically refrigerated cold storage compartment has been pre-cooled in accordance with shipper's requirements.

# CARRIER REQUIREMENTS

- The carrier must:
  - Supply transportation equipment that meets the shipper's written specifications, or
  - Is otherwise appropriate to prevent food from becoming filthy, putrid, decomposed or otherwise unfit for food from any source.



- The carrier must:
  - Once transportation is complete, demonstrate to the shipper, and if requested, to the receiver, that it has maintained temperature conditions consistent with shipper specifications.
- The carrier and shipper can enter an agreement making the shipper responsible for monitoring and ensuring acceptable temperature conditions during transportation operations.
- We think such agreements are unlikely unless the shipper is providing the refrigerated equipment.

# CARRIER REQUIREMENTS

- Before offering a vehicle to transport food that can support rapid growth of undesirable microorganism in the absence of temperature control, the carrier must:
  - Pre-cool each mechanically refrigerated freezer and cold storage compartment as specified by the shipper.
- A carrier offering a bulk vehicle for food transportation must provide the shipper information that identifies the previous three cargoes.
- The carrier must also provide information to the shipper describing the most recent cleaning.
- The shipper and carrier can agree to vary these requirements if other procedures establish the vehicle is safe and clean.

# CARRIER REQUIREMENTS

- A carrier must develop written procedures:
  - Specifying safe practices for cleaning and sanitizing transportation equipment.
  - Describing how it will comply with temperature control requirements.
  - Describing how it will comply with the requirements relating to bulk vehicles.
- A carrier must also provide training to personnel that provides an awareness of potential food safety problems that may occur during transportation (and maintain records of such training).



# EXEMPTIONS

- The following are exempt:
  - Shippers, receivers and carriers engaged in food transportation operations with less than \$500,000 in total annual sales.
    - ✓ Note that 90% of truckers have fewer than six trucks, so many will be exempt.
    - ✓ However, Hub may want to make the requirements applicable by contract.
  - “Shelf-stable” food product completely enclosed in a container: “canned juice, canned vegetables, canned meat, bottled water, and dry food items such as rice, pasta, flour, sugar, and spices.”
  - Live food animals and raw agricultural commodities.
  - Food transshipped through the U.S. to another country.
  - Food imported for future export that is neither consumed nor distributed in the U.S.

# DOES THIS APPLY TO SHIPPERS OF INTERMODAL EXPORT AND IMPORT SHIPMENTS?

- What about intermodal export and import shipments, or airfreight shipments?
- The comments to the proposed regulations make clear that it is the FDA's intent that they apply if domestic rail or motor carrier service is used.
- The transfer of the container (intermodal or air) to a motor carrier or rail would be considered initiated by the overseas exporter/shipper.

## CARMACK LIABILITY

- What does this mean for liability under Carmack?
- Prior case law can shed some light on how courts will interpret disputes under new law.
- Framework already exists for imposing liability for damage to goods based on market concerns.
- The USFDA comments to the new rule clarify that it is not meant to change Carmack liability rules or equate a broken seal to adulteration.

## OVERALL TREND AND IMPACT

- However, the new regulations will shift the burden of proof to the carrier to show compliance with instructions and all other aspects of the regulations.
- The practical impact will be that even more shipments than currently that experience even minor or brief temperature deviations from shipper requirements will be deemed “adulterated,” even if perfectly safe.

## OVERALL TREND

- This trends with the food industry’s “zero defect” approach to food transportation.
- The expectation is that this will all be addressed through higher prices for food items and through insurance.

## DAMAGE TO FOOD PRODUCTS | CASES

- *Land O'Lakes, Inc. v. Superior Serv. Trans. of Wis., Inc.*, 500 F. Supp. 2d 1150, 1156 (W.D. Wis. 2007)
- *Oshkosh Storage Co. v. Kraze Trucking, LLC*, 65 F. Supp. 3d 634 (E.D. Wis. 2014)
- *Atlantic Mut. Ins. Co. v. Napa Transp., Inc.*, 201 Fed Appx. 19 (2<sup>nd</sup> Cir. 2006)

## COGSA CASES – FOOD PRODUCTS

- *Orient Overseas Container Line LTD v. Crystal Cove Seafood Corp.*, 2012 WL 463927 (S.D.N.Y. 2012)
- *Atlantic Mut. Ins. Co., Inc. v. CSX Lines, LLC*, 432 F.3d 428 (2<sup>nd</sup> Cir. 2005)