
FSMA Finalizes Sanitary Transportation: Impact of Key Changes

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Q: How does this requirement apply to carriers who have owner operators?

A: Same requirements apply. The regulations must be met.

Q: How does this training after "hiring" apply to carriers who have owner operator who are in affect not employees?

A: When an agreement is in place between the shipper and the carrier that the carrier is responsible for the sanitation conditions during transport, training is required for carriers and documentation of training is required by carriers.

Q: What category do property brokers fall into?

A: That depends on what the broker does. If the broker arranges for the transportation of the food in the US, then the broker becomes a "shipper" under the FDA rule and definition.

Q: Do transportation companies need to consider PC [Preventive Controls] for their operation?

A: Depends if the transportation company has a Distribution Center or Warehouse. If so, they could also fall under the Preventive Controls Rule.

Q: So railcars of rice which are under USDA are exempt?

A: USDA Meat and Poultry inspected products are exempt at shipping but commodities are not. Depending on the packaging, rice might be covered under the rule.

Q: Can the BOL [Bill of Lading] be considered an agreement between shipper and carrier?

A: The agreement must have specific information regarding sanitation conditions and temperature requirements. If that information is included in the BOL, then it would meet the intent of the rule. However, most BOLs in the industry today don't have such information.

Q: So meat plant regulated / inspected by USDA are exempt?

A: Yes, see section 1.900 (a)(3) of the Rule.

Q: Can a shipper (broker) to carrier contract be considered a written agreement for the purpose of the agreed upon specifications? Also could a rate confirmation be considered a written agreement between a carrier and a shipper (broker)?

A: Contracts can be written agreements. Rate confirmations would need to include the information on cleaning procedures, sanitary conditionals, temperature requirements including pre-cooling.

Q: What about sanitizing evidence of the trucks?

A: Yes, and documentation.

Q: We are a farm and also process manufacturer of our own produce. Do we fall into the sanitary transportation rule because we place our raw food product onto wagons and transport that to our processing plant?

A: Farms are not shippers. The manufacturing plant will need to comply as the shipper if the product is TCS or not enclosed.

Q: What will third party logistics parties have to do and implement to survive this challenge in the future?

A: Depending on the services that the 3rd party logistics offers it can become subject to different parts of the rule as a shipper, carrier and maybe receiver.

Q: Would this apply to Amazon and Google?

A: Depends on the transportation methods used by those companies.

Q: What is the definition of Significant Temperature Abuse?

A: Not defined but we expect further FDA guidance on what constitutes "conditions that may render the food unsafe during transportation".

Q: Still not clear as to when the "food shipping container" falls under this rule. Not when on the ship, but when off-loaded onto a truck?

A: Rail and truck transportation in the US is covered under the rule. If a shipping container is imported into the US on a ship and transferred onto a truck at a port, the coverage starts at the truck at the US port.

Q: What or who defines "adequate temperature control"?

A: Temperature control is mentioned many times throughout the rule but is not defined.

Q: Please clarify statement made at end regarding who will have the most responsibility under this rule.

A: Shippers and carriers have the most responsibility under this rule as determined by the regulatory language applying to each.

Q: How will shipping and loading dock design apply to this rule?

A: The rule mentioned design of vehicles several times.

Q: Is there a reference document to guide the limitation of unsafe temperatures?

A: There are only 4 TCS produce items - cut leafy greens, cut melons, cut tomatoes and sprouts. All others are refrigerated for quality. USDA AMS has detailed information on ideal storage conditions of produce items.

Q: Transportation of food that is completely enclosed by a container except food that requires temperature control for safety is exempt from the Sanitary Transportation rule. What is definition of a "container" that is completely enclosed? Are sealed poly/vinyl bags considered as an enclosed container? Thank you.

A: Sealed bags should be considered enclosed. The FDA defines "Food not completely enclosed by a container means any food that is placed into a container in such a manner that it is partially open to the surrounding environment. Examples of such containers include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. This term does not include food transported in a bulk vehicle as defined in this subpart."

Q: Does ice cream considered a temperature controlled for safety food? If temp was lost, the product would melt....

A: The Blue Bell outbreak changed everything with ice cream. It probably depends on the temperature but I would say that ice cream is a TCS food.

Q: Is there a sense of what key requirements should be assigned to shippers or parties in the distribution chain and away from receivers.

A: The agreement should be between shippers and carriers. The sanitary conditions and temperature specifications should be shared.

Q: How often does a trailer need to be cleaned, is it after every load?

A: Depends on the trailer and what it is carrying.

Q: Can you explain the waiver more in regards to the Retailer? What is the retailer waived from?

A: This is what FDA stated in the preamble that they tentatively determined that it would be appropriate to waive the following: • "Food establishments, i.e., retail and food service operations, holding valid permits, only when engaged in transportation operations as receivers, or as shippers and carriers in operations in which food is relinquished to consumers after transportation from the establishment. "

Q: So, do retailers' loaders have to comply with the rule just not the receivers? Can you clarify the retailer DC responsibilities to comply with the Rule?

A: The DC will need to comply as a receiver. The shipments to the stores are expected to be exempt under the waivers.

Q: I work for a grocery store. I read where FDA will be issuing waivers for grocers. Is this still occurring or will we be held to the standard?

A: Shipments directly to grocery stores and directly to consumers are expected to be exempted under waivers. Since grocery stores are under the food code, the FDA sees these shipments as low risk.

Q: Regarding compliance date. We are a wholesaler with less than 500 FTE however our volume is greater than \$27M are we considered a motor carrier?

A: Good question. If you are acting as the carrier - it would probably be the one year, but if non-carrier, then you could make the case that you are a small business.

Q: FDA has said that they will not be applying the temperature monitoring record keeping requirements to frozen shipments. However, our vacuum packed fish fillets are labeled "Keep frozen" in order to prevent C. botulinum outgrowth. Does this mean that we do need to maintain temperature monitoring records for shipment of these vacuum packed products?

A: Continue to comply with your Seafood HACCP plan requirements.

Q: Are trailer refrigeration records on a per-unit, per load basis required and how long do they have to be kept?

A: The rule does not specify. However, the agreement between shipper and carrier can specify the required records. Records must be kept for 12 months beyond the time the agreement is in place.

Q: What if you are a manufacturer or processor who transports food between your own facilities or locations? Is that included in transportation?

A: Yes and your written procedures can be the documentation for compliance with the Sanitary Transportation rule.

Q: Do food manufacturers that warehouse food products prior to distribution have to have a preventive control plan for warehousing as well?

A: If the warehouse is in a separate location and under a separate FDA registration number than the manufacturing facility, then a separate PC plan for the warehouse might be necessary. For holding facilities, temperature control is the primary and sometimes the only control point.

Q: What is meant by "Equipment" when talking about must be cleaned or sanitized?

A: Transportation equipment is defined as "bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems." Also rail cars not on locomotives and trailers not attached to trucks.

Q: Are shelf stable foods exempted?

A: Yes- if it is enclosed and does not need temperature control.

Q: Would raw sugar be included in the scope?

A: Depends on the packaging. If bulk, then it would be covered by the rule to make sure it is transported in sanitary conditions.

Q: Can you define "material failure of temperature control"?

A: The phrase is used multiple times in the final rule but is not defined.

C: Just a comment - the reason we are attending this webinar is because we KNOW that we need to "dig into this rule". We're not looking for the "30K foot view."

R: Hopefully we provided more information about the rule and some clarity. If you need additional guidance, please feel free to contact either speaker through ReposiTrak.

Q: Will food enclosed in a multi wall bag or tote sack product be considered a food is completely enclosed? (eg. Wheat flour)

A: As long as there are no vents in the bag, it should meet the requirements. The definition for "Food not completely enclosed by a container means any food that is placed into a container in such a manner that it is partially open to the surrounding environment. Examples of such containers include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. This term does not include food transported in a bulk vehicle as defined in this subpart."

Q: If I have leased rail car, then will I be treated as carrier?

A: Yes, If you use it to transport food you it is very likely that you will fall under the shipper, carrier or receiver definitions of the rule (subject to how you will use the rail car).

Q: Does this rule cover bulk shipment in railcar i.e. bulk edible oil or animal food i.e. soybean meal?

A: Yes, these would be covered products under the rule.

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