

# **Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation: Guidance for Industry Small Entity Compliance Guide**

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
November 2017**

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# **Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation: Guidance for Industry<sup>1</sup>**

## **Small Entity Compliance Guide**

This guidance represents the Food and Drug Administration's (FDA or Agency) current thinking on this topic. It does not establish any rights for any person and does not bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance using the contact information on the title page.

### **I. INTRODUCTION**

**The FDA Food Safety Modernization Act of 2011 (FSMA)** directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. On April 6, 2016, FDA published in the *Federal Register* a final rule, *Sanitary Transportation of Human and Animal Food* (Sanitary Transportation rule) (81 FR 20091), that establishes requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. The final rule became effective on June 6, 2016. Compliance dates are staggered – see “WHEN DO I HAVE TO COMPLY WITH THE RULE?”

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document is intended to assist small entities in complying

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<sup>1</sup> This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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with the rule set forth in 21 CFR Part 1, subpart O concerning Sanitary Transportation of Human and Animal Food. The rule is binding and has the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

### **A. Purpose of this Compliance Guide**

This guide was developed to inform shippers, receivers, loaders, and carriers engaged in transportation operations about the Sanitary Transportation rule and how to comply with it. It contains important information that may affect your business.

For additional information on the Sanitary Transportation rule, see <https://www.fda.gov/food/guidanceregulation/fsma/ucm383763>.

### **B. Key Requirements**

The rule establishes requirements for:

- Vehicles and transportation equipment: The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports to become unsafe. (21 CFR 1.906)
- Transportation operations: The measures taken during transportation to ensure food safety. (21 CFR 1.908)
- Training: Training of carrier personnel in sanitary transportation practices and documentation of the training. This training is required when the carrier and shipper establish an agreement that the carrier is responsible for sanitary conditions during transport. (21 CFR 1.910)
- Records: Maintenance of records of written procedures, agreements and training (required of carriers). (21 CFR 1.912)

## **II. WHO MUST COMPLY WITH THE RULE?**

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Generally, the requirements of the Sanitary Transportation rule apply to shippers, receivers, loaders, and carriers engaged in transportation operations whether or not the food is being offered for or enters interstate commerce. (21 CFR 1.900(a))

### **A. Definitions**

The Sanitary Transportation rule uses a number of terms in very specific ways. A full list of these terms appears in this guide in section IX. The terms defined here and in the section “Who is exempt from the requirements of the Sanitary Transportation rule?” will help you determine if your business is subject to the rule. (21 CFR 1.904)

Table 1--Key Terms Used in Part 1, Subpart O

<b>Term</b>	<b>Definition</b>
Carrier	A person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.
Loader	A person that loads food onto a motor or rail vehicle during transportation operations.
Non-covered business	A shipper, loader, receiver, or carrier engaged in transportation operations that has less than \$500,000, as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the 3-year period preceding the applicable calendar year. The baseline year for calculating the adjustment for inflation is 2011.
Receiver	Any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.
Shipper	A person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.
Small business	1. A business that is not a motor vehicle carrier and that employs fewer than 500 full-time equivalent employees, or

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	2. A motor vehicle carrier that is not a shipper or receiver that has less than \$27,500,000 in annual receipts.
Transportation	Any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

**B. Who is exempt from the requirements for the Sanitary Transportation Rule?**

Non-covered businesses (see definition in Table 1) are not subject to the rule and therefore do not need to comply with the rule. In addition, shippers, receivers, loaders, or carriers subject to the Sanitary Transportation rule do not need to comply with the rule when they are engaged in the following transportation operations and activities.

Table 2--Exemptions for Part 1, Subpart O

<b>Exemption</b>	<b>Conditions</b>
Transportation operations of food that is transshipped through the U.S. to another country  21 CFR 1.900(b)(1)	
Transportation operations of food that is imported for future export  21 CFR 1.900(b)(2)	
Transportation operations of food located in food facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act  21 CFR 1.900(b)(3)	
Transportation activities performed by a farm  21 CFR 1.904 "Transportation operations"	



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<b>Exemption</b>	<b>Conditions</b>
Transportation of compressed food gases 21 CFR 1.904 “Transportation operations”	
Transportation of food contact substances 21 CFR 1.904	Food contact substances as defined in section 409(h) of the Federal Food, Drug, and Cosmetic Act
Transportation of human food byproducts for use as animal food without further processing 21 CFR 1.904 “Transportation operations”	See definition of “Transportation operations”
Transportation of food that is completely enclosed by a container 21 CFR 1.904 “Transportation operations”	Except a food that requires temperature control for safety
Transportation of live food animals 21 CFR 1.904 “Transportation operations”	Except molluscan shellfish

**C. Has FDA issued any waivers?**

Yes, FDA has waived the requirements of the Sanitary Transportation rule for three classes of businesses (see Section VIII for additional information about waivers):

1. Businesses holding valid permits that are inspected under the National Conference on Interstate Milk Shipments’ Grade “A” Milk Safety Program, only when transporting bulk and finished Grade “A” milk and milk products.
2. Businesses authorized by the regulatory authority to operate a food establishment (e.g., restaurants, grocery stores) when engaged in transportation as receivers, or as shippers and carriers in operations in which food is delivered directly to consumers, or to other locations the establishments or affiliates operate that serve or sell food directly to consumers. (This waiver applies to establishments that provide food for human consumption such as restaurants, supermarkets and home grocery delivery services. Establishments that only sell animal food are not included under this waiver. For additional information refer to the “Clarification on Food Establishment Waiver from Requirements of the Sanitary Transportation of Human and Animal Food Rule” guidance at:

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<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM571341.pdf>).

3. Businesses that are certified and inspected under the requirements established by the Interstate Shellfish Sanitation Conference's (ISSC) National Shellfish Sanitation Program (NSSP) when transporting shellfish (such as oysters, clams, mussels or scallops) in vehicles permitted under ISSC authority.

### **D. Do I have any modified requirements if I am a small business?**

No, all of the requirements of the Sanitary Transportation rule apply to a small business. However a small business has an additional year before it is required to comply with the rule (see Section III). (Also, a shipper, loader, receiver, or carrier engaged in transportation operations that has less than \$500,000 in average annual revenues is not covered by the rule. See section II.B.)

## **III. WHEN DO I HAVE TO COMPLY WITH THE RULE?**

We encourage you to comply with the Sanitary Transportation rule as soon as possible. However, we are not requiring you to comply with the rule right away. As shown in the table below, the amount of time we are allowing you to comply with the Sanitary Transportation rule depends on the size of your particular business.

Table 3--Compliance Dates for the Sanitary Transportation Rule Based on Size of Business

<b>Size of Business</b>	<b>Compliance Date</b>
Small businesses, i.e., a business other than a motor vehicle carrier with fewer than 500 full-time equivalent employees, or a motor vehicle carrier that is not also a shipper or a receiver that has less than \$27,500,000 in annual receipts	April 6, 2018
Other businesses that do not qualify for exemptions	April 6, 2017

## **IV. VEHICLES AND TRANSPORTATION EQUIPMENT**

### **A. What is a vehicle?**

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A “vehicle” is a land conveyance that is motorized, such as a motor vehicle, or that moves on rails, such as a railcar, which is used in food transportation operations. (21 CFR 1.904)

### **B. What can be considered transportation equipment?**

“Transportation equipment” means equipment used in food transportation operations and includes items such as bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor. (21 CFR 1.904)

### **C. What requirements apply to vehicles and transportation equipment?**

Vehicles and transportation equipment used in transportation operations must:

- Be designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe during transportation; (21 CFR 1.906(a))
- Be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation; and (21 CFR 1.906(b))
- Be stored in a manner that prevents their harboring pests or becoming contaminated in any other manner that could result in food for which they will be used becoming unsafe during transportation. (21 CFR 1.906(d))

### **D. Are there specific requirements for vehicles and transportation equipment for food requiring temperature control for safety?**

Yes, vehicles and transportation equipment used in the transportation of food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation. (21 CFR 1.908(c))

## **V. TRANSPORTATION OPERATIONS**

### **A. General Requirements**

#### **1. If I am both a shipper and a carrier, what requirements am I subject to?**

You must meet the requirements for each function you perform that is subject to the rule, i.e., as a shipper, receiver, loader or carrier. Therefore if you are functioning as both the shipper and the carrier, you must meet both the shipper’s and the carrier’s requirements. (21 CFR 1.908(a)(1))

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If you perform multiple functions under the rule, and are under the ownership or operational control of a single legal entity, as an alternative to meeting the rule's specific requirements for shippers, receivers and carriers, you may operate under common, integrated written procedures that ensure the sanitary transportation of food consistent with the requirements of the Sanitary Transportation rule. Establishing these common integrated procedures may make it easier for you to comply with the rule's requirements. These written procedures are subject to the records requirements of the rule which are discussed in Section VII. (21 CFR 1.908(a)(5))

### **2. Can I reassign my responsibilities under the rule to another person?**

Yes you can, if the other person is also subject to the rule. For example, if you are a loader, under the rule you would be responsible for verifying that a truck has been pre-cooled as specified by the shipper prior to loading food that requires temperature control for safety. However, you may establish an agreement with the carrier to perform this verification check for you. The carrier will then have this responsibility under the rule. Your agreement with the carrier is subject to the records requirements of the rule discussed in Section VII. (21 CFR 1.908(a)(1)).

### **3. Who in my company is responsible for making sure that we are following the requirements of this rule?**

Supervisory level personnel in your company must be assigned the responsibility for making sure that your company is meeting the requirements of the Sanitary Transportation rule. (21 CFR 1.908(a)(2))

### **4. Are there requirements for transportation operations that everyone subject to the rule must meet, in addition to the specific requirements that only apply to specific persons, such as shippers or carriers?**

Yes. Everyone subject to the rule must do these things in their transportation operations:

- You must take effective measures such as segregation, isolation, or the use of packaging to protect food from contamination by raw foods and nonfood items in the same load. (21 CFR 1.908(a)(3)(i))
- You must take effective measures such as segregation, isolation, or other protective measures, such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations. (21 CFR 1.908(a)(3)(ii))
- You must take effective measures to ensure that food that requires temperature control for safety is transported under adequate temperature control. (21 CFR 1.908(a)(3)(iii))

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### **5. Are the requirements of the rule the same for the transportation of human and animal food?**

Yes they are the same inasmuch as they require that food, whether human or animal food, be transported in a manner in which it will not become unsafe during transportation. However, we recognize that in certain instances, different practices to effectively accomplish this purpose have been established for the transportation of human and animal food. For example, certain types of equipment used for the transportation of human food and pet food use stainless steel food contact surfaces, while comparable equipment used for the transportation of animal feed uses a suitable non-stainless grade of steel called mild steel. (21 CFR 1.908(a)(4))

### **6. What am I required to do if I notice that food that requires temperature control has been transported in a way in which it could become unsafe, such as in very hot weather on a truck without a refrigeration unit?**

If a person subject to this rule becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, you must not sell or distribute the food and you must take appropriate action including, as necessary, communication with other parties to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe. (21 CFR 1.908(a)(6))

Therefore, if you are a receiver and your standard procedure is to reject a delivery if it shows an indication of severe temperature abuse or another serious problem, you must also take additional action such as calling the shipper or carrier and informing them of what you observed that may indicate that the food has become unsafe. It then becomes that person's responsibility to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.

## **B. Requirements Applicable To Shippers Engaged In Transportation Operations**

### **1. As a shipper, what are my responsibilities under this rule?**

As a shipper, you must establish written procedures subject to the records requirements discussed in Section VII, that describe how you conduct your operations to ensure that food does not become unsafe during transportation. There are as many as 3 specific types of written procedures you must establish, depending upon the type of food you ship:

- In all cases, as a shipper, you must develop and implement written procedures adequate to ensure that vehicles and equipment used in your transportation operations are in appropriate sanitary condition for the transportation of the food, i.e., they will prevent the food from becoming unsafe during the transportation operation. You may perform the measures to implement these procedures yourself, or they may be accomplished by the

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carrier or another party subject to the rule under a written agreement subject to the records requirements discussed in Section VII. (21 CFR 1.908(b)(3))

- If you ship food in bulk, you must also develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe. You may perform the measures to implement these procedures yourself, or they may be accomplished by the carrier or another party subject to the rule under a written agreement subject to the records requirements discussed in Section VII. (21 CFR 1.908(b)(4))
- If you ship food that requires temperature control for safety under the conditions of shipment you must also develop and implement written procedures to ensure that the food is transported under adequate temperature control. You may perform the measures to implement these procedures yourself, or they may be accomplished by the carrier or another party subject to the rule under a written agreement subject to the records requirements discussed in Section VII. These measures must include measures equivalent to those specified for carriers under 21 CFR 1.908(e)(1), (2) and (3) discussed in Section V. E. (21 CFR 1.908(b)(2))

### **2. If I establish an agreement with my carrier to implement some of my written procedures, what are my responsibilities with respect to working with my carrier?**

Depending upon the type of food you ship, you would have one or both of the following responsibilities:

- Unless you take other measures as allowed by 21 CFR 1.908(b)(3) to ensure that vehicles and equipment used in your transportation operations are in appropriate sanitary condition for the transportation of the food, you must specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier's vehicle and transportation equipment to achieve this purpose, including any specific design specifications and cleaning procedures. A one-time notification is sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported, in which case you must notify the carrier in writing before the shipment. (21 CFR 1.908(b)(1))
- In addition, if you ship food that requires temperature control for safety under the conditions of shipment, unless you take other measures as allowed by 21 CFR 1.908(b)(5) to ensure that adequate temperature control is provided during transportation of the food, you must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, and, when necessary, the loader, an operating temperature for the transportation operation including, if necessary, the pre-cooling phase. A one-time notification is sufficient unless a factor, e.g., the conditions of shipment, changes, necessitating a change in the operating temperature, in which case you must so notify the carrier in writing before the shipment. The information you submit to the carrier is subject to the records requirements discussed in Section VII. (21 CFR 1.908(b)(2))

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### **C. Requirements Applicable To Loaders Engaged in Transportation Operations**

#### **As a loader, what are my responsibilities under the rule?**

- Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment, you must determine, considering, as appropriate, any specifications provided by the shipper, that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, for example, it is in adequate physical condition, and free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation. You may accomplish this by any appropriate means. (21 CFR 1.908(c)(1))
- Before loading food that requires temperature control for safety, you must verify, considering, as appropriate, specifications provided by the shipper, that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, if necessary, and meets other sanitary conditions for food transportation. (21 CFR 1.908(c)(2))

### **D. Requirements Applicable To Receivers Engaged in Transportation Operations**

#### **As a receiver, what are my responsibilities under the rule?**

Upon receipt of food that requires temperature control for safety under the conditions of shipment, you must take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, e.g., for off-odors. (21 CFR 1.908(d))

### **E. Requirements Applicable To Carriers Engaged In Transportation Operations**

#### **1. Do the requirements of the rule always apply to carriers who transport food?**

The general requirements of the rule apply to all persons subject to the rule, i.e., shippers, receivers, loaders and carriers, at all times when they are engaged in the transportation of food.

However the specific requirements for carriers in 21 CFR 1.908(e) only apply to the carrier when the carrier and shipper have established a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operation. (21 CFR 1.908(e))

#### **2. What are the specific requirements for carriers when a shipper-carrier agreement has been established?**

When a shipper-carrier agreement has been established, the carrier is responsible for the following functions as applicable under the agreement:

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- The carrier must ensure that vehicles and transportation equipment meet the shipper's specifications and are otherwise appropriate to prevent the food from becoming unsafe during the transportation operation. (21 CFR 1.908(e)(1))
- The carrier must, once the transportation operation is complete and if requested by the receiver, provide the operating temperature specified by the shipper, as discussed in Section V. B. 2, and, if requested by the shipper or receiver, demonstrate that it has maintained temperature conditions during the transportation operation consistent with the operating temperature. The demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment. (21 CFR 1.908(e)(2))
- Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that requires temperature control for safety under the conditions of the shipment during transportation, the carrier must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper, as discussed in Section V. B. 2. (21 CFR 1.908(e)(3))
- If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the previous cargo transported in the vehicle. (21 CFR 1.908(e)(4))
- If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that describes the most recent cleaning of the bulk vehicle. (21 CFR 1.908(e)(5))
- A carrier must develop and implement written procedures subject to the records requirements discussed in Section VII that:
  - Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and the transportation equipment in appropriate sanitary condition as required by 21 CFR 1.906(b);
  - Describe how it will comply with the provisions for temperature control in 21 CFR 1.908(e)(2), and;
  - Describe how it will comply with the provisions for the use of bulk vehicles in 21 CFR 1.908(e)(4) and (5). (21 CFR 1.908(e)(6))

## **VI. TRAINING**

### **A. What training requirements apply to carriers?**



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If you are a carrier and you have a contract with the shipper to be responsible for any sanitary conditions during transportation, you must provide adequate training for your personnel involved in food transportation operations. The training must provide an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier under the rule. (21 CFR 1.910(a))

### **B. When must training be provided?**

You must provide the training when you hire personnel for food transportation operations and as necessary thereafter. For example, you may need to provide additional training if you previously transported only fully packaged refrigerated items but you now begin transporting produce in open containers and begin using different cleaning procedures for your trucks. (21 CFR 1.910(a))

### **C. Do I have to keep records of the training?**

Yes, you must establish and maintain records documenting the training. The requirements for these records are described in the table in Section VII A. (21 CFR 1.910(b))

### **D. Where can I get training for this rule?**

To assist carriers in their efforts to provide training to personnel, FDA offers a free web-based training module that covers the required training elements described above. You may offer this module to your personnel as a means of satisfying the rule's training requirement. The training module is available at: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm576097.htm>.

The FDA training module touches on a wide range of transportation food safety topics in a non-detailed manner. We anticipate that some carriers will wish to provide additional training that focuses on company-specific operations and procedures related to food safety.

You are not required to use the FDA training module. You may use training offered by third parties training vendors or you may train your personnel yourself. We do not require training offered by a company or a third party to be approved by FDA or that the instructors be certified.

## **VII. Records**

### **A. What records am I required to make and keep?**

You are required to make and keep the records shown in Table 4. (21 CFR 1.912)

Table 4--Records Required Under 21 CFR Part 1, subpart O

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<b>Required Records</b>	<b>Description</b>
<p>Information provided by shippers to carriers (21 CFR 1.912(a)(1))</p>	<p>Shipper records must demonstrate that the shipper:</p> <p>Provided, as a regular part of transportation operations, specifications and operating temperatures to carriers as required by 21 CFR 1.908(b)(1)</p>
<p>Written agreements and the written procedures of a shipper (21 CFR 1.912(a)(2))</p>	<p>The shipper's written agreements and written procedures must meet the requirements of 21 CFR 1.908(b)(3), (4), and (5).</p>
<p>Written procedures of a carrier (21 CFR 1.912(b))</p>	<p>The carrier's written procedures must meet the requirements of 21 CFR 1.908(e)(6)</p>
<p>Any written agreements subject to the rule that are not otherwise noted (21 CFR 1.912(d))</p>	<p>Written agreements that assign tasks required by the rule to another person</p>
<p>Records documenting required training by carriers (21 CFR 1.912(c))</p>	<p>The training records must:</p> <p>(1) Include the date of training, the type of training, and the persons trained; and</p> <p>(2) Be established and maintained in accordance with other records requirements.</p> <p>(21 CFR 1.910(b))</p>
<p>Written procedures of firms that operate in more than one capacity under the rule, under the ownership or operational control of a single legal entity, for example, as a shipper and a carrier.</p>	<p>The written procedures must:</p> <p>Be common integrated procedures that ensure the sanitary transportation of food consistent with the requirements of the rule.</p>

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<p>(21 CFR 1.912(e))</p> <p>This requirement is an alternative to meeting the requirements of 21 CFR 1.908 (b), (d) and (e)</p>	<p>(21 CFR 1.908(a)(5))</p>
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**B. What are the requirements for my records?**

Your records must be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. (21 CFR 1.912(g))

**C. Do my records have to be in electronic format?**

Your records do not have to be in electronic format.

Records that are established or maintained for the Sanitary Transportation rule that meet the definition of electronic records in 21 CFR 11.3(b)(6) are exempt from the requirements of 21 CFR Part 11. However, records that satisfy the requirements of this rule, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. (21 CFR 1.912(h))

**D. How long must I retain my records?**

All persons subject to this rule must retain records of written procedures and written agreements (except as described in the next paragraph) for a period of 12 months beyond when the procedures or agreements are in use in your transportation operations. (21 CFR 1.912(a)(2), (b) and (e))

All persons subject to this rule must retain records of written agreements that assign tasks required by this rule to another person for a period of 12 months beyond the termination of the agreements. (21 CFR 1.912(d))

Shippers must retain records that demonstrate that they provide specifications and operating temperatures to carriers as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers. (21 CFR 1.912(a)(1))

Carriers must retain training records required by 21 CFR 1.910(b) for a period of 12 months beyond when the person identified in the record stops performing the duties for which the training was provided. (21 CFR 1.912(d))

**E. Can I store my records offsite?**

### *Contains Nonbinding Recommendations*

Yes, you can store your records offsite, except for records of a carrier's written procedures required by 21 CFR 1.908(e)(6)(i) that describe practices for cleaning, sanitizing and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food. These carrier written procedures must remain onsite as long as the procedures are in use in your transportation operations. (21 CFR 1.912(i))

However any records stored offsite must be able to be retrieved and you must provide the records to us onsite within 24 hours of request for official review. (21 CFR 1.912(i))

Your electronic records are considered to be onsite if they are accessible from an onsite location. (21 CFR 1.912(i))

#### **F. Do I have to make my records available to FDA officials?**

Yes, you must make all records required by the Sanitary Transportation rule available to FDA promptly upon oral or written request. (21 CFR 1.912(f))

#### **G. If FDA collects or copies my records are they protected from public disclosure?**

Records collected or copied by FDA will be protected from public disclosure to the extent allowable under 21 CFR Part 20 and under applicable Freedom of Information Act exemptions. (21 CFR 1.912(j))

## **VIII. WAIVERS**

### **A. What is a waiver?**

A waiver is a notice published in the Federal Register by which FDA grants that all or some of the requirements of the Sanitary Transportation rule will not be applied to persons, vehicles, food, or nonfood products identified in the notice. A waiver is effective on the date the notice is published. (21 CFR 1.930)

### **B. How does FDA issue a waiver?**

We will issue a waiver by publishing a notification of the waiver in the Federal Register, when we determine that:

- (a) The waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health; and
- (b) The waiver will not be contrary to the public interest.

(21 CFR 1.914)

## *Contains Nonbinding Recommendations*

### **C. When will FDA consider issuing a waiver?**

We will consider whether to waive a requirement of the Sanitary Transportation rule on our own initiative or in response to a petition submitted under 21 CFR 10.30. (21 CFR 1.916 – 1.926)

### **D. Can FDA modify or revoke a waiver it has issued?**

Yes, we will modify or revoke a waiver if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health or that the waiver could be contrary to the public interest. (21 CFR 1.932)

If we modify or revoke a waiver, we will follow the procedures set forth in the Sanitary Transportation rule to inform the person who requested the waiver of our determination and to seek public input through the publication of a notice in the Federal Register. We will also publish a notice of our decision and the effective date in the Federal Register. (21 CFR 1.934)

### **E. Has FDA issued any waivers?**

Yes, see Section II C.

## **IX. DEFINITIONS**

Below is the full list of definitions in the rule (21 CFR 1.904):

*Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.

*Animal food* means food for animals other than man, and includes pet food, animal feed, and raw materials and ingredients.

*Bulk vehicle* means a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

*Carrier* means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term “carrier” does not include any person who transports food while operating as a parcel delivery service.

*Cross-contact* means the unintentional incorporation of a food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act into food, except animal food.

*Farm* has the meaning given in 21 CFR 1.227.

## *Contains Nonbinding Recommendations*

*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.

*Full-time equivalent employee* is a term used to represent the number of employees of a business entity for the purpose of determining whether the business is a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

*Loader* means a person that loads food onto a motor or rail vehicle during transportation operations.

*Non-covered business* means a shipper, loader, receiver, or carrier engaged in transportation operations that has less than \$500,000, as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the 3-year period preceding the applicable calendar year. For the purpose of determining an entity's 3-year average revenue threshold as adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

*Operating temperature* means a temperature sufficient to ensure that under foreseeable circumstances of temperature variation during transport, e.g., seasonal conditions, refrigeration unit defrosting, multiple vehicle loading and unloading stops, the operation will meet the requirements of 21 CFR 1.908(a)(3).

*Pest* means any objectionable animals or insects including birds, rodents, flies, and larvae.

*Receiver* means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

*Shipper* means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

*Small business* means a business employing fewer than 500 full-time equivalent employees except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to 21 CFR 1.900(a) having less than \$27,500,000 in annual receipts.

*Transportation* means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

### *Contains Nonbinding Recommendations*

*Transportation equipment* means equipment used in food transportation operations, e.g., bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

*Transportation operations* means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

*Vehicle* means a land conveyance that is motorized, e.g., a motor vehicle, or that moves on rails, e.g., a railcar, which is used in transportation operations.