DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 11

[Docket No. FDA–2013–N–0013]

RIN 0910–AG98

Sanitary Transportation of Human and Animal Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to establish 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. This action is part of our 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 of 2005 (2005 SFTA) and the Food Safety Modernization Act of 2011 (FSMA).

DATES: This rule is effective June 6, 2016. See section V for the compliance dates.

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Executive Summary

Purpose and Coverage of the Rule

This rule is part of FDA's implementation of the 2005 SFTA and the FSMA. These statutes require us to issue regulations requiring shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. This rule creates new requirements for the sanitary transportation of human and animal food by motor vehicle and rail vehicle to ensure that transportation practices do not create food safety risks. Practices that create such risk include failure to properly refrigerate food requiring temperature control for food safety, the inadequate cleaning of vehicles between loads, and the failure to otherwise properly protect food during transportation. This rule builds on current safe food transportation best practices and is focused on ensuring that persons engaged in the transportation of food that is at the greatest risk for contamination during transportation follow appropriate sanitary transportation practices. The rule is flexible to allow the transportation industry to continue to use industry best practices concerning cleaning, inspection, maintenance, loading and unloading of, and operation of vehicles and transportation equipment to ensure that food is transported under the conditions and controls necessary to prevent adulteration linked to food safety.

Summary of the Major Provisions of the Rule

As required by the 2005 SFTA, this final rule addresses the sanitary transportation of food (human and animal food) by establishing criteria and definitions that apply in determining whether food is adulterated because it has been transported or offered for transport by a shipper, loader, carrier by motor vehicle or rail vehicle, or receiver engaged in the transportation of food under conditions that are not in compliance with the sanitary food transportation regulations. This rule defines transportation as ''any movement of food in commerce by motor vehicle or rail vehicle'' and establishes requirements for sanitary transportation practices applicable to shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in food transportation operations addressing:

- Vehicles and transportation equipment;
- Transportation operations;
- Training;
- Records; and
- Waivers.

This rule allows the transportation industry to continue to use best practices, *i.e.,* ''commercial or professional procedures that are accepted or prescribed as being correct or most effective,'' (Ref. 1), concerning cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment that it has developed to ensure that food is transported under the conditions and controls necessary to prevent adulteration linked to food safety.

We made several revisions to this final rule, in response to comments that we received regarding the proposed rule, to affirm that the use of current sanitary food transportation best practices as described in these comments, *e.g.,* the ''Rendering Industry Code of Practice'' and ''Model Tanker Wash Guidelines For the Fruit Juice Industry,'' will allow industry to meet the requirements of this rule. Some of these best practices have been provided to the Agency as industry documents submitted with comments on the proposed rule, while others were described in the comments or the public meetings we held for the proposed rule.

As discussed in detail in later sections of the rule, we made several major revisions to the provisions of this rule mainly in response to comments that focus the rule more narrowly on food safety and are consistent with existing safe transportation best practices. These major revisions include the following:

- We have simplified the definitions for parties covered by the rule to make them all activity based and added a definition for ''loader'' as a new party covered by the rule, based on comments indicating that this was a relevant segment of the transportation industry that we had not previously identified.
- We have amended the definition of ''transportation operations'' such that additional transportation activities are not covered by the rule, including transport of food completely enclosed by a container, except food that requires temperature control for safety (broadens proposed exclusion for transport of shelf stable food completely enclosed by a container), food contact substances, and human food byproducts transported for use as animal food without further processing.
- We changed the provisions of the rule to focus on food safety concerns and not additionally adulteration as a result of spoilage or quality defects. Therefore, we have replaced language indicating that the goal of the rule is prevention of both food safety and non-safety concerns with language indicating that the goal is prevention of food becoming ''unsafe, *i.e.,* adulterated within the meaning of section 402(a)(1), (2), and (4) of the FD&C Act'' during transportation operations.
- We have removed prescriptive requirements for temperature monitoring devices and continuous monitoring of temperature during transport and replaced these provisions with a more flexible approach which allows the shipper and carrier to agree to a temperature monitoring mechanism for shipments of food that require temperature control for safety. We have also removed the provision requiring the carrier to demonstrate temperature control to the receiver for every shipment requiring temperature control. In this final rule, the demonstration must only be made if the shipper or receiver requests it, which is consistent with industry best practices and would likely only be done in situations in which it is suspected that there has been a material failure of temperature control.
- We have revised this rule to require that 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, the person must take appropriate action, 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.
- We have revised the requirements of this final rule to make it clear that its requirements account for the fact that the intended use of the vehicle or equipment with respect to the type of food that is being transported, *e.g.,* the transportation of animal feed versus food for humans, is relevant in establishing the applicable sanitary transportation requirements, as is the production stage of the food being transported, *e.g.,* raw materials, ingredients, or finished food products.
- Finally, we have revised the rule to primarily place the responsibility for determinations about appropriate transportation operations (*e.g.,* whether food needs temperature control for safety and the relevant operating temperature and mode of temperature monitoring, whether particular clean out procedures are needed, and whether previous cargo must be identified) on the shipper. The shipper may rely on contractual agreements to assign some of these responsibilities to other parties, such as a loader or carrier, if they agree to accept the responsibility. We believe the shipper is in the best position of the parties covered by this rule to know the appropriate specifications for transport of its food.

Costs and Benefits

This final rule implements requirements addressing the sanitary transportation of human and animal food. It establishes requirements for sanitary transportation practices applicable to shippers, carriers by motor vehicle and rail vehicle, loaders, and receivers. Specifically, these finalized requirements address design and maintenance of vehicles and transportation equipment; sanitary practices during transportation operations that apply to shippers, receivers, loaders, and carriers; training of carrier employees; and records related to, for example, training, and written procedures. As shown in table 1, the total annualized costs are estimated to be approximately $113 million per year, estimated with a 3 percent discount rate, and $117 million per year, estimated at 7 percent when discounted over 10 years. We do not have sufficient data to fully quantify the benefits of this regulation.

TABLE 1—ESTIMATED COSTS AND BENEFITS

[In millions of $]

	Initial costs	Annual	Benefits
	$162.7	$93.5	Not quantified.
Costs Annualized over 10 Years			
	Costs		Benefits
3%	$113		Not quantified.
7%	117		

I. Background

A. FDA Food Safety Modernization Act

FSMA (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages

partnerships with State, local, tribal, and territorial authorities and international collaborations with foreign regulatory counterparts. A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the seven foundational rules listed in table 2 and requested comments on all aspects of these proposed rules.

TABLE 2—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed human preventive controls regulation.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety regulation.	78 FR 3504, January 16, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed animal preventive controls regulation.	78 FR 64736, October 29, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed FSVP regulation ...	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 proposed third-party certification regulation.	78 FR 45782, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration regulation.	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food	2014 proposed sanitary transportation regulation.	79 FR 7006, February 5, 2014.

We also issued a supplemental notice of proposed rulemaking for the rules listed in table 3 and requested comments on specific issues identified in each supplemental notice of proposed rulemaking.

TABLE 3—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 supplemental human preventive controls notice.	79 FR 58524, September 29, 2014.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 supplemental produce safety notice.	79 FR 58434, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 supplemental animal preventive controls notice.	79 FR 58476, September 29, 2014.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2014 supplemental FSVP notice ...	79 FR 58574, September 29, 2014.

We finalized five of the foundational rulemakings listed in table 4 in September and November 2015.

TABLE 4—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.	Final human preventive controls regulation.	80 FR 55908, September 17, 2015.
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.	Final animal preventive controls regulation.	80 FR 56170, September 17, 2015.
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.	Final FSVP regulation	80 FR 74225, November 27, 2015.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	Final produce safety regulation	80 FR 74353, November 27, 2015.
Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications.	N/A	80 FR 74569, November 27, 2015.

As FDA finalizes these seven foundational rulemakings, we are putting in place a modern, risk-based framework for food safety, based on the most recent science, that focuses efforts where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. To achieve this, FDA has engaged in a significant amount of outreach to the stakeholder community to find the right balance between flexibility and accountability in these regulations.

After FSMA was enacted in 2011, we have been involved in approximately 600 stakeholder engagements on FSMA and the proposed rules, including public meetings, Webinars, listening sessions, farm tours, and extensive presentations and meetings with various

stakeholder groups (Refs. 2 and 3). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that stakeholders understand and engage in their respective roles in food safety. FDA believes these seven foundational final rules, when implemented, will affect the paradigm shift toward prevention that was envisioned in FSMA and be a major step forward for food safety that will help protect consumers into the future.

B. What risks to humans and animals have been associated with the transportation of food? How has this issue been addressed in the past?

Due to illness outbreaks involving human food and animal food that became contaminated during transportation (Refs. 4 and 5), and incidents and reports of insanitary transportation practices (Refs. 6 to 11), there have been concerns over the past few decades about the need to ensure that food is transported in the United States in a sanitary manner (Ref. 12). Press accounts in the late 1980s of trucks carrying food from the Midwest to both the East and West Coasts and returning with garbage for Midwest landfills caused concern that food products could become contaminated and unfit for human consumption if irresponsible vehicle operators failed to properly clean vehicles that had been previously used to haul waste or other nonfood materials (Refs. 13 to 15). Congress responded to these concerns by passing the Sanitary Food Transportation Act of 1990 (1990 SFTA) (Pub. L. 101–500), which directed the Department of Transportation (DOT) to establish regulations to prevent food or food additives transported in certain types of bulk vehicles from being contaminated by nonfood products that were simultaneously or previously transported in those vehicles. Following the passage of the 1990 SFTA it became clear that potential sources of food contamination during transport were not just limited to nonfood products. Most notably, a 1994 outbreak of salmonellosis occurred in which ice cream mix became contaminated during transport in tanker trucks that had previously hauled raw liquid eggs. That outbreak affected an estimated 224,000 persons nationwide (Ref. 4). In 2005, Congress reallocated authority for food transportation safety to FDA, DOT, and USDA by passing the 2005 SFTA, a broader food transportation safety law than the 1990 SFTA. The focus of the 2005 SFTA was not limited only to preventing food contamination from nonfood sources during transportation.

C. What did the Sanitary Food Transportation Act of 2005 and the Food Safety Modernization Act of 2011 do with respect to food transportation? What other activities did we conduct for this rulemaking?

The 2005 SFTA directed us to establish regulations prescribing sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food. Section 111(a) of FSMA also directed FDA to issue these sanitary transportation regulations. In April of 2010, we issued guidance to provide the industry with broadly applicable recommendations for controls to prevent food safety problems during transport while we worked toward implementing the 2005 SFTA (Ref. 16). We also published a **Federal Register** advance notice of proposed rulemaking in 2010 (the 2010 ANPRM; 75 FR 22713, April 30, 2010) to request data and information on the food transportation industry and its practices to prevent the contamination of transported foods and any associated outbreaks.

D. What did we propose to do?

We subsequently published a proposed rule in the **Federal Register** of February 5, 2014 (79 FR 7006), to establish sanitary transportation requirements for shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of both human and animal food to ensure the safety of the food they transport.

In brief, we proposed to address the sanitary transportation of food for humans and animals by establishing definitions and criteria that would apply to determine whether food is adulterated because it has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, or receiver under conditions that are not in compliance with the sanitary food transportation regulations. We proposed to define transportation as any movement of food in commerce by motor vehicle or rail vehicle. We proposed to establish requirements for sanitary transportation practices applicable to shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in food transportation operations. Specifically, we proposed to establish requirements for:

- Vehicles and transportation equipment;
- Transportation operations;
- Training;
- Records; and
- Waivers.

The proposed rule would allow the transportation industry to continue to use best practices concerning cleaning, inspection, maintenance, loading and unloading of, and operation of vehicles and transportation equipment that it has developed to ensure that food is transported under the conditions and controls necessary to prevent contamination and other safety hazards.

We received about 240 submissions in response to the proposed rule. We received comments from individuals, industry and trade associations, consumer and advocacy groups, academia, law firms, professional organizations, Federal and State, tribal and foreign government agencies and other organizations. In this document, we describe these comments, respond to them, and explain any revisions we made to the proposed rule in response to those comments. In addition, we held three public meetings to discuss the proposed rule. The meetings took place on February 27, 2014, in Chicago, IL; March 13, 2014, in Anaheim, CA; and March 20, 2014, in Washington, DC.

Some comments address issues that are outside the scope of this rule. For example, a comment suggests that we undertake a comprehensive examination of transportation that occurs by ship or barge within, into, or out of the United States to provide Congress with sufficient information to reevaluate our safe food transportation statutory authority (see responses to Comment 9 and Comment 30). Another comment states that this rule should identify the parties who are responsible for paying attorney's fees in cases where claims are made for damage that occurs during truck or rail transport of food. We do not discuss these types of comments in this document.

II. What is the legal authority for this rule?

We are issuing this rule under authority of the 2005 SFTA and as directed by section 111(a) of FSMA.

The 2005 SFTA amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act), in part, by creating a new section, 416 of the FD&C Act (21 U.S.C. 350e). Section 416(b) of the FD&C Act directs us to issue regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons

engaged in the transportation of food in the United States to use prescribed sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. Section 416(c) of the FD&C Act specifies that we shall prescribe those practices that we determine are appropriate relating to: (1) Sanitation; (2) packaging, isolation, and other protective measures; (3) limitations on the use of vehicles; (4) information to be disclosed to carriers and to manufacturers; and (5) recordkeeping. Section 416(c) of the FD&C Act also states that the regulations are to include a list of nonfood products that may, if shipped in a bulk vehicle, render adulterated food that is subsequently transported in the same vehicle, and a list of nonfood products that may, if shipped in a motor vehicle or rail vehicle (other than a tank vehicle or bulk vehicle), render adulterated food that is simultaneously or subsequently transported in the same vehicle. Section 111(a) of FSMA directed us to issue these sanitary transportation regulations not later than 18 months after the date of enactment of FSMA.

In addition, the 2005 SFTA created new section 402(i) in the FD&C Act (21 U.S.C. 342(i)) which provides that food that is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with the regulations issued under section 416 is adulterated. Also, new section 301(hh) in the FD&C Act (21 U.S.C. 331(hh)) prohibits the failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the regulations issued under section 416. The 2005 SFTA also amended section 703 of the FD&C Act (21 U.S.C. 373) by adding section 703(b), which provides that a shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 shall, on request of an officer or employee designated by FDA, permit the officer or employee, at reasonable times, to have access to and to copy all records that are required to be kept under the regulations issued under section 416.

FDA's authority for this rule is also derived from sections 402(a)(1), (2), and (4) and 701(a) of the FD&C Act (21 U.S.C. 371(a)). Section 402(a)(1) of the FD&C Act provides, in part, that a food is adulterated if it bears or contains any added poisonous or deleterious substance, which may render it injurious to health. Section 402(a)(2) of the FD&C Act provides that a food is adulterated if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity (RAC) or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of 21 U.S.C. 346; if it bears or contains a pesticide chemical residue that is unsafe within the meaning of 21 U.S.C 346a(a); or if it is or if it bears or contains (1) any food additive that is unsafe within the meaning of 21 U.S.C. 348; or (2) a new animal drug (or conversion product thereof) that is unsafe within the meaning of 21 U.S.C. 360b. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. This rule includes requirements that are necessary to prevent food from becoming unsafe, *i.e.,* adulterated under the aforementioned provisions of section 402 of the FD&C Act, due to insanitary transportation practices. These requirements allow for the efficient enforcement of the FD&C Act.

III. What general comments did we receive on the proposed rule?

A. Purpose of This Rule

(Comment 1) We stated in the proposed rule that the goal of this rulemaking is to ensure that transportation practices do not create food safety risks and that this rule builds on current food transport industry best practices. The rule is focused on ensuring that persons engaged in the transportation of food that is at the greatest risk for contamination during transportation follow appropriate sanitary transportation practices. This rule allows the food transportation industry to continue to use best practices concerning the cleaning, inspection, maintenance, loading and unloading of, and operation of vehicles and transportation equipment that it has developed to ensure that food is transported under the conditions and controls necessary to prevent contamination and other safety hazards.

Several comments support our intent to provide shippers, loaders, carriers and receivers with the flexibility to continue to utilize appropriate sanitary transportation industry best practices. A comment states that this approach allows companies to tailor their practices, as appropriate and necessary, based on the nature of the food and the transportation conveyance used, and to adopt new practices when there are advances in technology. Other comments agree with many aspects of the proposed rule, but conclude that some aspects need further refinement to reflect current industry best practices.

On the other hand, one comment states that this rulemaking is not necessary and that the food transportation industry, instead, should be given the flexibility to meet the standards placed upon it by the shippers without undue interference, or rules and regulations, that hinder the safe and efficient movement of human and animal food. One comment states that there are no systemic food safety issues related to the sanitary transport of food and that, therefore, this rulemaking is unnecessary.

(Response 1) As stated in the proposed rule, the SFTA requires FDA to issue regulations requiring shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. We have met this mandate, in part, by incorporating current best practices into this rule to the extent that we believe they are effective in achieving the goal of this rule. We disagree with the comments that stated this rule is unnecessary because Congress found that there was an adequate need to mandate that FDA issue these regulations in the 2005 SFTA and FSMA.

B. What regulatory approach should we take?

(Comment 2) Several comments express concern that the proposed rule applies the same requirements to human food and animal food. Many of these comments state that we should issue a separate rule for the sanitary transportation of animal food that is appropriately risk-based and specific to the types of ingredients and manufacturing processes used for animal food. Other comments state that we should distinguish between sanitary transportation requirements for animal food and human food in this rule to allow it to be reasonable and practical for the animal food industry.

(Response 2) We agree that this rule should more clearly recognize that sanitary transportation practices may differ for different types of food being transported to avoid confusion in its

interpretation and application. Accordingly, and as discussed in our responses to Comment 89, we have revised the requirements of this rule for vehicles and transportation equipment (§ 1.906), and for transportation operations (§ 1.908), to make it clear that these requirements take into account the intended use of the vehicle or equipment, *e.g.,* the transportation of animal feed. Also, as discussed in our response to Comment 130, we have also revised the requirements of this rule for transportation operations (§ 1.908) to state that the type of food being transported, *e.g.,* human food or animal feed, must be considered in establishing the applicable sanitary transportation practices.

(Comment 3) One comment states that there are two distinct animal food industries, the pet food industry, which employs standards and practices equivalent or close to those used for human food, and the animal feed industry, for which product is not normally handled with the same equipment used for human food transportation operations. This comment encourages us to recognize the significant difference between the purpose and function of these two ''markets'' for animal food, so that livestock feed transportation is not held to the same standards as pet food transportation. A related comment encourages us not to establish a pet food standard for all animal food and stated that the final rule should not require significant conversion of equipment used in animal feed sourcing and transport operations to pet food standards which necessitate the use of stainless steel equipment.

(Response 3) We agree that sanitary transportation practices for pet food differ from those for animal feed. The revisions we have made to this rule in § 1.906 and § 1.908, as explained in our response to Comment 2, will allow practices employed for the transport of pet food and animal feed to be appropriately tailored to the unique needs of those operations. This rule, therefore, will not necessitate the conversion of equipment used in animal feed operations to meet standards for pet food.

(Comment 4) Some comments suggest that produce safety could be improved by establishing general requirements under the FSMA produce safety rule for the transportation of produce after it leaves the farm, if the farm assumes the role of either the shipper or the carrier. These comments suggest that these FSMA produce safety requirements should be similar to the practices outlined in the proposed rule for the transport of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control. These comments also state that, by covering produce under a transportation provision in the FSMA produce safety rule, enforcement for sanitary transportation practices would be performed by Agencies already tasked with implementing the produce safety rule. One comment states that regulating the transportation of produce in this manner would provide a single source for compliance requirements and would likely reduce the possibility that any requirements might be overlooked.

(Response 4) The produce safety rule establishes science-based minimum standards for the safe production and harvesting of fruits and vegetables to minimize the risk of serious adverse health consequences or death, focusing on the most important routes of on-farm contamination of produce with biological hazards. By contrast this rule requires persons engaged in the transportation of all foods, including fresh fruits and vegetables, to use sanitary transportation practices in their operations to ensure that food is transported under conditions that prevent it from becoming unsafe. The sanitary transportation practices required by this rule are not limited to those that address potential contamination of food with biological hazards, they also apply to other forms of contamination, *e.g.,* with chemical and physical hazards, that could cause food to become unsafe. We believe it is most appropriate to establish requirements related to transportation of produce after it leaves the farm in this rule.

(Comment 5) One comment expresses concern that this rule's requirements would apply uniformly across the entire U.S. food transportation sector, despite the fact that current railroad industry best practices have resulted in very few reported cases of foodborne illnesses directly attributable to rail carriers. Another comment asserts that we should defer issuing this rule as it applies to railroads. It states that, in view of the absence of reported incidents of insanitary food rail transportation and the existing rail industry practices to prevent such incidents, applying the rule to the rail industry is not necessary at this time.

(Response 5) The 2005 SFTA directs us to issue regulations that require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. We are issuing this rule as directed by Congress. It is unlikely carriers who have successfully employed best practices for food transportation, whether they be motor or rail carriers, will need to alter their transportation practices significantly to comply with this rule, although we acknowledge that there are new costs associated with training and recordkeeping.

(Comment 6) One comment identifies smaller box trucks making local deliveries as a particular sanitary food transport problem. The comment states that most of the instances where food transportation problems were found in the 2007 Interstate Food Transportation Assessment Project study (Ref. 6) involved smaller box trucks as discussed in the proposed rule (79 FR 7006 at 7008). The comment suggests that FDA develop an enforcement plan focused on smaller box trucks engaged in local food delivery operations.

(Response 6) As we implement this rule, we will work with our partners, *i.e.,* DOT, and State, local, territorial and tribal officials, to direct our efforts to address the areas of greatest need with respect to practices that create potential food safety risks for local deliveries. To the extent that smaller box trucks making local deliveries fall below the ''Non-Covered Business'' cutoff of $500,000, we note that these trucks remain subject to the provisions, including the adulteration provisions, of the FD&C Act with regard to their transport of food.

(Comment 7) One comment states that the provisions of this rule are not specific and so broad based that they should be viewed only as non-binding recommendations. It further asserts that the only way we can protect the food supply is by implementing enforceable laws like the Sanitary Food Transportation Act of 1990 and that DOT already has a system in place in which vehicles are inspected wherein they could use an F (signifying food vehicle) on the inspection sticker of the trucks and trailers that transport food.

(Response 7) We reject this interpretation of this rule. The provisions of this rule are not guidance nor are they recommendations. Many of the requirements established in this rule address broadly applicable procedures and practices intended to provide flexibility for shippers, loaders, carriers, and receivers to comply with the requirements in a way that is most suitable for their practices, as many are already implementing the industry best practices on which the rule is based. Furthermore, Congress enacted the 2005

SFTA to grant FDA, DOT, and USDA shared responsibility over regulating the sanitary transportation of food.

C. How does this rule relate to other FSMA rules?

(Comment 8) Several of the comments express a preference for the farm definition in the proposed transportation rule over the definitions in other FSMA proposed rules because it does not limit the facility's activities to the packing and holding of a farm's own food. These comments recommend that we apply the sanitary transportation rule's farm definition throughout all of the FSMA rules. Conversely, another comment suggests that we use different definitions for entities such as ''farms'' in the various FSMA rules, allowing us to take a customized approach to each specific rule.

(Response 8) We agree that using a definition of the term ''farm'' in this rule that, to the extent practicable, is aligned with this term as defined in other FDA regulations, including the regulations we have established under FSMA, would be functionally efficient for us and for stakeholders. We explained in the proposed rule that we tentatively defined the term ''farm'' differently than it was defined in 21 CFR 1.227(b)(3), which is used to establish which facilities are required to register under section 415 of the FD&C Act (21 U.S.C. 350d), because 21 CFR 1.227(b)(3) applies only to facilities that pack or hold food if the food used in such activities is grown, raised, or consumed on that farm or a farm under the same ownership. We had tentatively concluded that the sanitary transportation practices that would be required by our proposed rule would not be necessary to prevent RACs from becoming adulterated during transportation by farms, regardless of whether the farms are conducting transportation operations for RACs that were grown, raised, or consumed on the same farm or on another farm under different ownership. We therefore tentatively concluded to use a different definition of the term ''farm'' for purposes of this rulemaking.

In the FSMA preventive controls for human food final rule (80 FR 55908 at 55925), we revised our definition of the term ''farm'' in 21 CFR 1.227 to clarify the types of activities that are included as part of the definition of the term ''facility'' and to clarify the scope of the exemption from the registration requirement for ''farms'' established in section 415 of the FD&C Act. This revised definition no longer requires that farms that pack or hold food only carry out these activities for food that was grown, raised, or consumed on that farm or a farm under the same management. This revised definition now governs the applicability of the provision in this final rule that excludes transportation operations performed by farms from coverage under this rule. We, therefore, have aligned this rule with the revised definition of the term ''farm'' in 21 CFR 1.227 by revising 21 CFR 1.904 to state that this term has the new meaning contained in 21 CFR 1.227. This action also aligns the definition in this rule with this term as defined in other FSMA rules, *i.e.,* the preventive controls rule for animal food and the produce safety rule.

(Comment 9) One comment urges us to create a party with the same responsibilities as the ''importer'' in the FSMA Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) rule who would be responsible for verifying that the practices of foreign suppliers are in compliance with our regulations. The comment states that this person would be responsible for verifying the safe transportation of imported products before and after the products arrive in the United States. The comment explains that in the preamble to the FSVP proposed rule, we stated that the person responsible for verifying the safety of the foreign supplier ''has a direct financial interest in the food and is most likely to have knowledge and control over the product's supply chain.'' The comment asserts that for imported food, the safety of the food transport is inextricably linked with the safety of the supply chain, starting with the foreign supplier. The comment further states that the person with a direct financial interest in the food product is the party most likely to have the knowledge and control necessary to ensure not just the safety of the foreign supplier, but also the safety of the transportation after the food arrives in the United States. The comment argues that there should be consistency between these two rules for imported products.

(Response 9) The 2005 SFTA direct us to issue regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food in the United States to use prescribed sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. It does not direct us to establish requirements for the transport of food destined for the United States before it reaches the United States. Shipments of food destined for consumption in the United States remain subject to the provisions of the FD&C Act, including the adulteration provisions.

(Comment 10) One comment states that the treatment of small businesses in the FSMA rules is not consistent. The comment states that modified requirements, compliance dates, and exemptions have been based on annual sales throughout the FSMA proposed rules, but the annual sales metrics have not been consistent, *i.e.,* the rules have addressed business size alternatively on the basis of total annual sales, rolling averages of total annual sales, numbers of employees, total annual food sales, and total sales in combination with qualified end user sales. The comment recommends that we create a simpler, consistent approach so that businesses can clearly discern whether they must comply with the regulations.

(Response 10) The only provisions of this final rule that are related to the business size or business volume are the number of employees threshold for businesses, other than carriers by motor vehicle, in the definition of a ''small business,'' the annual receipts threshold for carriers by motor vehicle in the definition of a ''small business,'' and the annual revenue threshold in the definition of a ''non-covered business.''

With respect to the number of employees threshold for businesses that are not carriers by motor vehicle, as explained in the proposed rule (79 FR 7006 at 7014) and the discussion of this definition in section IV.C. of this final rule, this provision is based upon the size based standard (expressed in terms of numbers of employees) that has been established by the U.S. Small Business Administration under 13 CFR 121.201 for most food manufacturers. This provision of the ''small business'' definition incorporates the same size based standard as we included in the preventive controls final rules for human and animal food.

With respect to the annual receipts threshold for small businesses that are motor carriers, as explained in the proposed rule (79 FR 7006 at 7014) and the discussion of this definition in section IV.C. of this final rule, this provision is based upon the size based standard of the U.S. Small Business Administration for truck transportation firms in 13 CFR 121.201. This provision of the ''small business'' definition is unique to this rule and has no relation to other FSMA rules, because only this rule establishes requirements for carriers.

With respect to the annual revenue threshold in the definition of a ''non-covered business,'' as we state in our response to Comment 62, we proposed

to establish this provision, in part, to treat firms subject to this rule comparably to those firms that are subject to FSMA preventive controls rules. As also explained in the discussion of this definition in section IV.C., we have revised this definition in this final rule to apply the same method for calculating a firm's annual revenue that we used in very small business definitions of the preventive controls rules.

(Comment 11) One comment states that we did not address the issue of routine security measures, such as the use of truck seals, in the proposed transportation rule and other proposed FSMA rules. The comment states that these measures provide a benefit in transportation similar to that of underlying prerequisite programs in the context of a food manufacturer's hazard analysis and critical control point (HACCP) system. The comment further states that these measures need to be addressed by the FSMA rules to ensure that potential contamination risks (that do not rise to the level of the massive, catastrophic threats that are the subject of the proposed FSMA intentional adulteration rule) are addressed.

(Response 11) This suggestion is outside the scope of this rulemaking. We agree that persons engaged in food transportation should consider the use of routine security measures. We have issued guidance on this subject: ''FDA Guidance on Food Security Preventive Measures for Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations, and Fluid Milk Processors;'' and ''FDA Guidance on Food Security Preventive Measures for Food Producers, Processors, and Transporters'' (Refs. 17 and 18). However, the purpose of this rule is to establish sanitary transportation practices to be used by shippers, carriers by motor vehicle and rail vehicle, receivers, and other persons engaged in food transportation to ensure that food is not rendered adulterated during transportation, which is distinct from the issue of the security of food transportation. FDA will be addressing food defense concerns in its upcoming final rulemaking on Intentional Adulteration; however, to the extent that certain food defense issues are not covered in the FSMA rulemakings, and it becomes apparent as we implement the rules that there are food defense concerns that would benefit from additional regulation, we will consider initiating such rulemakings in the future.

D. Effect of Other Statutes on the Applicability of This Rule and How This Rule Affects Food Regulated by Other Federal Agencies

(Comment 12) Several comments note that FDA lacks jurisdiction over meat, poultry, and egg products within meat, poultry, and egg product establishments that are subject to USDA regulation and inspection by USDA's Food Safety and Inspection Service (FSIS) under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). Some of these comments ask us to explicitly acknowledge in this rule that USDA has exclusive jurisdiction over meat, poultry, and egg products operations conducted in these establishments and over the meat, poultry, and egg products up until the time these food products leave these establishments. They also observed that the requirements of this rule would only apply to meat, poultry, and egg products after they have left the FSIS-inspected establishments and, therefore, that the requirements of this rule only apply to carriers as they transport meat, poultry, and egg products and receivers of those products, provided that the receiver is not exclusively inspected by FSIS.

In addition to the FDA–USDA jurisdictional issue, some comments state that a new layer of FDA sanitary food transportation regulation is unnecessarily duplicative with respect to the meat and poultry industries because meat and poultry establishments are already subject to FSIS regulations that address the transportation of meat and poultry products (see, 9 CFR part 325 and 9 CFR part 381, subpart S), as well as by guidance issued by USDA. These comments also state that FSIS's existing meat and poultry safety regulations and oversight activities are adequate and sufficiently robust, and are based on established industry best practices. Another comment suggests that we should dispense with any unnecessarily duplicative sanitary food transportation regulation of meat, poultry, and egg products by issuing a waiver, as provided for under this rule, or by establishing a Memorandum of Understanding (MOU) with FSIS that provides for FSIS to regulate transportation of these products from FSIS-regulated facilities.

(Response 12) We agree that FDA lacks jurisdiction for meat, poultry, and egg product activities that occur within meat, poultry, and egg product processing facilities regulated exclusively by USDA. We have consulted with USDA and modified § 1.900(b) in this rule by adding a third category of persons exempt from the requirements of this subpart. In this final rule, § 1.900(b)(3) excludes shippers, loaders, receivers, or carriers when they are engaged in transportation operations of food while the food is located in food facilities as defined in § 1.227, that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the FMIA, the PPIA, or the EPIA. However, there are dual jurisdiction establishments that prepare, pack, hold, or otherwise handle both foods regulated by USDA and foods regulated by FDA. In the case of dual jurisdiction establishments, FDA would inspect in accordance with its existing MOU with USDA (Ref. 19).

In addition, we did not tentatively conclude in the proposed rule that USDA guidance on the safe transportation and distribution of meat, poultry, and egg products is not adequate to ensure their safety. Rather, we stated that FSIS does not have requirements that directly address transportation operations for these foods once they leave FSIS-inspected facilities. However, FSIS has regulations that require that FSIS-regulated establishments to address sanitation during transportation, *e.g.,* 9 CFR 416.4(d) and 9 CFR 417.2(a)(1), and this rulemaking will complement FSIS's efforts to promote the application of sanitary food transportation practices for FSIS-regulated meat, poultry, and egg products.

(Comment 13) One comment opposes applying the sanitary food transportation rule to shell eggs on the grounds that the transportation of shell eggs is already regulated by FDA under 21 CFR part 118, and that the transportation of egg products is already regulated by USDA under requirements established under the EPIA. The comment further states that most shell egg producers also are subject to additional transportation safeguards either because of customers' proprietary specifications or customers' requests that the egg producers participate in voluntary quality-assurance programs, such as the Safe Quality Food (SQF–2000) standards or the United Egg Producer's 5-Star Egg Safety Program.

(Response 13) We disagree with this comment. The transportation requirements in 21 CFR part 118 address only the ambient temperature of vehicles used to transport shell eggs and do not include requirements for the design, condition, and sanitation of the vehicles or specific procedures to

ensure that the specified temperatures are consistently achieved. Similarly, USDA's requirements for the transportation and storage of eggs packed for the ultimate consumer (9 CFR 590.50) refer only to the ambient temperature at which shell eggs must be stored and transported. By contrast, this rule addresses the design, condition, and sanitation, as well as the temperature, of vehicles used to transport food.

With regard to customers' specifications and quality assurance programs, many types of foods are subject to customers' transportation specifications and quality assurance programs. However, we cannot rely on them, exclusively and under all circumstances, to keep food safe during transportation because they vary in effectiveness and are not uniformly administered. This rule establishes uniform, nationwide requirements for the sanitary transportation of food, including shell eggs. To the extent that transportation practices are covered under egg quality assurance programs, these egg producers should find it easier to comply with our requirements.

(Comment 14) A few comments ask us to amend this rule to clarify that under section 116(a) of the FSMA, a facility engaged in the manufacturing, processing, packing, or holding of beverage alcohol products is exempt from this rulemaking. The comments also suggest that we should exempt the transport of all bulk or packaged beverage alcohol products from this rule, including the transport of ingredients and the co-products or by-products of beverage alcohol manufacture. The comments state that the language of section 116 of FSMA specifies which sections of the statute apply to a facility engaged in the manufacturing, processing, packing, or holding of one or more beverage alcohol products, and note that unless a rule falls under sections 102, 206, 207, 302, 304, 402, 403 or 404 of FSMA, Congress does not intend for it to apply to a facility engaged in manufacturing, processing, packing, or holding beverage alcohol products. The comments further assert that because section 111(a) of the FSMA, which directs us to issue this rule, is not one of the listed sections, a facility that is exempt under section 116 should also be exempt from the sanitary food transportation rule. Some of the comments also state that we should exempt the transport of alcoholic beverage products, as well as any oversight of their production facilities, from this rule to avoid duplicative regulatory schemes implemented by both FDA and the U.S. Tax and Trade Bureau (TTB).

(Response 14) There is nothing in FSMA that indicates that transportation operations for beverage alcohol should be exempt from the requirements of this rule. Section 111(a) of the FSMA only creates a deadline for the implementation of the 2005 SFTA final rule, and nothing in the FSMA otherwise addresses the 2005 SFTA. Therefore, it seems that, based on a plain reading of the statute, transportation operations for beverage alcohol can be covered by this rule. In addition, we are not aware of TTB regulatory requirements that would duplicate the requirements of this rule. However, this final rule, as provided under the revised definition of ''transportation operations'' in § 1.904, does not apply to the transportation of food fully enclosed by a container that does not require temperature control to prevent it from becoming unsafe. This provision essentially excludes packaged beverage alcohol products from coverage under this rule.

(Comment 15) One comment asks that we consider issues regarding the rejection of produce shipments under this rule that are also subject to the Perishable Agricultural Commodities Act (PACA). The comment states that under the PACA, sellers and buyers must legally ship and accept the quantity and quality of produce specified in their contracts, and receivers must accept produce that is damaged and decayed, up to a certain percentage, depending on the product's grade standards. The comment contemplates a situation where a receiver would be required to accept shipments under the PACA, but, according to the comment, might be required to reject them under this rule for deviation from quality standards set by the shipper.

(Response 15) This rule does not require a receiver to reject a shipment that is transported under conditions that deviate from those specified by the shipper to the carrier and loader in accordance with § 1.908(b)(1). As explained in our response to Comment 129, the rule establishes requirements for shippers, loaders, carriers, and receivers in § 1.908(a)(6) that precludes the sale or distribution of any food subject to this rule where there is an indication of a material failure of temperature control or other conditions during transportation that may render the food unsafe, unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe. Contrary to the comment's assertions, this rule does not address the disposition of any produce delivered to a receiver that might deviate from quality standards set by a shipper.

E. Other Comments

1. Contractual Reassignment

(Comment 16) Several comments asserted that, to reflect common industry practice, we should explicitly recognize that companies that bear legal responsibility for compliance with this rule may contractually assign specific tasks, *e.g.,* vehicle inspections or taking a temperature measurement, to an alternative or better suited entity. Several comments state that we acknowledged the potential for parties to contractually allocate tasks in the preamble discussion of the proposed rule (79 FR 7006 at 7014) and that we should explicitly recognize in the final rule that shippers, carriers, and receivers may enter into contracts that allocate tasks either between them or to another entity. For example, one comment states that a carrier should be able to rely exclusively on a receiver to take the temperature of a refrigerated food load upon delivery to assess the potential for temperature abuse during transport given that the receiver may already be engaging in this activity for its own purposes. Several comments state that firms that contractually reassign tasks should maintain records that FDA could review during inspections to document these contractual agreements. One comment states that there may be entities involved in food transportation other than those that would be subject to the proposed rule, such as warehouses, that might contractually assume some of the requirements described in the proposed rule.

(Response 16) We acknowledge that industry practice is to alter, by contract, the tasks assigned to shippers, loaders, carriers, and receivers in this rule. Therefore, we also explicitly recognize that companies that bear legal responsibility for compliance with this rule may contractually assign specific tasks, *e.g.,* cleaning a vehicle or communicating previous loads hauled, to an alternative entity. We also understand that industry best practice is to memorialize the assignment of duties in a transportation operation with a written contract.

The duty to comply with the provisions in this rule can be reassigned via contract among parties covered by this rule (*e.g.,* as described in § 1.908(b)(5) where the shipper assigns responsibilities such as monitoring temperature during transit via written

contract to a carrier). We have further clarified this point by adding language at § 1.908(a)(1) that states that an entity subject to this rule (shipper, loader, carrier, or receiver) may reassign, in a written agreement, its responsibilities under this rule to another party subject to this rule. This provision also states that the written agreement is subject to the records requirements of § 1.912. Further, parties may accomplish their duty to comply with provisions in this rule by assigning tasks to parties not covered by this rule, as long as such assignment is covered by a written contract (*e.g.,* a carrier may contract with a truck wash station to wash a bulk tanker, where the truck wash station is not an entity that is covered by this rule). If responsibility under this rule is assigned via contract to another party covered by this rule (first example, aforementioned), FDA would consider the terms of the contract in determining who is responsible for compliance. If a task under this rule is assigned via contract to a party who is not covered by the rule (second example, aforementioned), FDA would hold the party covered by the rule ultimately responsible for compliance with the provisions of the rule. Any written agreements assigning duties in compliance with this rule will be subject to the recordkeeping provisions in § 1.912.

2. Intrastate Transportation

(Comment 17) One comment states that the application of this rule to both intrastate and interstate shipments would create consistent expectations among parties engaged in food transportation. Furthermore, the comment suggests that we consider addressing in this rule a common practice among the parties engaged in food transportation whereby they engage in a separate contract for the transportation of food, as authorized by 49 U.S.C. 14101(b). The comment states that because there is currently no standard transportation contract, parties are free to agree to any and all terms that they choose, and the various State laws apply to those terms. Further, the comment asked whether parties can shift responsibilities, agree to terms more or less onerous, and change the meaning of this rule by contract. The comment states that we should clarify whether the rule cannot be modified by contract or specify what parts can be modified. The comment also states that leaving these questions unsettled in the final rule might result in numerous State contract claims related to this rule.

(Response 17) We agree that the application of this rule to both intrastate and interstate shipments would create consistent expectations among parties engaged in food transportation.

Further, we acknowledge that under the provisions of 49 U.S.C. 14101(b), carriers by motor vehicle may ''expressly waive any and all rights and remedies under [that] part for transportation covered [by a contract between that carrier and a shipper].'' However, the purpose of this rule is not to address the ability of parties to contract under that provision. The purpose of this rule is to ensure that shippers, loaders, carriers, and receivers use practices that ensure the sanitary transportation of human and animal food. Therefore, as discussed in the previous comment, the roles being played by the particular parties involved in the transportation of food can be shifted among the parties within the contractual relationship However, entities covered by this rule cannot, via contract or otherwise, either change the meaning of the rule or establish sanitary transportation requirements that are less onerous than those contained in this rule.

(Comment 18) One comment states that intrastate activities should be exempt from the requirements of this rule. It asserts that the paperwork burden required by this rule would be onerous for local bulk animal feed facilities and that complying with this rule would make it difficult for these types of facilities to remain in business. The comment further states that the intrastate transportation of commercial animal feed historically has presented little to no risk to humans and animals.

(Response 18) We disagree that intrastate transportation activities should be exempt from this rule. As we noted in the proposed rule, section 416(b) of the FD&C Act directs us to create regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated. The scope of section 416(b) is not limited to interstate commerce. We are sensitive to the concerns voiced by this comment about the burden this rule might impose upon small facilities. As we discuss in sections IV.E.2 and 5, we have revised the requirements regarding the exchange of information between shippers and carriers (§ 1.908(b) and (e)), which in many cases will reduce or eliminate paperwork burdens imposed on parties subject to this rule, including facilities engaged exclusively in the intrastate shipment of bulk animal feed. In addition, feed facilities engaged in intrastate transportation operations are not subject to this rule if they are a ''non-covered business'' as defined in this rule. This final rule establishes appropriate requirements for such facilities and will not impose undue cost or paperwork burdens. Since the rule has its basis in industry best practices, many persons should be in substantial compliance with its provisions and should not find compliance burdensome. Accordingly, this comment does not persuade us that it would be appropriate or in keeping with the purpose of this statute to exclude intrastate activities from the scope of this rule.

3. Enforcement Issues Related to This Rule

(Comment 19) We received many comments regarding the enforcement of this rule. The comments cover a broad range of topics, such as: The need for clarification of the roles of various Agencies including DOT and State and local regulatory authorities in enforcing the rule; FDA's need to establish enforcement partnerships with other Agencies; how variations in the applicability of this rule (*e.g.,* those entities that are subject to the rule and those that are not, and the effects of the varying size of the entities covered by the rule) will be addressed; whether enforcement during transportation, as opposed to at points of origin and destination, is practical and/or necessary to ensure food safety; how enforcement actions might vary depending on the severity of a violation and the potential threat posed to food safety resulting from a violation; the training that inspectors will likely need to properly enforce this rule; how inspections will be carried out without compromising the safety of the food shipment; and the need for enforcement guidance for industry. Some comments express concern about unequal enforcement of this rule directed toward trucking as compared to railroad operations, because regulators can more readily develop and execute truck surveillance and inspection programs. Comparable surveillance and inspection activities are more difficult for railroad operations, *e.g.,* access to rail yards may be more limited and trains cannot be stopped for inspection during transit. One comment addresses the importance of ensuring that enforcement has a minimal impact on international trade, especially in the case of rail carriers operating between the United States, Canada, and Mexico. Some comments express concern that we currently lack the resources to carry out inspections

and that we will face staffing and training challenges in operationalizing this rule to achieve consistent enforcement of the rule.

(Response 19) The Secretary of Transportation, in consultation with the Secretary of Health and Human Services and the Secretary of Agriculture, is required by section 5701(a)(1) of the 2005 SFTA to establish procedures for transportation safety inspections to identify suspected incidents of contamination or adulteration of: Food in violation of regulations issued under section 416 of the FD&C Act; carcasses, parts of carcasses, meat, meat food products, or animals subject to detention under section 402 of the FMIA (21 U.S.C. 672) and the DOT's food transportation safety inspection requirements that appear at 49 U.S.C. 5701; and poultry products and poultry subject to detention under section 19 of the PPIA (21 U.S.C. 467a). The 2005 SFTA further states in section 5701(b) that the Secretary of Transportation shall promptly notify the Secretary of Health and Human Services or the Secretary of Agriculture, as applicable, of any instances of potential food contamination or adulteration of a food identified during DOT transportation safety inspections. We note that DOT and USDA have jointly produced a training video, entitled ''Considerations for the Safe Transportation of Food Video,'' that is available via the Department of Homeland Security at the University of Tennessee Knoxville's Web site: *http://www.vet.utk.edu/cafsp/online/ftsvideo.php.* DOT also has trained its enforcement officers to report any food safety violation they encounter to FDA or USDA, depending on the nature of the food being transported. We will work with DOT to support these inspection efforts. However, we note that while DOT has authority to conduct transportation safety inspections for the purpose of identifying suspected incidents of food shipments that are not in compliance with this rule and is authorized by section 416(f) of the FD&C Act to provide assistance upon request by FDA in the enforcement of this rule, FDA will generally be responsible for taking action when food or persons are found to be in violation of the statutes and regulations it administers.

We intend to allocate our resources for the enforcement of this rule by following up on information that DOT provides us or by initiating inspections and investigations. These comments raise issues that we will consider when developing enforcement strategies. The details of our prospective enforcement strategies, however, are beyond the scope of this rulemaking; however we believe that the impact of our enforcement activities upon international trade will be minimal since this rule allows the transportation industry to continue to use existing practices that have proven to be effective for the safe transportation of food. We know that we will need to address staffing and training needs, and we will seek to establish partnerships with other Federal Agencies and with State, local, and tribal governments to implement this rule. We also will communicate with the public, including with regulated industry, as appropriate, throughout the process of developing and implementing our enforcement efforts for this rule.

4. Intra-Corporate Operations

We received several comments asking us to include provisions in this final rule for food transportation operations that are conducted under the ownership or operational control of a single corporate/legal entity, *i.e.,* food shipments involving shippers, loaders, carriers, and/or receivers that are corporate subsidiaries or affiliates of a common corporate parent company/legal entity. The comments refer to these types of activities alternatively as ''intra-corporate'' or ''intra-company'' food transportation operations.

(Comment 20) Several comments state that intra-corporate transportation operations should be completely and expressly exempt from this final rule. Some of these comments suggest that we should define the term intra-corporate/intra-company in § 1.904 of the final rule and exempt these types of activities from the definition of ''transportation operations'' as that term is defined in § 1.904. Some of the comments ask us to exempt intra-corporate transportation operations by issuing a waiver as provided for under §§ 1.914 and 1.916 of this final rule. Most of these comments assert that intra-corporate shipments typically are conducted in accordance with integrated, intra-corporate Standard Operating Procedures (SOPs) and good sanitary food transportation practices and therefore should be exempt from the final rule. Some of the comments argue that food transportation operations that are predominantly, but not entirely intra-corporate, for example, in which a shipper and a receiver share a common corporate ownership, but in which the loader or carrier might be an independent, third-party entity operating under a contract with the shipper, also should be entirely and expressly exempt from this final rule.

Some of these comments assert that we should exempt intra-corporate food shipments from this rule because we contemplated exempting similarly situated entities under our FSMA FSVP proposed rule (78 FR 45730 at 45743). Two comments argue that exempting all intra-corporate food transportation operations from this rule is warranted because intra-corporate transfers would be addressed under the FSMA preventive controls rules for human and animal food. These comments assert that subjecting intra-corporate shipments to additional regulation and recordkeeping requirements under this sanitary food transportation rule therefore would be unnecessary and redundant.

One of the comments observes that the SFTA of 2005 and § 1.904 of the proposed rule define the term ''transportation'' to mean ''any movement in commerce by motor vehicle or rail vehicle.'' The comment asserts that intra-corporate food shipments therefore should be exempt from this rule because, for example, food shipped between facilities owned, leased, or operated by the same corporate entity ''does not enter the stream of commerce.''

(Response 20) We decline to establish a blanket exemption from all of this rule's requirements for food transportation operations that are conducted between shippers, loaders, carriers, and/or receivers that are part of the same corporate/legal entity either by revising the definition of ''transportation operations'' in the final rule, by issuing a waiver for intra-corporate shipments, or by any other mechanism. We conclude that the fact that shippers, loaders, carriers, and/or receivers may be operating within a unified corporate/legal entity or sanitary food transportation system does not necessarily ensure that all of the involved parties are operating in compliance with the portions of section 402 of the FD&C Act that are relevant to this rulemaking. While we acknowledge that parties involved in intra-corporate food transportation operations can lessen their recordkeeping burden by adopting a unified, company-wide approach to sanitary food transportation operations, *e.g.,* by creating comprehensive SOPs that are to be followed by shippers, loaders, carriers, and/or receivers that operate under common corporate ownership or control, such unified, company-wide SOPs must ensure that the food is transported in compliance with the requirements of this final rule. We address the use of contracts to assign specific food transportation tasks to independent, third parties in our response to Comment 16.

In the FSVP final rule, we declined to establish ''an exemption from the FSVP requirements for food that an importer obtains from a foreign supplier that is part of the same corporate structure as the importer,'' and we further declined ''to establish an exemption from the FSVP requirements where the foreign supplier and importer may otherwise be affiliated, and where the foreign supplier and importer are part of the same company-wide 'approach' to food safety'' (80 FR 74225 at 74255–56).

We also decline to exempt intra-corporate food transportation operations from this rule on the grounds that such activities will be covered by the requirements of the preventive controls rules for human and animal food. The primary purpose of the preventive controls rules is to establish modern science- and risk-based preventive controls requirements for the manufacturing, processing, packing, or holding of human and animal food. Although facilities under the preventive controls rules may identify refrigeration during transport as a preventive control, for example, the preventive controls rule, unlike this final rule, does not directly regulate carriers. We also note that SFTA was signed into law in 2005 and FSMA was signed into law in 2011. If Congress had intended for FSMA's preventive controls rules to supplant the sanitary food transportation statutory requirements set forth in SFTA under any circumstances, including but not limited to intra-corporate food shipments, Congress presumably would have stated so explicitly in FSMA's statutory language.

Finally, we also decline to completely exempt intra-corporate food transportation operations from this final rule on the commenter's theory that food shipments between shippers, loaders, carriers, and/or receivers that share a common corporate ownership do not fall within the rule's definition of ''transportation'' because such food shipments do not enter the stream of commerce. Although not explicitly stated in the comment that asserts this theory, the comment appears to suggest that the shipment of food between entities that operate under a common corporate ownership or control does not enter into the stream of ''commerce'' presumably because the food is not being offered for sale between the parties involved in the transportation operations. We conclude that this interpretation of the 2005 SFTA's statutory definition and the parallel definition of ''transportation'' in § 1.904 of this final rule is incorrect. The 2005 SFTA does not define the term ''in commerce'' and therefore does not explicitly limit the scope of the rule, for example, only to those transportation operations that involve the shipment of food that is offered for sale.

(Comment 21) We received several comments asking us to apply modified requirements regarding this rule's information sharing and recordkeeping provisions to shippers, loaders, carriers, and/or receivers engaged in intra-corporate food transportation operations. These comments state, for example, that to require a shipper under this rule that owns its own carrier fleet to provide to the carrier, in writing, all necessary sanitary requirements for the carrier's vehicles and transportation equipment would be redundant and serve no purpose because the information sharing required by this rule, under these circumstances, would presumably already be established by written intra-corporate food transportation SOPs.

Some of these comments assert that a precedent for exempting intra-corporate food shipments from the information sharing and recordkeeping provisions of this rule can be found in the recordkeeping final rule that we issued under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), at 21 CFR part 1, subpart J.

(Response 21) We agree with these comments and have revised the regulatory text accordingly. Section 1.908(a)(5) of this final rule stipulates that as an alternative to meeting this rule's applicable requirements, shippers, receivers, loaders, and carriers that are under the ownership or operational control of a single legal entity may conduct transportation operations in conformance with common, integrated, written procedures that ensure the sanitary transportation of food consistent with the rule. Section 1.908(a)(5) also states that these written procedures are subject to the records requirements of this rule in § 1.912, which are discussed in section IV.G of this document.

Finally, as we already mentioned earlier in this document, some of the comments invoked the Bioterrorism Act recordkeeping rule as a precedent for granting the revised information sharing and recordkeeping requirements of this rule for intra-corporate food transportation operations. As we explained in the preamble to the Bioterrorism Act recordkeeping rule, ''intra-corporate'' interactions, for purposes of the implementation of that rule, are limited to interactions between entities that are part of a ''vertically integrated company,'' for example, a food manufacturer that owns its own suppliers, carriers, distributors, and food retail outlets and, therefore, never releases the food to persons outside of its vertically controlled production path (69 FR 71562 at 71568–71569, December 9, 2004).

The definition of a vertically integrated company as used in the Bioterrorism Act recordkeeping rule is narrower in scope than the definition of ''intra-corporate'' in this rule. As we explain in our February 2012 guidance to industry entitled ''Questions and Answers Regarding Establishment and Maintenance of Records by Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)'' (Ref. 20), two corporate entities that have the same controlling corporate parent are not always part of a vertically integrated company. They may be legally distinct persons, for example, and therefore would not be exempt from the Bioterrorism Act rule's recordkeeping requirements. Similarly, two corporate subsidiaries that are legally distinct persons, but that are managed operationally as a single entity, would not be exempt from the Bioterrorism Act recordkeeping rule. We conclude that the information exchange and recordkeeping provisions set forth in § 1.908(a)(5) of this final rule are appropriate because shippers, carriers, receivers, and loaders operating under the control of a single legal entity can effectively use common integrated written procedures that prescribe sanitary food transportation practices. Accordingly, the provisions set forth in § 1.908(a)(5) of this rule will not be strictly limited to vertically integrated companies, like the Bioterrorism Act's recordkeeping rule.

(Comment 22) One comment asks us to exempt from this final rule's information exchange and recordkeeping requirements food transportation operations that involve shipments of food from centralized charitable food distribution centers that act as shippers, and sometimes also carriers, to member food banks that are separate legal entities, but are closely affiliated with the shippers. The comment also asks us to exempt shipments between food banks. This comment asserts that these types of operations are similar to intra-corporate food transportation operations and, therefore, adherence to this rule's information exchange and recordkeeping requirements should not be required because internal written SOPs are sufficient for ensuring the sanitary transportation of food between these types of entities.

(Response 22) We decline to exempt food transportation operations that involve shipments from centralized charitable food distribution centers to food banks, as well, as food shipments between food banks, from this rule's information exchange and recordkeeping requirements. The commenter describes itself as being a national, domestic hunger relief charity that acts as a shipper to distribute food to and through a network of 200 member community food banks. The comment also states that the individual food banks that form the network ''are separate legal entities,'' but are ''closely affiliated with the national organization.'' We decline to exempt these types of transportation operations from this rule because we do not believe that they are comparable to intra-corporate food transportation operations in which shippers, loaders, carriers, and/or receivers operate under the ownership or operational control of a single corporate/legal entity. The commenter and its network of independent food banks are ''affiliated'' only in the sense that they cooperate closely to advance their shared mission of delivering food assistance to people in need.

However, we have made revisions in this final rule that may lessen the information sharing and corresponding records requirements for organizations such as the ones described by this comment. As we note in our response to Comment 124, we have revised the information sharing provisions in § 1.908(b)(1) to only require one-time notification to the carrier and when necessary, to the loader, by the shipper, unless the design requirements and cleaning procedures required for sanitary transport change because of the type of food being transported. In addition, as we note in our response to Comment 129 and Comment 134, we have revised § 1.908(b)(2) to recognize that the specification of pre-cooling and operating temperature parameters by the shipper to the carrier, and to the loader, may not be necessary for transportation operations conducted during winter in cold areas or for short distance transportation of food in appropriate circumstances.

5. Lists of Nonfood Cargo That May Adulterate Food

We requested comments in the preamble to the proposed rule in response to our tentative decision not to identify and include, in this rulemaking, specific nonfood products that, under all circumstances, may adulterate food subsequently hauled in bulk or non-bulk vehicles. We also requested comment on our tentative conclusion that issuing guidance instead, regarding how some transportation practices may affect the potential for nonfood products to adulterate food products, and would be helpful to the transportation industry.

(Comment 23) Many comments support our decision not to issue lists of nonfood items that may adulterate food if transported simultaneously with food in a non-bulk vehicle, or prior to the transport of food in a bulk vehicle. Several comments agree with our tentative conclusion that issuing guidance regarding how specific transportation practices may affect the potential for nonfood products to adulterate food products would be helpful to the transportation industry. One comment states that the oilseed industry already uses lists of acceptable and unacceptable previous cargos to prevent the adulteration of edible oils during transport and encourages us to incorporate these lists as reference documents in this rulemaking or to establish corresponding guidance documents.

(Response 23) Based upon these comments, we affirm our decision not to include lists of nonfood items that may adulterate food if transported simultaneously with food in a non-bulk vehicle, or prior to the transport of food in a bulk vehicle, as part of this rulemaking. However, we will consider the utility of using such lists as references in any guidance we may issue on this subject in the future.

6. Need for Guidance

(Comment 24) Several comments express the need for guidance documents related to this rule. These comments state that guidance will be important for explaining our expectations (*e.g.,* what measures are ''effective'' or ''adequate''). Some comments state that, we should provide specific guidance for foreign individuals and entities to clarify who would be responsible for complying with the rule in complex transportation operations involving international shipments into the United States. In addition, a comment states that specific quantitative requirements should be included in guidance rather than in this rule to avoid implementation difficulties.

(Response 24) We agree that guidance are important for helping stakeholders to understand the application of this rule to their operations. As we note elsewhere in this document, we may issue future guidance, as resources allow, regarding issues such as the granting of waivers, transportation activities performed by farms, and how transportation practices may affect the potential for the adulteration of food products by nonfood products during transportation operations. We will consider whether guidance on these or other matters would be useful to clarify measures that entities engaged in the transportation of food may take to comply with this rule. We would not include requirements in any guidance because under our good guidance practices regulation (21 CFR 10.115), guidance documents do not establish legally enforceable rights or responsibilities.

(Comment 25) A comment addressing the transportation of RACs by farms agrees with our tentative conclusion in the proposed rule that the sanitary transportation practices that would be required by this rule are not necessary to prevent RACs from becoming adulterated during transportation by farms. However, to minimize the potential for adulteration, this commenter recommends that we develop a guidance document on good transportation practices, as well as user-friendly education materials. The comment suggests that such guidance should stress the importance of cleanout procedures in non-dedicated farm transportation conveyances and equipment used to haul RACs and other products, and provide sample clean-out procedures for such conveyances. The comment also suggests that the guidance could encourage farms that transport RACs to inform receivers about the previous load hauled in the conveyance.

(Response 25) We discussed the exemption of transportation activities for RACs performed by farms from this rule in the proposed rule (79 FR 7006 at 7016) and noted that the diversity of farms and their transportation operations pose challenges in developing mandatory requirements via rulemaking that would be broadly suitable and meaningful for this sector of the food transportation industry. As we discuss in Comment 79, we have revised this final rule to provide that all transportation activities performed by a farm are not subject to this rule. However, we agree that issuing a guidance document on farm transportation operations may be useful in setting forth good transportation practices, given the diverse practices that occur within this sector. We, therefore, intend to consider establishing such guidance and will consider the role that we might be able to play in promoting educational and training activities to address this issue.

7. Preemption

(Comment 26) Some comments expressed concern with the preemption provision of the 2005 SFTA and its potential impact on any State with existing transportation requirements. One comment stated that this rule should be flexible enough to permit State laws to stay in effect if the State law is stronger and its enforcement is superior to what is being achieved under this rule. Some of these comments asserted that the statutory exclusions in the coverage of the 2005 SFTA, *e.g.,* its non-coverage of barge transport, in combination with the preemption provision could weaken existing State activities and regulation of industry and prevent States from developing a unified sanitary transportation regulation.

(Response 26) As we stated in the proposed rule (79 FR 7006 at 7032), the 2005 SFTA includes an express preemption provision at section 416(e) of the FD&C Act, which provides that a requirement of a State or political subdivision of a State that concerns the transportation of food is preempted if: (1) Complying with the requirement of the State or political subdivision and with a requirement of section 416, or with a regulation issued under section 416, is not possible; or (2) the requirement of the State or political subdivision as applied or enforced is an obstacle to accomplishing and carrying out section 416 or a regulation issued under section 416. Section 416(e) of the FD&C Act further provides that the express preemption provision applies to transportation that occurs on or after the effective date of regulations issued under section 416. This express preemption provision applies to the requirements of this final rule upon their becoming effective. Nonetheless, a State law, including unified State laws, should States wish to adopt such laws, concerning the sanitary transportation of food by motor vehicle or rail vehicle, is not preempted if such laws do not fall under either section 416(e)(1) or (2) of the FD&C Act. Furthermore, it is highly unlikely that any State law addressing transportation operations not subject to the 2005 SFTA, *e.g.,* barge transport, would fall within the scope of the 2005 SFTA's preemption provision. In most cases, a more stringent provision in State law would not be preempted.

(Comment 27) Some comments urge us to affirm that this rule does not preempt related State laws when they are ''in addition to'' Federal regulation and do not present an obstacle to advancing the purposes of SFTA. The comments further state that we should construe the preemption clause in the SFTA of 2005 narrowly and that we should work in tandem with State authorities by treating this regulation as a floor, and not a ceiling, for State public health measures such that States wishing to enact sanitary food transportation requirements that are more rigorous than those imposed by this rule will be permitted to do so. These comments state that there are two ways that a Federal authority can block State regulation—either by ''conflict (or obstacle) preemption'' or by ''field preemption''—and the comment stated that the language in the SFTA is an example of the former. Conflict preemption only applies when a person or entity cannot satisfy both Federal and State law, and where State law is an obstacle to Federal goals.

(Response 27) Under section 416(e) of the FD&C Act, this rule does not preempt State laws or laws of a political subdivision regarding sanitary transportation of human and animal food unless complying with those laws and this law is impossible, or the requirement of the State or political subdivision as applied or enforced is an obstacle to carrying out this law. Section 416(e) of the FD&C Act further provides that the express preemption provision applies to transportation that occurs on or after the effective date of regulations issued under section 416.

We agree with the commenters that conflict preemption could apply to any State laws governing sanitary food transportation that would make it impossible to simultaneously comply with this rule. In addition, another aspect of conflict preemption could apply under a ''frustration of purpose'' or ''obstacle'' theory, whereby a State law requiring sanitary transportation practices would be preempted to the extent the State law frustrates the purpose of, or presents an obstacle to accomplishing the purpose of, this rule. Whether a State requirement is preempted by Federal law depends on specific factual situations. Therefore, although some State requirements may be preempted by Federal law, this law does not prevent States from developing sanitary transportation regulations at the State or local level.

8. Issuance of Sanitary Transportation Supplemental Proposed Rule

(Comment 28) Some comments ask us to publish a revised proposed rule or an interim rule before proceeding to a final rule because of anticipated, significant changes resulting from comments that we received in response to the proposed rule, as well as potentially significant changes in the other, interrelated FSMA rules. One comment states that because the FSMA rules are dependent on one another, all proposed FSMA rules should be issued concurrently so that a concurrent evaluation and comment period may be conducted. Some comments state that re-proposal and a second opportunity for public comment also is warranted because implementation of the sanitary transportation rule will require the complex coordination of efforts among multiple Federal Agencies.

(Response 28) We considered these comments requesting that we issue a supplemental proposal. This final rule includes numerous revisions to the proposed rule. These revisions, however, better achieve our stated objective in the proposed rule to align the provisions of this rule with current safe food transportation practices and to allow industry to continue to use existing practices that have proven to be effective. The revisions we made to this rule are also a logical outgrowth from the proposed rule and are supported by comments that we received in response to the proposed rule. Therefore, we have determined that issuing a supplemental proposal of the rule is not necessary.

We also do not believe that we need to issue a supplemental proposal because implementation will require complex coordination among multiple Federal Agencies. We have sufficiently addressed in our responses to Comment 12 and Comment 13 the application of this rule to food that is subject to the regulatory authority of USDA. In addition, while section 5701 of the 2005 SFTA directs DOT to establish procedures for transportation safety inspections for the purpose of identifying suspected incidents of contamination or adulteration of food during transport in violation of this rule, we do not consider any coordination that we must do with DOT on enforcement to be particularly complex, such that it would have benefited from an additional opportunity for public comment. Therefore, we have determined that issuing a supplemental proposal to consider further aspects of this rule that are relevant to our interactions and relationships with other Federal Agencies is not necessary.

With regard to the suggestion that we should re-issue all seven of the FSMA foundational proposed rules simultaneously for comment, we agree that this might have been helpful to commenters. However, given our deadlines under a consent decree for the seven rules (Ref. 21), this was not possible. We also believe that stakeholders were given adequate opportunity to comment on the

proposed rules, particularly those that are interrelated and were issued simultaneously as supplemental proposed rules in September 2014.

9. Retrospective Review

(Comment 29) One comment states that in line with the requirements of Executive Order 13563, the Office of Management and Budget's (OMB's) implementation memo for that Executive order (Ref. 22), and OMB's 2013 Report to Congress (Ref. 23), it is clear that FDA should incorporate specific plans for retrospective review and ex post evaluation into the text of its final rule. The comment also suggests that given the uncertainty of the underlying data used to formulate the provisions of this rule, we commit to measuring the actual effects of the regulation and use the data we collect during the implementation of the rule to annually review whether the standards are having their desired effects.

(Response 29) We disagree. As discussed in the Final Regulatory Impact Analysis for this rule (Ref. 24), we have examined the impacts of the proposed rule under Executive Orders 13563 and 12866, in relevant part. Section 6 of Executive Order 13563 addresses retrospective analysis of existing rules by agencies, but the Executive order does not require that agencies include retrospective review plans in the codified text. FDA is committed to reviewing its rules to ensure their implementation is effective.

10. Transportation by Modes Other Than Motor Vehicle and Rail Vehicle

(Comment 30) One comment expresses concern about gaps in FDA's authority to regulate different types of food transport conveyances under the 2005 SFTA. The comment notes that the statute specifically limits our regulatory authority to the transportation of food by motor carriers and rail vehicles, excluding transportation by barge or ship and by air. The comment asserts that these omissions create critical weaknesses in the sanitary food transportation system because significant amounts of animal feed grain are transported by barge or ship within the United States and because highly perishable food products are frequently transported by aircraft. Another comment recommends that we explicitly state in this rulemaking that these additional conveyances are excluded and provide a rationale for their exclusion.

(Response 30) The 2005 SFTA, as passed by Congress and signed into law by the President of the United States, expressly mandates that FDA issue regulations to ''require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices . . . to ensure that food is not transported under conditions that may render the food adulterated'' (21 U.S.C. 350e(b)). We do not believe that we need to issue any confirmatory statements or rationales in response to these comments because the relevant 2005 SFTA statutory language is plain and clear on its face. The 2005 SFTA does not mandate that we issue regulations applicable to the sanitary transportation of food by any other conveyances, including barges or ships and aircraft. However, if we find that there is a public health need for us to regulate air and barge or ship transportation, we will consider whether we want to pursue covering these routes under a non-SFTA authority in the future.

11. Waivers

We stated in the proposed rule (79 FR 7006 at 7029–7030) that we had tentatively determined that it would be appropriate to waive the applicable requirements of this rule, if finalized as proposed, with respect to the following classes of persons:

- Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade ''A'' Milk Safety Program, only when engaged in transportation operations involving Grade A milk and milk products; and
- 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.

We stated our intent to separately publish in the **Federal Register,** at the time of publication of this final rule, waivers and the reasons for the waivers for these two classes of persons from the applicable requirements of this rule. We requested comment regarding whether these proposed waivers could result in the transportation of food under conditions that would be unsafe for human or animal health, or could be contrary to the public interest. We did not receive any such comments.

However, we did receive comments requesting that we modify or expand the scope of these waivers beyond that which we discussed in the proposed rule. While we intend to publish waivers in the **Federal Register** addressing the aforementioned classes of persons prior to the compliance date of this final rule, we are evaluating these comments to determine whether we should modify either of these two waivers as requested, and we intend to post a notice on our Web site of our reasoning regarding the scope of these prospective waivers at the soonest possible date. We will also discuss, in this subsequent notice, our thinking on comments we received asking us to consider publishing an additional waiver for transportation operations for molluscan shellfish for entities that hold valid State permits under the National Shellfish Sanitation Program.

(Comment 31) We received comments that we should acknowledge Tribal food codes in addition to state and local food codes in our discussion of waivers and that we should refer to Tribal governments in this final rule in every instance in which we mention State or foreign governments.

(Response 31) We acknowledge that tribal authorities, as well as state and local government agencies, can issue permits to food establishments under their relevant regulatory authority. In light of comments, throughout this final rule we explicitly recognize Tribal governments as partners we intend to work with in the implementation of this rule,*e.g.,* as regulatory authorities we may partner with in future efforts to train regulators (see Comment 6, Comment 19, Comment 159, and Comment 176).

IV. What comments did we receive on the specific provisions of the proposed rule?

A. Who is subject to this subpart? (§ 1.900)

In table 5 we outline the revisions we have made to § 1.900 in finalizing this rulemaking. Following the table we respond to comments about these provisions.

TABLE 5—§ 1.900 WHO IS SUBJECT TO THIS SUBPART?

Proposed section (§)	Description	Revision
1.900(a)	Specifies that, except for certain exclusions and exceptions, this rule applies to shipper, loaders, carriers, and receivers engaged in transportation operations.	Added ''loaders'' to the list of covered entities.
1.900(b)(1)	Specifies that the provisions do not apply to food that is transshipped through the United States to another country.	No revisions.
1.900(b)(2)	Specifies that the provisions do not apply to food that is imported for export in accordance with 801(d)(3) and that is neither consumed or distributed in the United States.	Added ''in accordance with section 801(d)(3) of the FD&C Act'' to the regulatory text for clarity.
1.900(b)(3)	Specifies that the provisions do not apply to food in facilities regulated exclusively, throughout the entire facility, by USDA.	New provision.

(Comment 32) One comment expresses concern about whether the responsibilities that apply to persons subject to this rule would apply to a specific, individual person rather than to an entity. The comment notes that we indicated in the proposed rule that the intent of the rule is to establish accountability at the individual level for ensuring that transportation operations comply with the rule's requirements. However, the commenter asserts that it is not appropriate to place all responsibility onto a single individual. The comment supports having a qualified individual supervise and provide general oversight, but requests confirmation that the term ''person'' used in this rule refers to legal persons—including corporations.

(Response 32) The statement that this comment references from the proposed rule (79 FR 7006 at 7018) addresses the proposed requirement in § 1.908(a)(2) that responsibility for ensuring that transportation operations are carried out in compliance with all requirements of this rule must be assigned to competent supervisory personnel. That specific requirement does designate an individual as being responsible for this requirement, but we did not state that the intent of the rule is to establish accountability at the individual level for compliance with all requirements of the rule. The term ''person'' as used in this rule will include ''individuals, partnerships, corporations, and associations.''

(Comment 33) One comment asked us to affirm that, for cheese exported to the United States under ''freight on board'' (FOB) contracts, the shipper is not responsible under this rule once the goods are delivered to a warehouse in the United States. FOB contracts specify that, once the goods have been turned over to the transporting company, the purchaser assumes the risk of loss as defined by the Agreement on International Commercial Terms.

(Response 33) The responsibilities of a shipper under this rule are not affected by the type of shipping arrangement, *e.g.,* an FOB contract, and nothing in this rule specifies which party assumes the risk of loss.

(Comment 34) One comment asked whether the term ''other persons'' engaged in transportation might include governmental customs agencies that might withhold or load products during the agencies' custom processing operations for more time than considered to be usual in transport to their final destination. The commenter expresses concern that such a delay might potentially create food safety issues.

(Response 34) The 2005 SFTA authorizes us by regulation to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. Generally, governmental customs officials are not engaged in food transportation operations and typically would not be subject to this rulemaking. Their role in inspecting food does not bring them within the scope of what this rule is intended to cover.

(Comment 35) A few comments asked us to address responsibility under this rule in a few situations involving international shipments into the United States. One comment, for example, asked if a rail bulk container travels from Canada to a U.S. rail yard and then is transferred to a new train, is the person or entity that initiated the shipment in Canada the shipper, or is the shipper the person that transferred the bulk container at the U.S. rail yard for further transport in the United States? Another comment asks us to identify the carrier for a closed container that is shipped into the United States by ocean-going vessel and then is transferred, unopened, at the U.S. port of entry onto a truck. Finally, one comment asks us who would be held responsible under this rule if a refrigerated container is shipped from China to the United States via ocean-going vessel and then is transferred, unopened, at the U.S. port of entry onto a truck, and upon receipt, the U.S. receiver discovers evidence of temperature abuse.

(Response 35) In the first example, the shipper for any segment of transportation of the bulk container, *e.g.,* the Canada to U.S. rail segment and also the rail segment originating in the United States, is the person who arranges for that segment of the transportation of the food by a carrier. The shipper may be the same person throughout the transit of the container if a single person arranges for all segments of its transport. In the second instance, the carrier is the person who physically moves the food from the point it becomes subject to this rule, *i.e.,* at the origination of the truck segment in the United States. With respect to the third example, the matter of (legal) responsibility will depend on whether it can be established which actor(s) (*i.e.,* the shipper, loader, and/or carrier) failed to comply with the applicable requirements of § 1.908, and whether this non-compliance contributed to the food becoming unsafe as a result of the failure to provide temperature control. At any rate, whenever it is discovered that the food may have experienced a material failure of temperature control or other conditions that could render the food unsafe, the provision in § 1.908(a)(6) applies and the food shall not be sold or otherwise distributed until it is determined that the temperature deviation or other condition did not render the food unsafe, which may involve communication among the persons subject to this rule. The responsibilities

of persons subject to this rule are discussed in our response to Comment 129.

(Comment 36) One comment asks us to consider situations that include several different transportation legs in determining how parties are defined, or whether specific responsibilities assigned on the basis of the roles the persons involved in transportation operations play are even necessary. For example, corn grain is harvested and (1) taken in a semi-trailer by a farmer to the grain elevator, where it is (2) loaded in a rail car and transported to the Mississippi River, and (3) loaded in a barge for additional transport. Upon arrival, the grain is offloaded into a railcar and is then sent to a feed mill for mixing into hog feed. The comment seeks clarification on the applicability of the regulation if not all parties are subject to this rule, *e.g.,* the parties are performing a non-covered activity (*e.g.,* transport by barge or airplane) or are exempt by size.

(Response 36) In this example, the initial transportation operation would not be subject to this rule because it involves the transportation of food by a farm. In the example described in this comment, the grain elevator would be the receiver. The second segment of transit is subject to this rule because the transportation operation is by rail vehicle and the shipper, loader, carrier and receiver would be the persons who meet the definitions of these entities in this rule. These may not be separate persons, *i.e.,* the shipper and the loader may be the same person. The third segment of transit is not subject to this rule because it involves transportation by a river barge. The fourth segment of transit is subject to this rule in the same manner as the second segment.

We acknowledge that situations may occur where not all parties involved in a transportation operation are subject to this rule, *e.g.,* the shipper is a non-covered business, but the carrier is subject to this rule. In these situations, interactive requirements among covered entities established by this rule, *e.g.,* communication between shippers and carriers, would not be operative and the dialogue between the covered entities that will ensure that safe food transport requirements are understood and entities play their respective roles will not necessarily happen. This situation will disadvantage the entities that are covered businesses, especially if the shipper is not a covered entity. In situations where the shipper (or any entity) is not covered, we believe that the relevant information to ensure safe transport of food (such as appropriate temperatures for refrigeration for foods that require temperature control for safety) will be available in some form to those entities that are covered, though it may not be provided via written records which we consider ideal. Even if certain entities are not covered by this rule, all parties are subject to the general food safety requirements of the FD&C Act.

(Comment 37) A comment expressed concern with the shipper requirements because shipments originating abroad and destined for interior locations in the United States are arranged in the country of origin and the shippers in under-developed countries are not always accessible or easy to connect with, and may not be equipped to communicate with foreign companies and governments. There would be no U.S. shipper in this circumstance and it is unclear how the U.S. carrier and receiver would comply with reporting requirements related to the shipper.

(Response 37) International shipments such as those described in this comment can present difficulties for U.S. firms subject to this rule when it may be necessary to investigate the history of a shipment because, in addition to the circumstances described by the comment, a segment of the shipment, *i.e.,* ocean transport, is not subject to this rule. In circumstances where it would normally be necessary for a U.S. receiver or carrier to contact the foreign shipper under the requirements of this rule (*e.g.,* if a question arose concerning temperature control during shipment) if the shipper is not readily accessible for any reason, the carrier or receiver would have the responsibility under § 1.908(a)(6), which we discuss in Comment 129. We have added this provision to this final rule to ensure that any question relevant to whether the food may be adulterated is adequately addressed before the shipment is allowed to proceed in U.S. commerce. It is unlawful under section 301(a) of the FD&C Act (21 U.S.C. 331(a)) to introduce or deliver for introduction into interstate commerce any food that is adulterated. Further, even in cases where there is a foreign shipper, that shipper may be working in conjunction with a U.S. freight broker that could be contacted in its place to evaluate whether the food is unsafe. Moreover, if the freight broker has arranged the U.S. land-based transportation leg of the foreign shipment, the broker is the legally responsible ''shipper'' for purposes of the rule and therefore subject to the applicable requirements of § 1.908, including the requirement to specify to the carrier the conditions necessary to ensure the safe transport of the food. We also refer readers to our response to Comment 9.

(Comment 38) One comment states that this rule should also apply to entities that transfer a product from one mode of transportation to another (trans-loaders). It is common, particularly for feed ingredients, to have the cargo trans-loaded from a railcar to a truck. The comment recommends that FDA clarify the situations in which trans-loaders are to be considered shippers, carriers, or receivers because a trans-loader may be a separate (sub-contracted) entity.

(Response 38) An entity that only transfers food cargo from one mode of transportation to another, *e.g.,* from a railcar to a truck, would be subject to this rule as a receiver of food arriving by rail vehicle and as a loader of food onto trucks. The entity would not be considered to be a shipper if it simply holds the food pending truck transport and does not arrange for its transport by the trucking firm. The entity may also be subject to other FDA requirements that address the operation of its facility, *e.g.,* the preventive controls rules for human or animal food.

(Comment 39) One comment asks who acts as the shipper when a single container is shipped using multiple modes of transportation. A container, for example, may start its transit on a truck and then be transferred to a rail car and remain sealed until it reaches its final destination. The comment states that in such instances, the entity that initiated the shipment initially should be considered the ''shipper'' throughout the voyage and not an entity that transfers the container between conveyances. The comment states that if the second entity were considered to be the shipper, it might have to open the container to inspect it for cleanliness before the container continues in transit, which could impact the safety of the shipment because this would mean breaking the container's seal.

(Response 39) Under this rule, the shipper is the person who arranges for the transportation of food by the carrier. If, in the example given in this comment, a single person arranges for the shipment of the food via multiple modes of transportation, that person is the shipper throughout all stages of transport. The commenter's interpretation, that if another person becomes a subsequent shipper of a sealed container, that person would have to open the container and inspect it before shipment, is incorrect. Nothing in this rule would require the second shipper to open and inspect the sealed container.

1.900(b)

We are adding text for clarity to § 1.900(b)(2) to specify that ''food that is

imported for future export'' specifically refers to articles of food that are subject to the provisions of section 801(d)(3) of the FD&C Act (21 U.S.C. 381(d)(3)). The added text gives definitive clarity to inform regulated entities that, when we refer to ''food'' that lawfully can be ''imported for export,'' ''food'' means ''a food additive, color additive, or dietary supplement'' as specified by section 801(d)(3) of the FD&C Act.

(Comment 40) We received a comment asking us to clarify what actions food transporters must take to assure compliance when their food product is intended exclusively for export markets. Another comment states that many commodities intended for export are shipped in standard ocean containers (known in the industry as forty-foot equivalent units (FEUs) and twenty-foot equivalent units (TEUs)), which are owned or leased by steamship lines. This means that the shipper, carrier, and receiver, as identified in the proposed rule, do not own the ocean-going container, which often travels on a truck or rail chassis before reaching a U.S. port for export. The comment asserts that this complicates the relationships and documentation required in the proposed rule between the shipper and the container holder for exports.

(Response 40) The 2005 SFTA states that we must, by regulation, require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated. Further, the statute defines ''transportation'' as any movement in commerce by motor vehicle or rail vehicle. Thus, persons engaged in the transportation of food that is intended for export are subject to all applicable requirements of this rule when the food is in transit by motor vehicle or rail vehicle to the land-based U.S. border point of export or a port facility. For example, the loader for a truck transportation segment moving the food to a vessel port facility is subject to the rule because it is loading a motor vehicle. The loader for the trans-oceanic ship transport segment is not subject to the rule because the rule does not cover transportation operations for water borne transportation. However, the operations of the second loader are still subject to section 402(a)(4) of the FD&C Act, which prohibits the holding of food under insanitary conditions whereby it may be rendered injurious to health or may become contaminated with filth.

We recognize that under typical practices in the industry, ocean containers are likely to be inspected and otherwise prepared for transportation by the person who loads the container, *e.g.,* the shipper or loader, not by the owner or supplier of the container. As we discuss in our response to Comment 53, this rule does not place any requirements upon the owner or supplier of the container whether foreign or domestic, in circumstances where they are not a shipper, loader, or carrier, and thus we do not anticipate that there will be relational or documentation issues for shippers to address with such equipment owners as a result of this rule.

(Comment 41) Another comment asks us to include an exemption for human and animal food originating in the United States but bound for export from the requirements of this rule. The comment notes that the proposed rule would not apply to transportation operations for food that is imported but is not ''consumed or distributed'' in the United States because it is exclusively destined for subsequent export. The comment states that food that originates in the United States and is bound for export travels by vehicle or rail car to reach U.S. ports of exit and, like food that is transshipped through the United States to another country or food that is imported for export, it is neither consumed nor distributed until it reaches foreign soil. The comment therefore recommends that we exempt food that originates in the United States, but that is bound for export, from this rule by including under § 1.900(b) the provision: ''Human and animal food that moves under Customs and Border Protection (CBP) export reporting procedures including Automated Export System (AES) and is therefore neither consumed nor distributed in the United States.'' The comment asserts that requiring that the shipments of the food comply with CBP export reporting and documentation procedures ensures that cargo bound for export will not be diverted into the U.S. food supply for domestic consumption.

(Response 41) We decline to exempt persons engaged in the transportation of human and animal food originating in the United States and bound for export from the requirements of this rule, because food that originates in the United States and is bound for export is handled in a fundamentally different manner than food that is transshipped through the United States to another country, for example from Mexico for delivery to Canada, or food that is imported for future export in accordance with section 801(d)(3) of the FD&C Act, and that is neither consumed nor distributed in the United States. In the cases of import for export and transshipment, legally enforceable mechanisms exist that ensure that the food will not be diverted for consumption or distribution in the United States.

With respect to food that is transshipped through the United States to another country, CBP regulations in 19 CFR 18.10, ''Kinds of Entry,'' list the various entries and withdrawals that may be made for merchandise transported in bond. One kind of entry is the transportation and exportation (T&E) entry. A party that transships merchandise in bond through the United States must submit T&E documentation with the CBP and the CBP supervises the shipment of the merchandise through the United States, as well as the intact export of the goods to foreign destinations.

Similarly, under section 801(d)(3) of the FD&C Act, parties which import certain articles that are intended exclusively for further processing or incorporation into another product and for subsequent, mandatory export because the articles cannot be distributed or used in the United States must provide FDA with certain information at the time of initial importation. These articles include food subject to this rule, specifically, food additives, color additives and dietary supplements. These parties must provide, among other things, a statement that confirms their intent to further process such articles or incorporate such articles into a product for purposes of subsequent export, and must provide us with the identities of the entities in the chain of possession of the imported articles while the articles are in the United States. Importers also must provide us with certificates of analysis, as necessary, to identify the article of food. In addition, at the time of initial importation and before delivery to the importer, initial owner, or consignee, a bond must be executed providing for liquidated damages in the event of default, in accordance with CBP requirements. The initial owner or consignee of the article also must maintain records of the use and/or destruction of such imports and must submit the records or a report to FDA upon request. The initial owner or consignee also must destroy any article or portion thereof that is not used in an exported product.

The AES system, on the other hand, collects Electronic Export Information (EEI), formerly known as Shipper's Export Declaration (or any successor document) from persons exporting

goods from the United States, Puerto Rico, or the U.S. Virgin Islands; between Puerto Rico and the United States; and to the U.S. Virgin Islands from the United States or Puerto Rico. AES is the central point through which export shipment data required by multiple Federal Agencies is filed electronically with CBP and is operational at all ports and for all methods of transportation. It was designed to assure compliance with and enforcement of various export laws, improve trade statistics, reduce duplicate reporting to multiple agencies, and improve customer service.

However, AES is not specifically designed to function as a legally enforceable mechanism to ensure that food bound for export is not diverted into the domestic supply chain and consumed in the United States. The AES system does not become operative until food arrives at a point of export. Therefore, if a shipper states that any given food shipment that originates in the United States is destined for export and transports the food without complying with the requirements of this rule, but subsequently decides to divert the food for purposes of domestic consumption or distribution, neither we nor the CBP would have any way of knowing that the food had been diverted for domestic consumption, perhaps after being transported under insanitary conditions. In addition, unlike food transshipped through the United States and food imported exclusively for subsequent export, food that originates in the United States and is intended for export, whether it is diverted for domestic consumption or is actually exported, is not transported under a bond. Accordingly, we do not agree that a basis comparable to that for food transshipped through the U.S., or food imported for export, exists for exempting persons engaged in the transportation of human and animal food that originates in the United States but is bound for export from the requirements of this rule as suggested by this comment.

(Comment 42) One comment states that, when cargo is deemed to be adulterated, one of the primary salvage markets may be destinations outside of the United States. The comment observes that this rule appears not to apply to food outside of the United States and argues that, if that is the case, we should clarify that it should not apply to food that is shipped outside of the United States to a destination that was not the original, intended primary market.

(Response 42) If the product has already been offered for sale in the United States and is found to be adulterated, it cannot be legally exported for sale in markets outside the United States. (See *United States* v. *Kanasco, Ltd.,* 123 F.3d 209 (4th Cir. 1997) (although this case involved drug products and not food, it stands for the principle that, if product is adulterated, it cannot be legally offered for sale outside the United States).) The owner of the product can pursue other lawful options, such as reconditioning the product or diverting the product to nonfood uses. If, however, the food has not been offered for sale in the United States and otherwise meets the requirements of section 801(e)(1) of the FD&C Act, it can be shipped abroad and would not be subject to the adulterated food provisions of the FD&C Act and therefore would not be subject to this rule.

(Comment 43) A comment requests that we address the safe disposal of contaminated foods from a rejected delivery and the sanitization of trailers carrying such cargo. The comment states that when a delivery is rejected, the responsibility for and costs associated with safely disposing of the shipment is often placed on truckers, in some cases with little or no instructions from the shipper. Consequently, according to the comment, drivers who need to dispose of contaminated cargo sometimes simply dump it, give it away to the public, or sell it. The comment states that FDA should explore, in this or a separate rulemaking, the development of rules governing such rejections. The comment further suggests that we should address when rule violations can serve as the basis for the rejection of a delivery and/or a cargo insurance claim, acceptable methods of disposing of contaminated food products after rejection, and the apportionment of disposal costs among parties involved in the transportation of rejected cargoes.

(Response 43) This rule addresses the sanitary transportation of human and animal food to prevent practices that may create food safety risks. We recognize the burdens and uncertainties that may arise when a load is rejected. However, the basis on which a load may be rejected, and the disposition of and costs associated with the disposal of rejected loads of food, are beyond the scope of this rule. We do not agree that we should explore the development of rules to govern rejections and/or cargo insurance claims, or rejected product disposal issues, because they often involve purely economic considerations about food shipments, which do not fall within our jurisdiction. Also, issues of liability are similarly subject to Federal laws that we do not have the authority to administer. We note, however, that if a food shipment is rejected because it is adulterated, the person responsible for that food cannot distribute or offer it for sale. Further, the carrier of a rejected food shipment must ensure that the motor or rail vehicle used to transport the rejected load complies with the vehicle and equipment provisions of § 1.906 before it is used again to transport food.

B. How do the criteria and definitions in this subpart apply under the Federal Food, Drug, and Cosmetic Act? (§ 1.902)

The only change we made in the proposed provisions in § 1.902(a) and (b), which specify that the criteria and definitions in part 1, subpart O apply in determining whether food is adulterated within the meaning of section 402(i) of the FD&C Act and that failure to comply with the requirements of part 1, subpart O is a prohibited act, was to add ''loaders'' to the list of covered entities in both paragraphs.

(Comment 44) One comment asks us to replace the term ''in compliance'' throughout the final rule with the term ''in conformance.''

(Response 44) We decline this request. We have used the phrase ''in compliance'' in § 1.902(a) of this rule consistent with the language of section 7202(a) of the 2005 SFTA, which amends the FD&C Act by adding section 416 to the FD&C Act to provide that a food shall be deemed to be adulterated ''[i]f it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations promulgated under section 416.''

(Comment 45) Several comments express concern about food being considered adulterated under this rule simply because of the failure of a carrier to adhere to a shipper's specified conditions during transport, such as maintaining a specified temperature, regardless of whether the food is actually unsafe. In particular, these comments speak to concerns about the impact the rule, as proposed, would have on the cargo claims process governed by the ''Carmack Amendment'' found in 49 U.S.C. 14706. Under this provision of Federal law, a shipper or receiver seeking to recover money for cargo loss or damage from a carrier must show that the cargo is actually lost or damaged. The mere possibility of damage through ''potential'' exposure is not sufficient to prove an actual loss. One comment states that this rule is problematic because it directly links failure to

adhere to shipper-specified conditions for transportation with adulteration of, or damage to, food products during transport. According to this comment, the operation of this rule would mean that a claimant would no longer be required to prove that a shipment of food is actually damaged, but rather would only be required to prove the shipment was not maintained in accordance with a shipper's specified condition. One comment also states that this rule should clearly state in § 1.902 that ''Variance from the requirements of this rule does not create a per se presumption of adulteration, and that the provisions of the Carmack Amendment, 49 U.S.C. 14706, still apply in determining liability of the parties regarding loss or damage to cargo.''

(Response 45) We decline to make the specific change requested, but we have made other revisions to this rule that address the commenter's concerns. We have revised the provisions of this rule, for example, that address instances in which a carrier might not meet a shipper's specifications for temperature control during transportation. An inconsequential failure by a carrier to meet the shipper's temperature control specifications will not necessarily create a per se presumption that the affected food has become adulterated. However, as we discuss in our response to Comment 129, under this rule, in § 1.908(a)(6), 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, the person must take appropriate action 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. Failure to take such action may render the food adulterated.

We also have revised this rule in §§ 1.906 and 1.908, as we discuss in our response to Comment 89, to clearly state that the requirements for transportation equipment and transportation operations are intended to prevent food from becoming unsafe during transportation. This revision, in addition to others, makes it clear that under this rule we will apply section 402 of the FD&C Act, as it addresses food safety, to determine whether food has become adulterated during transport. Persons engaged in transportation operations should not expect that we will apply a different standard or different criteria for evaluating compliance with this rule. Therefore, we do not anticipate that this rule will have a significant impact on the cargo claims process.

(Comment 46) Some comments state that there are other common occurrences that they believe could unnecessarily result in a presumption of adulteration under the proposed rule. These commenters express concern that the proposed rule can be interpreted broadly enough to create potential issues if broken seals or evidence of tampering create a presumption of adulteration, absent any evidence of actual threats to the public health.

(Response 46) We have made revisions to this rule that address the concerns of these comments. As we stated in our response to the previous comment, when assessing transportation equipment and transportation operations, we will apply the food safety provisions of section 402 of the FD&C Act as the standard for determining whether food has become adulterated during transport. Persons engaged in transportation operations should not expect that we will apply a different standard or different criteria for evaluating compliance with this rule. A broken cargo seal or any evidence of food cargo tampering would not necessarily create a per se presumption of adulteration. However, we advise persons engaged in transportation operations that, if such situations should arise, they should carefully evaluate the facts and circumstances of each incident, on a case-by-case basis, to determine whether the safety of the food cargo may have been compromised.

(Comment 47) Some comments asked that we clarify, in certain particulars, the interpretation of ''conditions not in compliance'' in section 402(i) in the FD&C Act, the statutory adulteration provision added to the FD&C Act by the 2005 SFTA. Under that provision, a food is adulterated if it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations issued under section 416 of the FD&C Act, *i.e.,* this final rule. Some of these comments expressed concern that the application of this provision would lead to food being deemed adulterated by regulatory authorities in the absence of physical conditions indicating a food safety risk. One comment stated that non-compliance with the recordkeeping provisions of this final rule alone should not be a basis for deeming food to be adulterated, assuming the records and documentation of the firm do not indicate a systematic and continued failure of a firm to implement sanitary transportation practices. A comment also asked us to recognize that under this rule, an enforcement authority will retain the discretion to consider the specific circumstances in each situation, *e.g.,* if there are only minor deviations from the requirements of this rule, in determining whether food is adulterated.

(Response 47) Under section 402(i) of the FD&C Act, ''a food shall be deemed adulterated if it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations promulgated under section 416.'' Section 416(b) of the FD&C Act mandates that the Secretary create regulations requiring that food carriers use sanitary transportation practices. Section 416(c)(1)(E) of the FD&C Act states ''the regulations under section (b) shall—(1) prescribe such practices as the Secretary determines to be appropriate relating to— . . . (E) recordkeeping . . .'' The way that the statute is structured implies that lack of or incomplete records in section 416(c)(1)(E) of the FD&C Act would lead to the food being adulterated under section 402(i) of the FD&C Act. The establishment of records requirements under this rule is consistent with the statutory purpose of the 2005 SFTA. It is clear from the statute and the legislative history that Congress intended recordkeeping to be one of the requirements for maintaining sanitary food transportation practices (See section 416 of the FD&C Act and S. Rep. No. 109–120, at 46 (2005) (Ref. 25)).

Furthermore, the Senate report (S. Rep. No. 109–120, at 46 (2005)) (Ref 25) expresses Congress' intention to grant FDA authority to deem food adulterated on recordkeeping grounds. That report states that SFTA ''would amend section 402 of the Federal Food, Drug, and Cosmetic Act . . . to provide that food is adulterated if transported in violation of safe transportation practices prescribed in the new section 416 of the FD&C Act.''

In the seafood HACCP final rule (60 FR 65096 at 65100) we noted that in *National Confectioners Association* v. *Califano,* 569 F.2d 690 (D.C. Cir. 1978), the courts upheld FDA's authority to issue regulations under section 402(a)(4) of the FD&C Act that included recordkeeping requirements, when challenged on the grounds that they would permit prosecution where processing conditions were completely sanitary, but the records were deficient.

Such an outcome, it was argued, would be beyond the scope of section 402(a)(4) of the FD&C Act. Citing *Toilet Goods Association* v. *Gardner,* 387 U.S. 158 (1967), the court rejected this argument and held that the primary consideration was whether the statutory scheme as a whole, not just section 402(a)(4) of the FD&C Act, justified the Agency's regulations. (See *Nat'l Confectioners Ass'n,* 569 F.2d 690 at 693.) The court pointed out that this consideration involved an inquiry into practicalities as well as statutory purpose, *i.e.,* enforcement problems encountered by FDA and the need for various forms of supervision in order to accomplish the goals of the FD&C Act. (Id.)

Thus, the necessary conditions for compliance with these regulations encompass all of the requirements in this final rule, including those that may not appear to directly affect the safety of the food, such as training and records. The SFTA of 2005 does not differentiate between physical conditions indicating food safety risk and requirements, such as training and recordkeeping.

However, we recognize the concerns expressed by these comments and do not believe that the SFTA of 2005 changes the way we enforce our regulations. Before initiating enforcement action, we will consider all circumstances surrounding the deviation(s), *e.g.,* the nature of the deviation, from these regulations as we have in the application of other preventive control-type regulations, such as the seafood HACCP regulation and the Juice HACCP regulation.

(Comment 48) One comment states that the rule does not address the obligations of carriers if shelf stable food is compromised during transit or while on a dock or being loaded onto a trailer. The comment states that when a shipment is damaged in transit, or during loading or unloading, the carrier will frequently transport the shipment of damaged goods to a location of the shipper's choice. The commenter asks us, if the carrier is only qualified to handle shelf stable food, can the carrier continue to handle the shelf stable food with compromised packaging? The comment also asks whether the carrier would be required to hire another carrier who has chosen to comply with the record keeping and training requirements of the proposed rule to handle the return of such shipments.

(Response 48) We would have no concerns about the carrier transporting the damaged goods to a location specified by the shipper because, under § 1.908(a)(6), an evaluation must be performed before further distribution to determine whether the food has been rendered unsafe.

C. What definitions apply to this subpart? (§ 1.904)

We proposed to establish several definitions in § 1.904. In table 6, we describe revisions to the proposed definitions and following the table we respond to comments related to these provisions. We did not make changes to the definitions of adequate, animal food, bulk vehicle, cross-contact, food not completely enclosed by a container, pest, transportation, and vehicle.

TABLE 6—§ 1.904 WHAT DEFINITIONS APPLY TO THIS SUBPART?

Definition	Revision
Carrier	Revised definition to specify that carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States.
Farm	Applied farm definition given in § 1.227 (21 CFR 1.227).
Food	Removed the term because it is already defined in section 201 of the FD&C Act.
Full-time equivalent employee	A new definition. 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 × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.
Microorganisms	Removed the term because not needed with revised provisions in §§ 1.906 and 1.908.
Loader	A new definition. Loader means a person that loads food onto a motor or rail vehicle during transportation operations.
Non-Covered Business	Specified the limit of $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. Added ''loader'' to list of potential non-covered businesses.
Person	Removed the term because it is already defined in section 201.
Receiver	Revised definition to specify that 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.
Shelf Stable Food	Removed the definition, not needed for revised definition of ''transportation operations''.
Shipper	Revised to specify that shipper means a person who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially. Provided examples of shipper, such as the manufacturer or a freight broker.
Small Business	Specified the limit of $27,500,000 annual receipts. Specified that employee limit is fewer than 500 full-time equivalent employees.
Time/Temperature Control for Safety (TCS) Food.	Removed the definition, not relevant to revised temperature control provisions.
Transportation	Revised to specify that transportation means any movement of food by motor vehicle or rail vehicle in commerce within the United States.
Transportation Equipment	Removed ''other than vehicles'' for clarity.

TABLE 6—§ 1.904 WHAT DEFINITIONS APPLY TO THIS SUBPART?—Continued

Definition	Revision
Transportation Operation	Removed ''solely'' and ''shelf stable'' to specify that transportation operations do not include activities on a food completely enclosed by a container except a food that requires temperature control for safety. Added that transportation operations do not include any activities associated with the transportation of ''food contact substances as defined in section 409(h)(6) of the FD&C Act,'' ''human food byproducts transported for use as animal food without further processing,'' or live food animals ''except molluscan shellfish''. Removed ''for raw agricultural commodities'' to specify that transportation operations do not include any transportation activities performed by a farm.

1. Adequate

We proposed to define the term ''adequate'' to mean that which is needed to accomplish the intended purpose in keeping with good public health practice. We are finalizing this definition as proposed.

(Comment 49) One comment states that the term ''adequate'' is not suitable for a rule intended to achieve compliance with best transportation practices focused on reducing the risks of the adulteration of food products. The comment suggests that instead we should use the term ''to guarantee,'' which the comment defines as meaning ''to ensure and protect from any risk or need,'' to avoid ambiguity that might cause confusion and result in public health hazards.

(Response 49) We decline this request. The term ''adequate'' is a long-standing term that we defined in its current form when we first established Current Good Manufacturing Practices (cGMP) requirements for manufacturing, packing and holding food in 1969 (see 34 FR 6977 at 6978, '' 'Adequate' means that which is needed to accomplish the intended purpose in keeping with good public health practice.''). The requirements established in this rule address broadly applicable procedures and practices and our use of the term ''adequate'' is intended to provide flexibility for shippers, loaders, carriers, and receivers to comply with the requirements in a way that is most suitable for their practices. We are not aware that the term has caused confusion in its use with the cGMPs and the comment does not provide any examples of how our use of the term ''adequate'' may create confusion that might result in public health hazards.

2. Animal Food

We proposed to define the term ''animal food'' to mean food for animals other than man, including pet food, animal feed, and associated raw materials and ingredients. We are finalizing this definition as proposed.

(Comment 50) A few comments state that raw materials should not be included in this definition because processing these materials into feed ingredients and finished animal food products after they have been transported to processing facilities removes many, if not all, of the hazards that may be associated with the transportation of the raw materials. One of the comments also notes that the Association of American Feed Control Officials (AAFCO) Model Regulations exempt raw materials (such as meat scraps) from regulation because they are not suitable for use in animal feed without further processing.

(Response 50) We decline to change the definition of animal food. While the transportation of raw materials for animal feed manufacture may not require the same degree of sanitary control as the transport of finished animal feed, there may be circumstances in which processing the raw materials may not remove all health hazards, *e.g.,* fertilizer residue from a prior cargo hauled in a vehicle, that might be caused by the insanitary transportation of the raw materials. We have added provisions to § 1.908(a)(3) of this final rule to provide sufficient flexibility to allow persons engaged in the transport of raw materials, feed ingredients, or finished animal food to use sanitary transportation practices that are appropriate for their circumstances.

3. Bulk Vehicle

We proposed to define the term ''bulk vehicle'' to mean a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the interior surfaces of the vehicle. We are finalizing this definition as proposed.

(Comment 51) One comment asks us to add terms such as ''gondola'' to the examples included in this definition in the interests of clarity.

(Response 51) We decline to change the definition based on this request. We are using the definition of ''bulk vehicle'' in this rule exactly as it appears in the 2005 SFTA and as incorporated into section 416 of the FD&C Act. However, we note that the list of examples included in the definition is not intended to be comprehensive or all inclusive with respect to the types of vehicles that are bulk vehicles. We define the term to include ''any other vehicles in which food is shipped in bulk, with the food coming into direct contact with the vehicle.''

(Comment 52) Some comments state that in several respects, our definition of bulk vehicle is overly broad in scope. According to one commenter, the term ''hopper bin,'' for example, can be inferred to mean a grain hopper bottom storage bin that is part of a storage facility, and not a piece of transportation equipment. The comment requests that we delete the term ''hopper bin'' from this definition. Another comment asks us to explicitly exclude vehicles used to transport fruit and vegetable RACs from the definition because many RACs are thermally processed with a kill step or are cooked by the consumer before being consumed.

(Response 52) We decline these requests. A hopper bin constructed as part of a facility and used for storage would not be considered transportation equipment and therefore would not be subject to this rule. A hopper bin on a truck or other conveyance subject to this rule, however, is a piece of transportation equipment and therefore is subject to this rule. We also note that while some RACs that are transported in a bulk vehicle may undergo a kill step process or cooking before being consumed, there may be circumstances in which controls, *e.g.,* the cleaning of a vehicle that was last used to haul a nonfood item, are necessary to ensure the sanitary transportation of certain types of RACs. We have added provisions to § 1.908(a)(3) of this rule to provide sufficient flexibility to allow persons engaged in the transport of food intended for further processing to employ sanitary transportation practices that are appropriate for their circumstances.

4. Carrier

We proposed to define the term ''carrier'' to mean a person who owns, leases, or is otherwise ultimately responsible for the use of a motor vehicle or rail vehicle to transport food. The definition also specified that the carrier is responsible for all functions assigned to a carrier in this subpart even if they are performed by other persons, such as a driver that is employed or contracted by a trucking firm, and that a carrier may also be a receiver or a shipper if the person also performs the functions of those respective persons as defined in this subpart. In the final rule, as explained in the discussion of § 1.908(a)(1), we have added a general provision to that section about the multiple roles that can be played by a single entity to replace the separate provisions we had included in the proposed definitions of ''carrier,'' ''shipper'' and ''receiver''. We are finalizing the definition for ''carrier'' to mean a person who physically moves food in commerce and clarifying that a carrier does not include any person who transports food while operating as a parcel delivery service. We explain these changes in the responses to the next 3 comments.

(Comment 53) Some comments oppose defining the term ''carrier'' to mean a person who owns, leases, or is otherwise ultimately responsible for the use of a motor vehicle or rail vehicle to transport food. These commenters express concern that this definition would result in the inappropriate and unworkable application of this rule's requirements to railroad operators for the following reasons.

- Railroad operators in many cases do not own or lease the railcars they transport, are not responsible for their storage when they are stored in private facilities, and exercise no control over the cars other than to inspect them for mechanical soundness during the transportation process.
- The shipper or loader is generally responsible for inspecting a railcar to ensure that it is suitable for the particular food cargo, regardless of who owns the car.
- Railroad operators do not have the ability to ensure that the shipper's sanitary and temperature control requirements are met before or during transportation when, as is common in freight railroad transport, other parties, *e.g.,* the shipper, assume the responsibility for preparing the railcars for loading, maintain their operating conditions during transportation, and deliver the loaded car to the railroad operator for transport.
- Railroad operators generally do not clean the cars they provide and do not maintain documented cleaning procedures.
- The use of railcars in interchange service, in which railroads convey freight cars from other companies over their lines would likely mean that the railroad operator would not be able to provide information about the identity of a bulk vehicle's previous cargoes and its most recent cleaning if requested by the shipper.

The commenters note that for the stated reasons, railroad operators cannot meet requirements of this rule assigned to carriers under proposed §§ 1.906 and 1.908.

These comments also contrast rail carrier and motor carrier food transportation operations, noting that motor carriers generally own the vehicles they provide for transport and are directly involved in transportation operations, such as the loading and unloading of the trailers that they haul, and therefore can comply with requirements assigned to the carrier in §§ 1.906 and 1.908 of the proposed rule.

Finally, one comment asks us to establish separate definitions for motor and rail carriers which would assign appropriate responsibilities for each of the two distinct types of carriers. Another comment asks us to establish a definition specific to railroad carriers in this final rule, which would simply define a ''railroad carrier'' as a person providing railroad transportation services.

(Response 53) We carefully considered these comments and we agree that our proposed definition of the term ''carrier,'' when combined with the structure of the proposed requirements at § 1.908, which detail the required interrelationships between carriers, shippers and receivers, would establish requirements that some persons subject to the definition, *e.g.,* some railroad operators, typically cannot meet, and which are currently performed by other parties, *e.g.,* the shipper. Because it is our intent to pattern this rule on existing industry best practices, we agree that we should not reassign responsibilities for activities that affect food sanitation during transportation in this final rule in a manner that is so fundamentally divergent from current practice.

We recognize that, in practice, the person who assumes responsibility for functions assigned to a carrier under § 1.908 of the proposed rule is identified by mutual agreement between the shipper and that person, *e.g.,* the trucking firm, the railroad operator, the railcar management firm, or that the shipper may itself assume the responsibility. We also recognize, as one of the comments mentions, that railroad operators typically do not assume these responsibilities. Nonetheless, we are aware that, though not common in the rail transportation of food, some railroad operators do perform functions that affect the sanitary condition of a railcar during transportation of the food, *e.g.,* monitor the temperature of the car. However, we do not agree that a separate definition for rail carriers is the appropriate solution, because some rail carriers, in fact, perform functions that are typically performed by motor carriers. Rather, we have concluded that the appropriate solution with regard to the definition and the overall carrier regulatory requirements is: (1) A simplified definition of carrier that ties it to the movement of the food; (2) removal from the carrier definition of any assignment of duties; and (3) a default assignment of responsibility to the shipper for the activities assigned to carriers in the proposed rule, unless a written contract between the shipper and carrier assigns them to the carrier (or another party covered by this regulation, as may be the case). We are aware that contracts for services that impact food safety (*e.g.,* monitoring temperatures, cleaning vehicles) generally are in place when rail or motor carriers provide such services. Therefore, linking responsibility for the carrier to perform such functions to the existence of a contract with the shipper, in which such functions are specified, seems appropriate and consistent with current industry best practice.

For these reasons, we have revised the definition of carrier to mean a person who physically moves food by rail or motor vehicle in commerce in the United States. We have removed from the definition the proposed sentence that assigned duties to the carrier, because of the consequences of such assignment, especially relative to rail carriers, as discussed in this document, and because, upon further consideration, we view such language to be inappropriate for a definition. We have also removed from the definition the proposed sentence that stated that a carrier may also be a receiver or a shipper if the person also performs the functions of those respective persons. While we affirm that this statement is valid, we have consolidated this and similar statements in the proposed definitions of shippers and receivers in the regulatory text at § 1.908(a)(1).

(Comment 54) A few comments urge us to consider that home grocery delivery services may originate from locations other than food

establishments, such as a distribution center. According to the comments, the transportation of the food from distribution center to the consumer would be subject to the proposed requirements for a carrier. The commenters note, however, that there would be no receiver in this scenario because the definition of receiver explicitly excludes consumers. The comments ask us to revise the final rule so that it does not impose unnecessary regulatory burdens for home grocery deliveries originating at locations other than food establishments.

(Response 54) Home grocery delivery operations at food distribution centers are generally permitted by States as retail establishments and, therefore, would be included in a waiver of certain transportation operations performed by such retail food establishments. We stated in the proposed rule (79 FR 7006 at 7029–7030) that we had tentatively determined that it would be appropriate to waive the applicable requirements of this rule, if finalized as proposed, with respect to retail food establishments 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. As we stated in section III.E., we intend to publish a waiver in the **Federal Register** addressing this class of persons prior to the compliance date of this final rule.

(Comment 55) A participant in one of the public meetings we held on the proposed rule asked whether this rule applies to food shipped by the U.S. Postal Service or by private small parcel carriers. One submitted comment states that the impact of the rule would be significant and costly if it is applied to small-parcel common carriers, and therefore asks us to affirmatively state that small-parcel common carriers will be excluded from the definition of ''carrier.'' The comment notes that small-parcel common carriers handle millions of packages per day containing a broad range of goods, including clothing, shoes, food products, electronics products, and books. The comment asserts that requiring these carriers to understand the unique shipping requirements for every product that they transport would be unduly burdensome and nearly impossible to accomplish. The comment further argues that if FDA requires that small-parcel common carriers meet the requirements imposed on dedicated food carriers, some common parcel carriers, especially large-scale common carriers, will respond by simply excluding all food shipments from their operations. According to the commenter, this result would likely reduce the availability of some of the most cost-effective transportation channels for certain food shippers, even where there have been no demonstrated food safety risks associated with their food product delivery operations. Finally, the commenter suggests that the more appropriate way to ensure food safety under these circumstances would be to require the shipper of any small parcel to ensure that the selected method of transportation is appropriate for the food product at issue.

(Response 55) We agree that it is not appropriate to subject the operations of the U. S. Postal Service or private delivery services delivering parcels to consumers to this rule, given that these carriers transport a broad range of items and do not offer transportation services tailored to the transportation of food products. We, therefore, have added a provision to the definition of the term ''carrier'' in § 1.904 of this final rule stating that the term does not include any person who transports food while operating as a parcel delivery service. Our expectation is that the person shipping the package would ensure that the selected method and circumstances of transportation are appropriate for the food product at issue, including food that is delivered by small-parcel common carriers.

5. Cross-Contact

We proposed to define the term ''cross-contact'' to mean the unintentional incorporation of a food allergen as defined in section 201(qq) of the FD&C Act into food, except animal food. We did not receive any comments on this definition and are finalizing it as proposed.

6. Farm

We proposed to define the term ''farm'' to mean a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The proposed definition of ''farm'' included facilities that pack or hold food, regardless of whether all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership. We are revising the definition of ''farm'' in this rule to be consistent with the definition of ''farm'' used in other FSMA rulemakings. We discuss our considerations of the comments we received on the definition of ''farm'' in the response to Comment 55 and, additionally, in our response to Comment 8.

(Comment 56) Several comments that address provisions of the proposed definition of ''farm'' suggest that the definition include terms such as a ''facility,'' or an ''establishment,'' or a ''place.'' Other comments suggest that the definition should include consideration of the locations and the numbers of the structures that constitute a farm.

(Response 56) As we explained in our response to Comment 8, we have revised the definition of the term ''farm'' in this final rule to align it with the revised definition of the term in 21 CFR 1.227, which was recently established in the FSMA preventive control for human food final rule (80 FR 55908 at 55925). The comments that we received for this rulemaking address provisions of the farm definition that have already been addressed in the rulemaking for preventive controls for human food. Therefore, there is no need for us to address these issues further in this rulemaking.

7. Food

We included the definition of the term ''food'' in the proposed rule just as the term is defined in section 201(f) (21 U.S.C. 321(f)) of the FD&C Act. We have deleted this definition from this final rule, however, because § 1.904 of the rule clearly states that ''[t]he definitions and interpretations of terms in section 201 of the [FD&C Act] are applicable to such terms when used'' in this rule. Food includes animal food and food also food subject to the FMIA, the PPIA, and the EPIA.

(Comment 57) One comment asks us to explicitly exclude food contact shipping and storage equipment from the rule's definition of ''food.'' The comment also asks us to clarify that empty food contact shipping and storage equipment will be regulated exclusively as ''transportation equipment'' under this rule. Finally, the comment asks us to clarify that equipment suppliers, including food contact equipment suppliers, are not shippers, carriers or receivers of ''food.''

(Response 57) The definition of ''food'' given in section 201(f) of the FD&C Act applies to this term as used in this rule. Under section 201(f), the term ''food'' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. Shipping and storage equipment that is meant to contact food is not food and would be regulated exclusively as ''transportation equipment'' under this rule. Therefore, persons involved in the transportation of such equipment are not shippers, carriers or receivers of

''food.'' However, the food contact surfaces of such equipment must comply with any other applicable regulations we have established, *e.g.,* food additive regulations, for any components that may migrate into food under their intended conditions of use.

(Comment 58) A few comments ask us to exclude food contact substances as defined in section 409(h)(6) of the FD&C Act from the scope of this rule by excluding them from the definition of ''food.'' One of the comments notes that we excluded food contact substances from the definition of ''food'' in the food facility registration regulations in 21 CFR 1.227(b)(4). It further states that requiring manufacturers, shippers, receivers, and carriers of food contact substances to comply with the sanitary transportation requirements would impose a significant burden with respect to the transportation of products that present a very low food safety risk and for which any risk is already effectively managed.

(Response 58) We partially agree with these comments. In the 1990 SFTA, Congress included food additives along with other substances defined in the FD&C Act in designating the scope of the regulations that it directed DOT to issue. We take this to mean that Congress recognized that food could be made unsafe as a result of insanitary food additive transportation practices. Food contact substances are ''food additives'' and are also ''food'' as defined in the FD&C Act. In the absence of language in the 2005 SFTA that explicitly excludes food contact substances from regulation as food, we would not agree with the comment's view that food contact substances should not be considered to be ''food'' within the meaning of this rule.

However, section 416(c)(1) of the 2005 SFTA states that we shall prescribe sanitary transportation practices that we determine to be appropriate in issuing this rule. We, therefore, are revising the definition of transportation operations to exclude food contact substances as defined in section 409(h)(6) of the FD&C Act. Factors inherent to the transportation and downstream handling of food contact substances, described in this section, would strongly support that there is little risk of food products becoming adulterated because of insanitary food contact substance transportation practices. We agree, as one comment notes, that food contact substances are protected during transportation with additional outer packaging. In addition, the pathogenic microorganisms that are deleterious to conventional foods are not known to be a risk for food contact substances. We also note that the handling and processing that these substances undergo during the manufacturing of finished food contact articles, such as curing, drying, and extrusion, often involve very high temperatures, creating conditions under which there is little possibility that any microorganisms that might be present would survive. The nature of finished food contact articles also ensures that the risk of microbial contamination is very low. We, therefore, have determined that requirements under this rulemaking for the sanitary transportation of food contact substances are not necessary.

8. Food Not Completely Enclosed by a Container

We proposed to define the term ''food not completely enclosed by a container'' to mean any ''food that is placed into a container in such a manner that it is partially open to the surrounding environment.'' We stated in the proposed rule that examples of such containers would include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag, but would not include food transported in a bulk vehicles. We are finalizing this definition as proposed.

(Comment 59) One comment objects to our proposed inclusion of food packaged in vented cardboard cartons with tops as an example of ''food not completely enclosed by a container.'' Several comments disagree that the use of vented cartons by the tree fruit industry poses a measurable risk of contamination to fruit during transportation. One comment observes that vented cardboard cartons with tops are a commonly used for cooling fruit and contribute to the maintenance of fruit quality. According to the comments, vented cartons bearing fruit are stacked on pallets before being placed in refrigerated trucks by forklifts, and they are removed the same way and without ever coming into direct contact with the trucks' interior surfaces. The comments also assert that it is rare for loads of fruit packaged this way to be transported with any other food products, further reducing the risk of cross-contamination or adulteration. Finally, the comments also assert that no evidence of any threat to food safety has emerged over the many decades that the tree fruit industry has used these types of cartons for packaging and transportation.

(Response 59) We agree that when sanitary transportation practices are followed in the transportation of tree fruit, there should be no significant risk of contamination of the product. However, we decline the request to exclude vented cardboard cartons from the definition of ''food not completely enclosed by a container.'' The purpose of this rulemaking is to prescribe sanitary transportation practices to ensure that food does not become unsafe during transportation. We have determined that it is necessary to establish requirements related to the transportation of foods not completely enclosed by a container, including food transported in vented cardboard cartons with tops, because food, including tree fruits, packaged this way could be susceptible to environmental contamination, for example, if a vehicle used for transport is not in appropriate sanitary condition for the transportation operation.

(Comment 60) One comment states that it is unclear what we mean by a ''completely enclosed container'' as it relates to storage practices during loading and transportation operations. The comment asks whether this means food must be enclosed by a cardboard box or a plastic wrapped pallet, or whether food must be enclosed by a moisture impervious container such as ones made out of heavy plastic, glass or metal. The commenter states that it has seen ''extreme examples of cross contamination, such as raw poultry on ice, stored above fresh produce with bloody ice falling into the produce.'' The commenter asks us to provide clearer language.

(Response 60) We consider a ''completely enclosed container'' to be one that physically separates the food from the environment and functionally protects the food from environmental contamination during transportation. We would not consider items such as pallet wrap, which have the primary purpose of facilitating the handling of pallets, to be food containers. We provided examples of such containers in the proposed rule (79 FR 7006 at 7015), *e.g.,* a metal can, a glass or plastic bottle, or a sealed bag or box.

9. Full-Time Equivalent Employee

''Full-time equivalent employee'' is a new term in this rule and is 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 × 52 weeks). If the result is not a whole number, round down to the next lowest whole

number. We are adding this term to the rule to clarify its use in the revised definition of ''small business'' in this rule. The use of this term is consistent with the use of the same term in the preventive controls rules for both human and animal food.

10. Loader

We are adding the term ''loader'' to this rule and specifying that it means a person that loads food onto a motor car or rail vehicle used during transportation operations. We are adding this term in response to comments that indicated that there were certain functions assigned in the proposed rule that were typically performed by a segment of the transportation industry known as loaders and so we have added this function to the rule.

11. Microorganisms

We proposed to define the term ''microorganisms'' to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and to include species that have public health significance. We proposed to define the term ''undesirable microorganisms'' to include those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. We have removed this term as explained in the response to Comment 61.

(Comment 61) One comment states that although these definitions are familiar from the existing food cGMP regulations at 21 CFR part 110 (which have been revised in the preventive controls for human food final rule and are now in 21 CFR part 117, subpart B), they provide little assistance for purposes of identifying foods that can support the rapid growth of undesirable microorganisms in the absence of temperature controls. Other comments state that we should clarify that microorganisms that have only the potential to cause spoilage, without posing food safety risks, should not be excluded from these definitions of microorganisms.

(Response 61) We included a definition for the term ''microorganisms'' in the proposed rule that was to be applied to requirements in proposed §§ 1.906 and 1.908 that addressed measures necessary to prevent conditions that could lead to the rapid growth of undesirable microorganisms in food because of the use of insanitary transportation equipment and transportation practices. As we explained in our response to Comment 89, we have revised the language in these sections of this final rule to no longer refer to the term ''undesirable microorganisms.'' As a result of this revision, there is no longer a need to include a definition for the term ''microorganisms.''

12. Non-Covered Business

We proposed to define the term ''non-covered business'' to mean a shipper, receiver, or carrier engaged in transportation operations that has less than $500,000 in total annual sales. We have changed the annual sales qualifier in this provision to an annual revenue qualifier because under this rule, this definition applies to firms, *e.g.,* loaders that do not sell products. In addition, to be consistent with the models used in other FSMA rulemakings (*e.g.,* the preventive controls final rules) for similar calculations, we have revised this definition to provide that the annual revenue calculation is based upon an average value for 3 years preceding the applicable calendar year, and allows for adjustment for inflation.

(Comment 62) We received a large number of comments regarding this proposed provision. Most of them oppose granting any kind of size-based exclusion. Several themes emerge from the comments that we received opposing the inclusion of a size-based exclusion in this rule. Many of the comments ask us to create a ''very small'' category of businesses which would be subject to fewer requirements than other firms. Some of these comments state that the proposed exclusion provision leaves the most problematic group of transporters, operators of small box trucks, uncovered by this rule, citing the findings that we discussed in the proposed rule (79 FR 7006 at 7024), of the 2007 Interstate Food Transportation Assessment Project (Ref. 6). Some comments expressed the view that that all members of the food supply chain, regardless of size, must share responsibility in ensuring food safety. Some comments criticize the proposed exclusion for lacking a statutory basis, for not being risk-based, or for lacking merit and being unnecessary. One comment opposes the proposed exclusion on the grounds that we have failed to explain why the proposed rule's requirements would be prohibitive for those firms capable of qualifying for the exemption. Other commenters state that we should not grant any exclusions because the proposed requirements are similar to food cGMPs, which we impose on almost all food processors.

(Response 62) We articulated our reasons in the proposed rule (79 FR 7006 at 7014) for excluding certain businesses, *i.e.,* a ''non-covered business,'' from the requirements of this rule. We stated that we want to treat firms subject to this rule comparably to those firms that are subject to the FSMA preventive controls rules. We also stated that we want to treat carriers, who are not subject to the preventive controls rules, in the same manner as we treat other firms engaged in food transportation operations that are also subject to this rule. We chose to do this by providing an exclusion for these businesses, recognizing that their transportation operations are also, and will continue to be, covered under the adulteration provisions and other applicable provisions of the FD&C Act and all of our applicable implementing regulations. In light of this, and recognizing businesses that would qualify for this size-based exclusion would have fewer resources to dedicate to complying with this rule, we chose to exclude these businesses from this rule rather than create a separate category of very small business that would be subject to fewer requirements than other firms. We estimate that the removal from coverage of entities less than $500,000 in average annual revenues, as we have set out in this final rule, would result in only about 5 percent of food shipments not being covered by this rule. The risk of any foodborne outbreak associated with this narrow range of shipments therefore is, thus, necessarily limited in scope. Notwithstanding the information on small box trucks contained in the 2007 Interstate Food Transportation Assessment Project, we are not aware of data that supports the assertion of some comments that shipments by the smallest firms, *i.e.,* those that would meet the definition of a non-covered business, present a greater food safety risk than those of larger firms. Comments we received on the proposed rule have not presented any information tying risk of adulteration to firm size to persuade us that we should apply the requirements of this rule to the businesses we proposed to exclude. Operators of small box trucks would be covered unless they meet the definition of a non-covered business.

To further expand upon our thinking, we note that the preventive controls rules exempted ''qualified facilities'' as defined by the FSMA, from the requirement for hazard analysis and risk-based preventive controls and instead established very limited requirements (essentially statutorily mandated attestations by the firm to FDA) specific to this category of

facilities, *e.g.,* ''very small businesses,'' as defined in these rules. While the 2005 SFTA does not address ''qualified'' facilities and does not require us to include provisions in this rule for very small businesses, we determined in considering the costs and benefits of this rule, that a category of businesses, *i.e.,* ''non-covered'' businesses, should remain subject to the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations, but not be subject to the requirements of this rule. We point out that many non-covered businesses that are shippers, loaders and receivers, would be subject to the cGMP provisions in § 117.93 of the preventive controls rule that address transportation practices. We also point out that our proposed approach would not absolve a non-covered business from the responsibility to conduct its transportation operations in compliance with the adulteration provisions of the FD&C Act, upon which this rule is based.

Therefore we are retaining the exclusion for non-covered businesses from the requirements of this rule. However, to further promote the application of sanitary transportation practices throughout the industry, we will also consider establishing guidance for transportation activities carried out by non-covered businesses.

(Comment 63) Some comments are concerned about possible unintended consequences potentially associated with size-based exclusions, including confusion that could result when a covered firm attempts to do business with a non-covered firm, or the exit of small firms from the food transportation industry because shippers may discontinue doing business with carriers that are not subject to the rule. One comment opposed to the proposed provision expresses the view that small shippers, loaders, carriers, and receivers excluded from the rule based on size still could be penalized if the food they are transporting becomes adulterated because any party that introduces or receives an adulterated food product in interstate commerce may be held legally responsible.

(Response 63) Firms engaged in food transportation, including those exempt from this rule, must comply with all of the generally applicable requirements of the FD&C Act, including those that prohibit the holding of food under insanitary conditions whereby the food may become contaminated with filth or be rendered injurious to health. While differing requirements have the potential to affect business relationships among firms and their interactions with regulatory agencies, we believe that agencies and the marketplace can adapt appropriately, and that firms will not be unduly inconvenienced by them. Furthermore, if firms that are not covered by this rule because of their size voluntarily chose to meet the rule's requirements, for example, for competitive business purposes, there are resources, such as FDA and industry issued guidance on sanitary food transportation and training in sanitary food transportation practices, available to them.

(Comment 64) One comment states that the proposed exclusion may have the unintended consequence of motivating food transportation firms to create subsidiary companies for the purpose of dispersing their annual sales so that each newly created, related company would have less than $500,000 in annual sales, and therefore qualify for the exclusion.

(Response 64) In the proposed rule (79 FR 7006 at 7014) and in the responses to the previous comments, we articulated our reasons for excluding a ''non-covered business'' from the requirements of this rule. We cannot discount the possibility that some firms might form separate businesses to bring their disaggregated annual sales below the threshold for a non-covered business, but this is not likely to be a common occurrence and such separation may not be advantageous for business reasons. Therefore, we do not believe that the possibility poses a reasonable basis upon which to modify this provision of the rule.

(Comment 65) Among comments that we received in support of the proposed exclusion for non-covered businesses, some support keeping the provision at its proposed threshold of $500,000 in total annual sales. Another comment supports lowering the annual revenues threshold to $10,000, while a few support increasing it to $1,000,000. One comment supports the exclusion, but suggests defining a non-covered business exclusively as one that employs fewer than 500 people, regardless of annual revenues. According to this comment, annual revenues can vary from firm to firm, depending on the food products involved, for example, the differences between the prices of commodity items and premium or gourmet items. This comment proposes using a threshold of $1,000,000, consistent with the highest threshold in the proposed preventive controls for human food rule, in the event we decline to define a non-covered business in terms of the number of people employed. Another comment supports an increase in the threshold without explicitly suggesting a new one. Finally, one comment supporting the exclusion provision asks us to explicitly state that it would extend to foreign firms engaged in food transportation activities.

(Response 65) We explain our reason for retaining the exclusion of non-covered businesses from the requirements of this rule in our response to Comment 62. We are retaining the threshold for a non-covered business as a total annual revenues based threshold at the $500,000 level as proposed; however, we are allowing for adjustment for inflation and for basing the calculated value on average annual revenues, calculated on a rolling basis, during the 3 preceding years. We estimate that removing firms below this threshold from coverage by the rule would result in about 5 percent of food shipments not being covered by this rule

To define a non-covered business as one not exceeding $10,000 in total annual sales, as one comment suggests, would not be consistent with our stated purpose of extending comparable treatment to firms subject to this rule and similarly situated firms subject to the FSMA preventive controls rules. A $10,000 total annual sales limit corresponds to a business of much smaller size than one that could be a ''qualified facility'' as defined in the preventive controls rules and such a threshold would likely result in 100 percent of food shipments being covered by the rule.

We considered changing the total annual sales limit for a non-covered business to $1,000,000, which would be consistent with the definition of very small business in the Human Food Preventive Controls rule (the Animal Food Preventive Controls rule defined very small business as less than $2,500,000), but chose not to do so because it would result in about 10 percent of food shipments not being covered by this rule. While selecting a value of $1,000,000 for this rule would be more consistent with the Preventive Controls rules, which we believe to be a desirable endpoint, the percentage of food shipment not covered by this rule at that threshold would be vastly different than the less than 0.6 percent of food not covered by the Preventive Controls rules. We weighed the cost to this category of small businesses against the risk of adulteration, and determined that excluding 5 percent of shipments from coverage by this rule was more appropriate, because it would expose less food to any potential risk arising from non-coverage by this rule.

We decline to establish the threshold for a non-covered business in terms of fewer than 500 people employed, because that threshold is the basis of the definition of a ''small business'' under this rule, which is a covered business category.

(Comment 66) One comment asks us to add an additional exclusion for food establishments that sell to qualified end users, as defined by the FSMA preventive controls rules, as a separate category within the definition of ''non-covered business,'' or as a separate exclusion, rather than requiring this category of businesses to undergo the waiver process provided for in this rule. The comment states that such an exclusion would follow FSMA's mandate for the preventive controls rules and produce safety rule to be flexible, and scale- and supply-chain appropriate. The comment states that this mandate includes content requirements for the preventive controls rules and the produce safety rule to provide sufficient flexibility to be practicable for all sizes and types of businesses and facilities, and to provide modified requirements for small and mid-sized farmers and facilities engaged primarily in selling food through direct-to-consumer supply chains.

(Response 66) The Preventive Controls rules for human and animal food provide for modified requirements for qualified facilities. Qualified facilities are defined in those rules to mean a facility that is a very small business (*i.e.,* averaging less than $1,000,000 of annual sales of human or animal food), or a facility to which both of the following apply: (1) The average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and (2) the average annual monetary value of all food sold was less than $500,000. A qualified end-user is defined to mean the consumer of the food or a restaurant or retail food establishment that: (1) Is located: (i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or (ii) not more than 275 miles from such facility; and (2) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment. In sum, facilities that sell less than $1,000,000 of food are subject only to the modified requirements of the Preventive Controls rules, whether or not those sales are to qualified end users.

As explained in our response to previous comments, we have attempted to make consistent, to the extent possible, the size-based ''exemption'' from this and the Preventive Controls rules. Because we did not ''exempt'' from the preventive controls rules (*i.e.,* subject to only the modified requirements) all firms that make sales to qualified end users, as suggested by the commenter, we are similarly declining to do so here. As a practical matter, however, the $500,000 exemption provided for in this rule applies whether or not the sales are to qualified facilities, as does the $1,000,000 threshold in the Preventive Controls rules. We explain in the preceding comment response why we did not select a $1,000,000 threshold in this rule.

Nevertheless, we stated in the proposed rule (79 FR 7006 at 7029–7030) that we had tentatively determined that it would be appropriate to waive the applicable requirements of this rule, if finalized as proposed, with respect to retail food establishments 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. As we stated in section III.E., we intend to publish a waiver in the **Federal Register** addressing this class of persons prior to the compliance date of this final rule.

13. Person

In the proposed rule we defined ''person'' to mean individuals, partnerships, corporations, and associations. We have deleted this definition from this final rule, however, because § 1.904 of the rule clearly states that the definitions and interpretations of terms in section 201 of the FD&C Act are applicable to such terms when used in this rule. We did not receive any comments on our definition of the term ''person.''

14. Pest

We proposed to define the term ''pest'' to mean any objectionable animals or insects including birds, rodents, flies, and larvae. We are finalizing this definition as proposed.

(Comment 67) One comment states that, while the utmost care is taken to ensure that natural pests of tree fruit are eliminated during the packing process, the presence of naturally occurring plant pests in tree fruit is not an indication of contamination and, if found, should not be cause for concluding that the tree fruit is adulterated.

(Response 67) There is no provision in this rule by which we would automatically regard the presence of naturally occurring plant pests in tree fruit as grounds for determining that the food is unsafe. We do not intend to establish a standard for the adulteration of tree fruit because of the presence of naturally occurring pests. As we discuss in response to Comment 89, we have revised the provisions of the proposed rule that incorporated the adulteration provisions of the FD&C Act in addressing transportation equipment and operations. As we explained, we did this to avoid misinterpretation of this rule and to clarify that this rule only requires that transportation operations, including the use of transportation vehicles and equipment, must be conducted under conditions and controls necessary to prevent the food from becoming unsafe, *i.e.,* adulterated within the meaning of sections 402(a)(1), (2) and (4) of the FD&C Act.

15. Receiver

We proposed to define ''receiver'' to mean any person who receives food after transportation, whether or not that person represents the final point of receipt of the food. We further clarified in the proposed definition that the receiver may also be a carrier or a shipper and that a receiver does not include an individual consumer or a person who holds food on behalf of an individual consumer and who is not also a party to the transaction and not in the business of distributing food. In the final rule, as explained in the discussion of § 1.908(a)(1), we have added a general provision about the multiple roles that can be played by a single entity to replace the separate provisions we had included in the proposed definitions of ''carrier,'' ''shipper'' and ''receiver.'' We have also removed the specificity about the consumer or someone acting on his or her behalf because it was inappropriate for a definition, but we affirm that these entities are not subject to this definition. We did not receive any comments on our proposed definition of ''receiver.''

16. Shelf Stable

We proposed to define the term ''shelf stable'' to mean a food that can be stored under ambient temperature and humidity conditions and, if the package integrity is maintained, will not spoil or become unsafe throughout its storage life. Examples of shelf stable food include canned juices, vegetables, and meat, bottled water, and dry food items

such as rice, pasta, flour, sugar, and spices. We are removing this definition from the final rule because the proposed exclusion (in the definition of ''transportation operations'') of ''shelf stable food that is completely enclosed by a container'' has been changed to apply to ''food that is completely enclosed by a container except a food that requires temperature control.'' We made this revision in the definition of ''transportation operations'' because, as we have previously explained, we have narrowed the focus of this rule to adulteration linked to food safety.

While some non-shelf-stable foods that are completely enclosed by a container and do not require temperature control for safety, *e.g.,* pasteurized orange juice, may spoil and become unfit for consumption if temperature abused, such a food will not become unsafe. The adulteration of food in such a circumstance, due to spoilage, would have been subject to this rule as proposed. This is no longer the case, nonetheless, FDA has authority under existing adulteration provisions in section 402 of the FD&C Act to address such a circumstance. We are addressing comments that spoke to the proposed exclusion of shelf stable food from the transportation operations definition to better inform readers about the scope of foods that would fall within the broader exclusion in revised definition.

(Comment 68) One comment states that we should clarify the definition of ''shelf stable food'' so that it clearly applies to all shelf stable foods, including food ingredients such as flavoring substances and compounded flavors. The comment states that our proposed definition for ''shelf stable foods'' may be construed too narrowly because the examples we provided in the proposed language imply that the ''shelf stable food'' definition applies only to finished food products like canned juice, canned vegetables, or bottled water. The commenter voiced the view that it is unclear from the proposed rule whether we intend for that list to be exhaustive or exclusive. The comment asks us to ensure that the definition clearly applies to all foods, including food ingredients that meet the ''shelf stable food'' definition. Another comment recommends that we include examples of animal food, such as packaged animal food, in the definition of shelf stable food.

(Response 68) We agree with these comments and affirm that food ''completely enclosed by a container,'' as expressed in the definition of ''transportation operations'' encompasses food ingredients as well as finished food products for humans and animals. We are not including examples of such foods because this category of food is extremely broad, making any such list limited relative to the whole, and we believe that the revised definition describes the types of foods encompassed by this exclusion in an understandable manner.

(Comment 69) Some comments state that shippers and carriers need more clarity on which food shipments are shelf stable. One comment states that the proposed definition provides a broad description of what constitutes shelf stable food but does not contemplate the diverse characteristics of food items, such as shelf-lives, packaging, and handling requirements that shippers and carriers will need to consider when determining whether food is shelf stable. The comment, for example, asks: How long the shelf-life of an item must be before it is considered shelf stable; whether packaging susceptible to humidity or humidity abuse would be considered to be fully enclosed, *i.e.,* whether we would question if packaging susceptible to humidity or humidity abuse is capable of maintaining package integrity; and whether we would consider food items subject to spoilage when frozen and thawed at room temperature to be shelf stable? Another comment asks us to affirm that boxes with flaps that are sealed by tape qualify as acceptable packaging under this definition. This comment also asks us to affirm that this definition does not only apply to food products bound for retail outlets, but would also apply to food being shipped from a supplier to a re-packer. Another comment states that we should require shippers or loaders to give carriers unambiguous notice when they are given shipments of food that are not shelf stable.

(Response 69) The shipper of the food, who often is also its manufacturer, would be the person who would be expected to know whether a food falls within the scope of the exclusion from the definition of ''transportation operations'' applicable to food completely enclosed by a container and that does not require temperature control for safety. We would expect that the shipper would take the steps required under this rule with respect to the transportation of any food that falls within the scope of this definition. This rule does not require the shipper to inform the carrier that a shipment of food is not subject to this rule because it is excluded from the scope of this definition.

In addressing the other questions raised by these comments we can state: (1) The requirements applicable to any food subject to this rule apply during transportation to all receivers that are subject to this rule, not just food bound for retail outlets; (2) In general, we would consider boxes with flaps sealed by tape to be a container that completely encloses the food; (3) The transportation of frozen food is not subject to this rule. As we stated in the proposed rule for preventive controls for human food (78 FR 3646 at 3774), the temperature and time required for a frozen food to become unsafe if not maintained in the frozen state would result in significant quality issues for the food before posing any safety risk, and as we discuss elsewhere in this final rule, we have narrowed the focus of this rule to adulteration linked to food safety; (4) There are packages which physically separate food from its surrounding environment that, nonetheless, allow for oxygen and atmospheric moisture exchange (*e.g.,* paper, cardboard) under reasonably anticipated storage conditions during transportation, and for which we would regard the food to be completely enclosed by a container because the container would protect the food from any contamination that could directly enter the food from the environment; and (5) If a shelf stable food's container is subjected to abusive storage conditions during transportation which may compromise its package integrity and allow moisture to enter the food, the food product is not within the scope of the ''transportation operations'' definition, however, we would make a case-by-case determination as to whether the food complies with the requirements of FD&C Act, particularly, section 402(a)(4) which states that ''a food shall be deemed to be adulterated if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.''

17. Shipper

We proposed to define the term ''shipper'' to mean a person who initiates a shipment of food by motor vehicle or rail vehicle. We further clarified in the proposed definition that the shipper would be responsible for all functions assigned to a shipper in this subpart, even if they are performed by other persons, such as a person who only holds food and physically transfers it onto a vehicle arranged for by the shipper, and that a shipper may also be a carrier or a receiver if the shipper also performs those functions as defined in this subpart. We are finalizing a simplified definition of ''shipper'' to mean a person who arranges for the

transportation of a food by a carrier or multiple carriers sequentially. A ''shipper'' could be a manufacturer or a freight broker. In the final rule, as explained in the discussion of § 1.908(a)(1), we have added a general provision about the multiple roles that can be played by a single entity to replace the separate provisions we had included in the proposed definitions of ''carrier,'' ''shipper'' and ''receiver''. We explain our consideration of comments and our reasons for revising the final definition in the responses to Comment 70.

(Comment 70) Several comments oppose defining a shipper as the person who ''initiates'' transportation. One comment states that the term is unnecessarily broad and would create confusion about who is subject to the shipper requirements. Another comment states that the meaning of the proposed definition is unclear because shipments of food can be initiated by many different types of persons during the transportation process, such as manufacturers, distributors, brokers (parties who arrange for the transportation of food held by other parties), and retailers. Another comment states that the shipper definition should describe the person who performs an activity directly related to the transportation process.

Several comments suggest changes to the proposed ''shipper'' definition. Some stated that the shipper should be the person who physically loads or orders the loading of a motor vehicle trailer or railcar. Some comments state that the shipper should be the manufacturer of the food because that person is most knowledgeable about all relevant factors concerning sanitary transportation of the food. One comment states that the shipper should be the person who decides to ship a food product and sets the transportation process in motion.

Other comments state that the shipper should be the person who owns the food at the time of shipment. One of these comments notes that product owners can best meet the responsibilities assigned to a shipper under the proposed rule even when another party arranges for the transportation of the shipment. The comment states that it is common industry practice for owners of the product to provide third-party logistics providers with instructions for the conditions required for shipments. Several comments advocating these revisions state that their suggested changes would clarify which entities in the transportation chain must meet this rule's requirements for shippers.

Other comments state that the shipper definition should not place shipper responsibilities on persons such as brokers because they lack knowledge about food safety and sanitary food transportation practices. One comment stated that third-party logistics providers, such as distribution centers, should not be subject to the shipper definition. The comment states that, although third-party logistics providers arrange for the transportation of food, they lack knowledge about food safety and rely on product owners to provide that information in establishing sanitary transportation conditions.

One comment stated that brokers are nowhere near the location where a shipment of food is being loaded into a motor vehicle trailer or railcar and, therefore, it is impossible for them to carry out duties assigned to a shipper, such as visually inspecting a vehicle prior to loading. A related comment asserts that facilities that hold the food for which shipment is arranged by an offsite shipper should be responsible for proper storage, handling, and loading or unloading of the food in accordance with FDA and customer requirements. Another comment addressed concerns that under the proposed shipper definition, shipper responsibilities would fall upon receivers who purchase food under a FOB contract in which title to the food passes at the seller's location, even though the receiver would not be present at the time of loading, and therefore could not meet this rule's shipper requirements. The comment states that the entity that physically loads the goods, instead of the receiver, is in the best position to meet a shipper's obligations, such as maintaining written procedures and records, and inspecting vehicles and transportation equipment prior to loading.

(Response 70) We agree that our proposed definition for a shipper, *i.e.,* the person who ''initiates a shipment of food'' is not sufficiently clear to identify the person who would be subject to this definition because the term ''initiates'' is not sufficiently precise. In considering how to revise this definition, we note that under the proposed rule, the shipper would be responsible for functions involving communication with the carrier that take place before transportation occurs (proposed § 1.908(b)(1) and (3)), and with functions involving the inspection of vehicles and transportation equipment that take place prior to loading (proposed § 1.908(b)(2) and (4)).

We first considered which person would be best suited to perform those functions, which involve specifying to the carrier all necessary sanitary requirements for the carrier's vehicle and transportation equipment to ensure that the vehicle is in appropriate sanitary condition, and specifying temperature control parameters to the carrier if the food requires temperature control during transportation. Inasmuch as these functions involve communicating important information to the carrier about operating conditions during transportation, we have determined that the appropriate person to perform these functions is the person who makes the transportation arrangements with the carrier because this person communicates directly with the carrier and can directly provide the carrier with the information required by this rule. While the owner or the manufacturer of the food, or the person who loads the food onto a vehicle, may possess this information, we do not regard these persons as best suited to bear responsibility for providing information to the carrier if neither of these persons actually makes the transportation arrangements with the carrier.

We also considered whether a shipper would need to be knowledgeable about food safety and sanitary transportation practices to perform functions that involve communication with a carrier before transportation occurs. While we agree that persons such as brokers, who arrange for transportation of food held by other parties, likely do not possess the degree of knowledge about food safety that a food manufacturer would, we also agree that current industry practices demonstrate that these persons, *e.g.,* brokers and other third-party logistics providers, obtain the vehicle preparation and sanitary transportation information, as needed, for example, from manufacturers, to provide to the carriers. Therefore, we do not regard brokers and other third-party logistics providers as inappropriate persons to perform the functions assigned to a shipper that take place before transportation occurs.

We have determined, therefore, that the person who arranges for the transportation of food by a carrier is best suited to perform the functions of a shipper that take place before transportation occurs and that the person can be someone who only arranges for the transportation of food, for example, a broker, as long as they have, or obtain, the necessary food safety information. We have incorporated these provisions into the revised definition of the term ''shipper'' in § 1.904.

We also considered the second function assigned to the shipper in our

proposed definition, *i.e.,* those involving the inspection of vehicles and transportation equipment and confirming that the shipper's specifications have been met, *e.g.,* for cleaning and pre-cooling, which take place before food is loaded onto a conveyance. We agree with comments that state that a shipper who is not on site at the time of loading cannot readily perform these functions, and we do not believe that it would be practical to require an offsite shipper to arrange for a representative of the shipper to be present to perform these inspections. We therefore agree with the comment that states that these functions can be readily performed by the person who loads vehicles or transportation equipment if that person is not the shipper, provided that this person also receives the specifications for vehicle preparation that the shipper provides to the carrier under § 1.908(b)(1) and (2), because that person is on site and would typically be associated with the facility in which the food is held prior to loading. Further, the person likely would be knowledgeable with respect to basic sanitation practices applicable to loading food into vehicles and equipment because of his responsibilities in operating the facility. We also note that facilities that are subject to our cGMP requirements already have similar responsibilities under 21 CFR 117.93. This provision requires that storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

Therefore, we have determined that the shipper should not be responsible for the functions that person would have been assigned under § 1.908(b)(2) and (4) of the proposed rule involving inspection of vehicles and transportation equipment that take place prior to loading. We are defining an additional term, the ''loader'' as described previously in this section to designate the person who will be responsible for those functions under this rule under § 1.908(c), which has been redesignated in this final rule as ''Requirements applicable to loaders engaged in transportation operations.''

18. Small Business

We proposed to define the term ''small business'' to mean a business subject to § 1.900(a) that employs 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 § 1.900(a) that has less than $25,500,000 in annual receipts. In the final rule, we have revised the threshold for motor vehicle carriers to $27,500,000, consistent with the recent change made by the Small Business Administration in the size based standard for trucking firms in 13 CFR part 122.201. We have revised this final rule to base the calculation for ''small business'' on ''full-time equivalent employees.'' We used the same approach to calculate full-time equivalent employees for the purpose of this rule as we used to calculate full-time equivalent employees in the preventive controls rules (*e.g.,* see response to comment 140 in the preventive controls for human food final rule (80 FR 55908 at 55962), and also the discussion of the definition of a full-time equivalent employee in that final rule (80 FR 55908 at 55962)). In conjunction with this revision and as previously described, we have established a definition for ''full-time equivalent employee'' as a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies as a small business for the purpose of establishing its compliance date. Therefore, we are modifying the definition of ''small business'' to use the term ''500 full-time equivalent employees'' rather than ''500 persons.''

(Comment 71) One comment states that the proposed definition of a small business is overly broad and would unduly delay the timeframe for compliance with this rule for the majority of the carriers.

(Response 71) We do not agree that our proposed definition is overly broad. As we explained in the proposed rule (79 FR 7006 at 7014), our proposed definition for a small business was based upon the applicable size-based standards issued by the U.S. Small Business Administration (SBA) under 13 CFR part 121. We believe that allowing businesses that are formally classified ''small'' by the SBA additional time to come into compliance with the requirements of this rule is appropriate. We also believe that small businesses that are able to come into compliance before their compliance date would do so and use that fact for promotional purposes with prospective customer's, *e.g.,* shippers, rather than delay compliance with this rule.

(Comment 72) A comment stated that we should exempt Class II and Class III railroads (these classifications generally relate to short line and regional railroads respectively) with fewer than 400,000 labor hours from the requirements of this rule. The comment states that the 400,000 labor hours standard has been used by DOT from time to time as the standard for exempting small railroad carriers from regulatory requirements. The comment states that railroads are extremely capital intensive as they pay for their right of way and, typically, small business railroads invest much of their revenue into ties and track structure, equipment maintenance and inspections. The comment further states that shifting the responsibility for the sanitation of railcars carrying food products to the small railroad will be burdensome because these entities currently do not clean or sanitize cars or maintain facilities for such operations. Further, the comment states that it is difficult for railroads to know the storage condition of railcars, and that they cannot be reasonably held accountable for the storage conditions of cars in many circumstances of use.

(Response 72) As discussed in our response to Comment 53, we have revised the definition of the term ''carrier'' in this final rule, in part, because our proposed definition would have established requirements that railroad operators, typically, cannot meet. We stated that under the revised definition of the term ''carrier'' in this final rule, a railroad operator only bears responsibilities under this rule when it has agreed to do so in a written contract with the shipper. We believe that this revision addresses the concerns of this comment.

19. TCS Food

We proposed to define the term ''time/temperature control for safety (TCS) food'' to mean a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. As we explained in our response to Comment 111, we have not retained this definition in the final rule. We, therefore, do not need to address comments that we received that suggest revisions or clarifications to the proposed definition.

20. Transportation

We proposed to define ''transportation'' to mean any movement of food in commerce by motor vehicle or rail vehicle. We did not receive any comment on our proposed definition and are finalizing it as proposed.

21. Transportation Equipment

We proposed to define the term ''transportation equipment'' to mean equipment used in food transportation operations, other than vehicles, for example, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings,

hoses, gaskets, and loading and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor. We are finalizing this definition as proposed with the exception of the removal of the phrase ''other than vehicles,'' which we are removing for clarity and the internal consistency of the definition.

(Comment 73) One comment asks us to revise the proposed definition of ''transportation equipment'' to clarify that it encompasses only such equipment exclusively associated with a transportation conveyance. The comment states that the proposed definition is overly broad, and could be interpreted to include structures and equipment normally associated with storage, load-out, and receiving procedures (such as loading bins, spouting and other equipment located within a shipper's or receiver's facility), and not strictly to equipment that directly facilitates transportation activities. The comment suggests that we use the following revised definition: ''Transportation equipment means equipment used in food transportation operations, other than vehicles, *e.g.,* bulk and non-bulk containers, totes and pallets loaded onto transportation conveyances, and pumps, fittings, hoses, gaskets, loading systems and unloading systems that are integral and affixed to transportation conveyances.''

(Response 73) We decline this request. The definition of ''transportation equipment'' already specifies that such equipment is used in transportation operations. While some types of equipment used in food transportation, such as hopper bins, may also be constructed as part of a facility, as we state in our response to Comment 52, we would not consider a hopper bin, that is constructed as part of a facility and that is used for storage of materials (but not the movement of food), to be transportation equipment. Therefore, it would not be subject to this rule.

22. Transportation Operations

We proposed to define the term ''transportation operations'' to mean all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspecting, maintaining, loading and unloading, and operating vehicles and transportation equipment. We further proposed that transportation operations do not include any activities associated with the transportation of shelf stable food that is completely enclosed by a container, compressed food gases, or live food animals and that all transportation activities involving raw agricultural commodities (RACs) that are performed by a farm are also excluded from the definition of the term ''transportation operations.'' We are finalizing the definition of ''transportation operations'' as proposed with some additions. As we discuss in section IV.C., concerning our proposed definition of ''shelf stable,'' which we have not retained in the final rule, we have amended the definition of ''transportation operations'' to specify that this term does not include activities associated with transport of a food completely enclosed by a container except a food that requires temperature control for safety. We have also added that transportation operations do not include activities associated with transport of food contact substances as defined in section 409(h)(6) of the FD&C Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. Finally, we have revised the exclusion for transportation activities performed by a farm to all transportation activities performed by a farm, not just those related to the transport of RACs. We explain our consideration of comments and our reasons for the revisions in our responses to the next 12 comments.

(Comment 74) A few comments ask us to consider excluding, or granting a waiver for, the transportation of food additives and substances that are generally recognized as safe (GRAS), and their precursors, from the proposed requirements of this rule. One comment states that these substances always undergo further inspection, testing, and processing steps, which minimizes the possibility that they could render the food ingredient, or the food that the ingredient is eventually incorporated into, adulterated. One comment states that exemption or waiving is appropriate because the production and supply chain for these substances includes controls to prevent contamination during production, packaging and transport, and is often certified by third parties. One comment urges us to apply this rule's provisions for prior cargo disclosures, protections from allergen cross-contact, and recordkeeping to these substances. The comment expresses the view however that a shipper should be exempted from even these requirements if it can demonstrate that its food additives and GRAS substances have not been transported in containers that have come into contact with any of the seven major food allergens, either because these products are not comingled with other foods or because the carrier does not transport any other food items.

(Response 74) We decline these requests. We acknowledge that food additives, GRAS substances, and their precursors may undergo further inspection, testing, and processing that minimizes the possibility that they could render food adulterated, or that they may be subject to controls and third-party certification that address protection of the substance during transportation. However, this is a broad group of substances with diverse packaging and transportation practices (*e.g.,* bulk shipments), and it is likely that there are substances for which the controls included in this final rule are necessary to ensure sanitary transportation, depending upon the nature of the substance, the method used to transport it, and its intended use. Therefore, exempting or waiving food additives and GRAS substances and their precursors from the requirements of this rule would not be appropriate. However, we have added provisions to § 1.908(a)(3) of this rule to provide sufficient flexibility to allow persons engaged in the transportation of these substances to use sanitary transportation practices that are appropriate for their circumstances.

(Comment 75) One comment asks us to consider excluding shippers and carriers who transport byproducts from a processing facility, *e.g.,* spent grain from alcoholic beverage production facilities, from this rule. The comment states that many industries have developed sustainable and cost-effective ways to use these byproducts as animal feed. The commenter believes that the new recordkeeping and inspection requirements proposed in this rule would hinder a beneficial practice that has worked successfully for many years.

(Response 75) We have partially accommodated this request in this final rule by excluding from the definition of transportation operations, ''human food byproducts transported for use as animal food without further processing.'' The intent of this new language is to exclude from the definition human food byproducts that are not further processed into a manufactured animal feed. Most commonly, we expect that these byproducts move directly from the human food manufacturer to the farm, where they are fed directly to livestock, often by spreading on the ground. We do not intend to exclude from the definition of transportation operations human food byproducts that are transported to a business to be used as an ingredient in a manufactured animal food, or to be further processed in some

way (*e.g.,* rendered) in the production of animal feed. We believe the scale of the public health risk posed by the former activity to be minimal, with the byproducts being transported to only one or several farms, while the scale of the public health risk posed by the latter would be substantially greater, with the byproducts being manufactured into large quantities of animal feed, possibly with a wide distribution. Our concern here is primarily with the potential for chemical contamination, as we are aware that many of the byproducts will be heat treated (*e.g.,* rendered) in a way that will minimize the risk of microbiological contamination.

With respect to transportation of human food byproducts for further processing into animal feed, we decline the request to remove such operations from the definition of transportation operations because we have determined that this final rule's recordkeeping and inspection requirements as applied to the transportation of such products are not burdensome and are appropriate for these types of transportation operations. The requirements we are establishing in this rule require that transportation operations be conducted so as to prevent food from becoming adulterated during transportation. We do not envision, for example, that carriers who transport spent grain materials to animal feed manufacturing facilities would have to clean or inspect their vehicles any more frequently under this final rule than what is already typically being done to facilitate safe transportation. However, if carriers haul intervening loads of fertilizer, for example, they would need to clean their vehicles before transporting spent grain intended for use as animal feed. In addition, as we explained in our response to Comment 149 and Comment 160, in § 1.908(e)(4) and (e)(5) of this final rule, we have revised the proposed previous load and cleaning reporting requirements for bulk carriers in a manner that will reduce, and in some cases eliminate, recordkeeping requirements for these carriers.

(Comment 76) Several comments support our proposed provision that would exclude the transport of live animals from the definition of ''transportation operations.'' One comment disagrees with our tentative conclusion that sanitary transportation practices are not necessary to prevent live food animals from becoming adulterated during transportation and our proposal, therefore, to exclude their transport from the scope of this rule. This comment suggests that transportation during hot and cold weather, as well as long-distance transport, causes stress in the animals, resulting in increased shedding of pathogenic microorganisms in the manure of the animals being transported. The commenter asserts that these pathogenic microbes may be spread from one animal to another via physical contact in transportation vehicles, possibly resulting in a higher percentage of animals arriving at slaughter facilities with high levels of pathogenic microbes on their hides or feathers. The comment asserts that the more animals that arrive at slaughter with pathogens on their hides or feathers, the more likely that the mitigations applied by the slaughter facilities will be ineffective. The commenter further asserts that FSIS inspection at slaughter facilities is inadequate to mitigate this increase in risk and, therefore, asks us to require the cleaning of transportation vehicles with disinfectants between animal loads to mitigate the risk.

(Response 76) We disagree with this comment. We recognize that the stress of transportation may increase the shedding of pathogenic bacteria in the manure of animals during transport, but we are not aware of scientific information that establishes that this leads directly to an increased level of pathogenic bacteria in food products originating from animals coming from FSIS-inspected slaughter facilities that could be controlled by establishing requirements through this rulemaking. The slaughter facilities handling the processing of these animals, as well as the regulatory agencies responsible for oversight of the facilities, such as the FSIS, are aware of these issues and the procedures they use to process these animals have been developed with this risk in mind. Slaughter operations at facilities subject to FSIS jurisdiction, for example, are already subject to requirements intended to minimize the risk of adulteration posed by the presence of contaminants on the external surfaces of live food animals.

(Comment 77) One comment asks us to apply this rule's waiver provisions to determine whether to waive requirements for the transport of live food animals. The comment further asserts that we should use the waiver procedure, in part, to provide for an additional opportunity for public comment with respect to the risks that may be associated with the transportation of live food producing animals.

(Response 77) We disagree. Section 416(d)(1)(A–B) of the FD&C Act provides us with the authority to waive any requirement of this rule with respect to any class of persons, vehicles, food, or nonfood products, if we determine that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health, and will not be contrary to the public interest (21 U.S.C. 350e(d)(1)(A–B)). As we discussed in the proposed rule (79 FR 7006 at 7015), we are not aware of food safety concerns related to the transportation of live food animals intended for slaughter that could be addressed through this rule's sanitary transportation requirements. Furthermore, we also address specific concerns the commenter raised about this issue in our response to Comment 76, and explain why we have concluded that establishing requirements through this rulemaking to address those concerns is not necessary. The prerequisite condition for considering whether we should waive the requirements of this rule for the transportation of live food animals therefore does not exist, *i.e.,* we are not aware of any concerns that would necessitate establishing sanitary transportation requirements applicable to live food animal transportation and, therefore, there are no requirements to waive. We, therefore, have recognized in our definition of ''transportation operations'' that the transportation of live food animals does not meet the criteria for inclusion in this definition.

(Comment 78) One comment on our proposed definition of ''transportation operations'' notes that the exclusion of live food animals from the definition possibly conflicts with our own guidance under the National Shellfish Sanitation Program (Ref. 26). It stated that some states, operating under FDA guidance, require temperature control during the transport of raw molluscan shellfish between the harvest area and the first receiver (also known as the ''dealer''). Participants made similar comments during the public meetings that we held on this proposed rule.

(Response 78) We agree that temperature control is necessary to ensure the sanitary transportation of molluscan shellfish (*e.g.,* oysters, clams, mussels) when transported live. As such, and to maintain consistency with guidance we have issued, we have revised the definition of ''transportation operations'' to state that molluscan shellfish are not included in the provision that otherwise excludes the transportation of live food animals from this definition.

(Comment 79) Many comments support the exclusion of transportation activities for RACs performed by farms and voice the view that the exemption should be retained in our final rule. Several comments advocate for limiting

the exclusion only to RACs that will undergo further processing and a kill step before they are consumed. The comments argue that RACs covered by the produce safety rule will not be processed further before being consumed and therefore are particularly at-risk for becoming contaminated during transportation. Some comments oppose this exclusion provision. Some of these express the view that requirements for the same activity should not differ based on who performs the activity and argue that farm trucks transporting RACs should be covered under this rule. Another comment asks us to include a separate section in this rule that would apply to transportation activities for RACs performed by farms, and states that RACs transported by farms at a minimum should be subject to the rule's modification or revocation procedures applicable to waivers. One comment asks us to engage with industry and other key stakeholders, including trade associations, to establish a maximum distance that a farm exempt from this rule should be able to transport RACs.

(Response 79) We are not aware of food safety concerns related to the transportation of RACs by farms that could be addressed through the sanitary transportation practices set forth in this rule, as we stated in the proposed rule (79 FR 7006 at 7016). We also stated in the proposed rule that we are not aware of instances in which insanitary conditions or practices, for example, improper temperature control, improper equipment construction, or inadequate equipment cleaning involving the transportation of RACs by farms have contributed to foodborne illnesses. We further stated that we recognize the diversity of farms and their transportation operations, including the size of the operation, the nature of the crop(s) being transported (*e.g.,* large trailer loads of dry grain or livestock, small loads of fresh produce or shell eggs), the nature of existing transportation equipment (*e.g.,* large tractor-trailers, small farm trucks and wagons), and the destination of the shipment (*e.g.,* a local cooling facility, farmers market or restaurant, a more distant market), and the challenge that this diversity presents in developing a set of mandatory requirements that would be practical and broadly suitable for this sector. Therefore, we tentatively concluded that the sanitary transportation practices that would be required by this proposed rule are not necessary to prevent RACs from becoming adulterated during transportation by farms. We acknowledged that transportation from farm to market is often performed by independent carriers as arranged by shippers or receivers that are not farms. Similarly, farms may arrange for transportation (*i.e.,* serve as a shipper) by a common carrier. Transportation by independent carriers, as compared to farms, is likely to be over long distances and to involve the use of much larger vehicles and transportation equipment that is generally more consistent with equipment used outside the farm sector. Furthermore, long distance transportation operations may involve several stops for dropping and picking up additional loads. Communication and coordination between carriers, shippers and receivers is a critical element in properly carrying out such transport where different parties are handling various transportation responsibilities, as opposed to transport performed by a farm where the farm is responsible for all of the roles covered by this rule except the receiver. To advance best practices for the transport of produce, the industry has developed guidance that addresses among other things, recommended practices for independent carriers (Ref. 27). Building on industry experience we have concluded that the requirements of this regulation should not apply to such carriers with regard to the transportation of food by farms. We did not receive any comments to the proposed rule that would cause us to alter our determination to provide this exclusion or that convince us that modifications or qualifying conditions should be added to the proposed exclusion for transportation of food by farms.

Upon further consideration, we have also concluded that the exclusion from the transportation operations definition related to transportation activities performed by farms should not be limited to RACs. We are aware that farms ship and receive food items that are not RACs (*e.g.,* feed received to sustain their livestock, value added packaged food, such as jams, honey, baked goods) and that these food items are transported in the same manner as described earlier in this document for RACs. We have concluded that the diverse handling of these non-RAC food items by farms presents the same challenge for developing a set of mandatory requirements that would be broadly suitable for this sector, as described earlier in this document for RACs. For this reason, we are removing the limiting clause ''for raw agricultural commodities'' from the exclusion of transportation activities performed by farms from the definition of transportation operations. Consistent with the preamble to the proposed rule, the exclusion is intended to apply to the activities of farms, regardless of whether the farm is serving in the role of shipper, loader, carrier, or receiver.

Section 416(d)(1)(A) and (B) of the FD&C Act provides us with the authority to waive any requirement of this rule with respect to any class of persons, vehicles, food, or nonfood products, if we determine that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health, and will not be contrary to the public interest. As we discussed in the proposed rule with respect to the transportation of RACs (79 FR 7006 at 7016), and are affirming herein, and as we discussed previously in this response with respect to other types of food transported by farms, we are not aware of food safety concerns related to transportation activities performed by farms that could be addressed through the sanitary transportation practices set forth in this rule. Accordingly, the prerequisite condition for considering whether we should waive the requirements of this rule for transportation activities performed by farms does not exist, *i.e.,* we are not aware of any concerns that would necessitate establishing sanitary transportation requirements applicable to such transportation operations, and therefore there are no requirements for us to consider waiving.

(Comment 80) One comment asserts that if transportation activities for RACs performed by a farm are excluded from this rule, we should clarify that a carrier would not be held responsible for any contamination that may have occurred before the RACs were loaded into the carrier's vehicle.

(Response 80) Under this final rule, as revised, transportation activities for any food, including RACs, performed by farms, while not subject to the requirements of the rule, are still subject to the adulteration and other applicable provisions of the FD&C Act and our applicable implementing regulations. A farm that acts as a carrier, for example, that transports RACs and that is excluded from this rule, is still subject to section 402(a)(4) of the FD&C Act, which prohibits the holding of food under insanitary conditions whereby it may be rendered injurious to health or may become contaminated with filth.

(Comment 81) One comment asks us to clarify whether fruit transported to a processing facility falls under the proposed exclusion for the transportation of RACs performed by a farm.

(Response 81) Transportation activities for RACs, including fruit, to processing facilities are excluded from coverage under this rule, only if the activity is performed by a farm as defined in this rule. However, farms subject to the produce safety rule will be required to take steps to address the transportation of covered produce under that rule. Section 112.125 of the produce safety rule requires that equipment subject to that rule that is used to transport covered produce must be adequately clean before use in transporting covered produce and adequate for use in transporting covered produce.

(Comment 82) One comment asks us to clarify whether this rule applies to dairy farmers who transport bulk animal feed in their own vehicles from a facility to their own farm. A second comment asks us to clarify whether almond hulls and shells are eligible for the rule's RACs transported by farms exemption.

(Response 82) As we discuss in Comment 79, we have revised this final rule to provide that all transportation activities performed by a farm, and not solely those activities involving the transportation of RACs, are not subject to this rule.

(Comment 83) Some comments ask us to clarify whether this rule applies to non-farm carriers who transport RACs on farms or from farms to processing facilities where additional sanitation procedures or microbial kill steps occur, for example, when fruit RACs are processed at the receiving facility into canned fruit. Some comments argue that RACs that are moved on a farm or from a farm to a processing facility should not be subject to the requirements of this rule, regardless of who owns and operates the vehicles and transportation equipment.

(Response 83) Non-farm carriers, unless they are non-covered businesses, engaged in transportation operations, as defined by this rule for RACs, are subject to this rule regardless of whether the RACs are intended to be further processed. While the RACs in question may be further processed, there may be circumstances in which controls, for example, a specific vehicle cleaning procedure, are necessary to ensure that sanitary transportation practices are followed. We have added provisions to § 1.908(a)(3) of this rule to provide sufficient flexibility to allow persons engaged in the transport of food intended for further processing to use sanitary transportation practices that are appropriate for their circumstances. The movement of RACs on a farm that have not entered commerce is not subject to this rule because such on-farm movement is not considered to be transportation, as defined in this rule.

(Comment 84) One comment agrees that transportation of a shelf stable food that is completely enclosed by a container should be excluded from coverage under this rule, as we proposed. It states that, in addition, the exclusion should be extended to those same materials shipped in dedicated bulk containers, so long as the containers meet the criteria for sanitary food transportation.

(Response 84) We wish to make it clear that this comment addresses transportation equipment and not vehicles. We agree with this comment provided that the shelf stable food as packaged within the equipment, *i.e.,* the reusable dedicated bulk container, is completely enclosed by the container. As provided under the revised definition of ''transportation operations,'' the described container, when used to transport any food that does not require temperature control for safety, meets the criteria for exclusion from the definition of ''transportation operations.''

(Comment 85) Several comments ask us to delete the word ''solely'' from the language in the definition of transportation operations excluding activities associated with the transportation of shelf stable foods from this definition. One comment states that the term ''solely'' is confusing and appears to suggest that shelf stable food should be shipped in separate loads apart from non-food items and other covered food items.

(Response 85) We agree that the word ''solely,'' as used in the proposed definition of ''transportation operations,'' may be confusing and we have concluded upon further consideration that it is not necessary. We, therefore, have removed the term ''solely'' from the definition of transportation operations.

23. Vehicle

We proposed to define the term ''vehicle'' to mean a land conveyance that is motorized, *i.e.,* a motor vehicle, or that moves on rails, *i.e.,* a railcar, which is used in transportation operations. We are finalizing this definition as proposed.

(Comment 86) One comment asserts that the definition of ''vehicle'' as any ''land conveyance that is motorized'' and the use of the term ''motor vehicle'' are excessively broad and could be misinterpreted to include a wide range of motorized vehicles, including automobiles. The comment also notes that there are instances in which railcars, trucks, and trailers can be used to store food products. This comment asks us to narrow this definition to read: ''Vehicle means a truck or railcar, which is used in transportation operations and not to hold food.''

(Response 86) We decline to make the suggested change. The definition of vehicle is intentionally broad and could include automobiles. We do agree that sometimes railcars, trucks, and trailers can be used to store food products, and we will incorporate that possibility into our implementation of this rule. A truck or trailer used for the permanent or semi-permanent storage of ingredients or finished food products is not within the scope of this rule and could be considered as part of a facility and regulated under another of our applicable regulations, *e.g.,* the FSMA human or animal preventive controls rules that apply to the facility. A truck, trailer, or railcar being used, or being prepared for use, to transport human or animal food or food ingredients, would be subject to this rule. In either case, the equipment would need to be used in a manner consistent with the appropriate set of regulations, and in such a way that the food is not rendered unsafe.

D. What requirements apply to vehicles and transportation equipment? (§ 1.906)

In table 7 we outline the revisions we have made to § 1.906 in finalizing this rulemaking. Following the table we respond to comments about these provisions and describe the changes we have made to the provisions in finalizing the rule.

TABLE 7—§ 1.906 WHAT REQUIREMENTS APPLY TO VEHICLES AND TRANSPORTATION EQUIPMENT?

Proposed section (§)	Description	Revision
1.906(a)	Specifies that vehicles and transportation equipment must be designed and of such material and workmanship to be suitable and adequately cleanable for their intended use to prevent food from becoming adulterated.	Removed the text that described the goal of the provision to be prevention of food from becoming ''filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source'' from the regulatory text because we have narrowed the focus of this rule to adulteration linked to food safety. In the final rule, we have replaced this text with ''to prevent the food . . . from becoming unsafe, *i.e.,* adulterated within the meaning of section 402(a)(1), (2), and (4) of the FD&C Act.''
1.906(b)	Specifies that vehicles and transportation equipment must be maintained in such sanitary condition for their intended use to prevent food from becoming adulterated.	Added ''for their intended use'' to the regulatory text for clarity. Removed the text that described the goal of the provision to be prevention of food from becoming ''filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source'' from the regulatory text because we have narrowed the focus of this rule to adulteration linked to food safety. In the final rule, we have replaced this text with ''to prevent the food . . . from becoming unsafe.''
1.906(c)	Specifies that vehicles and transportation equipment used for 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 adulterated.	Removed the phrases ''that can support the rapid growth of undesirable microorganisms in the absence of temperature control'' and ''maintain the food under temperature conditions that will prevent the rapid growth of undesirable microorganisms'' from the regulatory text because our goal with this provision is prevention of adulteration linked to food safety. Revised regulatory text to specify that vehicles and transportation equipment used for 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.''
1.906(d)	Specifies that freezers and mechanically refrigerated cold storage compartments to be equipped with an indicating thermometer, temperature measuring device, or temperature recording device to show the temperature accurately with the compartment.	Removed this provision as unnecessarily prescriptive.
1.906(e)	Specifies that vehicles and transportation equipment must be stored in a manner that prevents harborage of pests or becoming contaminated in any other manner that could result in food becoming adulterated.	As a consequence of eliminating former 1.906(d), this provision is finalized as 1.906(d). Removed the text that described the goal of the provision to be prevention of food from becoming ''filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source'' from the regulatory text because we have narrowed the focus of this rule to adulteration linked to food safety. In the final rule, we have replaced this text with ''to prevent the food . . . from becoming unsafe.''

1. Proposed § 1.906(a)

We proposed to require that vehicles and equipment used in transportation operations must be so 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 filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations. Consistent with a decision to more narrowly focus this rule on adulteration linked to food safety as explained in responses to comments below, we have finalized this provision to require that vehicles and equipment used in transportation operations must be so 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, *i.e.,* adulterated within the meaning of section 402(a)(1), (2), and (4) of the FD&C Act during transportation operations.

(Comment 87) A comment from a non-profit organization that develops and updates equipment standards and processing practices asks us to include a provision in the final rule stating that vehicles and transportation equipment that have been fabricated in conformance with its standards and/or operated in accordance with its practices, and have been maintained in a sanitary manner, will be deemed to have met the minimum requirements of this rule.

(Response 87) We are not making this suggested revision. It is the responsibility of the persons subject to this rule to determine whether the vehicles and transportation equipment that they use or offer for use in food transportation operations meet the requirements of this rule.

(Comment 88) A few comments state that this regulation should not preclude

the use of food transportation vehicles and equipment constructed of wood, and ask us to clarify under what conditions we would deem the use of vehicles and equipment constructed of wood to be acceptable.

(Response 88) Similar to statements we made in the produce safety rule (80 FR 74353) and final human food preventive controls regulation (80 FR 55908) about wooden bins, we are not precluding the use of transportation vehicles and equipment constructed of wood under this rule. However, where the intended use of the vehicle or equipment is such that food would be in direct contact with the wooden surface of transportation vehicles or equipment, we expect that such vehicles or equipment would be used only to the extent they are cleanable and unlikely to support conditions that may make the food unsafe (see Comment 95).

(Comment 89) Several comments address provisions of this rule for transportation equipment used in operations involving food materials destined for animal consumption. One comment asserts that the provisions in proposed 1.906(a), (b), and (e), do not seem to consider the transportation of materials that are already in a condition not suitable for consumption without further processing, such as viscera, offal, and other byproducts from the chicken slaughtering process. The comment notes that firms transport these materials to facilities where they will be further processed and treated to recondition the materials to make them suitable for animal consumption. Although the transportation conveyances used to transport these materials to processing facilities may, in fact, allow the growth of microorganisms during transport, the subsequent treatment process accounts for this and effectively renders the materials suitable for animal consumption. A similar comment states requiring transportation conveyances for animal food to be free of ''filthy, putrid, or decomposed substances'' should not apply to unprocessed raw materials destined for rendering. These materials include offal and trimmings from animal slaughter, dead animals, and spoiled or outdated meat from retail food establishments. They are transported by renderers in specialized equipment to prevent leakage and spills, but requirements related to refrigeration, microbial contamination, decomposition, and adulteration during transportation are not germane to these raw materials destined for further processing and hazard control. Another comment asks us to revise the rule to state explicitly that vehicles and transportation equipment must be designed, maintained, and stored in appropriate sanitary condition ''for their intended use.'' According to this comment, doing so would clarify that different sanitary food transportation requirements can be applied to vehicles and transportation equipment, depending on the intended uses of the vehicles and equipment, while still making it clear that appropriate precautions must be followed in all circumstances. The commenter notes, for example, that although byproduct materials do not need to be transported under conditions that prevent them from becoming decomposed because they already are in this condition at the start of transportation, it would not be appropriate to transport these materials in a container that previously held a chemical contaminant that will not be eliminated through further processing if the container was not adequately cleaned before use.

(Response 89) We agree that in the proposed rule, we applied language from section 402 of the FD&C Act identifying circumstances under which food is adulterated in an overly broad manner so as to suggest, unintentionally, that any food in transport that exhibits any cited criteria of section 402 is adulterated, regardless of the nature of the food or its intended use. We understand how a reader might interpret proposed §§ 1.906 and 1.908 to mean that vehicles must be maintained and operated to always preclude food from becoming filthy, putrid, decomposed or otherwise unfit for food during transport, and that all food, including, for example, materials destined for rendering, that become filthy, putrid, decomposed or otherwise unfit for food as the result of transportation operations are adulterated. We, therefore, have revised § 1.906(a), (b), and (d), and § 1.908(a) to state that the relevant requirements for transportation vehicles, equipment and operations take the intended use of a vehicle or equipment into account and that the intent of these requirements is to prevent food from becoming unsafe, *i.e.,* adulterated within the meaning of section 402(a)(1), (2), and (4) of the FD&C Act, during transportation. Therefore, we would not regard a transportation vehicle used to haul materials destined for rendering, *e.g.,* viscera, offal, trimmings from slaughter operations, to be operating under insanitary conditions, given that the vehicle's intended use is to haul materials that will undergo further processing to make them suitable for animal consumption. We also would not regard rendering materials in transport to be adulterated for the same reason. However, we note that those engaged in transport of materials destined for rendering should consider whether previous cargo that could cause the material to be unsafe due to potential chemical contamination is a relevant consideration.

We also recognize that provisions in §§ 1.906 and 1.908 of the proposed rule that refer to the need, under certain circumstances, for temperature control of food during transport to prevent the ''rapid growth of undesirable microorganisms'' are used without appropriate consideration of the intended use of the food, *e.g.,* it is intended to undergo further processing, and also suggest that any food in transportation in which undesirable microorganisms are present is adulterated. The proposed provisions further suggest that vehicles or transportation equipment that allow these conditions to prevail are insanitary for transportation purposes. We, therefore, have revised §§ 1.906(c) and 1.908(a)(3)(iii) in this final rule to state that these requirements are applicable to food that requires temperature control for safety during transportation. Unless otherwise stated, we use the phrase ''food that requires temperature control for safety'' in this rule to mean that such temperature control is needed to prevent the food from becoming unsafe during transportation. Therefore, we would not regard an unrefrigerated transportation vehicle used to transport bulk materials destined for rendering to be in violation of this rule because the vehicle's intended use is to transport materials that do not require temperature control because they will undergo a subsequent heat processing treatment to destroy pathogens. We also would not regard rendering materials in transport, *e.g.,* viscera, offal, trimmings from slaughter operations, to be adulterated for the same reason.

As we discuss in our response to Comment 130, regarding revisions we have made to proposed § 1.908(a)(3), we are also clarifying that, under this rule, the consideration of the type of food and its stage in the relevant production cycle are relevant in determining the necessary sanitary conditions and controls for any given transportation operation.

(Comment 90) One comment asks us to exempt equipment used for transporting fruit and vegetable culls, for deposit into pastures as food for grazing animals, from the bulk vehicle requirements of this rule. It notes that Florida fresh citrus packinghouses often

load open-air dump trucks or dump trailers with culls for deposit onto the ground of local pastures. The cattle eating the culls are grazing animals and regularly feed from the ground. A similar comment asks us to exempt transportation operations that use certain classes of vehicles to transport raw and processed agricultural commodities, as well as feed and feed ingredients, from this rule at the outset to avoid a deluge of waiver petitions that this segment of the food transportation industry would otherwise submit to us for our consideration. This commenter singles out, for example, the use of shuttle trains and privately owned railcars that are dedicated exclusively to hauling grains and oilseeds as the types of transportation operations that it believes should be exempt from the rule. The comment also notes that animal feed and feed ingredient manufacturers often use their own dedicated truck fleets to haul large quantities of bulk and bagged products directly to farms and livestock and poultry operations. The commenter believes that these types of bulk vehicles and transportation equipment should be exempt from this rule because they pose limited risks for cross-contamination because SOPs for sequencing and cleaning-out these vehicles are already followed by these firms in order to comply with FDA's existing regulations for medicated animal feed.

(Response 90) As we discuss in Comment 75, we have added a provision to this final rule excluding human food byproducts transported for use as animal food without further processing from coverage by this rule. Therefore, transportation operations for fruit and vegetable culls, for deposit into pastures as food for grazing animals, are not subject to this rule.

We do not agree that the other types of vehicles described in these comments, or the transportation operations in which they are used, should be exempt from this rule. The requirements we are establishing for vehicles and transportation equipment, as we explained in our response to the previous comment, require that vehicles and transportation equipment be designed, maintained, and stored to prevent food from becoming adulterated during transportation under the vehicles' intended uses. These requirements are not burdensome and are appropriate even for vehicles used in operations where the risk of food adulteration is low.

Finally, we note in response to the comment that bagged animal feed and bagged animal feed ingredients are exempt from this rule. These items fall outside of the scope of ''transportation operations'' (as defined in § 1.904) that are subject to the rule because they are food completely enclosed by a container that does not require temperature control for safety.

(Comment 91) A few comments ask us to address the appropriate sanitary conditions for the use of wood pallets. One comment observes that wood is a porous material and therefore is vulnerable to water absorption and potential contamination, but asserts that as long as the food is in appropriate containers and does not come into direct contact with wood pallet surfaces, the opportunity for contamination is slight. Another comment asserts that the pallet conditions that we described as being insanitary in the proposed rule are too restrictive for animal feed transport and allow an FDA inspector too much subjectivity in determining whether a pallet is fit for its intended use.

(Response 91) Pallets need to be maintained so that they do not pose a risk of contaminating food during transportation or of compromising the integrity of the food containers that are supported by the pallet. For example, where the intended use of the pallet is such that food would be in direct contact with the wooden surface of the pallet, we expect that pallets would be used only to the extent they are cleanable and unlikely to support conditions that may make the food unsafe. (See Comment 88). In addition, pallets should not have jagged edges that protrude into the carrying surface in a way that could damage the product being shipped, *e.g.,* wood splinters that could puncture food containers.

(Comment 92) One comment asks us to amend the rule to allow railcars currently in use to remain in use until they are retired from service. The comment states that the absence of recent food safety incidents involving the rail transportation of food demonstrates that the design of railcars currently used in food transportation operations is adequate.

(Response 92) There are no provisions in this rule that would require a railcar currently in use to be removed from service, as long as its condition permits the safe transport of food in accordance with established industry practices. If a railcar is in a condition not suitable for such use, we would expect that the railcar provider would take that car out of service for refurbishment or that the shipper would refuse to use the car if it is offered for food transport.

(Comment 93) A few comments state that the term ''adequately cleanable'' used in proposed § 1.906(a) is vague. One comment asserts that it fails to provide any discernable benefit to food transporters in preventing food contamination.

(Response 93) As we state in our response to Comment 49, the term ''adequate'' is a long-standing term that we defined in its current form when we first established cGMP requirements for the manufacturing, packing, and holding of human food. We are using the terms ''adequate'' and ''adequately cleanable'' to provide flexibility for shippers, loaders, carriers, and receivers to comply with the requirements of this rule in a way that is both effective for purposes of preventing the adulteration of food during transport and most suitable for their particular operations.

(Comment 94) One comment states that we should recognize that not all transportation equipment needs to be cleaned before being used. The comment observes that cleaning wooden pallets can do more harm than good if proper precautions are not followed to prevent mold growth from moisture. The commenter notes that while it may be appropriate to expect water-based cleaning of certain types of transportation equipment, like hoses, for example, between every use, these kinds of cleaning practices should not be used for wooden pallets. The comment states that a visual inspection of pallets for cleanliness and suitability is sufficient to demonstrate that the pallets are acceptable for use and that the ''adequately cleanable'' standard for pallets should focus on the dry removal of debris like dust and dirt, when necessary.

(Response 94) We agree that there are circumstances under which some transportation equipment would not need to be cleaned before each use and that pallets that are adequately clean for their intended use do not necessarily need to be cleaned after each use. However, when the cleaning of vehicles and transportation equipment is necessary for a transportation operation to meet the requirements of this rule, we would expect that appropriate cleaning practices will be followed. We address our principal concerns about the use of pallets in our response to Comment 91.

2. Proposed § 1.906(b)

We proposed to require that vehicles and transportation equipment be maintained in such a sanitary condition as to prevent the food they transport from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations. Consistent with a decision to more narrowly focus this rule on

adulteration linked to food safety as explained in responses to comments below, we have finalized this provision to require that vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.

(Comment 95) One comment states that this rule should explicitly distinguish between the terms ''sanitize'' and ''clean'' with respect to the intended use of the food being transported. The comment states that human food should be transported using equipment and vehicles that have been ''sanitized'' to prevent illness while a ''clean'' vessel is acceptable for the transport of animal feed.

(Response 95) We did not define the terms ''sanitize'' or ''clean'' in the proposed rule and we decline the commenter's suggestion that we do so in this final rule. Section 1.906(b) states that vehicles and transportation equipment must be maintained in a ''sanitary condition.'' We do not consider ''sanitary condition'' to be synonymous with ''sanitize.'' We consider ''sanitary condition'' to be a state of cleanliness. The term ''sanitize'' is associated with the reduction of potentially harmful microorganisms. Section 1.906(b) further states that the requisite sanitary conditions of vehicles and transportation equipment are to be determined by the ''intended use'' of the vehicles and equipment in order ''to prevent the food they transport from becoming unsafe during transportation operations.'' Accordingly, as we state in our response to Comment 2, we recognize that the applicable sanitary transportation practices may vary depending on the types of food that are being transported. More stringent practices, for example, that might be necessary to ensure the sanitary transportation of one type of food, *e.g.,* human food or pet food, might not be necessary to ensure the sanitary transportation of a different category of food, *e.g.,* animal feed. Our response to Comment 2 discusses revisions we have made to §§ 1.906 and 1.908 to clarify this point. However, whether the transportation operation involves human food or animal feed, the responsible persons under this rule must use all necessary sanitary transportation practices, given their circumstances, to prevent the food from becoming unsafe.

(Comment 96) One comment states that proposed § 1.906(b)'s requirement that vehicles and transportation equipment, such as hoses and pumps, be maintained in a ''sanitary'' condition is too ambiguous. The comment asks what it means for vehicles and equipment to be clean or sanitary, how we expect firms to meet this regulatory requirement, and what other types of transportation equipment we anticipate will be subject to this provision. The comment asserts that under certain circumstances, animal feed for livestock can still be protected from becoming unsafe even if the equipment used to transport it is not sanitary, clean, or washed out prior to shipment. The comment states, for example, that a firm can use dedicated equipment, product sequencing, and equipment flushing with water or another appropriate fluid followed by blowing the lines clear. Another comment states that railway hopper cars and semi-trailers used for transporting feed ingredients are not always dedicated to a single ingredient, but rather frequently are also used to haul RACs. This comment notes that, as a matter of current industry practice, cleaning between feed ingredient and RAC loads is minimal because there is an assumption that minor co-mingling of different plant materials does not result in adulteration or otherwise present health hazards.

(Response 96) We are requiring in § 1.906(b) that vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent food from becoming unsafe during transportation operations. We are not prescribing, in this rule, methods (such as washouts) for the cleaning and maintenance of vehicles and equipment, nor are we establishing required intervals for cleaning operations. Firms may employ any cleaning procedures and intervals that meet the requirements of this rule.

(Comment 97) One comment states that the term ''sanitary'' as used in proposed § 1.906(b), and throughout the rule, is misleading because its general meaning infers a standard that exceeds the common understanding of the term ''clean.'' The comment states that transportation equipment and containers for animal feed for livestock do not need to be ''sanitary,'' but clean enough so as to prevent adulteration of the feed. The comment suggests that we delete the word ''sanitary'' from the rule except when we refer to the transportation requirements for human or pet food.

(Response 97) We decline to remove, or otherwise limit the use of, the word ''sanitary'' from this rule. We have not defined this term to mean ''beyond clean'' and our use of this term in the rule is not ambiguous. As we note in our response to Comment 95, we consider the term ''sanitary'' to be a state of cleanliness and we do not consider the term ''sanitary'' to mean that vehicles and transportation equipment necessarily must be ''sanitized'' to ensure that food is not rendered unsafe during transportation operations. We use the word ''sanitary'' in §§ 1.906 and 1.908 as it would apply to the conditions and controls employed for transportation operations, vehicles, and equipment to ensure that food will not be rendered unsafe during transportation. This is consistent with our responsibilities under section 7202 of the 2005 SFTA, which states that we shall, by regulation, require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food unsafe.

Finally, as we also state in our response to Comment 2, we agree that this rule should more clearly recognize that sanitary transportation practices may differ depending on the types of food being transported, for example, human food versus animal food. Our response to that comment discusses revisions we have made to §§ 1.906 and 1.908 to clarify this point.

(Comment 98) One comment asks us to acknowledge that polymerized oil residues that form on the interior steel surfaces of rail tanker cars during the repeated hauling of edible oils for processing into feed ingredients do not adulterate the oil. The comment notes that these residues only present food quality concerns and are removed by filtration and further processing.

(Response 98) We agree. Residues that may form during edible oil transportation operations as described in the comment, which we would expect to be removed during further processing steps, are constituents of the oil which are not toxic by nature and do not make the food unsafe.

3. Proposed § 1.906(c)

We proposed to require that vehicles and transportation equipment that are used in transportation operations for food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation must be designed, maintained, and equipped, to maintain the food under temperature conditions that will prevent the rapid growth of undesirable microorganisms. Consistent with a decision to more narrowly focus this rule on adulteration linked to food safety and to add flexibility with regard to the approach to monitoring

temperature control as explained in responses to comments below, in this final rule we have revised proposed § 1.906(c), with consideration of the provisions of proposed § 1.906(d), such that final § 1.906(c) requires that vehicles and transportation equipment used in transportation operations for 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 operations.

(Comment 99) Several comments ask that we acknowledge that means other than refrigerated vehicles can be used to keep food adequately cold during transport. These include the use of ice, dry ice, insulated coolers, and cooler totes. Another comment asks us to clarify that firms are not required to purchase cold foods from vendors with refrigerated vehicles, that is, the comment seeks clarification that firms can purchase cold foods from vendors who use means other than refrigerated vehicles for purposes of maintaining necessary temperature control of food products during transport.

(Response 99) There is no requirement in this rule that foods subject to temperature control requirements must be transported in refrigerated vehicles or must be purchased from vendors with refrigerated vehicles. The use of the alternative methods described in this comment for keeping food cold during transport are acceptable under this rule if the vehicles, for example, catering trucks and commissary delivery vehicles, equipment, and transportation operations comply with the requirements of §§ 1.906 and 1.908.

4. Proposed § 1.906(d)

We proposed to require that each freezer and mechanically refrigerated cold storage compartment in vehicles or equipment used in transportation operations for food that can support the rapid growth of microorganisms in the absence of temperature control during transportation must be equipped with an indicating thermometer, temperature measuring device, or temperature recording device to show the temperature accurately within the compartment. We have removed § 1.906(d) as proposed from the rule.

(Comment 100) A few comments address this proposed requirement. A participant at one of the public meetings we held on the proposed rule stated that we should require a temperature recording device for all transport vehicles that use refrigeration. One submitted comment states that it should not apply to a carrier if the shipper has provided its own device or relies on measures such as ice packs to maintain adequate temperature control. Another comment asks us to explicitly permit the use of hand-held temperature recording devices as an alternative to devices installed in or on a cold storage cooler. A few comments assert that low cost, time-temperature indicators are generally adequate for temperature monitoring purposes and that we should not require the use of expensive installed recording devices. A comment from the seafood industry states that ensuring continuous temperature control during the entire transit time requires the use of time-temperature recording devices (or the effective use of ice or other cooling media) and that indicating thermometers and temperature measuring devices are inadequate because they do not provide continuous documentation of temperature readings.

(Response 100) We agree that there are a number of effective methods for monitoring temperature control during food transportation, some of which do not require the permanent installation of a device in the compartment. We reconsidered this proposed provision and have determined that persons subject to this rule should be able to use any effective means to monitor temperature control, such as those suggested by the comments, and that it is not necessary to retain this proposed requirement. Therefore, we have removed this provision from this final rule.

(Comment 101) One comment also states that the proposed rule did not discuss the need for temperature indicating devices to be checked for accuracy and calibration.

(Response 101) As we stated in our response to Comment 100, we have removed the requirement that vehicles and transportation equipment be equipped with a temperature indicating device from this final rule. Therefore, there is no need to establish temperature measuring equipment calibration requirements in this final rule.

5. Proposed § 1.906(e)

We proposed to require that vehicles and transportation equipment must be stored in a manner as to prevent the vehicles or transportation equipment from harboring pests or becoming contaminated in any other manner that could result in food for which they will be used becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations. Consistent with a decision to more narrowly focus this rule on adulteration linked to food safety as explained in responses to comments that follow (particularly see Comment 89), in this final rule we are requiring that vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in food for which it will be used becoming unsafe during transportation operations. In the final rule, this provision is redesignated § 1.906(d) consistent with the removal of proposed § 1.906(d).

(Comment 102) One comment notes that some end-users store pallets used in transportation operations out-of-doors prior to use. The comment argues that end-users' pallet storage practices are just as, if not more, important for food safety than the programs and processes followed by pallet manufacturers and that pallets must be stored in an area with adequate light and airflow to prevent the formation of mold on the pallets.

(Response 102) We have established requirements for the storage of transportation vehicles and equipment, including pallets, in § 1.906(d). The outdoor storage of pallets is permissible if the pallets meet the requirements of this section when they are used in transportation operations, *i.e.,* they must be in such a condition that they will not cause the food that will be placed on them to become unsafe. When pallets are used to hold fully packaged foods, no or minimal cleaning may be necessary after outdoor storage. However, when they are used in such a way that ready to eat food comes into contact with the pallet, such as when they are used to hold some open mesh crates of produce, cleaning may be necessary after outdoor storage, especially if visible contaminants are present.

(Comment 103) One comment states that railroad carriers shouldn't be responsible for how a railcar is stored at a third-party facility and asks us to clarify that the current industry practice of storing railcars on spur tracks and in rail yards is acceptable.

(Response 103) We agree that the storage of railcars on spur tracks and in rail yards is acceptable if such storage meets the requirements of this rule (*e.g.,* it does not become infested with rodents in such a way that subsequent cleaning will be ineffective). In most cases, empty railcars will be cleaned by or for the shipper after such storage, before use in holding food. However, if a railcar is stored in a manner that can lead to food that is subsequently loaded onto it becoming unsafe, that food may

be rendered adulterated. Determining who is responsible for such adulteration would be performed on a case-by-case basis, according to the specifics of the situation. As discussed in section IV.E.2., a shipper must develop and implement written procedures adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food. These measures may be accomplished by the shipper or undertaken by the carrier or a third party.

E. What requirements apply to transportation operations? (§ 1.908)

In table 8, we describe revisions to proposed § 1.908 and following the table we respond to comments related to these provisions.

TABLE 8—§ 1.908 WHAT REQUIREMENTS APPLY TO TRANSPORTATION OPERATIONS?

Proposed section	Description	Revision
1.908(a)	General Requirements	
1.908(a)(1)	Requirements apply to all shippers, carriers, loaders, and receivers and a person may be subject to these requirements in multiple capacities.	Added ''loaders'' to the provision and moved statement out of individual definitions that a person could be, for example, both a shipper and a carrier.
1.908(a)(2)	Ensuring compliance with requirements must be assigned to competent supervisory personnel.	No change.
1.908(a)(3)(i)–(iii)	Transportation operations must be conducted so as to prevent food from becoming unsafe, including taking measures such as segregation, isolation, and packaging to separate foods; taking protective measures for food in bulk vehicles or not completely enclosed in a container from contamination and cross contact; and ensuring that food that requires temperature control for safety is transported under adequate temperature control.	Replaced ''filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health'' with ''unsafe'' in 1.908(a)(3) and replaced description of ''food that can support the rapid growth of undesirable microorganisms in the absence of temperature control'' with ''food that requires temperature control for safety'' in 1.908(a)(3)(iii).
1.908(a)(4)	Specify relevant factors (*e.g.,* animal food vs. human food, raw material vs. finished food) in determining the necessary conditions and controls for the transportation operation.	New provision.
1.908(a)(5)	Specify that shippers, receivers, loaders and carriers which are under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of paragraphs (b), (d), and (e) of this section may conduct transportation operations in conformance with common, integrated, written procedures that ensure the sanitary transportation of food consistent with the requirements of this section.	New provision.
1.908(a)(6)	If a covered entity becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe the food shall not be sold or otherwise distributed until it is determined that the temperature deviation or other condition did not render the food unsafe.	New general requirement, which was previously assigned to the receiver in consultation with the carrier and the shipper.
1.908(b)	Requirements applicable to shippers	
1.908(b)(1)	Requires that the shipper provide in writing to the carrier and, when necessary, the loader all necessary sanitary specifications for the carrier's vehicle and transportation equipment to prevent the food from becoming unsafe. The shipper may take other measures in accordance with 1.908(b)(3).	Added ''loaders'' to the provision and the clause that a shipper may take other measures in accordance with 1.908(b)(3). Added that a one-time notification of the sanitary specifications shall be sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported.
1.908(b)(2)	Shipper must specify in writing to the carrier, except a carrier who transports food in a thermally insulated tank, and when necessary the loader an operating temperature including, if necessary, the pre-cooling phase for a food requiring temperature control for safety. Shipper may take other measures in accordance with 1.908(b)(5) to ensure adequate temperature control.	Was proposed as 1.908(b)(3) and required the shipper of a ''Time/temperature control for safety'' (TCS) food to provide information on the temperature conditions necessary for transport in writing to the carrier to prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being injurious to health. The revised provision focuses on the food safety concerns with temperature control.
1.908(b)(3)	Shipper must develop and implement written procedures adequate to ensure that vehicles and equipment are in appropriate sanitary condition for the transport of food. Measures to implement the procedures may be done by the shipper or another party under the terms of a written agreement.	New provision.
1.908(b)(4)	Shipper of food transported in bulk must develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe. Measures to implement the procedures may be done by the shipper or another party under the terms of a written agreement.	New provision.

TABLE 8—§ 1.908 WHAT REQUIREMENTS APPLY TO TRANSPORTATION OPERATIONS?—Continued

Proposed section	Description	Revision
1.908(b)(5)	Shipper of food that requires temperature control for safety must develop and implement written procedures to ensure the food is transported under adequate temperature control. Measures to implement the procedures may be done by the shipper or another party under the terms of a written agreement and must include measures equivalent to those specified for carriers under 1.908(e)(1)–(3).	New provision.
1.908(c)	Requirements applicable to loaders	
1.908(c)(1)	Before loading food not completely enclosed by a container, the loader must determine, based as appropriate on shipper specifications, that the vehicle or transportation equipment is in appropriate sanitary condition (*e.g.,* adequate physical condition, free of visible evidence of pest infestation, and previous cargo that could make the food unsafe).	This new requirement for loaders is similar to requirements that were proposed for the shipper at proposed 1.908(b)(2), but the shipper may not be on site. Proposed 1.908(c)(1) was about access to handwashing facilities and has been removed from the rule.
1.908(c)(2)	Before loading food requiring temperature control for safety, the loader must verify, considering as appropriate the shipper specifications, that each mechanically refrigerated cold storage compartment or container is adequately prepared, including proper pre-cooling if necessary.	This new requirement for loaders is similar to proposed 1.908(c)(2), which required shippers and receivers of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control to load and unload under conditions that would not support such growth. This new loader requirement is also similar to proposed 1.908(b)(4) which required shippers to verify that each mechanically refrigerated cold storage compartment or freezer has been properly pre-cooled.
1.908(d)	Requirements applicable to receivers engaged in transportation operations. Upon receipt of a food requiring temperature control for safety, receivers 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, or smelling for off-odors.	This provision specifically for receivers is new, resulting from comments and our understanding that receivers would typically make a determination that a shipment may have been subject to significant temperature abuse. Proposed 1.908(d) contained the provisions applicable to carriers, which are finalized as 1.908(e) in this rule.
1.908(e)	Requirements applicable to carriers	
1.908(e)(1)	Per an agreement with the shipper that the carrier is responsible, the carrier must ensure that vehicles and equipment meet the shipper's specifications in accordance with 1.908(b)(1) is otherwise appropriate to prevent the food from becoming unsafe.	Similar to proposed 1.908(d)(1) except "filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health" has been replaced with "unsafe" per our focus on adulteration linked to food safety.
1.908(e)(2)	Per an agreement with the shipper that the carrier is responsible, upon completion of the transport and if requested by the receiver, provide the operating temperature specified by the shipper and, if requested by the shipper or receiver, demonstrate that temperature conditions were maintained during transport consistent with shipper specifications.	Similar to proposed 1.908(d)(2) which would have required the carrier to demonstrate to shippers and, if requested, to the receiver that temperature conditions were maintained consistent with shipper specifications. The revisions in final 1.908(e)(2) are consistent with our new provision in 1.908(d) that receivers take steps to adequately assess that the food was not subjected to significant temperature abuse.
1.908(e)(3)	Per an agreement with the shipper that the carrier is responsible, carriers must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper before offering a vehicle for transport of food requiring temperature control for safety.	Similar to proposed 1.908(d)(3) except that the focus is on food requiring temperature control for safety rather than foods that support the rapid growth of undesirable microorganisms, such as those that cause spoilage. The focus on food safety is also why the final provisions regarding pre-cooling have eliminated references to freezers, since it is likely that there would be significant quality defects with time/temperature abused frozen foods prior to the point at which they would become unsafe.
1.908(e)(4)	Per an agreement with the shipper that the carrier is responsible and if requested by a shipper, a carrier that offers a bulk vehicle must identify the previous cargo.	Similar to proposed 1.908(d)(4), which would have required the carrier to identify the three previous cargoes. We realized that requiring provision of three previous cargoes was not necessary for food safety and we heard in comments that a carrier may not have any previous cargo information in the normal course of its business. Therefore, our final provision specifies that this information must be provided by the carrier if it agrees to provide the information. Otherwise, the shipper is responsible for considering the sanitary requirements necessary to prevent food from becoming unsafe during transport.

TABLE 8—§ 1.908 WHAT REQUIREMENTS APPLY TO TRANSPORTATION OPERATIONS?—Continued

Proposed section	Description	Revision
1.908(e)(5)	Per an agreement with the shipper that the carrier is responsible and if requested by a shipper, a carrier that offers a bulk vehicle must provide information that describes the most recent cleaning of the vehicle.	Similar to proposed 1.908(d)(5), which would have required the carrier to describe the most recent cleaning of the bulk vehicle to the shipper. We heard in comments that a carrier may not have any previous cleaning information in the normal course of its business. Therefore, our final provision specifies that this information must be provided by the carrier if it agrees to provide the information. Otherwise, the shipper is responsible for considering the sanitary requirements necessary to prevent food from becoming unsafe during transport.
1.908(e)(6)(i)—(iii)	Carriers must develop and implement written procedures that (i) specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment to maintain them in appropriate sanitary condition, (ii) describe how it will comply with the temperature control requirements in 1.908(e)(2), and (iii) describe how it will comply with the provisions for use of bulk vehicles in 1.908(d)(4) and (d)(5).	No change from proposed 1.908(d)(6), except to change references to paragraph (d) to (e).

1. General Requirements (Proposed § 1.908(a))

We set forth in proposed § 1.908(a) general provisions and requirements applicable to transportation operations.

(Comment 104) We received many comments expressing concern that the proposed rule did not sufficiently recognize that practices for the transportation of raw materials may differ from those for finished food products, and that practices for the transportation of animal feed may differ from those used to transport pet food and finished human food.

(Response 104) We agree with the comments and have added new § 1.908(a)(4) to make it clear that the type of food *e.g.,* animal feed, pet food, human food, and its' production stage *e.g.,* raw material, ingredient or finished food, are relevant to and must be considered in determining the necessary conditions and controls for transportation operations.

(Comment 105) One comment expresses concern about the potential for cross contamination during the transportation of RACs. The comment states that the cross utilization of any equipment, including transportation vehicles, should be conducted in a manner that does not subject RACs to contamination and that equipment used to transport any food products that are minimally processed and consumed raw should be subject to sanitary requirements tailored to ensure the safety of the products.

(Response 105) We agree that cross utilization of vehicles and equipment should not subject any food, including RACs, to cross contamination during transport. The provisions of § 1.906 require the design, maintenance and storage of vehicles and transportation equipment, to be such that they will not cause food to become unsafe during transportation operations. In addition, § 1.908(a)(3), which in part addresses the proper use of vehicles and equipment in transportation operations, requires that all transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe.

a. Proposed 1.908(a)(1)

As previously discussed in the sections of this document related to the definitions of carrier, shippers and receivers, we have removed from these definitions the proposed sentence in each definition that stated that a party may serve in more than one capacity under this rule, *e.g.,* a carrier may also be a receiver or a shipper, if the person also performs the functions of those respective persons. While we affirm that these statements are valid, we have consolidated them into a new sentence at § 1.908(a)(1), which states that a person may be subject to these requirements in multiple capacities, *e.g.,* the shipper may also be the loader and the carrier, if the person also performs the functions of those respective persons as defined in this subpart.

b. Proposed 1.908(a)(3)

(Comment 106) One comment asserts that the requirements of this rule appear to duplicate warehousing and distribution requirements that appear in the FSMA preventive controls for human food rule, which require that food storage and transportation must be conducted under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and its container.

(Response 106) The preventive controls rule for human food requirements in 21 CFR 117.93 provide broad good manufacturing practice (GMP) standards for warehousing and transportation-related activities that occur within the context of warehousing and distribution operations of facilities engaged in the manufacturing, packing, and holding of human food. This rule is intended to be complimentary to those and other provisions of the Preventive Controls rules for human and animal food and establishes more detailed requirements for shippers, loaders, receivers, and carriers to use sanitary transportation practices to ensure that food is transported under conditions that will prevent it from becoming unsafe. This is FDA's only rule that addresses the transportation of food in an integrated manner from beginning to end by establishing the interactions that must occur between shippers, loaders, carriers, and receivers to ensure that sanitary food transportation practices are used by the food industry. It is also the only rule to which carriers are directly subject. Accordingly, this rule is not redundant, as asserted by this comment, because it expands on the transportation-related requirements contained in the GMPs.

(Comment 107) A few comments question the appropriateness of using the terms ''under such conditions and controls necessary to prevent the food from becoming . . . decomposed or otherwise unfit for food'' to describe requirements for transportation

operations. The comments state that fresh fruits and vegetables are perishable food products and therefore by their very nature eventually enter the senescence stage and begin to degrade (decompose) after they are harvested. The comments further state that such foods can be in this stage during transportation without yet becoming unfit for food. These comments assert that we are confusing the concepts of food safety and food quality by including these terms in this rule. The comments state that the terms should be removed and that the final rule should be strictly limited to ensuring the safe transportation of human and animal food.

(Response 107) We acknowledge in our response to Comment 89 that we applied the language from section 402 of the FD&C Act in an overly broad manner in the proposed rule, so as to suggest, unintentionally, that any food in transport that is undergoing a natural process, *i.e.,* senescense, is per se adulterated under this rule. As we also note in our response to Comment 89, we have revised § 1.908(a) in this final rule to state that the intent of this provision is to prevent food from becoming unsafe. We would not regard perishable fruits and vegetables that are senescing during transport to be adulterated or unsafe.

(Comment 108) One comment encourages us to ensure that time/temperature control provisions of this final rule will complement related provisions contained in our seafood HACCP regulation.

(Response 108) Our intent in drafting this final rule is to make it compatible with the seafood HACCP rule, which does not include requirements applicable to carriers. Under the seafood HACCP regulation, receivers are required to ensure that transportation was performed under appropriate temperature control, where such control is necessary for the safety of the food. To accomplish this, receivers of seafood often request temperature monitoring information from the carrier upon receipt. As we discuss in our response to Comment 129, this rule should assist receivers of seafood products by requiring that, upon their request, carriers must provide the operating temperature specified by the shipper and demonstrate that it has maintained temperature conditions during the transportation operation consistent with that operating temperature.

c. Proposed 1.908(a)(3)(i)

We proposed to require that persons take effective measures, such as segregation or isolation, to prevent raw foods and nonfood items from contaminating other food products that might be shipped in the same load during transportation operations.

(Comment 109) One comment addressing proposed § 1.908(a)(3)(i) asserts that current industry practices ensure the adequate separation of ready-to-eat food items from raw foods and nonfood items through the use of packaging and impermeable barriers. The comment also states that our *Food Code* (Ref. 28) also considers packaging to be an adequate barrier for protecting food from contamination. Section 3–302.11 A. (4) of the *Food Code* states that ''[f]ood shall be protected from cross-contamination by storing the food in packages, covered containers, or wrappings.'' The comment argues that because we acknowledged in the proposed rule that industry has developed practices that ''ensure that food is adequately protected from contamination by raw food items on the same load,'' there is no need to include the ''segregation and isolation'' language in this rule. The commenter further stated, however, that if we retain this language in the final rule, we should revise it to clarify that this provision should not be interpreted as requiring the complete isolation of raw foods from ready-to-eat foods during transportation.

(Response 109) The 2005 SFTA mandates that we issue regulations to require that shippers, carriers, receivers and other persons engaged in the transportation of food use sanitary transportation practices to ensure that food does not become adulterated during transportation. We agree that both packaging, and segregation or isolation can be effective means of protecting food from contamination by raw foods or nonfood items in the same load. Therefore, we have revised proposed § 1.908(a)(3)(i) to include packaging as one of the examples of such preventive measures during transportation operations.

d. Proposed 1.908(a)(3)(ii)

We proposed to require that persons engaged in transportation operations take effective measures such as segregation, isolation, or other preventive 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.

(Comment 110) One comment addressing proposed § 1.908(a)(3)(ii) asserts that persons who handle animal feed or raw feed ingredients without using gloves or washing their hands are not going to contaminate or adulterate food while engaged in loading, unloading, or transportation activities. The comment, therefore, asks us to exempt persons who handle animal feed from this provision.

(Response 110) This provision does not require that persons who handle animal feed or raw feed ingredients always wear gloves and/or wash their hands. These measures are provided only as examples of steps persons may take to meet the requirements of this rule. As proposed, § 1.908(a)(3)(ii) provides persons engaged in food transportation the flexibility to determine for themselves which measures are necessary to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations. For this reason, we have not modified this section.

e. Proposed 1.908(a)(3)(iii)

We proposed to require persons engaged in the transportation of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation to follow transportation practices, including attention to temperature conditions, to prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source.

(Comment 111) Several comments ask us to reconsider including temperature control requirements for non-TCS foods that require temperature control only for purposes of preventing spoilage and not for purposes of ensuring food safety.

One comment states that because there are no potential safety hazards associated with such non-TCS foods, strict transportation temperature control requirements are not warranted. One comment observes that we proposed to exempt facilities that hold completely packaged refrigerated food from the requirements of the proposed FSMA preventive controls rule for human food, with the exception of facilities that hold TCS food. Under the preventive controls rule, facilities that hold such TCS food are only subject to preventive controls requirements to provide appropriate temperature control for such food. The comment asserts that we should not impose more stringent requirements on the transportation of food than we require for the holding of food under the preventive controls rule. The comment asserts that this rule, therefore, should not apply transportation requirements for temperature control to non-TCS foods that require temperature control

only for purposes of preventing spoilage.

One comment acknowledges that the language of the 2005 SFTA is somewhat different from the language FSMA in that it directs us to issue regulations that are meant to ensure that food is not transported under conditions that may render the food adulterated. The comment further notes that adulteration is broadly defined by the FD&C Act and can encompass issues such as food spoilage in addition to the narrower issue of food safety. However, this comment states that such considerations are already addressed by the FD&C Act's adulteration provisions in section 402, and notes that FDA has the discretion to implement the provisions of the 2005 SFTA in a manner consistent with a risk-based framework focused more narrowly on food safety risks.

Another comment states that while the temperature control provisions of this rule should not address non-TCS foods, it does not object to the inclusion of references in § 1.906 to the prevention of the rapid growth of undesirable microorganisms (which would include microorganisms that cause spoilage) with respect to the design and maintenance of vehicles and transportation equipment, and in § 1.908 with respect to conditions for loading and unloading food, because these provisions do not relate to the maintenance of temperature control during transportation.

(Response 111) We agree with the comments and explain in our response to Comment 89 that we have revised this rule to require temperature control only for foods that require temperature control for safety. Conversely, the temperature control requirements do not apply to food that is transported under temperature control for other reasons, for example, for marketability purposes, or to prevent spoilage of the food. In particular, we agree with the comment that stated that nonsafety considerations are already adequately addressed by the FD&C Act's adulteration provisions in section 402, and that we have the discretion to implement the provisions of the 2005 SFTA in a manner consistent with a risk-based framework focused more narrowly on food safety hazards.

We also have reconsidered whether to define a descriptive category for the type of food (*i.e.,* ''Time/Temperature Control for Safety (TCS) Food'') that would be subject to the temperature control provisions of this rule. We conclude that such a definition would serve no purpose because the revision we discuss in the preceding paragraph adequately designates the foods that would be subject to this rule's temperature control requirements. Therefore, we have removed the term ''Time/Temperature Control for Safety (TCS) Food'' in the definitions section of this final rule in § 1.904 and we have removed from this final rule the descriptive categories, ''TCS and non-TCS,'' which appeared in § 1.908(b)(3) of the proposed rule.

The temperature control requirements of this rule apply to any food that requires temperature control for safety during transport, and foods in the latter category, though not subject to the temperature control requirements of this rule, are still subject to the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations.

(Comment 112) One comment asks us to rewrite the temperature control provisions of this rule to clarify the requirements applicable to TCS and non-TCS foods. Other comments recommend that we establish temperatures for use by shippers in crafting instructions to be given to carriers, to prevent discrepancies in temperature control recommendations among shippers. Some comments also suggest that we should provide guidance to the transportation industry for temperature control that would include extensive lists of TCS and non-TCS foods. One of these comments states that clarifying temperature controlled food requirements and providing such guidance would have the added benefit of assisting regulators tasked with the responsibility of enforcing this rule. One comment asks us to establish a maximum transportation temperature of 45 degrees Fahrenheit for TCS foods.

(Response 112) We decline these requests. As we explain in our response to the preceding comment, we have removed the term ''Time/Temperature Control for Safety (TCS) Food'' from the definitions section of this final rule in § 1.904, and we have removed from this final rule the descriptive categories ''TCS and non-TCS,'' which appeared in § 1.908(b)(3) of the proposed rule. We have replaced the definition with the concept of ''foods that require refrigeration for safety.''

Because of the vast diversity of human and animal food types, FDA does not have the resources to compile exhaustive lists of foods that require or do not require temperature control for refrigeration nor a list of the appropriate temperature controls for foods. Such a task is made even more daunting because similar foods produced by different manufacturers may have different temperature control requirements, because of differences in formulation. We expect shippers of food to be aware of whether the foods that they are shipping require refrigeration for safety, either because they are the manufacturer of the food or are otherwise knowledgeable about the food safety attributes of the food, or because they have obtained such information from the manufacturer or another knowledgeable person. The Preventive Controls rules for human and animal food require the manufacturer of a food to consider the transportation needs of foods that they manufacture when they develop their food safety plans.

Furthermore, as we explain in our response to Comment 129, we are no longer requiring shippers to specify temperatures to carriers that would be regarded as critical limits for food safety purposes. In many circumstances, the shipper is required to specify an operating temperature to the carrier, and the food is not necessarily unsafe or otherwise adulterated if that temperature is exceeded during transportation. Operating temperatures are generally set to allow for refrigeration compartment temperature fluctuations due to normal activities such as defrosting and opening and closing doors. They also are often set to minimize product deterioration, which is usually a more restrictive requirement than food safety. Regulatory limits for operating temperatures would need to integrate all of these factors for the diversity of foods and operations on the market. We will consider establishing guidance in the future for operating temperatures for the transportation of foods that require temperature control, should the need arise.

We disagree with the suggestion that we should establish a maximum transportation temperature of 45 degrees Fahrenheit for TCS foods. As we explain in our response to Comment 129, we have established requirements, as revised in this final rule, that would preclude the sale or distribution of any food that upon receipt presents an indication of a possible temperature control material failure during transport, unless it can be determined that the temperature deviation has not rendered the food unsafe. We conclude that this is an appropriate science-based approach to apply when assessing whether a potentially significant temperature deviation has occurred during transport because it provides for consideration of all significant factors, *e.g.,* the ability of the specific food to support pathogens that are reasonably likely to be present in the food, and the duration of the temperature deviation, rather than simply whether a

temperature limit was exceeded. Furthermore, allowing a TCS food to be transported at temperatures up to 45 degrees Fahrenheit would not provide appropriate temperature control for some TCS foods, which may have to be transported at lower temperatures to ensure the safety of the food, *e.g.,* some vacuum packaged fish.

(Comment 113) We requested comment in the proposed rule regarding whether, unlike the proposed regulation, the final regulation should apply to the transportation by farms of TCS RACs, which require time/temperature control for food safety purposes, *e.g.,* raw seed sprouts. One comment offers the view that we should not include transportation by farms of TCS RACs in this regulation and that the industry's current best practices, which were not identified in the comment, sufficiently protect TCS RACs from adulteration during transportation.

(Response 113) As we discuss in our response to Comment 111, we have removed the term ''Time/Temperature Control for Safety (TCS) Food'' from the definitions section of this final rule in § 1.904, and we have removed from this final rule the descriptive categories ''TCS and non-TCS,'' which appeared in § 1.908(b)(3) of the proposed rule. Nonetheless, we received no comments that provided any information that changed our tentative conclusion to exclude from coverage TCS RACs when they are being transported by farms. Consequently, we have made no change in that regard. However, when such a RAC is being transported by a person other than a farm, it is subject to the applicable provisions of §§ 1.906 and 1.908 of this rule that require transportation temperature control when it is necessary to prevent the food from becoming unsafe.

(Comment 114) One comment asks us to acknowledge that fresh whole apples, pears, and cherries are transported under temperature control exclusively for quality purposes. The comment also asks us to acknowledge that we regard these fruits as being comparable to bananas, which we stated in the proposed rule are not subject to proposed § 1.908(a)(3)(iii) because there is no risk they will become adulterated if they are transported under conditions that are not temperature controlled. Another comment asks us to provide more examples of foods that would not be subject to proposed § 1.908(a)(3)(iii), and suggests that these additional examples should include potatoes intended for processing into potato chips and chocolate and dairy based seasoning ingredients. The comment also asks us to train FDA inspectors to understand the circumstances under which foods would or would not require temperature control under this rule. Another comment asks us to exclude nuts, which are sometimes refrigerated during transport for quality purposes, from the scope of proposed § 1.908(a)(3)(iii).

(Response 114) This rule only requires temperature control during transportation when it is necessary to prevent the food from becoming unsafe. This rule does not establish requirements for the use of temperature control during food transportation for any other purpose, such as for marketability purposes, or to preclude the spoilage of food subject to this rule. We will ensure that our inspectors understand which factors generally distinguish foods that require temperature control to prevent the food from becoming unsafe from other foods that are transported under temperature control for quality purposes. As discussed earlier in this document, shippers are responsible for determining whether a food is subject to the temperature control provisions of this rule, because they require temperature control for safety. Whole, fresh apples, cherries, pears and potatoes are all examples of foods that generally do not require temperature control for safety. As we state in our response to Comment 112, we do not have the resources to provide an exhaustive list of foods that are transported under temperature control only for marketability purposes.

(Comment 115) One comment asserts that the temperature control provisions of this rule do not apply to the transportation of refined fats and oils. The comment notes that the presence of temperature specifications in transportation documents such as bills of lading is related to quality and performance attributes of the refined fats or oils, and therefore should not serve as a basis for extending this rule's temperature control provisions to the transportation of refined fats and oils. The comment also notes that refined fats and oils are manufactured in closed systems and that the final product does not support the growth of undesirable microorganisms.

(Response 115) We recognize that there may be occasions where temperature control is necessary for maintaining certain product attributes such as product quality, but not to prevent the food from becoming unsafe, as is the case, generally, for refined fats and oils. If temperature control is not required to prevent the food from becoming unsafe during transportation, the temperature control provisions of this rule do not apply to those transportation operations.

2. Requirements Applicable to Shippers Engaged in Transportation Operations (Proposed § 1.908(b))

a. Proposed § 1.908(b)(1)

We proposed to require that the shipper must specify to the carrier, in writing, all necessary sanitary requirements for the carrier's vehicle and transportation equipment, including any specific design requirements and cleaning procedures to ensure that the vehicle is in appropriate sanitary condition for the transportation of the food, *e.g.,* that will prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during the transportation operation. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a) of this rule.

(Comment 116) One comment states that proposed § 1.908(b)(1) should be revised so that it would apply only to requirements for the carrier's vehicle and transportation equipment that exceed the carrier's basic obligation to provide vehicles and transportation equipment that are clean, appropriate, and in safe condition for transportation of the food intended to be shipped.

(Response 116) As we state in our response to Comment 119, we are aware that written information sharing between shippers and carriers currently is a routine part of the working relationship between these entities. We are retaining § 1.908(b)(1) to ensure that all necessary requirements for the preparation of a vehicle or transportation equipment are communicated to carriers. However, this provision allows the shipper to use reasonable judgment in deciding what information must be communicated to a carrier to meet the requirements of this rule. We understand that a shipper could reasonably determine that it is not necessary to specify any procedures that are commonly understood by carriers such as those described by the comment.

We have, however, modified this provision in several ways. First, because we have added a definition of loader, in response to comments that urged that we account for activities performed by the person loading a vehicle when that person is not also the shipper, receiver or carrier (see Comment 70). We recognize that there will be times when the shipper must provide instructions to the loader in addition to the carrier, *e.g.,* instructions about any special sanitary

conditions to look for during the a preloading inspection. For this reason, we have included the loader as a person to whom the shipper must provide instructions about the sanitary specifications for the carrier's vehicle, when necessary. Second, we have changed the word ''requirements'' to ''specifications'' in two places in this provision. We believe that this word better conveys the idea of conditions set out by the shipper to the carrier and loader, and is less likely to be confused with regulatory requirements of the rule. Third, we have changed the proposed phrase ''prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health'' to ''prevent the food from becoming unsafe'' for consistency with our previously stated objective of focusing this final rule on food safety only. Finally, we have prefaced the requirement with the phrase, ''unless the shipper takes other measures in accordance with paragraph (b)(3) of this section, to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food.'' We have added this language in response to comments from the railroad industry (see Comment 53) that stated that they generally do not have a relationship with shippers whereby the shipper provides them with instructions relative to the sanitary condition of the railcar that they are to deliver. Our intent is that the language will establish the requirements of § 1.908(b)(1) as the default arrangement whereby the shipper ensures that the vehicle and equipment meet appropriate sanitary conditions by providing instructions to the carrier and, when necessary, the loader, while also allowing for alternative arrangements (*e.g.,* whereby the shipper personally ensures that the specifications are met), when that is consistent with the shipper's written SOPs, as provided for in § 1.908(b)(3). We expect that many shippers that work with rail carriers will elect this latter approach, relieving them of the necessity to instruct the carrier about the necessary sanitary conditions for the railcar.

(Comment 117) One comment states that while obtaining written specifications from a shipper about vehicle and equipment sanitation, cleanliness procedures, and temperature requirements is an industry best practice, it is not always feasible or practical. The comment asserts that there is no evidence to suggest that shipper specifications communicated verbally to the carrier instead of in writing create a higher food safety risk.

(Response 117) We continue to assert that written specifications are consistent with industry best practice and are necessary to avoid confusion about the responsibilities of the various parties engaged in transportation operations. Such records are also valuable to assist FDA and other regulatory agencies in their verification role.

(Comment 118) One comment singles out proposed § 1.908(b)(1) as an example of a requirement for which we should afford firms flexibility and latitude to vary the content and level of detail contained in written specifications. The comment states that flexibility is needed, for example, to account for variations in the type of food type being transported, packaging, equipment, the transportation environment, and the shipper's experience with the carrier.

(Response 118) We acknowledge that numerous, variable factors can affect the types of procedures that are required to prepare a vehicle or equipment to be offered to a shipper. For example, the nature of the previous cargo transported in a tanker truck might affect the type of cleaning procedure that would need to be followed to prepare the tanker truck for its next cargo. We would expect that these types of factors will affect the content and degree of detail contained in written specifications that shippers would provide to carriers and loaders under § 1.908(b)(1). Nevertheless, the shipper must provide specifications to the carrier, and loader as necessary, that are adequate to enable them to ensure that the vehicle or transportation equipment is in appropriate sanitary condition for the transportation of the food, *e.g.,* that will prevent the food from becoming unsafe during the transportation operation.

(Comment 119) One comment asserts that the food transportation industry already has proven its ability to manage successfully information sharing between shippers and carriers through, for example, contractual agreements. The comment also asserts that proposed § 1.908(b)(1) will only add an additional, unnecessary layer of recordkeeping that will not add to the goal of feed safety, and that § 1.908(b)(1) seems unnecessary, given that we require carriers to inspect transportation vehicles prior to loading. Finally, the comment states that we should provide clarification regarding how frequently information must be shared between shippers and carriers if we decide to retain this provision.

(Response 119) As this comment observes, written information sharing between shippers and carriers engaged in food transportation already is a part of the routine working relationship between these entities. We do not envision that § 1.908(b)(1) would require additional information sharing above and beyond that which routinely occurs and is necessary for purposes of enabling a carrier to offer a vehicle or transportation equipment in appropriate sanitary condition for the transportation of the food. Furthermore, the requirement in proposed § 1.908(b)(2), that a vehicle or transportation equipment be inspected prior to loading prescribed cargoes, is a verification step that also reflects existing best practice and does not obviate the need for shippers to provide specifications to carriers that are adequate to enable a carrier to offer a vehicle or transportation equipment in appropriate sanitary condition for the transportation of the food. Therefore, we are retaining this requirement.

However, as we note in our response to Comment 124, we have added language to § 1.908(b)(1) stating that a one-time notification by a shipper to a carrier, and, when necessary, to a loader, shall be sufficient, unless there is a factor, *e.g.,* the food or the conditions of shipment change, necessitating a change in the design requirements or cleaning procedures, in which case the shipper shall so notify the carrier and, as necessary, the loader in writing before the shipment.

(Comment 120) A comment observes that a shipment may change hands many times during transit as it is transferred between carriers. The comment notes that in these instances, the shipper is not in contact with all of the subsequent carriers that may be involved and, therefore, would not be in a position to ensure its original requirements are met from start to finish. Therefore, the commenter argues that the original carrier, which has initial responsibility for ensuring that the food is handled in accordance with the shipper's requirements, should be responsible for transferring that responsibility to the next carrier down the line. The comment also states that, although an overseas shipper is in the best position to know the transportation conditions appropriate for a given food shipment when it is initiated, the shipment could change hands after it arrives in the United States and the sequential carriers, therefore, should bear responsibility for ensuring that the food is handled in accordance with the shipper's requirements.

(Response 120) This rule would require that the shipper meet the requirements of § 1.908(b)(1) for all

segments of a shipment's transit, no matter how many carriers might be involved in the transportation process. As we discuss in our response to Comment 70, those requirements have been established for the shipper based upon our determination that the person who arranges for the transportation of food by a carrier, *i.e.,* the shipper, is best suited to perform these functions.

(Comment 121) A comment addressing vehicle cleaning procedures states that with the exception of food-grade tanker trucks, there are no industry standards or protocols for cleaning and sanitizing vehicles that transport food. The comment opines that, other than general statements regarding the need to supply vehicles and transportation equipment that prevent food from becoming adulterated, the rule seems to allow shippers and carriers to agree upon the required cleaning practices. The comment also offers the view that the flexibility provided for by the rule may not be adequate, given the lack of any industry standards or vehicle and equipment cleaning best practices. Finally, the comment notes that if we elect to impose vehicle and equipment cleaning standards, we must recognize that there are a limited number of vehicle washout facilities available to the transportation industry, and that they vary in the type of services they are capable of providing.

(Response 121) The commenter is correct that this rule provides flexibility to shippers and carriers to determine the appropriate protocols for cleaning transportation vehicles and equipment to comply with the requirements of this rule. In general, we do not expect that the requirements of this rule will necessitate a change in the procedures for vehicle and equipment cleaning. Nonetheless, § 1.908(b)(1) will require that these procedures be communicated to the carrier in writing. However, as we stated in response to Comment 116, this provision allows the shipper to use reasonable judgment in deciding what information must be communicated to a carrier to meet the requirements of this rule. We understand that a shipper could reasonably determine that it is not necessary to specify any procedures that are commonly understood by carriers, *e.g.,* removal of dunnage, sweeping. To the extent that there is a need for guidance on cleaning procedures that go beyond those that are commonly understood, but not as extensive as those for bulk tankers (for which there is written industry best practice, as noted by the comment) we will consider issuing guidance or working with industry trade associations to develop written industry best practice on this subject.

We are not establishing vehicle cleaning standards in this rulemaking. This rule provides flexibility to shippers and carriers to determine the appropriate protocols for cleaning transportation vehicles and equipment to comply with the requirements of this rule. We will consider issuing guidance on this subject in the future should the need arise.

(Comment 122) One comment asserts that the proposed rule lacks sufficient flexibility to ensure that it can be implemented effectively by the food transportation industry. According to the comment, shippers are not always sufficiently knowledgeable to be able to specify ''all necessary sanitary requirements for the carrier's vehicle and transportation equipment.'' The comment also observes that shippers, carriers, and receivers typically work together to establish sanitary requirements that are appropriate for each particular type of food shipment.

(Response 122) Persons responsible for complying with this rule may work with any other persons covered by this rule or third-party experts, for assistance in developing their specifications. For example, a shipper that is not the manufacturer may consult with the manufacturer or with a third-party expert.

(Comment 123) One comment states that the design and construction of tanker trucks varies across the transportation industry and that variations can occur even within a given vehicle manufacturer's model lines. According to this comment, a preparatory procedure that is suitable and adequate for one tanker, therefore, may not necessarily be suitable and adequate for a differently designed or constructed tanker, and only an individual carrier has the best knowledge of the characteristics of its particular tanker.

(Response 123) In order to prescribe the appropriate sanitary conditions for shipment of a bulk cargo, the shipper must have knowledge of the safety requirements of the food, as well as the construction of the vehicle and transportation equipment. We expect that the shipper will either have that knowledge based on prior training or experience, or will obtain information from someone with the necessary expertise. In the case of knowledge about the construction of tankers, it may well be that the shipper's best source of information will be from the carrier. An exchange of information between the carrier and the shipper, leading to a written specification from the shipper to the carrier, is fully consistent with the intent and language of § 1.908(b)(1).

(Comment 124) One comment asks us to confirm that a shipper's written communication required by proposed § 1.908(b)(1) can be executed for a particular commodity for the duration of its agreement with each carrier rather than just for each particular product load. A second comment suggests that this requirement should specify that one-time notifications will be sufficient unless the design requirements and cleaning procedures required by the shipper change because of changes in the types of food being transported, in which case the shipper would be required to supply the carrier with a new written notification.

(Response 124) We agree with both commenters. Therefore we have added the language to § 1.908(b)(1) in this final rule that states that one-time notification shall be sufficient unless a factor, *e.g.,* the food or the conditions of shipment, changes, necessitating a change in the design requirements or cleaning procedures, in which case the shipper shall so notify the carrier, and, as necessary, the loader, in writing before the shipment.

b. Proposed § 1.908(b)(2)

We proposed to require that a shipper must visually inspect the vehicle or the transportation equipment provided by a carrier for cleanliness before loading food that is not completely enclosed by a container onto a vehicle or into transportation equipment provided by the carrier. We proposed that the shipper would have to determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, for example, that it is free of visible evidence of pest infestation and of debris, of previous cargo, or of dirt that could cause the food to become adulterated (revisions to the proposed provision are discussed in Comment 89). As we previously discuss in several sections of this document, responsibility for the pre-loading inspection no longer resides with the shipper, as we had initially proposed. Rather, in this final rule, the loader now bears this responsibility under § 1.908(c)(1).

(Comment 125) One comment states that proposed § 1.908(b)(2) is inapplicable to bulk liquid tanker shipments because personnel do not enter the cavity of a tanker after it has been cleaned and made ready for loading. The comment recommends that we modify this requirement to make it goal-based by requiring the shipper to determine that the vehicle or transportation equipment is in sanitary

condition for the transport of the food by any appropriate means. The comment also asks us to provide examples of ways to accomplish this, for example, through the use of visual inspection, documentation, or cleaning.

(Response 125) We agree that the pre-loading inspection requirement in this final rule should specify the inspection's objective without restricting it to a specific method, *e.g.,* visual inspection. We have decided that the objective of pre-loading inspections should be a determination that the vehicle or equipment is in appropriate sanitary condition for the transport of food. At times, *e.g.,* transportation of food that is not fully enclosed by a container, such an inspection would generally involve a visual inspection to ensure that the walls, floors, and ceiling of the vehicle are adequately clean, such that they are not likely to cause the food to become unsafe during transportation. However, at other times, *e.g.,* bulk shipments in tanker trailers, the tanker trailer may already be washed and sealed before it arrives at the shipper's place of business, and the inspection may be as simple as checking for a wash ticket. We therefore have revised this provision in § 1.908(c)(1) to state that the loader must determine through the pre-loading inspection process that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, *e.g.,* 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. We have also revised this provision to state that this inspection may be accomplished by any appropriate means.

(Comment 126) One comment states that checking for the physical condition of a vehicle during the pre-load inspection, for example, checking for holes in the floor, walls and ceiling and the presence of off-odors and stains that might constitute residual evidence of a chemical spill or pooled water, is not specifically included in proposed § 1.908(b)(2). The comment recommends that we expand the scope of the pre-loading inspection to include these items.

(Response 126) We agree that in certain circumstances, *e.g.,* transportation of food that is not fully enclosed by a container, the items discussed in the comment should be included in a pre-loading inspection. However, we are not specifying pre-loading inspection requirements in this rule because the nature of these inspections may vary from one type of operation to another depending on what would be necessary to determine that the vehicle or equipment is in acceptable sanitary condition for its intended use for the transportation of food. We have added the physical condition of the vehicle as an example of what may be included in a pre-loading inspection in § 1.908(c)(1) of this final rule.

(Comment 127) A comment states that, during the transport of animal feed, the carrier's driver often performs loading functions without having a shipper's employee present. The comment notes that this practice is established through contract stipulations between the shipper and carrier. The shipper may also choose to inspect the truck, depending on the feed to be loaded and customer requirements. The comment further states that, as a practical matter, a bulk trailer is often inspected after delivering a load to ensure that all the feed was delivered and that it is ready for loading the next load. The commenter asserts that this practice and verification of the last load delivered, in addition to contract requirements, sufficiently ensures the safety of the feed.

(Response 127) This comment describes a situation where the carrier is also the loader. The practices described by the comment are consistent with the provisions of the final rule. In § 1.908(c), this rule requires loaders, in this case also the carrier, to take actions before loading food not completely enclosed by a container onto a vehicle or into transportation equipment to determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food. In this case, where a dedicated bulk truck is repeatedly used for the same cargo that does not require refrigeration for safety, *e.g.,* animal feed, an inspection of the inside of the bulk vehicle after delivery of a load may be sufficient to ensure that it is in a suitable condition for loading the next shipment.

(Comment 128) A few comments address proposed § 1.908(b)(2) within the context of partial load shipments, which are also known as less-than-truckload (LTL) shipments. LTL shipments are those in which additional loads are subsequently added to a partially loaded truck. These comments state that the shipper of a partial load will likely be present only for the loading of its own shipment, but not for subsequent loads, and therefore cannot ''visually inspect the vehicle . . . for cleanliness'' or ensure ''that the vehicle . . . is in appropriate sanitary condition'' for subsequent loads. One of these comments states that the rule must also account for cross-docking situations in which cargo is transferred from the original vehicle to another vehicle or mode of transport. In cross-docking transfers, employees of neither the shipper nor receiver will be present during loading into the subsequent vehicle, and the subsequent vehicle may even be from another carrier.

(Response 128) Under this final rule, the loader, and not the shipper or receiver, is responsible for performing the inspection upon loading as required by § 1.908(c)(1). This requirement would apply to the loader for each sequential loading of a vehicle that makes multiple stops to pick up partial loads. This also applies to the loader for a trans-loading (cross docking) operation, as we discuss in our response to Comment 38.

c. Proposed § 1.908(b)(3)

We proposed to require that a shipper of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control, whether a TCS food or a non-TCS food, must specify in writing to the carrier, except to a carrier who transports the food in a thermally insulated tank, the temperature conditions needed during the transportation operation, including the pre-cooling phase, to ensure that the carrier will maintain the proper temperature and meet the requirements of § 1.908(a)(3). We also proposed to make this information subject to the records requirements in § 1.912(a) of this rule.

(Comment 129) A large number of comments oppose our proposed provisions in § 1.908(b) and (d) for shippers and carriers engaged in the transportation of temperature controlled foods. These comments urge us to incorporate provisions into this rule that would allow for the continued use of existing food transportation industry best practices that have proven to be effective. They argued that management of temperature control for foods during transportation is a complex issue because it involves interactions between shippers, carriers and receivers who must address a variety of circumstances that may arise during the transportation of the food. We will first summarize the numerous comments we received on this matter.

- These comments universally oppose any requirement that carriers routinely demonstrate for each delivered load that they have met shipper temperature specifications. They state that confirming the functionality and settings of the refrigerator unit, or the temperature of the compartment upon loading and

upon receipt, and visually inspecting the food upon arrival for signs of temperature abuse is sufficient. The comments note, for example, that when a truck arrives at its destination, the receiver checks the trailer temperature setting. The receiver often also conducts a visual inspection to confirm that there are no visible signs of temperature abuse, such as sweating, the presence of ice crystals, signs of moisture, leaking products, moisture damage to packaging, or the loss of the structural integrity of packaging. According to these comments, checking the temperature of the food itself after transport has not been found to be necessary for purposes of ensuring food safety. The comments state that this is the case, in part, because if a refrigeration unit is turned off during shipment long enough to affect the temperature of the food product, a visual inspection of the food would be sufficient for purposes of determining whether a material temperature deviation that would have affected the safety of the load had occurred. The comments, therefore, assert that the current standard industry practice in most cases is to request temperature information about the load from the carrier upon delivery if there is a suspected food safety problem, for example, as indicated by a visual inspection.

• These comments also note that truck trailers often have devices onboard that can continuously record the refrigeration unit temperature that can be reviewed when necessary to investigate potential temperature deviations during transport that could affect food safety. These comments state, however, that this recorded information can be difficult to download and takes considerable time and expense to analyze because the process involves, among other things, identifying the container unit in transit, removing it from service, and delivering it to a facility capable of downloading the data. The comments further state that the cost of just extracting the data can be up to $200 per load and may require the services of a third-party vendor and that additional expense is incurred in analyzing the data. The comments therefore conclude that requiring the routine review of recorded onboard refrigerator temperature data is neither practical nor necessary.

• These comments also argue that the language of proposed § 1.908(d)(2)(i) could be interpreted to require continuous temperature monitoring during food transport and suggest that we may be under the misimpression that the use of continuous monitoring devices is the norm in the refrigerated food transport industry. Some comments state that current best industry practices in many cases can give shippers confidence that appropriate temperatures are maintained during transit, without the use of continuous monitoring devices. One comment urges us to permit other forms of adequate temperature monitoring, such as documented alarm systems or properly documented manual temperature records. Many comments state that the rule should allow the carrier to use any means agreeable to the shipper to demonstrate the carrier's adherence to temperature specifications, such as recording trailer temperature settings when the vehicle is loaded and unloaded or periodic temperature checks during transit. Finally, some of the comments note that with the limited exception of the transportation of highly temperature-sensitive food products, such as vacuum packed seafood, where the shipper or receiver voluntarily may determine that the use of continuous monitoring devices is necessary to ensure product safety, using continuous temperature monitoring and recording devices is not necessary for purposes of ensuring the safety of the food during transport.

• These comments also state that a deviation from the shipper's temperature specifications does not necessarily cause the food to be unsafe. According to the comments, the temperature included in a shipment's bill of lading is the temperature at which the trailer's refrigerator unit needs to be set, but is often lower than the temperature needed to ensure the safety of the food shipment. A food that requires time/temperature control to ensure its safety (TCS food) and needs to be maintained at or below 40 degrees Fahrenheit, for example, may be transported during the winter in cold regions of the country at refrigerator settings very close to 40 degrees because this is adequate to ensure the temperature required for safety is not exceeded given the low outside air temperature. If, however, this food is transported during the summer, the shipper may direct the carrier to set the refrigerated trailer temperature much lower than 40 degrees Fahrenheit (*e.g.,* 33 degrees Fahrenheit) because the warmer outside air temperature could cause the ambient temperature in the trailer to rise during transit. In this scenario, according to these commenters, the ambient temperature in the trailer upon arrival at the receiver's facility may be 36 degrees Fahrenheit, but this does not mean that the food is unsafe, even though the temperature is higher than what was indicated in the shipment's bill of lading. These comments conclude that for these reasons, this rule should clearly state that a deviation from the shipper's temperature specifications does not necessarily cause the food to be unsafe.

• Finally, these comments urge us to accord shippers the flexibility to assess the conditions under which the food was transported in determining whether temperature deviations cause the food to be unsafe. The commenters assert that, in many cases, the food may still be fit for its original intended use, notwithstanding any temperature deviations that might have occurred during transit. The comments also assert that in a case where a food may no longer be fit for its original intended use because of temperature deviations, the food may still be fit for an alternative use. A food product that may no longer be fit for its intended use as food for humans because of temperature deviations that might have occurred during transit, for example, might still be safe and fit for use as animal food. The comments argue that automatically deeming food adulterated because there was a temperature deviation during transit, without allowing for an evaluation of whether that deviation affected the safety of the food, would result in significant amounts of food waste without providing any corresponding food safety benefit.

(Response 129) We agree that the provisions we proposed for persons engaged in the transportation of foods that require temperature control for safety should be revised to clearly focus their requirements on functions that ensure that adequate temperature control is provided, and to permit the continued use of established industry best practices that provide for the safe transportation of these foods. In revising these provisions, which are now designated as § 1.908(b)(2) in this final rule, we considered the steps that occur before, during, and after the transportation of foods that require temperature control for safety to ensure the transportation operation is in accord with sanitary transportation practices. Our changes to this final rule involve revisions that affect the responsibilities of shippers (§ 1.908(b)), loaders (§ 1.908(c)), receivers (§ 1.908(d)), and carriers (§ 1.908(e)).

In revising this rule's provisions for foods that require temperature control for safety during transportation, we recognized the fact, expressed in several comments, that the temperature control measures we are establishing in this rule may not be necessary for some

transportation operations, *e.g.,* those conducted during winter in cold areas or for short distance transportation of food in appropriate circumstances. As such, we are using in § 1.908(b)(2), the phrase, ''food that requires temperature control for safety under the conditions of shipment,'' to indicate that the requirements of this provision do not apply in situations in which the shipper determines that they are not necessary to ensure that the food does not become unsafe during transportation. We would expect that a shipper would be able to articulate the basis for any such determination if asked why temperature control is not necessary under the conditions of shipment.

Under conditions of shipment where it is necessary to provide temperature control to ensure that food does not become unsafe during transportation, the shipper must provide written instructions to the carrier and, when necessary (*e.g.,* if the shipper is not also the loader), to the loader, specifying temperature conditions to be maintained during transport.

The comments we received clearly state that this provision, as proposed, may be interpreted to mean that we are requiring the shipper to specify a critical limit for the transport of the food, such that food held in a vehicle that exceeds the specified temperature may be unsafe and, therefore, adulterated. We recognize that under established industry practices, the temperature specification provided to a carrier is often lower than the temperature needed to ensure food safety and that if the ambient temperature in a trailer were to exceed the specified temperature, the food would not necessarily be unsafe. We agree with the comments that ask us to clarify that a deviation from the shipper's temperature specifications does not necessarily and automatically cause the food to be unsafe, and, therefore, adulterated. Therefore, we are revising this provision in § 1.908(b)(2) to require that the shipper specify to the carrier, and, when necessary, to the loader, an operating temperature required for the given transportation operation, including, if necessary, the pre-cooling phase. We are adding a definition for the term ''operating temperature'' in § 1.904 to state that this term 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 § 1.908(a)(3). This revision clarifies that we do not intend for the temperature specified by the shipper to the carrier to be used as a critical limit, and that we understand that the specified temperature might be exceeded because of foreseeable circumstances that occur during transport, and that such deviations do not necessarily cause the food to become unsafe, and, therefore, adulterated.

We next considered how this rule should address temperature monitoring during transportation and under what conditions data acquired during temperature monitoring should be communicated by a carrier to a receiver or shipper. The comments we received clearly state that under established industry practices, parties involved in food transportation use a wide variety of approaches for monitoring temperature conditions. In some instances, for example, the transportation of some vacuum packaged seafood products, the continuous monitoring of temperature during transportation is necessary to ensure that the food is maintained under safe conditions. In most other instances, the transportation industry relies primarily on means, other than reviewing temperature monitoring information acquired during transit, to establish that adequate temperature control was provided during transportation, *e.g.,* vehicle temperature checks at loading and unloading, product temperature checks at receiving. In some instances, *e.g.,* cross-country shipments, manual vehicle temperature checks may be made periodically during transit.

We agree with comments that state that the proposed rule could be interpreted to require continuous temperature monitoring during transit, due in part to the proposed requirement at § 1.908(d)(2)(i) that a carrier must, once the transportation operation is complete, demonstrate to the shipper, and if requested, to the receiver, that it maintained temperature conditions during the transportation operation as specified by the shipper. We affirm that the carrier bears the responsibility for demonstrating, when necessary, that it transported food under appropriate temperature control conditions consistent with those specified by the shipper. However, we have revised this final rule at § 1.908(e)(2) to allow that demonstration to be made by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting recordings of the ambient temperature of a trailer when it was loaded and unloaded, or in the form of time/temperature data recorded during the shipment. This revision also clarifies that we are not requiring that the carrier conduct continuous monitoring of the temperature conditions on a vehicle during transport, but it also recognizes that in some circumstances it may be necessary to ensure the safety of the food and that, in these circumstances, the shipper and carrier may agree to this approach.

We also considered circumstances in which it would be necessary for a carrier to provide information to the shipper about temperature conditions during shipment. We agree with comments that state that requiring a carrier to routinely demonstrate for each delivered load that it had met the shipper's temperature specifications is not necessary for purposes of ensuring food safety and is not consistent with current industry best practice. Therefore, we have revised this rule at § 1.908(e)(2) to provide that the carrier's demonstration must be made only upon request by the shipper or the receiver. This revision clarifies that a carrier is not required to routinely provide this demonstration, but requires such a demonstration when, for example, as explained below, the receiver assesses the food upon receipt and determines that there may have been a material failure of temperature control during the shipment, or when the shipper and receiver have agreed that it is necessary to ensure the safety of the food (*e.g.,* some shipments of vacuum packaged seafood).

We also considered what measures, if any, should be required after a food transportation operation has been completed. Many of the comments that we received observe that receivers currently routinely check the function and settings of the transportation vehicle's refrigeration unit and conduct visual inspections of the delivered food products for which temperature control is required for signs of temperature abuse. We regard these types of inspections as essential for ensuring that the food was transported in accordance with appropriate sanitary transportation practices and was not rendered unsafe because of inadequate temperature control. Accordingly, we have revised this final rule in § 1.908(d), which now includes requirements applicable to receivers, to provide that upon receipt of food that requires temperature control, a receiver must take steps to determine whether the food was subjected to significant temperature abuse. We also have provided examples of measures a receiver could employ for this purpose, such as determining the food product's temperature, the ambient temperature of the vehicle and its refrigeration unit's temperature settings and conducting a sensory inspection to

ascertain whether there are signs of temperature abuse, such as off-odor. We also note that the receiver at this stage may review temperature monitoring information from an onboard temperature monitoring device that might have been employed during the food transportation process, and that such an approach would meet the requirements of this rule.

We also added a provision to the general requirements of this rule § 1.908(a)(6) that is applicable to circumstances in which temperature abuse of a food may have occurred or another event may have occurred that could have jeopardized the safety of the food (*e.g.,* spillage of a toxic substance on food items in the same load). This provision states that 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, the person must take appropriate action, 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.

This provision would, for example, require a receiver of food that requires temperature control for safety, that has performed a check of the vehicle compartment temperature as a way to comply with § 1.908(d), and determined that the temperature is above the operating temperature specified by the shipper, to hold the product until it can make a determination that the temperature deviation did not make the food unsafe. It could make that determination on its own, if it is qualified to do so, or could consult with the carrier, loader, shipper, or a third party to make such a determination or to assist it in making such a determination. Whomever makes such a determination should be qualified by training or experience to make such a determination, *i.e.,* he should have a scientific understanding of how the temperature deviation could affect the growth of pathogens or production of toxins in the food. It is our expectation that, under such a circumstance, the receiver (or shipper, if that is the more appropriate party to make the determination) would request temperature control information from the carrier. The carrier would be obligated to provide that information to the shipper or receiver under the provisions of § 1.908(e)(2).

We have included in § 1.908(a)(6) a provision that, if requested by the receiver, the carrier must provide to the receiver the operating temperature specified by the shipper in accordance with § 1.908(b)(2). This is a necessary exchange of information to facilitate the receiving examination provided for in § 1.908(d), when the receiver may not be aware of the operating temperature that the shipper provided to the carrier.

The new provision at § 1.908(a)(6) would also, for example, require the carrier of a food that notices leakage of liquid from boxes of raw poultry onto partially enclosed crates of produce during a stop in transportation to hold the food until the carrier can obtain a determination from a qualified individual, *e.g.,* the shipper, that the condition did not cause the food to be unsafe for its intended use.

We agree with the comments that we received that argued that if a food has become unfit for its intended use because of material temperature abuse during transportation, the food may still be fit to an alternative use, such as for animal food. We would judge such circumstances on a case-by-case basis.

We have further modified the provisions of proposed § 1.908(b)(3) (now § 1.908(b)(2)) in several ways. First, because we have added a definition of loader, in response to comments that urged that we account for activities performed by the person loading a vehicle when that person is not also the shipper, receiver or carrier (see Comment 70), we recognize that there will be times when the shipper must provide instructions to the loader in addition to the carrier, *e.g.,* instructions about pre-cooling conditions to look for during the a preloading inspection. For this reason, we have included the loader as a person to whom the shipper must provide instructions about the sanitary specifications for the carrier's vehicle, when necessary. Second, we have changed the proposed phrase ''food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, whether a TCS food or a non-TCS food'' to ''food that requires temperature control for safety'' for consistency with our previously stated objective of focusing this final rule on food safety only.

Finally, we have prefaced the requirement with the phrase, ''Unless the shipper takes other measures in accordance with paragraph (b)(5) of this section to ensure that adequate temperature control is provided during the transportation of food that requires temperature control for safety.'' We have added this language in response to comments from the railroad industry (see Comment 53) that stated that they generally do not have a relationship with shippers whereby the shipper provides them with instructions relative temperature control of the railcar that they are to deliver. Our intent is that the language will establish the requirements of § 1.908(b)(1) as the default arrangement whereby the shipper ensures that the vehicle is operated during transportation at a temperature that prevents the food from becoming unsafe by providing instructions to the carrier and, when necessary, the loader, while also allowing for alternative arrangements (*e.g.,* whereby the shipper personally ensures that the temperature conditions are met), when that is consistent with the shipper's written SOPs, as provided for in § 1.908(b)(5). We expect that many shippers that work with rail carriers will elect this latter approach, relieving them of the necessity to instruct the carrier about the necessary temperature control conditions for the railcar.

(Comment 130) Several comments state that the proposed temperature control requirements are excessive and inappropriate for the animal food industry, and ask us to revise and better align them with risk-based practices that are commonly used in that industry. One comment states that refrigeration and temperature control are not relevant to rendering industry ingredients because the high-temperature cooking process of rendering destroys the pathogens contained in the raw materials. Another comment states that maintaining temperature conditions should only be considered when a firm has identified a hazard that needs to be controlled.

(Response 130) We have revised § 1.908(a)(3), as we discussed in our response to Comment 2, to clarify that the type of food involved, for example, animal feed, pet food, human food, and the food's given stage in the production process, for example, whether the food is a raw material, an ingredient, or a finished food product, must be considered when determining the conditions and controls, including temperature controls, that may be necessary to ensure the sanitary transportation of the food. We, therefore, agree that it would not be necessary to provide temperature control during the transportation of ingredients destined for rendering because these materials will eventually be treated with high heat to destroy pathogens. As we have previously stated, we have revised this final rule so that it focuses entirely on food safety issues. For this reason, control of temperature during transportation would not be required by the rule if

such control is not necessary to ensure its safety, *e.g.,* where its only purpose is to minimize decomposition of the food.

(Comment 131) Two comments observe that the proposed rule does not address the issue of how a shipment of food requiring temperature control, for which a material failure of temperature control during transport is suspected, should be handled. One of these comments expresses the view that that the rule should remain silent on this matter. The other comment argues that the issue is beyond the scope of this rule and the matter would be best resolved by a risk assessment to be conducted by the receiver and/or shipper.

(Response 131) As we explained in our response to Comment 129, we have revised § 1.908(a)(6) of this final rule to require that 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, the person must take appropriate action, 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.

While we agree that it is unnecessary to prescribe the details of the mechanics of how such a determination is made, we do not agree that the actions of a receiver after taking delivery of a food shipment that may have been transported without appropriate temperature control, for example, are beyond the scope of this rule. We are charged under the 2005 SFTA to establish sanitary transportation practices to be used by shippers, carriers by motor vehicle or rail vehicle, receivers and other persons engaged in the transportation of food to ensure that food is not transported under conditions that may render it adulterated.

As we discussed in our response to Comment 129, we revised § 1.908(d) to establish duties for receivers of foods that require temperature control because we have determined that they are essential for ensuring that the food was transported in accordance with appropriate sanitary transportation practices, consistent with industry best practices. The new provisions at § 1.908(a)(6) are an appropriate extension of the provisions at § 1.908(a)(6), in that they ensure that the safety of the food is verified before a suspect food is moved further in commerce.

(Comment 132) A comment asserts that if a shipper is shipping a TCS food product and holds it unrefrigerated on a dock before the food is loaded into a transportation vehicle, the temperature of the product will rise, which will increase the ambient temperature of the refrigerated trailer compartment after the food is loaded, perhaps causing a deviation from the shipper's temperature control specifications. The comment argues that this outcome is completely beyond the carrier's control and that it needs to be taken into account when monitoring the temperature of the transportation vehicle throughout the transport process.

(Response 132) Under § 1.908(a)(3)(iii), persons subject to this rule must ensure that food that requires temperature control to prevent it from becoming adulterated during transportation is transported under adequate temperature control. This requirement also applies to the holding of food on a loading dock. Responsibility for complying with this requirement resides with the loader and not with the carrier. Although this rule does not require the use of temperature controlled loading docks, it does require that the loader handle food that requires refrigeration for safety in such a way that will prevent it from becoming unsafe. This may be accomplished by a loader by, for example, rapidly moving the refrigerated product from its refrigerated storage to a precooled vehicle, or by temporarily holding the refrigerated product in a refrigerated loading dock prior to loading onto a precooled vehicle backed up to the loading dock.

(Comment 133) Several comments ask us to clarify that the written temperature condition specifications that shippers must provide to carriers can appear in existing documents, such as contracts or bills of lading, and that they do not have to be conveyed by shippers to carriers in new, separate, dedicated documents.

(Response 133) We agree. The shipper may meet the requirements of § 1.908(b)(2) by communicating written information to the carrier in the form of existing contracts or bills of lading. Shippers do not need to create new, separate written temperature conditions specification documents for transmittal to carriers.

(Comment 134) Some comments state that the proposed rule can be interpreted to require pre-cooling only when it is necessary to maintain temperature conditions during transport, and ask us to clarify this point. One comment, for example, states that pre-cooling may not be required for transportation during the winter in cold areas or for short distance transportation of food.

(Response 134) We did not intend to suggest in the proposed rule that a shipper must always provide pre-cooling parameters to a carrier for the transportation of foods subject to the temperature control requirements of this rule. We agree that pre-cooling may not be required for transportation operations conducted during winter in cold areas or for short distance transportation of food in appropriate circumstances. Under this rule, the shipper must determine whether pre-cooling a vehicle or transportation equipment by the carrier is necessary for the sanitary transportation of the food being shipped. We have revised § 1.908(b)(2) to clarify this point by specifying that the shipper must provide pre-cooling specifications to the carrier and when necessary, to the loader (*e.g.,* if the shipper is not also the loader), only if the shipper deems this step to be necessary to ensure that the transportation operation will be conducted under such conditions and controls necessary to prevent the food from becoming unsafe.

(Comment 135) One comment states that pre-cooling transportation equipment is inadequate without pre-cooling the product. The comment singles out RACs as an example, noting that if the RACs are not adequately pre-cooled prior to transportation, they will cause the temperature of the pre-cooled carrier container to rise above the specified temperature limits, thereby potentially creating conditions for bacterial growth. Another comment asks us to modify the language of this rule to clarify that it does not prevent the loading of harvested RACs directly from the field into pre-cooled trailers provided by carriers. This comment states that although under these circumstances, the temperature in the trailer will increase after is has been loaded, this is still a beneficial practice because it begins decreasing the field heat of RACs as soon as possible. The commenter asks us to allow this practice to continue even though it may not be possible for a carrier operating under these circumstances to meet the proposed requirement that the carrier follow the shipper's temperature controls.

(Response 135) Under § 1.908(a)(3) of this rule, all transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe. In addition, it is the shipper's responsibility under § 1.908(b)(2) (revised from proposed § 1.908(b)(3)) to specify to the carrier and, when necessary, the loader, whether pre-cooling a vehicle or transportation

equipment is necessary for purposes of compliance with this rule. We have added the term ''if necessary'' to the pre-cooling provision of § 1.908(b)(2) to clarify that we are not requiring pre-cooling in all circumstances. If pre-cooling the food product is necessary to meet the requirements of this rule, we would expect that the shipper and the loader would ensure that this step is effectively applied as part of their responsibilities under this rule. As we discuss in our response to Comment 129, however, we have made it clear in this rule, as revised, that we are not requiring shippers to specify temperatures to carriers and loaders that would be regarded as critical limits for food safety purposes. Accordingly, an increase in the temperature of the food compartment of a pre-cooled vehicle after products that have not been pre-cooled have been loaded into the compartment would not necessarily be of concern, as long as the temperature control measures applied during the operation ensure that the food will not become unsafe during transportation. Finally, nothing in this rule specifically precludes the loading of harvested RACs directly from the field into pre-cooled trailers provided by carriers because most RACs are refrigerated during transportation to minimize spoilage and not to ensure their safety. Exceptions include seed sprouts and raw molluscan shellfish.

(Comment 136) Some comments ask us to acknowledge that pre-cooling procedures should account for the potential for condensation formation during loading operations. One of these comments states that a transit container should be pre-cooled only if it is connected to a cold storage unit because product temperature and container temperature need to be in equilibrium to prevent hotter air from entering the container when its doors are opened during loading. The entry of hotter air into the container causes condensation, which can create a number of problems, including the formation of ice and structural damage to shipping containers.

(Response 136) Under § 1.908(a)(3) of this rule, all transportation operations, including loading operations, must be conducted under such conditions and controls as necessary to prevent the food from becoming unsafe. It is the shipper's responsibility under § 1.908(b)(2) to specify to the carrier whether pre-cooling a vehicle or transportation equipment is necessary for purposes of complying with this rule. We would expect that, if necessary under the requirements of this rule, the shipper (who is often also the loader), and the loader (if the loader is a different entity), will follow appropriate procedures to address the formation of condensation during the loading of a pre-cooled vehicle.

(Comment 137) One comment expresses the view that the carrier needs to have unambiguous notice that it is being tendered a shipment of food that is not shelf stable and that such notices should be uniform and clearly noted in shipping documents so the carrier can make an informed decisions regarding the handling of the shipment. Another comment recommends that the carrier should be notified in writing when a shipment includes a TCS food.

(Response 137) As we have previously stated, this final rule is focused only on food safety, and we have accordingly revised language that previously referred to ''foods that are not shelf stable'' to ''foods that require refrigeration for safety.'' We are using the latter term instead of the term TCS food. We agree that it is imperative that a carrier that takes responsibility for ensuring that a food that requires refrigeration for safety be informed by the shipper the operating temperature of the vehicle that is necessary to safely transport the food. Such disclosure is now required by revised § 1.908(b)(2).

(Comment 138) One comment asserts that thermally insulated tankers should be pre-cooled after a high temperature wash. The comment is concerned that the contents of the tanker would increase in temperature if a tanker is not pre-cooled. The comment suggests removing the exclusion for a carrier who transports food in a thermally insulated tank from the requirement of proposed 1.908(b)(3).

(Response 138) We decline this request. It is our understanding that it is a common industry practice to clean thermally insulated tankers right after unloading products rather than immediately before loading. The practice would allow the tankers to cool down after a hot temperature wash. Even if a product is loaded into a thermally insulated tanker that has just been cleaned with a high temperature wash, considering the small surface to volume ratio, we do not believe that the product temperature would be raised to a degree that is significant with respect to the maintenance of appropriate temperature control.

In addition, thermally insulated tankers are designed and built to limit the degree of temperature increase of a food in a given amount of time. Therefore, we are retaining the exclusion relating to food in a thermally insulated tank from the requirement of 1.908(b)(3).

d. New § 1.908(b)(3) to (5)

Many of the previously discussed comments depicted a food transportation system that is highly diverse, with shippers, receivers, loaders, and carriers developing and implementing food safety controls that are tailored to their specific circumstances. These controls take into account the nature of the food (*e.g.,* ready-to-eat vs. RACs for further processing, animal feed vs. human food), the manner of transportation (*e.g.,* motor freight vs. rail freight), the nature of the transportation vehicle (*e.g.,* owned or leased by the shipper, receiver or carrier, tanker vs. hopper vs. boxcar, refrigerated vs. unrefrigerated), the location and distance between shipper and receiver), the relationship between the shipper and the carrier (*e.g.,* simply providing a working boxcar to providing full service transportation including temperature control assurance), and the involvement of third parties (*e.g.,* brokers, contract loaders at remote sites), among other factors. Many comments urged flexibility to allow the best practices that have evolved over time for these various scenarios to continue to be implemented as long as they are effective in assuring food safety. Perhaps the starkest differences raised in the comments were between common practices in the motor freight and rail freight sectors. Notwithstanding those differences, some members of the rail freight sector informed us that they operated in a manner similar to many of those in the motor freight sector (for example, providing services such as refueling and monitoring refrigerated units and arranging for cleaning of bulk cargo cars), and vice versa. These commenters argued that assigning specific duties to specific categories of entities (*e.g.,* shippers, carriers, even within a sector) could, in many cases, have the effect of making some arrangements that have worked over time difficult or impossible.

We acknowledge this diversity and agree that the final rule should be structured to accommodate it. We also agree that the rule should be structured as much as possible so as not to restrict innovation in the relationships between the parties covered by the rule. On the other hand, we are compelled to develop a rule that is not so fluid that it is unenforceable. Especially when things go wrong, it is important to know who is responsible for what functions and to be able to hold them accountable. Even during day to day operations, it is important for the interacting parties to know where they are responsible and the responsibilities of the other parties,

in order that all parties understand their roles and are sufficiently motivated to accomplish their piece of the system.

In response to Comment 70, we have explained our thinking relative to the revised definition of shipper, which reads, ''a person who arranges for the transportation of food by a carrier or multiple carriers sequentially.'' We explained that we have concluded that this is the entity that is in the best position to determine the necessary conditions for safe transportation of food. Further, this is the party that causes the food to move in commerce, and, as a result, we believe, should bear the burden of setting out the safe conditions for that movement and assuring that they are met. As a result of these determinations, we have concluded that the shipper should be charged by this rule with developing and implementing written procedures that address how the safety of the food will be assured relative to the three major focus areas of this rule, to the extent that they apply to the foods that they ship. The three major focus areas are: (1) Assurance that vehicles and equipment used in its transportation operations are in appropriate sanitary condition; (2) assurance that, for bulk cargo, a previous cargo does not make the food unsafe; and (3) assurance that, for foods that require refrigeration for safety, the food is transported under adequate temperature control. It is necessary for these procedures to be in writing in order to facilitate consistent implementation by the shipper, especially with changes in personnel, and to provide for effective enforcement by FDA and other regulatory agencies. We expect that shippers would maintain such written procedures to facilitate their operations.

We recognize that, while the shipper is charged with developing and implementing these procedures, in many scenarios the shipper will need to secure the services of other parties, such as the receiver, loader, or carrier, to accomplish some or all of the measures. We expect that those services will be secured under a written agreement, subject to the records requirements of § 1.912(a). It is necessary for these agreements to be in writing in order to facilitate a consistent understanding of responsibilities and consistent implementation of the provisions by the shipper, carrier, loader and receiver, and to provide for effective enforcement by FDA and other regulatory agencies. Again, it is our understanding, based in part on comments discussed earlier in this document, that such agreements, usually in the form of contracts, are consistent with industry best practice.

Consequently, we have added three new sections to the proposed rule at § 1.908(b)(3) to (5). These new sections require that:

- A shipper must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.,* that will prevent the food from becoming unsafe during the transportation operation. Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement, subject to the records requirements of § 1.912(a).
- A shipper of food transported in bulk must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that a previous cargo does not make the food unsafe. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement, subject to the records requirements of § 1.912(a).
- The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures subject to the records requirements of § 1.912(a), to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement, subject to the records requirements of § 1.912(a), and must include measures equivalent to those specified for carriers under § 1.908(e)(1) to (3).

We proposed at § 1.908(b)(5) that the shipper assumes the requirements applicable to the carrier in § 1.908(d)(2)(i) with respect to providing a demonstration to the receiver if the shipper and carrier have agreed in writing under § 1.908(d)(2)(ii) that the shipper is responsible for ensuring that the food was held under acceptable temperature conditions during transportation operations. When the shipper and carrier have established such an agreement, the shipper also assumes the corresponding records requirements of §§ 1.908(d)(6)(ii) and 1.912(b). This provision was proposed to provide flexibility in the manner in which temperature control was assured during transportation, and, in particular, who was responsible for demonstrating to the receiver that such control was maintained. This provision is no longer necessary, and has been deleted from the final rule, because the new provision at § 1.908(b)(5) provides the same kind of flexibility for temperature control assurance, for foods that require refrigeration for safety, as discussed earlier in this document.

3. Requirements Applicable to Shippers and Receivers Engaged in Transportation Operations (Proposed § 1.908(c))

We had proposed to establish requirements for shippers and receivers addressing food handling during loading and unloading, in proposed § 1.908(c). As we discuss in this section, we have determined that it is not necessary to include these requirements, as they were proposed, in this final rule. We have redesignated § 1.908(c) in this final rule to specify requirements applicable to loaders engaged in transportation operations, which we discuss in the following section.

(Comment 139) One comment states that we should ensure that receivers have the ability to test a food product before automatically discarding it because the shipper's temperature control specifications were exceeded during transport.

(Response 139) Nothing in this rule requires receivers to discard food if the food was subject to deviations from a shipper's temperature control specifications during transport. We discuss a receiver's responsibilities for handling food that requires temperature control in our response to Comment 129.

(Comment 140) Several comments oppose proposed § 1.908(c)(1) on the grounds that the provision would be unnecessarily burdensome and would not improve food safety or otherwise contribute to the sanitary transportation of food.

One comment states that foods that are shipped without being completely enclosed in packaging, such as RACs, are freely handled by consumers when offered for sale in retail establishments. The comment notes that no rule currently requires consumers to wash their hands prior to the handling these foods and that there is no evidence to suggest that transportation vehicle operators present a greater risk of contaminating food not completely enclosed in packaging than do a food retailer's employees or consumers who also handle these food products prior to consumption. The comment also argues that while our proposed rule compares § 1.908(c)(1) to requirements in the cGMP regulations for human food, particularly 21 CFR 110.10(b), they are

not the same (the cGMP regulations for human food have been revised in the preventive controls for human food final rule and are now in 21 CFR part 117, subpart B). The commenter notes that 21 CFR 110.10(b) generally requires all persons who work in direct contact with food to conform to hygienic practices to the extent necessary to protect against food contamination. According to the comment, the proposed hand washing provision in this rule does not contemplate that the requirement might not be necessary to protect against contamination given the existing cGMP hygienic practices provisions.

Other comments argue that proposed § 1.908(c)(1) should only apply if the vehicle operator is reasonably expected to come in physical contact with the food. One comment asserts that this proposed requirement lacks supporting scientific data, is unnecessary, is not feasible in many instances, and would appear to be appropriate only if human contact with the food poses a risk that the food will become adulterated or otherwise poses a valid health risk to humans or animals. Another comment recommends that any requirement for hand-washing facilities be risk-based and be linked directly to the effectiveness of hand-washing for purposes of reducing the risk that human handling of food would cause the food to be rendered injurious to health or otherwise adulterated.

Another comment suggests that firms should train drivers with respect to safe handling practices and that we should leave the selection of the sanitary methods for the handling of foods not entirely enclosed by packaging up to the transportation firms. The comment suggests, for example, that vehicle operators may be instructed to use disposable gloves, sanitary wipes, and/or a customer's hand washing facilities depending on the circumstances. One comment expresses concern that this provision would require the installation of additional sinks in virtually all food distribution centers at a great cost to the industry.

(Response 140) After considering these comments, we have decided to remove the provision in proposed § 1.908(c)(1) from this final rule. We have determined that this provision is unnecessary because the specific circumstance that proposed § 1.908(c)(1) would address, vehicle operators handling food not completely enclosed by a container, is already addressed by the broader requirement of § 1.908(a)(3), which requires that all transportation operations be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations. In particular, § 1.908(a)(3)(ii) includes hand washing as an example of measures that can be taken to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations. Providing vehicle operators access to hand washing facilities is one method for preventing the contamination of food, but we agree that it may not always be necessary. By removing proposed § 1.908(c)(1) from this rule, we are allowing flexibility for the transportation industry to determine what control measures would be necessary in any given set of circumstances.

Furthermore, we have reached the same conclusion concerning the provision in proposed § 1.908(c)(2), which would have required shippers and receivers of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, to carry out loading and unloading operations under conditions that would ''prevent the food from supporting such microbial growth.'' We have removed that provision from this final rule because our expectations for temperature control during loading and unloading operations are set forth in new § 1.908(a)(3)(iii), which requires persons subject to this rule to take effective measures to ensure that food that requires temperature control for safety is transported under adequate temperature control; see Comment 132 and Comment 141.

(Comment 141) One comment states that there are no provisions in the rule to ensure that insanitary conditions have not contaminated the food before a carrier becomes involved. The comment asserts that the rule does not require specifications for conditions that must be maintained on loading and unloading docks, and that carriers are not given an opportunity to inspect and confirm either the condition of the cargo or the facilities where the food is picked-up or delivered.

(Response 141) We disagree with the comment. The requirements of § 1.908(a)(3) and (c), while general in nature, address sanitary transportation practices applicable to the loading and unloading of food. In addition, this rule does not preclude a carrier from establishing agreements with the owner or operator of the facility or loading dock to inspect or confirm the condition of cargo or facilities prior to accepting a load.

4. Requirements Applicable to Loaders Engaged in Transportation Operations (New § 1.908(c))

As we stated in the previous section, we have redesignated § 1.908(c) in this final rule as, ''Requirements applicable to loaders engaged in transportation operations.'' The provisions we have included in this section arise from our consideration of comments relevant to loading operations in other sections of this final rule; see Comment 125, Comment 126, Comment 127, Comment 128, and Comment 129.

5. Requirements Applicable to Receivers Engaged in Transportation Operations (New § 1.908(d))

We have established requirements applicable to receivers engaged in transportation operations in § 1.908(d) of this final rule and have moved the corresponding requirements applicable to carriers (proposed § 1.908(d)) to new § 1.908(e), discussed in the following section. The provisions we have included in new § 1.908(d) arise from our consideration of comments relevant to food that requires temperature control for safety, which we discuss in Comment 129.

6. Requirements Applicable to Carriers Engaged in Transportation Operations (Proposed § 1.908(d), Now New § 1.908(e))

As discussed in section IV.E.2, we have concluded that the shipper should be charged by this rule with developing and implementing written procedures that address how the safety of the food will be assured relative to the three major focus areas of this rule, to the extent that they apply to the foods that they ship. The three major focus areas are: (1) Assurance that vehicles and equipment used in its transportation operations are in appropriate sanitary condition; (2) assurance that, for bulk cargo, a previous cargo does not make the food unsafe; and (3) assurance that, for foods that require refrigeration for safety, the food is transported under adequate temperature control. We recognize that, while the shipper is charged with developing and implementing these procedures, in many scenarios the shipper will need to secure the services of other parties, such as carrier, to accomplish some or all of the measures. We expect that those services will be secured under a written agreement, subject to the records requirements of § 1.912. It is our understanding, based in part on comments discussed earlier in this document, that such agreements,

usually in the form of contracts, are consistent with industry best practice.

Consequently, we have added three new sections to the proposed rule at § 1.908(b)(3) to (5). These new sections require that:

- A shipper must develop and implement written procedures subject to the records requirements of § 1.912(a), adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.,* that will prevent the food from becoming unsafe during the transportation operation. Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement subject to the records requirements of § 1.912(a).
- A shipper of food transported in bulk, must develop and implement written procedures subject to the records requirements of § 1.912(a), adequate to ensure that a previous cargo does not make the food unsafe. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement subject to the records requirements of § 1.912(a).
- The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures subject to the records requirements of § 1.912(a), to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement subject to the records requirements of § 1.912(a) and must include measures equivalent to those specified for carriers under § 1.908(e)(1) to (3).

Consistent with these new provisions in the previous section applicable to requirements for shippers, we have included language at § 1.908(e) (proposed § 1.908(d)) that makes the provisions of that section applicable to a carrier only when the carrier and shipper have a written agreement that the carrier is responsible, in whole or part, for sanitary conditions during the transportation operation. Each provision is applicable only when it is relevant to the provisions of the agreement between the carrier and the shipper. For example, the carrier and the shipper may have a written agreement that states that the carrier is to precool the vehicle and set and monitor operating temperatures in the vehicle, based on instructions from the shipper. In this case, the carrier would be responsible for meeting the requirements of § 1.908(e) that are relevant to temperature control (*i.e.,* § 1.908(e)(2) and (3), discussed in this document). If the agreement did not assign responsibility for other sanitary conditions to the carrier, *e.g.,* cleanliness of the vehicle, previous cargo control, the other provisions of § 1.908(e) would not be applicable to the carrier.

a. Proposed § 1.908(d)(1)

We proposed to require that a carrier must supply a vehicle and transportation equipment that meets any requirements specified by the shipper in accordance with § 1.908(b)(1), and is otherwise appropriate to prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during the transportation operation.

We have made the following revision to proposed § 1.908(d)(1) (now § 1.908(e)(1)) for consistency with changes elsewhere in the final rule to focus the rule on food safety only. We have changed the proposed phrase ''prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health'' to ''prevent the food from becoming unsafe.''

(Comment 142) One comment asks us to require LTL carriers to implement written procedures to ensure the compatibility of each food contained within an LTL load and to require that the carrier be able to demonstrate full compliance with each shipper's food transportation specifications upon request.

(Response 142) We decline to make this change. We have assigned responsibility for ensuring that a vehicle onto which food not completely enclosed by a container is loaded is in appropriate sanitary condition, to the loader, giving consideration to specifications provided by the shipper (see Comment 70). Among other factors, the loader is to consider whether the vehicle is in adequate physical condition and whether it is free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe. In the case of an LTL load, we would expect that the loader would check to see if any previously loaded cargo could potentially contaminate food not completely enclosed by a container in a subsequent load. We would also expect that the shipper of food not completely enclosed by a container on an LTL load would generally instruct the loader to inspect (where the loader and the shipper are not the same person), consistent with the shipper's obligations under § 1.908(b)(3).

(Comment 143) Another comment notes that the carrier has the responsibility for providing a container in good mechanical condition and that is reasonably clean of dirt, debris and foul odors. However, the comment states that the shipper should be responsible for any ''sanitizing'' that might be required for the sanitary transportation of a particular food/beverage or commodity.

(Response 143) We are aware that, depending upon the circumstances and the agreement between the parties, current practice is that either shippers, loaders or carriers may wash and/or sanitize vehicles before they are loaded, or they may contract with a third party to perform that function. We see no public health benefit in changing current practice by mandating that one party or another perform the function. As previously discussed, in new § 1.908(b)(3) we have required that shippers develop and implement written procedures specifying how they will ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food. We would expect such procedures to include cleaning and sanitizing procedures as appropriate to the food and conditions of shipment. However, new § 1.908(b)(3) also provides that the shipper may reach an agreement with the carrier, or another party covered by this rule, to perform this function. If a carrier agrees to perform this function, § 1.908(e)(1) requires that they ensure that the vehicle meets the shippers specifications in that regard.

(Comment 144) One comment states that some jurisdictions prohibit carriers from washing out their truck's trailers because of local water quality regulations designed to protect the environment from contaminated water runoff. The comment further asserts that this rule, therefore, places carriers in the untenable position of having to choose which regulation to follow. The comment asks us to provide clarity regarding the interaction between this rule and state and local regulations that may restrict or prohibit truck washing.

(Response 144) This rule is not intended to preempt state and local requirements regarding water runoff and water quality issues that would affect truck washing. Carriers affected by local requirements that restrict or prohibit truck washing must, even now, determine how to meet any

requirements imposed upon them by their shipper customers when faced with local washing restrictions. This rule does not change that fact. As discussed in response to the previous comment, in new § 1.908(b)(3) we have required that shippers develop and implement written procedures specifying how they will ensure that vehicles and equipment used in their transportation operations are in appropriate sanitary condition for the transportation of the food. We would expect such procedures to include cleaning and sanitizing procedures as appropriate to the food and conditions of shipment. However, new § 1.908(b)(3) also provides that the shipper may reach an agreement with the carrier, or another party covered by this rule, to perform this function. If a carrier agrees to perform this function § 1.908(e)(1) requires that they ensure that the vehicle meets the shippers specifications in that regard. In some cases the shipper may choose to perform the function, if it has facilities to do so.

b. Proposed 1.908(d)(2)

We proposed to require that a carrier must, once the transportation operation is complete, demonstrate to the shipper and if requested, to the receiver, that it has maintained temperature conditions during the transportation operation consistent with those specified by the shipper in accordance with § 1.908(b)(3). We proposed that these demonstrations may be accomplished by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting printouts of a time/temperature recording device or a log of temperature measurements taken at various times during the shipment. We also proposed that a carrier would not be subject to the requirement of § 1.908(d)(2)(i) if the carrier and shipper agree in writing, before initiation of the transportation operations, that the shipper would be responsible for monitoring the temperature conditions during the transportation operation or otherwise ensuring that the food was held under acceptable temperature conditions during the transportation operation. Finally, we proposed that a carrier must provide the written agreement to the receiver, if requested, and that this written agreement would be subject to the records requirements of § 1.912(b).

Consistent with our discussion concerning the duties of the shipper as a result of the requirements of § 1.908(b)(5), we have removed the provisions of proposed § 1.908(d)(2)(ii), concerning alternative arrangements for the responsibility to provide temperature control information to the shipper and receiver. This provision is no longer needed because new § 1.908(b)(5) and the new language at new § 1.908(e) provide the same flexibility to assign responsibility for this function as was provided by proposed § 1.908(d)(2)(ii).

(Comment 145) One comment asserts that an LTL carrier should have the flexibility to deviate from the temperature specified by the shipper when transporting mixed loads that contain food from more than one shipper. The comment further asserts that we should allow LTL carriers to set temperatures for such mixed loads based on the lowest temperature needed to safely transport TCS foods in any given load, even though this temperature may differ from that specified by any of the other LTL shippers.

(Response 145) We agree with the comment. Our expectation is that, generally, each of the shippers of food that require temperature control for safety in an LTL load would provide an operating temperature to the carrier. These temperatures represent temperatures that will ensure that the food does not become unsafe during transportation. In most cases, they will also assure marketability and quality preservation, as desired by the shipper. With regards to the requirements of this regulation, if a carrier who has accepted responsibility for temperature control during transit selects the coldest temperature of those provided by the shippers they will be meeting their responsibility under § 1.908(e)(2). However, we note that there may be times when a shipper does not want their product to be exposed to excessively cold temperatures for quality reasons. In this case, the shipper would be well advised to so instruct the carrier. We would consider such instructions to be outside the scope of this regulation as they do not impact food safety.

(Comment 146) Another comment asks us to develop and require carriers to adhere to air and product temperature-monitoring standards to meet the requirements specified by the shipper under proposed § 1.908(b)(3). The comment asserts that these requirements should include adequate and sanitary representative sampling methods, address appropriate temperature measurement device placement, and consider the effects of load configurations and other contributing factors on temperature control during transportation. The comment asks us to consider the potential need for shippers to require both air and product temperature monitoring and recommends that any requirements related to verification of product temperatures should be incorporated in a manner that would not involve undue or burdensome costs.

(Response 146) We do not agree. We think these types of detailed provisions are better for guidance than for regulations. Because of the diversity of transportation operations, including the variety of foods transported, we have concluded that shippers need to be given considerable latitude to develop temperature controls for their operations, as long as they do, in fact, serve to prevent the food from becoming unsafe during transportation. Some of the recommendations contained in the comment, *e.g.,* a requirement to monitor both air and product temperature, would, in many cases, establish a level of temperature control substantially more rigorous than current best industry practices, which have proven to be effective in providing for sanitary food transportation and which we have incorporated into this final rule.

c. Proposed § 1.908(d)(3)

We proposed to require that, before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control, a carrier must precool each mechanically refrigerated freezer and cold storage compartment as specified by the shipper in accordance with paragraph (b)(3) of this section.

We have made the following revisions to proposed § 1.908(d)(3) (now § 1.908(e)(3)) for consistency with changes elsewhere in the final rule to focus the rule on food safety only. We have changed the proposed phrase ''food that can support the rapid growth of undesirable microorganisms in the absence of temperature control'' to ''food that requires temperature control for safety.'' We have also removed the word ''freezer,'' because we believe that the pre-cooling of freezer vehicles is a step taken to preserve product quality and marketability and not to prevent the food from becoming unsafe.

d. Proposed § 1.908(d)(4)

We proposed to require that a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the three previous cargoes transported in the vehicle. We proposed that the shipper and carrier would be able to agree in writing that the carrier would provide information identifying fewer than three

previous cargoes, or that the carrier would not need to provide any such information if procedures have been established that would ensure that the bulk vehicle being offered would be adequate for the intended transportation operation, for example, if the carrier by contract would agree to offer vehicles dedicated exclusively to transporting a single type of product. We also proposed that the written agreement would be subject to the records requirements of § 1.912(b).

Consistent with our discussion concerning the duties of the shipper as a result of the requirements of § 1.908(b)(4), we have removed the provisions of proposed § 1.908(d)(4), concerning alternative arrangements for the responsibility to provide previous cleaning information to the shipper. This provision is no longer needed because new § 1.908(b)(4) and the new language at new § 1.908(e) provide the same flexibility to assign responsibility for this function as was provided by proposed § 1.908(d)(4).

(Comment 147) A few comments support this proposed provision. One comment notes that the proposed requirement is an existing common industry practice. Another comment informs us that our proposal is feasible. Another comment expressed the view that requiring identification of the three previous loads hauled is excessive and unnecessary for accomplishing the goal of sanitary food transport.

Several comments state that it is currently common for carriers to provide information about the single previous cargo hauled on a bulk transport vehicle to shippers under procedures already in place and widely accepted within both the human and animal food transportation industries. One of these comments states that for shippers, knowing the immediately previous load hauled in a bulk conveyance and knowing whether appropriate clean-out procedures have been followed, if needed to ensure the conveyance meets the needs of the shipper based upon the type of food to be loaded, is critically important. Another comment states that knowing what type of feed was hauled in a dedicated truck immediately before the present load is useful information when assessing the possibility of the contamination of the present load. Another comment offers the view that the shipper, in accordance with the FSMA preventive controls rules, would maintain written procedures as part of its food safety plan to ensure adequate cleanout of vehicles is performed and documented. According to this commenter, this written plan should suffice in lieu of any additional documentation required to support compliance to this rule.

Another comment states that the request for three previous cargoes is impractical for LTL shipments, where tractors hauling trailers with packaged goods may stop at multiple locations to pick up shipments. Several comments assert that the carrier's release of information regarding multiple previous loads could result in the improper disclosure of sensitive business information because it could involve divulging to a shipper's competitors detailed information regarding the shipper's deliveries to their customers. A related comment asserts that the tracking of three previous cargoes is impractical, and perhaps impossible, because trailers are attached to tractor transportation vehicles on a continually changing basis.

(Response 147) These comments indicate that under current industry practices, in some cases, shippers acquire information from carriers about cargo previously transported in a bulk vehicle and that this information has value to them in ensuring that their cargo will not be at risk of contamination during transportation. In other cases, shippers do not seek to obtain this information and instead rely on other measures to ensure that contamination will not occur, such as guarantees that the carrier will provide a vehicle dedicated to transporting a single type of cargo. Further, we have concluded that such a common practice demonstrates that this provision would not adversely impact businesses because of concerns about the disclosure of sensitive business information.

However, none of the comments supported the need to identify more than the single previous shipment and some suggest that it would be unduly burdensome. We are persuaded by these comments, and, consequently, while we have retained proposed § 1.908(d)(4) (new § 1.908(e)(4)), we have revised it to require the carrier to provide, on request from the shipper (when such function is the subject of a written agreement between the shipper and the carrier as provided for under § 1.908(b)(4)), information about the last previous cargo transported in a bulk vehicle. With respect to LTL shipments, we note that this provision does not apply in circumstances where the vehicle is used to transport packaged goods. This provision only applies to vehicles in which food is shipped in bulk, with the food coming into direct contact with the inner surfaces of the vehicle.

(Comment 148) A comment asks us to exempt vehicles that transport raw materials to rendering operations from the requirement of identifying prior cargoes.

(Response 148) While we recognize that materials destined for rendering will receive a heat treatment to destroy pathogens, we are not exempting carriers from the requirement that they identify the vehicle's previous cargo to the shipper supplying raw materials to a rendering operation because the shipper might wish to determine whether the bulk vehicles carried some previous cargoes that could contaminate the raw material in a way that would not be addressed by the heat processes of the rendering operation (*e.g.,* heat stable chemical contaminants). We are retaining this provision to allow the shipper to obtain this information from the carrier, if the shipper deems it necessary for the purposes of ensuring that his product does not become unsafe during transportation.

(Comment 149) Another comment asserts that carriers that offer bulk food vehicles for food transportation already comply with comparable requirements under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and further asserts that compliance with these existing requirements is sufficient to protect food safety during transportation operations.

(Response 149) We disagree. We have not established requirements in any other regulations that carriers must provide information to shippers that identifies previous cargoes transported in bulk vehicles or that describes the most recent cleaning of the vehicle. We are establishing these requirements in this rule pursuant to the objective of this rulemaking, which is to require that persons engaged in the transportation of food use sanitary transportation practices to ensure that food does not become unsafe during transportation. The regulations we have established under the Bioterrorism Act, as they pertain to food transportation, address a different purpose. Those regulations in 21 CFR part 1 address records that must be kept by certain persons, including food transporters, that would be available to FDA to identify the immediate previous sources, and immediate subsequent recipients, of food, in order for FDA to address contamination that presents serious adverse health consequences or death to humans or animals.

(Comment 150) A comment states that if a bulk trailer is offered for loading with a wash ticket, there is little reason to provide information about what was previously hauled therein. This commenter asserts that in many cases a

tractor operator will obtain a trailer with a wash ticket and not know the last food hauled in the trainer.

(Response 150) As we discuss in our response to Comment 149, we revised this rule in § 1.908(e)(4) so that carriers will only have to provide shippers with information about the previous load if the shipper requests the information (in cases where the carrier and shipper have a written agreement requiring the shipper to provide such information). We would not expect that a shipper would request this information under circumstances in which the shipper does not regard it as necessary under the terms of its business relationship with the carrier, for example, when the carrier by contract has agreed to only provide vehicles that have previously hauled compatible ingredients or to present a wash ticket to the shipper when the vehicle is offered.

(Comment 151) Another comment notes that railroads do not maintain information on previous cargoes. The commenter states that there is no industry process to track and identify prior shipments in rail cars that travel throughout the general system of rail transportation in interchange service. Railroads would not have this information for privately owned rail cars and they would not necessarily have the information for their own rail cars that have been in service on other railroads or rail cars that have been placed into pool arrangements. Finally, the commenter asks us to revise this final rule so that a railroad carrier would only be required to provide information to the shipper that identifies the three previous movements when a shipper requests this information, the railroad carrier has access to the information through its ordinary course of business, and the information is not otherwise available to the shipper.

Similar comments state that it can be difficult to obtain last-load hauled information from rail carriers unless the railcars being utilized are owned, leased, or controlled by the shipper, or the shipper is the one who is the consignee/consignor or payer of the freight bill. Currently, no consistent or reliable mechanism exists among rail carriers from which to obtain such information.

One comment states that, given the complexity of the rail transport network and the efficiency and safety of current industry practices, the final rule should exclude rail carriers to avoid imposing needless and onerous burden on railroads. The commenter states that the shipper is uniquely positioned to understand the sanitary needs of the goods it ships and therefore can prevent cross-contamination and inspect and clean railcars prior to loads.

Another comment states that section 11904 of the Interstate Commerce Commission Termination Act (ICCTA) prohibits railroads subject to the Surface Transportation Board (STB's) jurisdiction from disclosing any ''information about the nature, kind, quantity, destination, consignee, or routing of property tendered or delivered to that rail carrier for transportation . . . that may be used to the detriment of the shipper or consignee or may disclose improperly, to a competitor, the business transactions of the shipper or consignee.'' 49 U.S.C. 11904(a)–(b). The commenter also notes that the statute prohibits other shippers from soliciting or knowingly receiving such information from a railroad. The commenter notes, for example, if loaded railcars are delivered to one shipper in a terminal area and the empty railcars are provided to a second shipper in the same terminal area, disclosing the prior load would inform the second shipper as to the nature of its competitor's previous cargo. The commenter argues that this type of disclosure is prohibited by ICCTA.

(Response 151) We acknowledge that the use of railcars in interchange service as described by these comments would likely make it difficult or impossible for the railcar's provider, *e.g.,* a railroad operator, to be able to provide information about the identity of a bulk vehicle's previous cargoes to the shipper as we proposed in § 1.908(d)(4). We also acknowledge the challenge that section 11904 of the ICCTA may pose with respect to exchanging such information for rail shipments. However, as discussed previously, we have revised this rule at § 1.908(b)(4) to require the shipper to develop written procedures adequate to ensure that a previous cargo does not make the food unsafe. These procedures may describe actions that the shipper may take to provide this assurance (*e.g.,* cleaning the vehicle, using a dedicated vehicle), or they can include actions that the carrier in accordance with § 1.908(e), or another party covered by this regulation may take to provide this assurance (*e.g.,* providing information about the last previous cargo of the vehicle, providing a dedicated vehicle). In the case of a rail operator that does not provide services related to the safety of bulk food cargoes to be loaded onto rail cars that they provide to the shipper (*e.g.,* identifying previous cargos) we would not expect that there would be a written agreement between the shipper and the carrier to provide such information. Consequently, this rule would place no burden upon such a rail operator to provide such information.

(Comment 152) Another comment notes that contract transportation haulers notify renderers and feed manufacturers about prior loads, including nonfoods and animal feed ingredients such as restricted use proteins (*i.e.,* relative to the concern for the agent that causes transmissible spongiform encephalopathy). The comment asserts that carriers should be responsible for cleaning out the truck trailer, container, or railcar after hauling restricted use proteins or hazardous materials before hauling other animal feed ingredients.

(Response 152) While the procedures described by the commenter may reflect the practices of most contract haulers handling raw materials for rendering, as we discussed previously, we have revised this rule at § 1.908(b)(4) to require the shipper to develop written procedures adequate to ensure that a previous cargo does not make the food unsafe. These procedures may describe actions that the shipper may take to provide this assurance (*e.g.,* cleaning the vehicle, using a dedicated vehicle), or they can include actions that the carrier in accordance with § 1.908(e), or another party covered by this regulation may take to provide this assurance (*e.g.,* cleaning the vehicle, providing a dedicated vehicle). We believe that it would be unnecessarily restrictive to place the burden for on food sanitation step, *i.e.,* cleaning, on a specific category of persons covered by this rule, and that the system described at § 1.908(b)(4) and (e) is sufficiently protective of public health.

This rule does not address controls for specific food safety hazards, such as the agent that causes transmissible spongiform encephalopathy. As we stated in the proposed rule (79 FR 7006 at 7011), we have established requirements in § 589.2000 (''Animal proteins prohibited in ruminant feed'') and § 589.2001 (''Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy'') addressing cleanout requirements and dedicated equipment requirements for equipment used in the distribution of specified feed ingredients to prevent the contamination of ruminant feed and animal food or feed, respectively.

e. Proposed § 1.908(d)(5)

We proposed to require that 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, except that a shipper and carrier may agree in writing that the carrier need not provide any such information, if the carrier follows procedures that would ensure that the bulk vehicle offered will be adequate for the intended transportation operation, *e.g.,* if the carrier has contractually agreed to use a specified cleaning procedure at specified intervals or if the shipper cleans the vehicle at his own facility, subject to the records requirements of § 1.912(b).

Consistent with our discussion concerning the duties of the shipper as a result of the requirements of § 1.908(b)(4), we have removed the provisions of proposed § 1.908(d)(5), concerning alternative arrangements for the responsibility to provide previous cleaning information to the shipper. This provision is no longer needed because new § 1.908(b)(4) and the new language at new § 1.908(e) provide the same flexibility to assign responsibility for this function as was provided by proposed § 1.908(d)(5).

(Comment 153) Some comments support the proposed provision. One comment states that all cleanout procedures, including wash out for trailers, should be documented.

(Response 153) We have retained these provisions in this final rule with some modifications as noted in the paragraphs immediately preceding this comment.

(Comment 154) One comment asserts that given the strict procedures currently in place to manage medicated feed transport, we do not need to include a previous vehicle cleaning provision in this rule with respect to the transportation of medicated feed.

(Response 154) Under this rule as we have revised it, the shipper has the prerogative to request from the carrier information describing the bulk vehicle's most recent cleaning when a contract between the shipper and receiver provides for such information exchange. We are retaining this provision to allow the shipper to obtain this information from the carrier if the shipper deems it necessary under these circumstances for the purposes of ensuring that his product does not become unsafe during transportation. Our regulations addressing medicated feed cleanout procedures (21 CFR 225.65 and 225.165) do not provide shippers with access to this type of information from carriers. If, however, a shipper has determined that the provisions of 21 CFR 225.65 or 225.165 adequately address his circumstances, the shipper may choose to not request this information from the carrier.

(Comment 155) Another comment states that providing information to the shipper describing the cleaning of a bulk rail car is beyond the current capabilities of railroad operators. The commenter observes that railroads do not generally clean rail cars and do not track the cleaning of railcars. The commenter states that railroad operators do not have access to cleaning records for rail cars that they do not own that are cleaned by customers on site or at third-party locations. The commenter also states that, even if a railroad owns the railcar, railcar operators routinely enter into contractual arrangements whereby the lessee becomes responsible for cleaning the railcar, and that based on the lack of incidents involving food transported in bulk railcars, there is no reason to impose these burdensome requirements on railroad carriers. The commenter therefore asks us to revise this final rule to require a railroad carrier to provide information to the shipper that describes the most recent cleaning of a bulk vehicle when a shipper requests such information, the railroad carrier has access to the information through its ordinary course of business, and the information is not otherwise available to the shipper.

(Response 155) We acknowledge that the use of railcars in interchange service as described by this these comments would likely make it difficult or impossible for the railcar's provider, *e.g.,* a railroad operator, to be able to provide information about the previous cleaning of a bulk car to the shipper as we proposed in § 1.908(d)(5). However, as we discussed previously, we have revised this rule at § 1.908(b)(4) to require the shipper to develop written procedures adequate to ensure that a previous cargo does not make the food unsafe. These procedures may describe actions that the shipper may take to provide this assurance (*e.g.,* cleaning the vehicle, using a dedicated vehicle), or they can include actions that the carrier in accordance with § 1.908(e), or another party covered by this regulation may take to provide this assurance (*e.g.,* cleaning the vehicle, providing a dedicated vehicle). In the case of a rail operator that does not provide services related to the safety of bulk food cargos to be loaded onto rail cars that they provide to the shipper (*e.g.,* providing information related to the cleaning of vehicles) we would not expect that there would be a written agreement between the shipper and the carrier to provide such information. Consequently, this rule would place no burden upon such a rail operator to provide such information.

(Comment 156) Another comment asks us to permit companies to use a written single generic guideline for all hired carriers with procedures addressing prior loads and the cleaning of bulk vehicles. The comment states that if a carrier commits to a shipper to use dedicated bulk containers or compatible raw ingredients and products, there should be no need for further procedures unless the shipper and carrier want to specify further details.

(Response 156) A shipper may operate in the manner described in this comment consistent with the requirements of this rule in § 1.908(e)(4) and (5). We acknowledge that an agreement provided to all hired carriers might state circumstances in which the shipper would want to know the identity of the previous cargo and information about the most recent cleaning of a bulk vehicle.

F. What training requirements apply to carriers engaged in transportation operations? (§ 1.910)

We proposed to require that carriers must provide training to personnel engaged in transportation operations that provides 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 this rule. The training must be provided upon hiring and as needed thereafter. We also proposed to require that carriers must establish and maintain records documenting the aforementioned training. Such records must include the date of the training, the type of training, and the person(s) trained. These records are subject to the records requirements of § 1.912(c). In table 9, we describe revisions to proposed § 1.910 and following the table we respond to comments related to these provisions.

TABLE 9—§ 1.910 WHAT TRAINING REQUIREMENTS APPLY TO CARRIERS ENGAGED IN TRANSPORTATION OPERATIONS?

Proposed section	Description	Revision
1.910(a)	Requires carriers to provide awareness training to personnel engaged in transportation operations.	Requires carriers to provide awareness training to personnel engaged in transportation operations when the carrier and shipper have agreed via written contract that the carrier is responsible for the sanitary conditions during transportation operations.
1.910(b)	Requires that carriers maintain records documenting the training required in (a).	No change.

(Comment 157) Several comments state that the training requirements should also apply to shippers and receivers who conduct loading and unloading operations in which they contact or handle food.

(Response 157) We do not agree and affirm our tentative conclusion in the proposed rule (79 FR 7006 at 7027) that training needs for shippers and receivers would be most appropriately addressed through the training provisions in our cGMP regulations for human and animal food because these regulations contain provisions related to sanitation focused employee training specifically tailored for entities that would operate as shippers, receivers and loaders under this rule.

(Comment 158) Some comments from the railroad industry state that railroads that do not handle food should not be subject to the training requirements of this rule and that these requirements should instead apply to shippers and receivers who actually contact and handle food shipped by rail.

(Response 158) We have addressed the portion of this comment that relates to training for shippers and receivers in our response to Comment 157. We agree that carriers, including railroads, that do not perform food transportation activities that may affect the sanitary condition of food would not benefit from training related to sanitary food transportation. For this reason, we have modified the carrier training requirement to require such training when the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or part, for the sanitary conditions during transportation operations. This revision is designed to be consistent with revisions at § 1.908(b)(3), (4), (5), and (e), discussed in the relevant sections of this document, that address when the carrier is made responsible for certain sanitary conditions during food transportation operations under this rule.

(Comment 159) Some comments state that training should be available to State and local regulatory officials.

(Response 159) As we discuss in our response to Comment 19, we are aware of the training needs for regulators and we will seek to establish partnerships with other Federal Agencies, and States and Tribes in implementing this rule which would include addressing these training needs.

(Comment 160) A comment requests more information about what type and amount of training would be sufficient to meet the requirements of this rule. It also states that a one-size-fits-all approach would likely overburden carriers who have little or no contact with food in their operations and likewise be insufficient for carriers whose operations involve a high degree of contact with food. Some comments mention that the content, frequency and length of training should be within the discretion of the carrier. Some comments state that a half-day long training seems unnecessary for this regulation. One comment requests that we provide flexibility in the training requirements for the transportation of chemical food additives and GRAS substances.

(Response 160) Beyond the general requirements stated in § 1.910, we are not prescribing details on aspects of the training such as its frequency, length, and subject matter. Given the diversity of food transportation operations, we do not intend to require that the entire industry use a single training approach. Training may vary in particular aspects, *e.g.,* length, provided that it meets the requirements of this rule. Thus, firms conducting differing types of transportation operations may employ training that is tailored to their operations provided that it meets the requirements of this rule. A firm that does not transport temperature controlled foods need not train their employees and food handlers in practices for providing temperature control during transportation. Transporters of chemical food additives may exercise the same selectivity in designing training programs for their operations.

(Comment 161) Some comments ask that we acknowledge in the final rule that industry training on food and feed safety systems will be acceptable and that we will not require that training be specific to this rule.

(Response 161) If industry training programs not specifically designed to address the requirements of this rule, nonetheless meets the requirements of § 1.910, such training would be acceptable under this rule. However, note that § 1.910 prescribes that the training, among other things, address the responsibilities of the carrier under this rule.

(Comment 162) A comment states that there will not be sufficient time or resources to train ''qualified individuals'' during the one year implementation period following the publication of the final rule. Some comments request that we establish guidelines for the development of standardized training materials. A comment requests that we develop standardized training programs that can be downloaded from our Web site, similar to the educational materials we have made available for food defense training and education.

(Response 162) The term ''qualified individual'' was not used in the proposed rule. It is used in this final rule in connection with determinations that food is safe when an indication of a possible material failure of temperature control or other conditions that may render the food unsafe occurs during transportation (§ 1.906(a)(6)). While the Preventive Controls rules for human and animal feed set minimum training requirements for qualified individuals, as that term is used in those regulations, no training or other standards are set in this regulation with regard to qualified individuals.

With regard to training for carriers, small businesses will have 2 years after the publication of the final rule to comply with its requirements. All other businesses subject to this rule will have 1 year. We believe firms will be able to comply with the training requirements of this rule within their allotted timeframes given these size based compliance dates and given the relatively brief and readily accessible

nature of the training we envision. We have given additional consideration to the nature of training needed to raise awareness by carriers of food sanitation concerns and controls and have concluded that it can be accomplished in less than one hour. That is not to say that some carriers may not find it valuable to provide more detailed training to individuals, for example on specific duties, such as bulk container cleaning. But the training that is mandated as a minimum by § 1.910(a) is intended to raise awareness rather than set out carrier-specific duties. It is our intention to develop and place on our Web site a course that can be downloaded or taken online that would meet the requirements of this provision. The model for this training effort is our on-line food defense training materials. We anticipate working with interested third-party alliances in the development of this material. Carriers would also be able to print a copy of a certificate of participation in the course to satisfy the training recordkeeping requirement of the rule (§ 1.910(b)). Participation in the course posted on FDA's Web site would not be mandatory. Training from other sources, or conducted in-house by carriers, may also meet the requirements of 1.910(a). Our intent is to provide a low cost (labor cost only) means of satisfying the requirement.

(Comment 163) A comment asks whether we have considered having this training be a requirement to obtain a truck driver's license.

(Response 163) A Commercial Driver's Licenses (CDL) is required to operate a tractor-trailer for commercial use. CDLs are issued by the States and are subject to requirements of DOT's Federal Motor Carrier Safety Administration. FDA has no authority to establish requirements for obtaining a CDL. Further, we believe that a requirement for safe food transportation training for all CDL holders would be unnecessarily burdensome, since many such drivers are not involved in transporting food.

(Comment 164) Some comments express willingness to work with us and other carrier and shipper organizations to develop sanitary food transportation training. Several comments state that the Seafood HACCP Alliance could best serve this purpose since it already has an established history in providing training, and has sufficient stakeholder involvement and the infrastructure in place to design, develop, and deliver training.

(Response 164) We commend the willingness of organizations to partner in developing sanitary food transportation training. Training alliances such as the Seafood HACCP Alliance have effectively functioned for this purpose in the past. We believe that a similarly constituted alliance would be useful for developing and promoting training for sanitary food transportation.

G. What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations? (§ 1.912)

We proposed that shippers and carriers: (1) Must retain all records required under this rule for a period of 12 months beyond a specified date when these records are used in their operations; (2) must retain all training records for a period of 12 months beyond when the person identified in the records continues to perform the duties for which the training was provided; (3) must make these records available to a duly authorized individual promptly upon oral or written request; (4) must keep required records as original records, true copies or as electronic records, which must be kept in accordance with part 11 (21 CFR part 11); and (5) may store specified records offsite after 6 months following the creation of the record, if the records can be retrieved and provided onsite within 24 hours of requests for official review. We also specified that all records required by this rule are subject to the disclosure requirements of part 20 (21 CFR part 20). In table 10, we describe revisions to proposed § 1.912 and following the table we respond to comments related to these provisions.

TABLE 10—§ 1.912 WHAT RECORD RETENTION AND OTHER RECORDS REQUIREMENTS APPLY TO SHIPPERS, RECEIVERS, LOADERS, AND CARRIERS ENGAGED IN TRANSPORTATION OPERATIONS?

Proposed section	Description	Revision
1.912	Records requirements for shippers and carriers	Add ''receiver'' and ''loader'' to be subject to certain records requirements.
1.912(a)	Records that shippers must retain to demonstrate that they provide information to carriers as a regular part of their operations for 12 months beyond when the shipper may need to provide such information.	Split requirement into 2 parts: (1) Requires shippers to retain records that demonstrate that they provide specifications and operating temperatures to carriers for 12 months beyond termination of the agreement with the carriers (2) Requires shippers to retain records of written agreements and procedures required by 1.908(b)(3), (4), and (5) for a period of 12 months beyond when the agreements and procedures are in use.
1.912(b)	Carriers must retain certain written agreements and records of written procedures for 12 months beyond when the agreements and procedures are in use.	Removed reference to retention of written agreements required by 1.908(d)(2)(ii) and redesignated 1.908(d) to (c).
1.912(c)	Carriers must retain training records for 12 months beyond when the person identified in records continues to perform the duties for which they were trained.	Revised ''continues to perform'' to ''stops performing''.
1.912(d)	Requires persons subject to the rule to retain written agreements assigning tasks covered by the rule for 12 months beyond the termination of the agreement.	New provision in the final rule.
1.912(e)	Requires covered parties which operate under ownership or control of a single legal entity must retain records of their written procedures for 12 months beyond when the procedures are in use.	New provision in the final rule.
1.912(f)	Requires that cover parties make all records available to duly authorized individuals upon request.	Adds ''loaders'' and ''receivers'' to this provision Provision was proposed as 1.912(d).

TABLE 10—§ 1.912 WHAT RECORD RETENTION AND OTHER RECORDS REQUIREMENTS APPLY TO SHIPPERS, RECEIVERS, LOADERS, AND CARRIERS ENGAGED IN TRANSPORTATION OPERATIONS?—Continued

Proposed section	Description	Revision
1.912(g)	Records must be kept as original records, true copies, or electronic records.	Remove the requirement that electronic records must be kept in accordance with part 11 of this chapter. Provision was proposed as 1.912(e).
1.912(h)	Clarifies that electronic records are exempt from the requirements of part 11.	New provision resulting from the change to 1.912(g).
1.912(i)	Allows for offsite storage of records after 6 months and clarifies that electronic records are onsite if they are accessible from an onsite location.	Remove ''after 6 months following the date that the record was made'' limitation for offsite storage of records. Provision was proposed as 1.912(f).
1.912(j)	All records subject to disclosure requirements of part 20	No change. Provision was proposed as 1.912(g).

(Comment 165) Several comments assert that we should exempt sanitary food transportation electronic records from compliance with part 11 and instead should take a more practical and simpler approach to requiring the authentication of electronic records. Some of these comments assert that requiring compliance with part 11 would be overly burdensome and cost-prohibitive and that this requirement is unnecessary because it would not significantly benefit the public health and is disproportionate to the regulatory need. Other comments assert that few, if any, entities engaged in the transportation of food would be able to meet this requirement because of the complexities involved with complying with part 11.

Some comments state complying with part 11 would mean that current electronic records and recordkeeping systems would have to be redesigned and would require the use of specialized and expensive software, which many small shippers, carriers and receivers might not be able to afford. Another comment states that compliance with the electronic records requirements in part 11 would be onerous for operations that currently use a combination of paper and electronic recordkeeping systems and that the effective integration of electronic recordkeeping systems throughout the food transportation chain might not be achievable given the diverse nature of the parties involved in the food transportation system and the different types of electronic systems that are currently used by the industry.

One comment acknowledges the importance of requiring that firms have adequate safeguards in place to ensure that electronic records cannot be altered, but asks us to provide the transportation industry with the flexibility to allow it to continue using, or to begin using, any existing electronic recordkeeping system that accomplishes this goal without mandating complete compliance with the prescriptive requirements in part 11. According to these comments, allowing the transportation industry to use existing electronic recordkeeping systems would enable industry to achieve our stated electronic recordkeeping goals efficiently and cost-effectively. A related comment urges us to provide a clear statement that companies may use any electronic recordkeeping systems as long as they ensure that all records are valid, accurate, and cannot be surreptitiously altered even if those electronic recordkeeping systems do not meet the prescriptive requirements of part 11.

(Response 165) We agree that redesigning large numbers of existing electronic records and recordkeeping systems would create a substantial burden disproportionate to the public health need. Therefore, we are providing in new § 1.912(g) of this final rule that records that are established or maintained to satisfy the requirements of this rule, and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. We also are specifying that 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. The rule provides that parties covered by this rule may rely on existing records to satisfy the requirements of this rule, and this rule does not change the status under part 11 of any such records if those records are currently subject to part 11. We are also establishing a conforming change in part 11, as new § 11.1(n), which says that part 11 does not apply to records required to be established or maintained by this rule, and that 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.

Although we are not specifying that part 11 applies, we expect parties covered by this rule to take appropriate measures to ensure that records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(Comment 166) Some comments assert that the 12 month record retention requirement in proposed § 1.912(a) is unnecessary and burdensome. One comment states that the time and costs required to create and maintain records for this rule will far outweigh the benefits of collecting and storing the information. One comment states that requiring record retention for 12 months beyond the last date of the activity described by the record as set forth in proposed § 1.912(a) is confusing. The comment interprets the language of proposed § 1.912(a) as requiring perpetual record retention activity for persons covered by this rule by continually adding an additional 12 month record retention period beyond the latest requirement. The comment also states that the proposed requirement that carriers retain training records for a period of 12 months beyond when the person identified in such records continues to perform the duties for which the training was provided is confusing, and asks us to restate the requirement more clearly. The comment asks, for example, if a person receives a refresher training course 11 months after the initial training, and then receives another refresher training course 13 months later, all the while continuing to perform the duties for which the training was provided, how long must the original and refresher training records be retained?

(Response 166) We are requiring that records be retained for a period 12 months beyond the last date of the activity described by the record, so that we can review the past practices of a shipper or carrier that may not currently be engaged in food transportation operations. Maintaining such records on

an ongoing basis will not be burdensome because the practices described in such records, *e.g.,* vehicle cleaning practices, procedures for providing information to shippers and carriers, etc., are likely to be ongoing operating practices that change very little over time. We therefore do not believe that further clarification of § 1.912(a) is necessary. With respect to refresher training, we would only expect records of the refresher training to be retained for our examination if such training was necessary for the person to continue to meet the training requirement of § 1.910(a). For example, if a carrier previously only transported food that does not require temperature control for safety, *e.g.,* was refrigerated strictly for quality purposes, and thus, not subject to this rule, but was beginning to transport shell eggs, it would be necessary to ensure that a vehicle operator was aware of the potential food safety problems and associated temperature control needs for shell egg transportation.

(Comment 167) A few comments commend our ''practical approach'' of not proposing that carriers or shippers would have to maintain a ''roomful of records'' documenting conditions for individual shipments. These comments state that while our generally practical approach has been conveyed to the food transportation industry repeatedly at FDA's public meetings, it was not discussed in detail in the preamble to the proposed rule. These comments encourage us to explain our regulatory philosophy in the preamble to this final rule in order to prevent deviations from our public statements in the future and to reinforce our intent. These comments also state that our field inspectors should be trained to understand that this regulation's recordkeeping requirements differ from the requirements under other FSMA regulations and that FDA inspectors should be trained not to ask for transportation records beyond those that are legally required under this final rule. A similar comment states that this rule is silent with respect to the retention of shipment records related to truck inspections, pre-cooling activities, and temperature monitoring, and asks us to make clear that the retention of such records is outside the scope of the rule.

(Response 167) Some of these comments refer to statements that we made in public meetings (Refs. 29 and, 30) in Chicago, IL and College Park, MD regarding the proposed rule.

In the Chicago meeting, for example, we stated: ''[A] carrier will have to provide information to shippers if it's a bulk carrier, about prior cargoes in its vehicle. We're not looking for a record of every prior cargo that was transported in every bulk vehicle the carrier operates. What we want to see is an SOP, that's the carrier's record . . . that states how it provides this information to the shipper.'' We further stated during the Chicago meeting that: [W]e're not looking for operational records that are going to fill a room up to the ceiling—[for example,] time, temperature, strip chart recordings—for every transportation operation for refrigerated food or cleaning records for every bulk tanker, we're looking for a procedure from the carrier that describes how he will provide this information to the shipper.'' Finally, we also said during the Chicago public meeting that: ''[W]e've done all that we can to minimize the burden of this recordkeeping requirement, but enable us to verify that this information exchange, which we think is an important part of sanitary transportation practices, is taking place.'' We stated during the College Park public meeting that: ''[W]e are not looking for carriers to fill up some room with time-temperature strip chart recordings for every load of refrigerated food that they transport and show those records for every operation that they conduct to the FDA. We are looking for the carrier to, in the form of a record, provide FDA [with] records that demonstrate that they do conduct this information exchange with shippers, that they do provide, as a part of their operation, information about the maintenance of temperature control to shippers.'' We again emphasized during the College Park public meeting that we ''tried to develop this recordkeeping provision in a way that minimizes the burden but recognizes the accountability of the carrier to demonstrate to shippers that they are transporting refrigerated foods or bulk foods under conditions that comply with requirements of the rule.'' Accordingly, these comments are correct in observing that the records retention requirements of this rule do not require carriers or shippers to maintain for our examination, records documenting conditions, such as temperature conditions, for individual shipments. Carriers may, however, choose to retain such information to provide to shippers upon request in accordance with § 1.908(e)(2)(i).

These comments also are correct in stating that this rule differs from other FSMA rules because this rule does not require the maintenance of records of ongoing transportation operations in the same way that some other FSMA rules require the retention of specific operating records. This rule, for example, does not mandate that persons covered by this rule must maintain monitoring records as does the FSMA preventive controls rules. We will ensure that our investigators are trained to understand the unique recordkeeping requirements of this rule.

Finally, there are no requirements in this rule concerning the retention of individual shipment records for our examination related to truck inspections, or precooling and temperature monitoring activities. Shippers and carriers, however, may choose to retain such information for business purposes.

(Comment 168) One comment states that the proposed rule requires carriers to demonstrate the temperature conditions that are maintained during transport, but fails to specify how long a carrier must maintain these temperature condition records.

(Response 168) A carrier may, but is not required to, create records of temperature conditions maintained during the transportation of food to provide to a shipper or a receiver upon request pursuant to § 1.908(e)(2)(i). This rule does not establish any retention time requirements for these optional temperature condition records.

(Comment 169) Some comments state that the proposed requirements to store records onsite are contrary to accepted and effective recordkeeping practices. Some of these comments state that companies frequently keep records of food safety activities, as well as transportation, cleaning, and training records at their corporate offices and not at operating facilities and asks us to allow this practice to continue. These comments also state that there is little practical difference between maintaining records onsite at food transportation facilities versus maintaining them offsite, for example, at corporate offices, provided that they can be provided to duly authorized individuals promptly upon an oral or written request, that is, within 24 hours.

(Response 169) We agree with this comment. Therefore, we have revised § 1.912(h) of this final rule to allow offsite storage of all records, except for the written procedures required by § 1.908(e)(6)(i), provided that the records can be retrieved and made available to us within 24 hours of a request for official review. As proposed, we will continue to require that the written procedures required by § 1.908(e)(6)(i) remain onsite as long as the procedures are in use in transportation operations. These written procedures comprise cleaning, sanitizing and inspection procedures for

vehicles and equipment, and we believe that they would normally be kept on site because they are used in operations at the site. We are not requiring that carriers maintain records of their actual cleaning, sanitizing and inspection operations they perform on vehicles and equipment. We anticipate that many records will be stored electronically and therefore will be accessible from an onsite food transportation facility.

(Comment 170) A few comments state that it may be difficult for some carriers to promptly provide records, depending on what we mean by the term ''promptly.'' The comment provided an example of a small carrier such as a motor vehicle owner/driver who might own a single motor vehicle used to transport food, who may not carry required records (*e.g.,* training records) while in transit and who might maintain the required records in a private residence. One of these comments asks us to apply reasonable and flexible records production timeframes in these circumstances.

(Response 170) We anticipate that, to the extent feasible, we will carry out records examinations at a carrier's fixed business location. If we were to determine for any reason that it is necessary to request records for examination from a small carrier while the carrier is in transit, we would not necessarily expect the carrier to have the records in its immediate possession, and would provide the carrier with a reasonable amount of time to provide the records. Similarly, if for any reason we were to request records that a carrier maintains at a private residence, we would take into account the circumstances of the of the transportation operation as they may affect the carrier's ability to produce the records promptly.

(Comment 171) One comment states that the records requirements of the proposed rule would be difficult to comply with because the shipper, carrier and receiver roles are not always easily identifiable when food is transported sequentially by more than one person between its point of origin and final destination.

(Response 171) We understand that the sequential shipment of food by multiple persons might involve many persons such as brokers, rail carriers, motor carriers, distributors, etc., and that the roles of these persons may vary from one circumstance to another. Therefore, we have revised this final rule to better define the persons who are subject to the requirements of this rule. As we explained in our response to Comment 70, we have revised the definition of the term ''shipper'' to clarify the scope of this definition. As we also discussed in our response to Comment 53, we have revised the definition of the term ''carrier'' to focus it more narrowly on the person who is responsible for the sanitary condition of the vehicle or transportation equipment used to transport food and to exclude from the definition, a person who is solely responsible for the movement of the vehicle or equipment. We believe the clarity we have added to the shipper, loader, carrier and receiver roles will make recordkeeping easier.

(Comment 172) Some comments state that written agreements assigning duties in compliance with this rule to other persons, as discussed in our response to Comment 16, should be subject to the record keeping provisions of this rule.

(Response 172) We agree. As we discussed in our response to Comment 16, we expect that the parties would have a written contract as proof of their agreement. To enable us to determine which party has responsibility to fulfill a duty assigned by this rule, we are establishing in § 1.912(b) that written agreements assigning duties in compliance with this rule are subject to the record keeping provisions of this rule.

(Comment 173) Some comments express concern that this rule's recordkeeping requirements will pose a burden on businesses. One of these comments states that this rule adds to other FDA records requirements. Another comment questioning the necessity of the records requirements of this rule, states that food transportation vehicles are pre-cooled and inspected before they are loaded and if they do not meet the required sanitary standards, they are refused or sent to be washed out and that this information is recorded in the shipping paperwork and can be provided to shippers, receivers, and FDA if necessary. Another comment acknowledges that it is important for a carrier to be able to demonstrate that a process is in place for training, sanitizing and cleaning, but asserts that retaining records that document these activities for one year would not serve any meaningful food transportation safety purpose.

(Response 173) We have made several revisions to this final rule in response to comments that we received on the proposed rule that will lessen the recordkeeping requirements for persons who are subject to the rule (see Comment 129, Comment 149, Comment 165, and Comment 169). Section 7202(b) of the 2005 SFTA requires us to issue a regulation that ''require[s] shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated.'' Section 7202(c) also states that we must prescribe practices that we deem to be appropriate and necessary relating to, among other things, recordkeeping. As we have explained throughout the preamble to this final rule, we have determined that the records provisions in this final rule are appropriate for this purpose and required of us by our statutory mandate.

(Comment 174) One comment asks us to codify all of the recordkeeping requirements that apply to both the manufacture and transportation of animal feed in one location for ease of accessibility by the animal industry.

(Response 174) We have issued this rule for the sanitary transportation of human and animal food under the 2005 SFTA and the preventive controls rule for animal food under the FSMA, which are two separate grants of statutory authority given to us by Congress. These rules and their records requirements have been codified in distinct parts of Title 21 of the Code of Federal Regulations to reflect these two different authorizing statutes. However, FDA maintains a Web site dedicated to the FSMA, which can be found at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm,* from which industry can quickly access information about this sanitary food transportation rule and the other FSMA rules.

(Comment 175) One comment notes that records that are required by our seafood and juice HACCP rules are exempt from public disclosure under the Freedom of Information Act (FOIA), and asks us to similarly exempt the records required by this final rule from public disclosure. The comment's concern is that the records required by this rule may contain proprietary and confidential information (*e.g.,* contracts between carriers and shippers under proposed § 1.908(d)(2)(ii)), may contain information that could be used to compromise food safety measures (*e.g.,* carrier's written procedures for cleaning and inspecting vehicles and transportation equipment), and could be misunderstood if taken out of context.

(Response 175) We first note that in the rulemaking for the seafood and juice HACCP rules we did not state that records required by these rules are exempt from public disclosure. In this regard, the Agency concluded in the seafood HACCP final rule (60 FR 65096 at 65138), that HACCP plans, as a general rule, meet the definition of trade

secret information, and thus, even if these plans are in Agency files, they likely would not be available under FOIA. However, because FDA is bound by FOIA and the Agency's implementing regulation in 21 CFR part 20, the Agency is unable to exclude categorically all HACCP records in Agency files from public disclosure.

We would determine whether records required by this rule that we copy are either publicly disclosable or protected from public release under the FOI Act on a case-by-case basis. We copy records on a case-by-case basis as necessary and appropriate. We primarily intend to copy such records if the preliminary assessment by our investigator during a routine inspection is that regulatory followup may be appropriate (*e.g.,* if these records demonstrate that cleaning procedures to maintain vehicles in appropriate sanitary condition are not being followed in a food transportation operation). We may consider it necessary to copy records when, for example, our investigators may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate followup regulatory actions. Even in these circumstances, however, certain information in the records could be considered confidential within the scope of the FOI Act and would be redacted from any records that would otherwise be publicly disclosable.

H. Waivers (§§ 1.914–1.934)

In table 11, we describe revisions to proposed §§ 1.914 to 1.934 and following the table we respond to comments related to these provisions.

TABLE 11—§§ 1.914 TO 1.934 WAIVERS

Proposed section	Description	Revision
1.914(a) and (b)	Under what circumstances will FDA waive a requirement of this subpart?	Replaced "FDA" with "we".
1.916	When will FDA consider whether to waive a requirement of this subpart?	Replaced "FDA" with "we".
1.918(a) and (b)	What must be included in the Statement of Grounds in a petition requesting a waiver?	No change.
1.920	What information submitted in a petition requesting a waiver or submitted in comments on such a petition is publicly available?	No change.
1.922	Who will respond to a petition requesting a waiver?	No change.
1.924(a)–(d)	What process applies to a petition requesting a waiver?	No change.
1.926	Under what circumstances may FDA deny a petition requesting a waiver?	Replaced "FDA" with "we".
1.928	What process will FDA follow when waiving a requirement of this subpart on FDA's own initiative?	Replaced "FDA" with "we". Replaced "FDA" with "our".
1.930	When will a waiver granted by FDA become effective	Replaced "granted by FDA" with "that we grant".
1.932	Under what circumstances may FDA modify or revoke a waiver?	Replaced "FDA" with "we".
1.934(a)–(c)	What procedures apply if FDA determines that a waiver should be modified or revoked?	Replaced "FDA determines" with "we determine".

(Comment 176) A comment asks that we clarify how we would waive requirements if we determine that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and that is in the public interest, and how we would communicate these waivers to state agencies.

(Response 176) In §§ 1.924 and 1.928 of the proposed rule, we outlined the processes we will follow when waiving a requirement of this subpart, depending on whether the waiver is granted in response to a submitted petition or on our own initiative. In both cases, we will publish a notice in the **Federal Register** setting forth the waiver and the reasons for such waiver. We believe this explanation is clear; therefore, we are retaining the language in §§ 1.924 and 1.928 in this final rule. Additionally, publication in the **Federal Register** provides notice to all interested parties, including State and Tribal agencies.

(Comment 177) Some comments support our proposal to include in the final rule a petition process whereby we can grant a waiver from the proposed requirements of this rule. Additionally, a few comments urge us to not make such a petition too onerous or burdensome for individuals, small shippers, and owner/operator carriers and to provide lenience and guidance for such situations.

(Response 177) We agree that we should allow a petition process to grant waivers from the requirements of this rule. In § 1.916 of the proposed rule, we stated that we will consider whether to waive a requirement of this rule on our own initiative or on a petition submitted under 21 CFR 10.30. In proposed § 1.918 we outlined what must be included in the Statement of Grounds in the petition. And in proposed § 1.924 we outlined the process that will apply to a petition requesting a waiver. We do not believe that the petition described in § 10.30, the Statement of Grounds described in § 1.918, or the process described in § 1.924 is onerous or burdensome and, therefore, are retaining the language in these sections in the final rule. We do not plan to publish guidance on the petition itself, since it is explained in detail in 21 CFR 10.30.

(Comment 178) A comment strongly urges that we issue public notice of potential waivers and petitions for waivers in the **Federal Register** and allow public comment on each proposed waiver. The comment states that our proposed system of granting waivers for some sanitary transportation requirements without first soliciting public comment is inconsistent with the FD&C Act and the Administrative Procedures Act (APA), since the FD&C Act requires the Secretary to publish waivers and any reasons for the waiver in the **Federal Register** (21 U.S.C. 350e(d)(2)). The comment states that this demonstrates Congress's intent to have the public involved in the waiver process and notes that FDA itself recognized that public comment may be necessary to inform its determination

whether to grant a waiver (79 FR 7006 at 7029).

(Response 178) We will consider whether to waive a requirement of this subpart in one of two ways: (1) On a petition submitted under 21 CFR 10.30 or (2) on our own initiative. For a filed petition, § 1.924(b) states that we will publish a notice in the **Federal Register** requesting information and views on the petition, including information and views from persons who could be affected by the waiver if the petition were to be granted. For waivers to be established on our own initiative, § 1.928 states that we will publish a notice in the **Federal Register** setting forth the waiver and the reasons for such waiver. We disagree that our system of granting waivers for some sanitary transportation requirements without first soliciting public comment is inconsistent with the FD&C Act and the APA. As we discussed in the proposed rule (79 FR 7006 at 7028), when we have determined that a waiver is appropriate in accordance with the standard set forth in section 416(d)(1) of the FD&C Act and proposed § 1.914, we may grant a waiver without first soliciting public comment. We have concluded that this process is sufficient for us granting a waiver on our own initiative because it is the process set forth in section 416(d)(2) of the FD&C Act.

(Comment 179) Some comments recommend that we expedite written responses to waiver petitions and include in the final rule a timeframe for our decision on a petition (*e.g.,* 180 days) and steps to be taken if the deadline is missed.

(Response 179) We disagree with these comments. In proposed § 1.924, we stated that the procedures set forth in 21 CFR 10.30 govern our response to a petition requesting a waiver. 21 CFR 10.30 outlines the petition process and states that we will respond to the petitioner within 180 days of receipt of the petition. 21 CFR 10.30 does not address steps to be taken if the 180-day timeframe is missed.

(Comment 180) Some comments request that we establish a waiver application process that resembles the process for granting a variance under the proposed FSMA produce safety regulation and ensures engagement with the applicant. One of the comments suggests that this process provide an avenue for an industry or a person to request a waiver without the involvement of a state or foreign government. These comments also state that the process should include an opportunity to re-obtain a revoked waiver after a period of time to incentivize long-term commitments to food safety improvement.

(Response 180) The process for granting a variance under the FSMA produce safety rule is very similar to the waiver petition process described in §§ 1.914 to 1.934 of this final rule. Both require the submission of a petition under 21 CFR 10.30, and both require that we publish a notice in the **Federal Register** requesting information and views on the filed petition. Also, in both cases, we will respond to the petitioner in writing and also will make public a notice on our Web site announcing our decision to either grant or deny the petition. Much of the rest of the processes are similar, as well. Both ensure our engagement with the applicant by requiring us to provide a written response to the applicant. Additionally, the process in this final rule does not require involvement of a state or foreign government. Finally, while the waiver petition process doesn't specifically address the opportunity to re-obtain a revoked waiver, it does not preclude an interested party from reapplying for a revoked waiver using the petition process described in this final rule.

(Comment 181) Some comments request clarification regarding whether a waiver can be revoked in whole or part from the group to which it was granted. A few comments suggest that we develop a policy that would allow us to revoke a waiver from a single ''bad actor,'' even when the waiver has been granted to an entire industry. The comments state that by doing so, each member of the industry still maintains individual responsibility for ensuring compliance.

(Response 181) We outlined the process we will follow for modification and revocation of waivers in §§ 1.932 and 1.934 of the proposed rule. Specifically, we stated in § 1.932 that we may 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. We believe the language in §§ 1.932 and 1.934 is clear and, therefore, are retaining it in the final rule. We do not agree that we should establish a policy for revoking a waiver from a single firm. The Sanitary Food Transportation Act of 2005 states that ''the Secretary may waive any requirement under this section, with respect to any class of persons, vehicles, food, or nonfood products . . . .'' Since the SFTA gives FDA the authority to issue waivers to cover any class of persons, vehicles, food, or nonfood products, we believe that revocation of a waiver must also cover that same class of persons, vehicles, food, or nonfood products to which it was issued and not a subset thereof. Nonetheless, FDA can take appropriate action against an individual firm, such as described by this comment, if the firm fails to comply with the requirements of this rule.

(Comment 182) A comment urges us to adopt appropriate provisions in the regulation governing waivers to protect against the disclosure of confidential business information of shippers, carriers, and receivers.

(Response 182) We have adopted appropriate provisions in this regulation related to protection of confidential information. Proposed § 1.920 states that we will presume that information submitted in a petition requesting a waiver and comments submitted on such a petition does not contain information exempt from public disclosure under 21 CFR part 20 and would be made public as part of the docket associated with this request. As we stated in the proposed rule, we do not believe that information exempt from disclosure under 21 CFR part 20 is the type of information that we are requiring to be submitted in such a petition or that would be relevant in any comments submitted on such a petition. We will publicly disclose a petition for waiver or comments on such a petition unless information in those documents falls within the exemption for confidential commercial or trade secret information in 21 CFR part 20.

(Comment 183) A few comments suggest that we provide a window of 60 days for industry to come into compliance with the regulation when a waiver is revoked. The comments state that regulators could increase food safety surveillance of the product or industry during this short time.

(Response 183) We disagree with these comments. In proposed § 1.934(a)(2) we stated that we will publish a notice of our determination that a waiver should be revoked in the **Federal Register.** We believe that this will serve as a notification to the affected industry that we are considering revocation of the waiver and will allow affected parties to plan for changes, should the waiver, in fact, be revoked. Therefore, we are retaining this language in the final rule. After considering written comments on the revocation notice, we will publish our decision in the **Federal Register.** The effective date of the revocation will be the date of publication of the notice.

V. Effective and Compliance Dates

A. Effective and Compliance Dates for Part 1, Subpart O

We proposed that any final rule based on proposed part 1, subpart O become effective 60 days after its date of publication in the **Federal Register**, with staggered compliance dates (79 FR 7006 at 7032). Businesses other than small businesses would have 1 year from the date of publication of the final rule to comply with the rule, whereas small businesses would have 2 years to comply with the rule.

After considering the following comments addressing the proposed compliance dates for this rule, we are establishing the effective and compliance dates as proposed.

(Comment 184) One comment encourages us to allow a phased-in timeframe for compliance with this rule because companies will need time to develop written protocols and train company personnel. One comment states that it is not reasonable to expect the industry to be in compliance in 1 or 2 years, given the cultural changes required by the proposed regulation. One comment states that the 2-year period for compliance for small businesses seems overly generous because many, if not most, of the requirements of this rule should already be in place under existing rules and regulations. A comment states that it will be difficult to implement phased-in compliance dates because inspectors will not be able to determine a business' size when performing single vehicle inspections. The comment recommends that we establish a single compliance date that is possible for all businesses to meet.

(Response 184) It is our general practice for this type of rulemaking, which does not address a public health emergency or other matter that would require a uniform compliance date for all businesses, to consider business size in establishing timeframes for businesses to come into compliance with the rule. After considering these comments, we are retaining the proposed compliance dates for this rule, *i.e.,* 1 year after the date of publication of the final rule for businesses other than small businesses, and 2 years after the date of publication of the final rule for small businesses, because we believe that they are reasonable for businesses subject to this rule. We do expect that questions, such as how would an inspector determine a business' size, may arise during the implementation of this rule. We intend to work closely with the food transportation industry, extension and education organizations, and State, local, and tribal partners to facilitate implementation of this rule. Furthermore, this rule is based upon industry best practices already in place, which should minimize the time for industry to come into compliance.

B. Effective Dates for Conforming Changes

The conforming amendment to part 11 adds a reference to the scope of part 11 that the records required under part 1, subpart O are not subject to part 11. This conforming amendment is effective on June 6, 2016, the same date as the effective date of part 1, subpart O. We are not establishing compliance dates for these conforming amendments. As a practical matter, compliance dates will be determined by the dates for compliance with part 1, subpart O.

VI. Executive Order 13175

In accordance with Executive Order 13175, FDA has consulted with tribal government officials. A Tribal Summary Impact Statement has been prepared that includes a summary of tribal officials' concerns and how FDA has addressed them (Ref. 31). Persons with access to the Internet may obtain the Tribal Summary Impact Statement at *http://www.fda.gov* or at *http://www.regulations.gov.* Copies of the Tribal Summary Impact Statement also may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). We believe that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule defines small business as one subject to this rule 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 this rule having less than $27,500,000 in annual receipts. The Agency concludes that the final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule to result in a 1-year expenditure that would meet or exceed this amount.

The final analysis conducted in accordance with these Executive orders and statutes is available in the docket for this rulemaking (Ref. 24) and at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses.*

VIII. How does the Paperwork Reduction Act of 1995 apply to this final rule?

This final rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (PRA). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping and reporting burdens. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Sanitary Transportation of Human and Animal Food.

Description: This new collection of information will be performed by shippers, receivers, loaders, and carriers of human and animal food. The records requirements of this final rule include records pertaining to: Sanitary specifications, temperature during transportation operations, cleaning of bulk vehicles, training, and written procedures. In addition, this final rule includes submission requirements pertaining to waiver petitions, when appropriate.

We have concluded that recordkeeping and submissions are necessary for the success of the food transportation operation. Records of actions taken due to each requirement are essential for manufacturers to

implement this rule effectively. Further, records and reports are essential for us to be able to determine whether a firm is in compliance with the rule.

Analysis of Burden Estimates Resulting From This Final Rule

Description of Respondents: Shippers, receivers, loaders, and carriers of human and animal food.

In the following paragraphs, we describe and respond to the comments that we received on the PRA for our 2014 proposed rule. We numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

(Comment 185) We received many comments regarding the burden of proposed § 1.908(d)(2)(i), which required demonstration of temperature conditions during a shipment. The comments stated that these burdens can include adoption of a method of monitoring and recording temperatures during shipment, purchase of equipment, implementation of those systems, and the costs of downloading data. One comment stated that, although most carriers have temperature data on temperature-controlled shipments, this data is not readily available and easily retrievable without incurring significant costs. Furthermore, as another comment stated, if the proposed requirement were finalized, far more than the 1 percent of industry estimated in the economic analysis would have to incur these costs. Another comment stated that, while ''reefer'' trailers are generally equipped with thermometers, they do not ordinarily create any kind of permanent printout record to be shown to the receiver. The comment emphasized that any requirement to have this would put unnecessary burdens on industry, particularly small firms. One comment stated that the current practice is for such records to be provided only if there is an indication of a problem (*i.e.,* signs of temperature abuse) upon receipt of the load.

(Response 185) We acknowledge the lack of data available to us when estimating the cost of this proposed requirement. However, as a result of public comment, this requirement has been amended (final § 1.908(e)(2)(i)) to require this demonstration of temperature conditions only when the carrier has agreed by contract with the shipper to assume this responsibility, and only if requested by the shipper or receiver and in a way agreeable to the shipper and carrier, which can include measurements of ambient temperature. We believe this is aligned with current industry practices and is not estimated to represent new cost to industry.

(Comment 186) One commenter stated that proposed § 1.908(d)(4), requiring carriers offering bulk vehicles for food transportation to provide written documentation to the shipper that identifies the three previous cargoes transported in the vehicle, would be overly burdensome. Another comment stated that the estimated burden of this requirement did not include the cost of implementing industry-wide software changes for railroads, as tracking this information is not current industry practice.

(Response 186) These comments did not provide any data to allow us to calculate this burden, and we acknowledge the simplicity of our assumptions in the estimations of the cost related to this provision. However, in response to comments on the proposed rule, this provision has been amended (final § 1.908(e)(4)) to require carriers to provide information identifying the last previous cargo only when they have agreed by contract with the shipper to assume this responsibility, and *only if requested* by the shipper. We believe this provision is aligned with current industry practice. No new burden is estimated for this information collection.

(Comment 187) A commenter stated that proposed § 1.908(d)(5), which required carriers to provide information to shippers describing the most recent cleaning of bulk vehicles, would be beyond the current capabilities of railroads. The comment stated that compliance with this requirement would likely require expensive investments to track this information, as this is not current industry practice.

(Response 187) This comment did not provide any data that would allow us to estimate this burden. However, in response to comments on the proposed rule, this provision has been amended (final § 1.908(e)(5)) to require information describing the most recent cleaning of bulk vehicles only when the carrier has agreed by contract with the shipper to assume this responsibility, and only if requested by the shipper. This provision is believed to be aligned with current industry practice. No new burden is estimated for this information collection.

(Comment 188) One commenter stated that requiring firms to retain records for 1 year would not benefit those along the supply chain and would be unnecessarily burdensome.

(Response 188) This comment does not describe how the 12-month retention requirement would be more burdensome. This final rule reduces the total number of records related to sanitary food transport, which will reduce new burden to industry. Furthermore, the codified provides a wide range of options on how these records must be kept. We estimate that firms will maintain electronic records, which further reduces burden.

(Comment 189) One comment expressed appreciation regarding the ability of industry to diverge from certain proposed requirements, such as those for bulk shipments, by contractual agreement. This comment stated that reflects a practical understanding of the way business is conducted and how flexibility is essential because of the highly complex nature of the transportation chain. This comment went on to state that FDA should permit flexibility to allow businesses to enter into contractual agreements allocating the responsibilities for shippers, carriers, and receivers to other parties.

(Response 189) While this comment did not address the PRA of the proposed rule specifically, it does allow us to estimate that contractual agreements, such as those addressed in § 1.908(b)(3), are common business practice. No additional information collection burden to industry is estimated for such agreements.

FDA estimates the burden of this collection of information as follows:

The total one-time estimated burden imposed by this collection of information is 254,923 hours (228,832 recordkeeping hours + 144 submission hours + 25,947 third-party disclosure hours). The total annual estimated burden imposed by this collection of information is 120,342 hours (120,163 recordkeeping hours + 48 submission hours + 113 third-party disclosure hours). There are no capital costs or operating and maintenance costs associated with this collection of information. FDA estimates that firms will be able to fulfill recordkeeping requirements with existing record systems; that is, FDA estimates that it will not be necessary for firms involved in food transportation to invest in new recordkeeping systems.

One-time burdens are estimated for establishing written procedures regarding integrated transportation operations, written procedures for transportation operations with respect to sanitary condition of vehicles and equipment, previous cargoes, and adequate temperature control; written procedures for cleaning and sanitizing; procedures for use of bulk vehicles; training; notification of operating temperature and written sanitary

specifications, disclosure of information; and submission of waiver petitions, when appropriate. Annual burdens are related to disclosure of written sanitary specifications, operating temperatures, and training records.

First-year and annual burdens related to recordkeeping requirements are presented in table 12. In the economic analysis of this final rule, cost estimations were estimated based on a percentage of, for example, shippers that may have to change behavior as a result of this final rule, or shipments that would have new records associated with them. Calculating percentages of firms or shipments often resulted in fractions; these numbers were rounded to the nearest whole number to be presented in the analysis. Therefore, any discrepancies in table 12 are attributable to rounding.

It is estimated that about 343 recordkeepers will each spend 2 hours (one-time) developing written procedures related to integrated transportation operations, as required by § 1.908(a)(4). Therefore, 343 × 2 = 686 (686.13) one-time hours, as presented in line 1.

The one-time cost of developing written procedures to ensure sanitary condition of vehicles and equipment, as required by § 1.908(b)(3), is estimated at the shipper level. It is estimated that these written procedures are relatively simple and easy to assemble, and that one recordkeeper for about 4,483 firms will spend 0.5 hour adjusting current practices with respect to this requirement. Therefore, 0.5 hours × 4,483 = 2,242 (2,241.69) one-time hours for § 1.908(b)(3), as shown in line 2.

The one-time cost of developing written procedures to ensure that previous cargo does not make food unsafe, as required by § 1.908(b)(4), is estimated at the shipper level. It is estimated that these written procedures are relatively simple and easy to assemble, and that one recordkeeper for about 4,483 firms will spend 0.5 hour adjusting current practices with respect to this requirement. Therefore, 0.5 hours × 4,483 = 2,242 (2,241.69) one-time hours for § 1.908(b)(4), as shown in line 3.

The one-time cost of developing written procedures to ensure that food is transported under adequate temperature control, as required by § 1.908(b)(5), is estimated at the shipper level. It is estimated that these written procedures are relatively simple and easy to assemble, and that one recordkeeper for about 4,483 firms will spend 0.5 hour aligning current practices with this requirement. Therefore, 0.5 hours × 4,483 = 2,242 (2,241.69) one-time hours for § 1.908(b)(5), as shown in line 4.

The one-time cost of development of written procedures related to cleaning and sanitation, as required by § 1.908(e)(6)(i), is estimated at the carrier level. It is estimated that one recordkeeper for about 37,249 firms will spend 2 hours developing written procedures. Therefore, 2 hours × 37,249 = 74,498 (74,498.48) one-time hours for § 1.908(e)(6)(i), as shown in line 5.

The one-time cost of development of written procedures related to bulk vehicles, as required by § 1.908(e)(6)(iii), is estimated at the bulk carrier level. It is estimated that one recordkeeper for about 6,713 firms will spend 2 hours developing written procedures. Therefore, 2 hours × 6,713 = 13,426 (13,426.48) one-time hours for § 1.908(e)(6)(iii), as shown in line 6.

The one-time cost of establishing training records, as required by § 1.910(b), is estimated at the employee level. It is estimated that one recordkeeper will establish a record for about 1,668,698 workers, and this will take 5 minutes (0.08 hours) for each worker. Therefore, 0.08 hour × 1,668,698 = 133,496 (133,495.86) one-time hours for § 1.910(b), as shown in line 7.

The total one-time hourly recordkeeping burden is 228,832 (228,832.02) hours.

The annual cost of training records, as required by final § 1.910(b), is estimated at the worker level. It is estimated that one recordkeeper for each of about 1,502,032 workers will spend 5 minutes (0.08 hour) minutes completing records related to annual training (the time spent training is estimated separately and not included in this PRA analysis). We believe recordkeeping will be very simple and can consist of, for example, printing off a certificate of completion. Therefore, 0.08 hour × 1,502,032 workers = 120,163 (120,162.59) annual hours for § 1.910(b), as shown in line 8. Therefore, the annual hourly recordkeeping burden is 120,163 hours.

TABLE 12—FIRST YEAR ONLY AND ANNUAL RECORDKEEPING BURDENS

21 CFR section	Number of recordkeepers	First year frequency of recordkeeping	Total records	Hours per record	Total hours
First Year Only Hourly Burden					
1. Written Procedures for Integrated Operations (1.908(a)(4))	343	1	343	2	686 (686.13)
2. Written procedures to ensure sanitary condition of vehicles (1.908(b)(3))	4,483	1	4,483	0.5	2,242 (2,241.69)
3. Written procedures to ensure that previous cargo does not make food unsafe (1.908(b)(4))	4,483	1	4,483	0.5	2,242 (2,241.69)
4. Written procedures to ensure that food is transported under adequate temperature control (1.908(b)(5))	4,483	1	4,483	0.5	2,242 (2,241.69)
5. Written procedures, cleaning and sanitation (1.908(e)(6)(i))	37,249	1	37,249	2	74,498 (74,498.48)
6. Written procedures, bulk vehicles (1.908(e)(6)(iii))	6,713	1	6,713	2	13,426 (13,426.48)
7. Training Records (1.910(b))	1,668,698	1	1,668,698	0.08	133,496 (133,495.86)
First Year Only Hourly Recordkeeping Burden					228,832 (228,832.02)

21 CFR section	Number of recordkeepers	First year frequency of recordkeeping	Total records	Hours per record	Total hours
Recurring Hourly Burden					
8. Training Records (1.910(b))	1,502,032	1	1,502,032	0.08	120,163 (120,162.59)
Annual Hourly Recordkeeping Burden					120,163 (120,162.59)

The one-time and annual hourly burdens related to submission of waiver petitions (§ 1.914) are presented in table 13. This final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in § 10.30 have been approved under OMB control number 0910–0183 (General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions).

In the first year, it is estimated that one recordkeeper from each of a total of six firms will each spend 24 hours submitting a waiver petition to FDA (per the estimate for the petition process in § 10.30, approved and estimated under OMB control number 0910–0183 as 24 hours per submission). Therefore, 6 waiver petitions × 24 hours = 144 one-time hours for § 1.914, as shown in line 1. Annually, it is estimated that one recordkeeper from each of a total of two firms will spend 24 hours submitting a waiver petition to FDA. Therefore, 2 waiver petitions × 24 hours = 48 annual hours for § 1.914, as shown in line 2.

TABLE 13—FIRST YEAR AND ANNUAL SUBMISSION BURDEN

21 CFR section	Number of recordkeepers	First year frequency of recordkeeping	Total records	Hours per record	Total hours
Estimated First Year Only Submission Burden					
1. Waiver Petitions (1.914)	6	1	6	24	144

21 CFR section	Number of recordkeepers	First year frequency of recordkeeping	Total records	Hours per record	Total hours
Estimated Annual Submission Burden					
2. Waiver Petitions (1.914)	2	1	2	24	48

The one-time and hourly burdens related to third-party disclosures are presented in table 14. The one-time cost of developing written sanitary specifications necessary for transportation, as required by § 1.908(b)(1), is estimated at the shipper level. It is estimated that one recordkeeper for each of about 10,163 firms will spend 30 minutes developing written sanitary specifications. Therefore, 0.5 hour × 10,163 firms = 5,082 (5,081.57) one-time hours for § 1.908(b)(1), as shown in line 1.

The one-time cost of developing initial notifications of operating temperature, as required by § 1.908(b)(2), is estimated at the shipper level. It is estimated that one recordkeeper for each of about 5,646 firms will spend 30 minutes (0.5 hour) developing these notifications. Therefore, 0.5 hour × 5,646 firms = 2,823 (2,823.13) hours, as shown in line 2.

The one-time cost of establishing records pertaining to disclosure of information, as required by § 1.912(a), is estimated at the firm level. It is estimated that one recordkeeper will establish a record at a total of about 36,084 firms, and this will take 30 minutes (0.5 hour) for each record. Therefore, 0.5 hour × 36,084 = 18,042 (18,041.88) one-time hours for § 1.912(a), as shown in line 3.

The total one-time hourly third-party disclosure burden is 25,947 (25,946.57) hours.

The annual cost of disclosing necessary sanitary specifications, as required by § 1.908(b)(1), is estimated at the firm level. It is estimated that 1 recordkeeper for each of about 226 firms will spend 5 minutes disclosing sanitary specifications. Therefore, 0.08 hour × 226 shipments = 18 (18.07) annual hours for § 1.908(b)(1), as shown in line 4.

The annual cost of disclosing operating temperature conditions, as required by § 1.908(b)(2), is estimated at the shipper level. It is estimated that 1 recordkeeper for each of about 226 firms will spend 30 minutes (0.5 hour) disclosing necessary temperature conditions. Therefore, 0.5 hour × 226 firms = 113 (112.93) annual hours for § 1.908(b)(2), as shown in line 5.

The total annual hourly third-party disclosure burden is 131 (130.99) hours.

TABLE 14—THIRD-PARTY DISCLOSURE BURDEN

21 CFR section	Number of recordkeepers	First year frequency of recordkeeping	Total records	Hours per record	Total hours
Estimated First Year Only Third-Party Disclosure Burden					
1. Written Sanitary Specifications (1.908(b)(1))	10,163	1	10,163	0.5	5,082 (5,081.57)
2. Notification of operating temperature (1.908(b)(2))	5,646	1	5,646	0.5	2,823 (2,823.13)
3. Records pertaining to disclosure of information (1.912(a))	36,084	1	36,084	0.5	18,042 (18,041.88)
Total					25,947 (25,946.57)
Estimated Annual Third-Party Disclosure Burden					
4. Sanitary Specifications (1.908(b)(1))	226	1	226	0.08	18 (18.07)
5. Operating temperature conditions (1.908(b))(2)	226	1	226	0.5	113 (112.93)
Total					131 (130.99)

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. What is the environmental impact of this rule?

We have determined, under 21 CFR 25.30(j), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment (Refs. 32 and 33). Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. What are the federalism impacts of this rule?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132 on federalism. We have examined the effects of the requirements of this rule on the relationship between the Federal Government and the States. We conclude that Federal preemption of State or local rules that establish requirements for the sanitary transportation of human and animal food such that: (1) Complying with the requirements of the State or political subdivision and with a requirement of section 416 of the FD&C Act, or with this rule, is not possible; or (2) the requirements of the State or political subdivision, as applied or enforced, is an obstacle to accomplishing and carrying out section 416 of the FD&C Act or this rule, is consistent with this Executive order. FDA has not incorporated text in this rule to reflect this preemptive effect because section 416(e) of the FD&C Act expressly provides for this preemption.

Section 3(b) of Executive Order 13132 recognizes that Federal action limiting the policymaking discretion of States is appropriate ''where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance.'' The constitutional basis for FDA's authority to regulate food safety is well established. Section 4(a) of Executive Order 13132 expressly contemplates preemption where the exercise of State authority conflicts with the exercise of Federal authority under a Federal statute. Moreover, section 4(b) of Executive Order 13132 authorizes preemption of State law by rulemaking when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute, or there is clear evidence to conclude that Congress intended the Agency to have the authority to preempt State law.

Section 4(e) of the Executive order provides that, ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' As required by the Executive order, FDA provided the States and local governments with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the proposed rule in the **Federal Register** on February 5, 2014 (79 FR 7006). In the proposal, FDA specifically described this preemptive effect. In addition, we held three public meetings during the comment period for the proposed rule to discuss the provisions of the rule, answer questions, and solicit comments from stakeholders, including from State and local government representatives. Meetings were held February 27, 2014, in Chicago, IL; March 13, 2014, in Anaheim, CA; and March 20, 2014, in College Park, MD.

We received comments on the proposed rule from several State government agencies. Most of these comments addressed matters in this rulemaking other than the issue of preemption of State and local requirements for the sanitary transportation of human and animal food. One comment stated that the preemptive provision of section 416(e)(1) or (2) of the FD&C Act could function to prevent States from developing a unified sanitary transportation regulation that would address all modes of transportation. However, a State law, including unified State laws, should states wish to adopt such laws, concerning the sanitary transportation of food by motor vehicle

or rail vehicle, is not preempted if such laws do not fall under either section 416(e)(1) or (2) of the FD&C Act. Furthermore, it is highly unlikely that any State law addressing transportation operations not subject to the 2005 SFTA, *e.g.,* barge transport, would fall within the scope of the 2005 SFTA's preemption provision. In conclusion, we have determined that the preemptive effects of this final rule are consistent with Executive Order 13132.

XI. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Oxford Dictionary (2015). ''Definition of ''Best Practice,'' (*http://www.oxforddictionaries.com/us/definition/american_english/best-practice*), accessed and printed on December 16, 2015.
2. FDA Memorandum, ''FDA Memorandum to Dockets on Records of Outreach,'' 2013. Available in Docket No. FDA–2011–N–0920.
3. FDA Memorandum, ''Memoranda of Outreach,'' 2015.
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List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 11 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342i, 343, 350c, 350d, 350e, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Add subpart O, consisting of §§ 1.900 through 1.934, to part 1 to read as follows:

Subpart O—Sanitary Transportation of Human and Animal Food

General Provisions

Sec.
1.900 Who is subject to this subpart?
1.902 How do the criteria and definitions in this subpart apply under the Federal Food, Drug, and Cosmetic Act?
1.904 What definitions apply to this subpart?

Vehicles and Transportation Equipment

1.906 What requirements apply to vehicles and transportation equipment?

Transportation Operations

1.908 What requirements apply to transportation operations?

Training

1.910 What training requirements apply to carriers engaged in transportation operations?

Records

1.912 What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations?

Waivers

1.914 Under what circumstances will we waive a requirement of this subpart?
1.916 When will we consider whether to waive a requirement of this subpart?
1.918 What must be included in the Statement of Grounds in a petition requesting a waiver?
1.920 What information submitted in a petition requesting a waiver or submitted in comments on such a petition is publicly available?
1.922 Who will respond to a petition requesting a waiver?
1.924 What process applies to a petition requesting a waiver?
1.926 Under what circumstances may we deny a petition requesting a waiver?
1.928 What process will we follow when waiving a requirement of this subpart on our own initiative?
1.930 When will a waiver that we grant become effective?
1.932 Under what circumstances may we modify or revoke a waiver?
1.934 What procedures apply if we determine that a waiver should be modified or revoked?

Subpart O—Sanitary Transportation of Human and Animal Food

General Provisions

§ 1.900 Who is subject to this subpart?

(a) Except for non-covered businesses as defined in § 1.904 and as provided for in paragraph (b) of this section, the requirements of this subpart apply to shippers, receivers, loaders, and carriers engaged in transportation operations whether or not the food is being offered for or enters interstate commerce. The requirements of this subpart apply in addition to any other requirements of this chapter that are applicable to the transportation of food, *e.g.,* in 21 CFR parts 1, 117, 118, 225, 507, and 589.

(b) The requirements of this subpart do not apply to shippers, receivers, loaders, or carriers when they are engaged in transportation operations:

(1) Of food that is transshipped through the United States to another country; or

(2) Of food that is imported for future export, in accordance with section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act, and that is neither consumed nor distributed in the United States; or

(3) Of food when it is located in food facilities as defined in § 1.227 of this chapter, that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.902 How do the criteria and definitions in this subpart apply under the Federal Food, Drug, and Cosmetic Act?

(a) The criteria and definitions of this subpart apply in determining whether food is adulterated within the meaning of section 402(i) of the Federal Food, Drug, and Cosmetic Act in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations under conditions that are not in compliance with this subpart.

(b) The failure by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations to comply with the requirements of this subpart is a prohibited act under section 301(hh) of the Federal Food, Drug, and Cosmetic Act.

§ 1.904 What definitions apply to this subpart?

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions also apply:

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 § 1.227 of this chapter.

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.

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 § 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 § 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.

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.

Vehicles and Transportation Equipment

§ 1.906 What requirements apply to vehicles and transportation equipment?

(a) Vehicles and transportation equipment used in transportation operations must be so 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, *i.e.,* adulterated within the meaning of section 402(a)(1), (2), and (4) of the Federal Food, Drug, and Cosmetic Act during transportation operations.

(b) Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.

(c) Vehicles and transportation equipment used in transportation operations for 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 operations.

(d) Vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in food for which it will be used becoming unsafe during transportation operations.

Transportation Operations

§ 1.908 What requirements apply to transportation operations?

(a) *General requirements.* (1) Unless stated otherwise in this section, the requirements of this section apply to all shippers, carriers, loaders, and receivers engaged in transportation operations. A person may be subject to these requirements in multiple capacities, *e.g.,* the shipper may also be the loader and the carrier, if the person also performs the functions of those respective persons as defined in this subpart. An entity subject to this subpart (shipper, loader, carrier, or receiver) may reassign, in a written agreement, its responsibilities under this subpart to another party subject to this subpart. The written agreement is subject to the records requirements of § 1.912(d).

(2) Responsibility for ensuring that transportation operations are carried out in compliance with all requirements in this subpart must be assigned to competent supervisory personnel.

(3) All transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations including:

(i) Taking 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.

(ii) Taking 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.

(iii) Taking effective measures to ensure that food that requires temperature control for safety is transported under adequate temperature control.

(4) The type of food, *e.g.,* animal feed, pet food, human food, and its production stage, *e.g.,* raw material, ingredient or finished food, must be considered in determining the necessary conditions and controls for the transportation operation.

(5) Shippers, receivers, loaders, and carriers, which are under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of paragraphs (b), (d), and (e) of this section may conduct transportation operations in conformance with common, integrated written procedures that ensure the sanitary transportation of food consistent with the requirements of this section. The written procedures are subject to the records requirements of § 1.912(e).

(6) If a shipper, loader, receiver, or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the food shall not be sold or otherwise distributed, and these persons 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.

(b) *Requirements applicable to shippers engaged in transportation*

operations. (1) Unless the shipper takes other measures in accordance with paragraph (b)(3) of this section to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.,* that will prevent the food from becoming unsafe, the shipper 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. One-time notification shall be sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported, in which case the shipper shall so notify the carrier in writing before the shipment. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a).

(2) Unless the shipper takes other measures in accordance with paragraph (b)(5) of this section to ensure that adequate temperature control is provided during the transportation of food that requires temperature control for safety under the conditions of shipment, a shipper of such food 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. One-time notification shall be sufficient unless a factor, *e.g.,* the conditions of shipment, changes, necessitating a change in the operating temperature, in which case the shipper shall so notify the carrier in writing before the shipment. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a).

(3) A shipper must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.,* will prevent the food from becoming unsafe during the transportation operation. Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of § 1.912(a).

(4) A shipper of food transported in bulk must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that a previous cargo does not make the food unsafe. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of § 1.912(a).

(5) The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures, subject to the records requirements of § 1.912(a), to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of § 1.912(a) and must include measures equivalent to those specified for carriers under paragraphs (e)(1) through (3) of this section.

(c) *Requirements applicable to loaders engaged in transportation operations.* (1) Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment the loader must determine, considering, as appropriate, specifications provided by the shipper in accordance with paragraph (b)(1) of this section, that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, *e.g.,* 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. This may be accomplished by any appropriate means.

(2) Before loading food that requires temperature control for safety, the loader must verify, considering, as appropriate, specifications provided by the shipper in accordance with paragraph (b)(2) of this section, 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.

(d) *Requirements applicable to receivers engaged in transportation operations.* Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver 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.

(e) *Requirements applicable to carriers engaged in transportation operations.* When the carrier and shipper have a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operation, the carrier is responsible for the following functions as applicable per the agreement:

(1) A 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.

(2) A carrier must, once the transportation operation is complete and if requested by the receiver, provide the operating temperature specified by the shipper in accordance with paragraph (b)(2) of this section and, if requested by the shipper or receiver, demonstrate that it has maintained temperature conditions during the transportation operation consistent with the operating temperature specified by the shipper in accordance with paragraph (b)(2) of this section. Such 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.

(3) 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, a carrier must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper in accordance with paragraph (b)(2) of this section.

(4) 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.

(5) 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.

(6) A carrier must develop and implement written procedures subject to the records requirements of § 1.912(b) that:

(i) 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 § 1.906(b);

(ii) Describe how it will comply with the provisions for temperature control in paragraph (e)(2) of this section, and;

(iii) Describe how it will comply with the provisions for the use of bulk vehicles in paragraphs (e)(4) and (5) of this section.

Training

§ 1.910 What training requirements apply to carriers engaged in transportation operations?

(a) When the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, the carrier must provide adequate training to personnel engaged in transportation operations that provides 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 this part. The training must be provided upon hiring and as needed thereafter.

(b) Carriers must establish and maintain records documenting the training described in paragraph (a) of this section. Such records must include the date of the training, the type of training, and the person(s) trained. These records are subject to the records requirements of § 1.912(c).

Records

§ 1.912 What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations?

(a) Shippers must retain records:

(1) That demonstrate that they provide specifications and operating temperatures to carriers as required by § 1.908(b)(1) and (2) as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers.

(2) Of written agreements and the written procedures required by § 1.908(b)(3), (4), and (5), for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.

(b) Carriers must retain records of the written procedures required by § 1.908(e)(6) for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.

(c) Carriers must retain training records required by § 1.910(b) for a period of 12 months beyond when the person identified in any such records stops performing the duties for which the training was provided.

(d) Any person subject to this subpart must retain any other written agreements assigning tasks in compliance with this subpart for a period of 12 months beyond the termination of the agreements.

(e) Shippers, receivers, loaders, and carriers, which operate under the ownership or control of a single legal entity in accordance with the provisions of § 1.908(a)(5), must retain records of the written procedures for a period of 12 months beyond when the procedures are in use in their transportation operations.

(f) Shippers, receivers, loaders, and carriers must make all records required by this subpart available to a duly authorized individual promptly upon oral or written request.

(g) All records required by this subpart 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.

(h) Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

(i) Except for the written procedures required by § 1.908(e)(6)(i), offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The written procedures required by § 1.908(e)(6)(i) must remain onsite as long as the procedures are in use in transportation operations. Electronic records are considered to be onsite if they are accessible from an onsite location.

(j) All records required by this subpart are subject to the disclosure requirements under part 20 of this chapter.

Waivers

§ 1.914 Under what circumstances will we waive a requirement of this subpart?

We will waive any requirement of this subpart with respect to any class of persons, vehicles, food, or nonfood products, 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.

§ 1.916 When will we consider whether to waive a requirement of this subpart?

We will consider whether to waive a requirement of this subpart on our own initiative or on the petition submitted under § 10.30 of this chapter by any person who is subject to the requirements of this subpart with respect to any class of persons, vehicles, food, or nonfood products.

§ 1.918 What must be included in the Statement of Grounds in a petition requesting a waiver?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a waiver must:

(a) Describe with particularity the waiver requested, including the persons, vehicles, food, or nonfood product(s) to which the waiver would apply and the requirement(s) of this subpart to which the waiver would apply; and

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

§ 1.920 What information submitted in a petition requesting a waiver or submitted in comments on such a petition is publicly available?

We will presume that information submitted in a petition requesting a waiver and comments submitted on such a petition does not contain information exempt from public disclosure under part 20 of this chapter and would be made public as part of the docket associated with this request.

§ 1.922 Who will respond to a petition requesting a waiver?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN) or the Center for Veterinary Medicine (CVM), or the Director, Office of Compliance, CFSAN, or the Director, Office of Surveillance and Compliance, CVM, will respond to a petition requesting a waiver.

§ 1.924 What process applies to a petition requesting a waiver?

(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a waiver.

(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the **Federal Register,** requesting information and views on a filed petition, including information and views from persons who could be affected by the waiver if the petition were to be granted.

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing.

(1) If we grant the petition, either in whole or in part, we will publish a notice in the **Federal Register** setting forth any waiver and the reasons for such waiver.

(2) If we deny the petition (including partial denials), our written response to the petitioner will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting waivers, including the status of each petition (for example, pending, granted, or denied).

§ 1.926 Under what circumstances may we deny a petition requesting a waiver?

We may deny a petition requesting a waiver if the petition does not provide the information required under § 1.918 (including the requirements of § 10.30 of this chapter), or 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.

§ 1.928 What process will we follow when waiving a requirement of this subpart on our own initiative?

If we, on our own initiative, determine that a waiver is appropriate, we will publish a notice in the **Federal Register** setting forth the waiver and the reasons for such waiver.

§ 1.930 When will a waiver that we grant become effective?

Any waiver that we grant will become effective on the date that notice of the waiver is published in the **Federal Register**.

§ 1.932 Under what circumstances may we modify or revoke a waiver?

We may 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.

§ 1.934 What procedures apply if we determine that a waiver should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify the entity that initially requested the waiver, in writing at the address identified in its petition, if we determine that a waiver granted in response to its petition should be modified or revoked.

(2) We will publish a notice of our determination that a waiver should be modified or revoked in the **Federal Register.** This notice will establish a public docket so that interested parties may submit written submissions on our determination.

(b) We will consider timely written submissions submitted to the public docket from interested parties.

(c) We will publish a notice of our decision in the **Federal Register.** The effective date of the decision will be the date of publication of the notice.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 4. Section 11.1 is amended by adding paragraph (n) to read as follows:

§ 11.1 Scope.

* * * * *

(n) This part does not apply to records required to be established or maintained by subpart O of part 1 of this chapter. Records that satisfy the requirements of subpart O of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

Dated: March 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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