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21 CFR Part 1
Sanitary Transportation of Human and Animal Food; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2013–N–0013]

RIN 0910–AG98

Sanitary Transportation of Human and Animal Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to establish requirements for shippers, 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 FDA Food Safety Modernization Act of 2011 (FSMA).

DATES: Submit either electronic or written comments on the proposed rule by May 31, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0013 and/or Regulatory Information Number (RIN) 0910–AG98, by any of the following methods except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document):

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA–2013–N–0013, and RIN 0910–AG98 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number found in brackets in the heading of this document into the ''Search'' box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

With regard to this proposed rule: Michael E. Kashtock, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2022.

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, 1350 Picard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Proposed Rule

The Food Safety Modernization Act 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. Isolated incidents of insanitary transportation practices for human and animal food and outbreaks and illnesses caused by contamination of these foods during transport there have resulted in concerns over the past decades about the potential that food can become contaminated during transportation. The goal of the proposed rule is to ensure that transportation practices do not create food safety risks. Practices that create such risk include failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food during transportation. The proposed rule builds on current safe food transport 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. It otherwise 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. The proposed rule would not cover shippers, receivers, or carriers engaged in food transportation operations that have less than $500,000 in total annual sales. In addition, the requirements in the proposed rule would not apply to the transportation of fully packaged shelf-stable foods, live food animals and raw agricultural commodities (RACs) when RACs are transported by farms. In addition, persons subject to the rule could request waivers from its requirements if they can show that the waiver will not result in the transportation of food under conditions that would be unsafe for human and animal health and will not be contrary to the public interest.

Summary of the Major Provisions of the Proposed Rule

As required by FSMA, the proposed rule would address the sanitary transportation of food (human and animal food) by establishing criteria and definitions that would apply in determining 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 engaged in the transportation of food under conditions that are not in compliance with the sanitary food transportation regulations.

The proposed rule would define transportation as any movement of food in commerce by motor vehicle or rail vehicle. The proposed rule would also establish requirements for sanitary transportation practices applicable to shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in food transportation operations.

Specifically, the proposed rule would 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.

The proposed rule is intended to ensure that persons engaged in the transportation of food that is at the greatest risk for contamination during transportation follow appropriate sanitary transportation practices. For example, the proposed rule would require that shippers inspect a vehicle for cleanliness prior to loading food that is not completely enclosed by its container, e.g., fresh produce in vented boxes, onto the vehicle. The proposed rule would also require that persons engaged in transportation operations for foods that require time/temperature control to ensure their safety (TCS food), e.g., meat, poultry, seafood, raw seed sprouts, or unpasteurized shell eggs, or to prevent microbial spoilage, e.g., pasteurized juice, take actions to ensure the maintenance of the transportation cold chain such as the pre-cooling of the vehicle by the carrier with subsequent verification by the shipper before the food is loaded onto the vehicle.

The proposed rule would require that shippers specify to carriers in writing the sanitary requirements for a vehicle or transportation equipment to be provided for all food subject to this proposal and the temperature requirements for foods subject to temperature control requirements. The proposed rule would require that shippers maintain records that demonstrate that they provide this information to carriers.

Additionally, for food subject to temperature control requirements, the proposed rule would require that carriers demonstrate to shippers and, upon request, to receivers that they have maintained appropriate temperature control for the food during the transportation operation. The proposed rule would also require carriers to provide information to shippers about previous cargoes hauled in bulk vehicles offered for the transportation of food and the intervening cleaning of those vehicles. The proposed rule would require that carriers develop and implement written procedures subject to recordkeeping that describe how they will provide these items of information to shippers and receivers.

The proposed rule would establish requirements for carriers to develop and implement written procedures subject to recordkeeping that specify its practices for cleaning, sanitizing, and inspecting vehicles and transportation equipment as required by this rule.

The proposed rule would establish requirements for the training of carrier personnel engaged in transportation operations, including a requirement for records that document the training.

Further, the proposed rule would establish procedures by which FDA will waive any of these requirements if FDA determines 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, and procedures that FDA will follow when revoking such waivers.

The proposed rule would not cover shippers, receivers, or carriers engaged in food transportation operations that have less than $500,000 in total annual sales.

We have developed this proposed rule implementing the 2005 SFTA and FSMA to operate in conjunction with other rules we will be issuing under FSMA to ensure that the safety of food during transportation is effectively addressed as part of FDA's comprehensive effort to strengthen the food safety system. Under FSMA, FDA has proposed rules on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (78 FR 3646, January 16, 2013) and animal (78 FR 64736, October 29, 2013) food facilities (the proposed preventive controls rules for human and animal food, respectively) and on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (78 FR 3504, January 16, 2013).

Costs and Benefits

This proposed rule is estimated to cover 83,609 firms. This number includes carriers engaged in food transportation and food facilities including the U.S. Department of Agriculture (USDA) establishments that ship food subject to this proposed rule. Total first year cost is estimated to be $149.1 million (with an average of $1,784 per firm), and total annual cost is estimated to be $30.08 million (with an average of $360 per firm).

We lack sufficient data to quantify the potential benefits of the proposed rule. The causal chain from inadequate food transportation to human and animal health and welfare can be specified but not quantified. Because no complete data exist to precisely quantify the likelihood of food becoming adulterated during its transport, we are unable to estimate the effectiveness of the requirements of the proposed rule to reduce potential adverse health effects in humans or animals. Furthermore, while we expect small changes in behavior (in the form of safer practices), we do not anticipate large scale changes in practices as a result of the requirements of this proposed rule. Nevertheless, improving food transportation systems could reduce the number of recalls, reduce the risk of adverse health effects related to such contaminated human and animal food and feed, and reduce the losses of contaminated human and animal food and feed ingredients and products.

Table of Contents

I. Background

Due to illness outbreaks involving human food and animal food that became contaminated during transportation (Ref. 1) (Ref. 2) and incidents and reports of insanitary transportation practices (Ref. 3) (Ref. 4) (Ref. 5) (Ref. 6) (Ref. 7) (Ref. 8), 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. 9). 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 led to concern that food products could become contaminated and unfit for human consumption if irresponsible vehicle operators failed to prevent contamination of food products in vehicles that had been previously used to haul waste or other non-food materials. Congress responded to these concerns by passing the Sanitary Food Transportation Act of 1990 (1990 SFTA) 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. 1).

In 2005 Congress withdrew the 1990 SFTA and passed the 2005 SFTA, a broader food transportation safety law than the 1990 SFTA in that its focus was not limited only to preventing food contamination from nonfood sources during transportation. The 2005 SFTA directed FDA 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.

In April of 2010 FDA issued guidance to provide the industry with broadly applicable recommendations for controls to prevent food safety problems during transport while it was in the process of implementing 2005 SFTA (Ref. 10).

As part of our implementation of the 2005 SFTA, we also issued an advance notice of proposed rulemaking in 2010 (the 2010 ANPRM; 75 FR 22713) to request data and information on the food transportation industry and its practices and on the contamination of transported foods and any associated outbreaks.

In the 2010 ANPRM we discussed the concerns about safe food transportation dating from the 1980s as well as current practices in the food transportation industry and areas where food is at risk for contamination. We discussed DOTs actions in response to the 1990 SFTA. We also noted findings released in 2007, of an Interstate Food Transportation Project carried out by a number of Midwestern states (Refs. 3) (Ref. 4). The purpose of the project was to determine the current state of food safety and food defense in the context of in-transit food in interstate commerce. The project identified several areas of concern in food transport relevant to this rulemaking that increase the likelihood of food contamination, such as improper refrigeration, transport of raw meat and poultry in a manner that could result in cross-contamination of fresh fruits and vegetables transported in the same vehicle (cross-contamination is the transfer of harmful bacteria to food from other foods when food is improperly handled), improper packaging, infestation with insects, insanitary storage (e.g., roof leaks and moldy walls, animal blood and food on bed floors), low driver awareness of safe food temperatures, and inadequate food safety training of drivers. Most of the specific instances where food transportation problems were found involved smaller box trucks; there were ''little or no areas of concern'' identified with larger (semi-tractor trailer) trucks inspected during the project's survey.

We also discussed the findings, issued in a 2009 report, of a study conducted for FDA by the Eastern Research Group (the ERG report) to characterize current baseline practices in the sectors involved in food transportation and to identify current areas where food is at risk for adulteration (Ref. 9).

The ERG report identified a number of areas where food may be at risk for physical, chemical, or biological contamination during transport and storage:

- Improper refrigeration or temperature control of food products (temperature abuse).
- Improper management of transportation units or storage facilities to preclude cross-contamination, including improper sanitation, backhauling hazardous materials, not maintaining tanker wash records, improper disposal of wastewater, and aluminum phosphide fumigation methods in railcar transit;
- Improper packing of transportation units or storage facilities, including incorrect use of packing materials and poor pallet quality;
- Improper loading practices, conditions, or equipment, including improper sanitation of loading equipment, not using dedicated units where appropriate, inappropriate loading patterns, and transporting mixed loads that increase the risk for cross-contamination;
- Improper unloading practices, conditions, or equipment, including improper sanitation of equipment and leaving raw materials on loading docks after hours;
- Poor pest control in transportation units or storage facilities;
- Lack of driver/employee training and/or supervisor/manager/owner knowledge of food safety and/or security;
- Poor transportation unit design and construction;
- Inadequate preventive maintenance for transportation units or storage facilities, resulting in roof leaks, gaps in doors, and dripping condensation or ice accumulations;
- Poor employee hygiene;
- Inadequate policies for the safe and/or secure transport or storage of foods;
- Improper handling and tracking of rejected loads and salvaged, reworked, and returned products or products destined for disposal; and
- Improper holding practices for food products awaiting shipment or inspection, including unattended product, delayed holding of product, shipping of product while in quarantine, and poor rotation and throughput.

To obtain data that would be current and relevant and to augment the information in the ERG report, we requested public comments containing data and information on questions associated with several specific issues (see the 2010 ANPRM for the issues and questions). We received about 45 comments from a variety of submitters including human and animal food processors and their trade organizations, food distributors and their trade organizations, food retailers and their trade organizations, transportation equipment manufacturers and suppliers, motor and rail carriers and their trade organizations, an organization representing independent truck owner-operators, a State government agency, a consumer advocacy organization, and individual consumers. Where comments informed specific provisions of this proposed rule, we discuss those comments in the relevant part of section III of this document.

A few comments addressed section 416(c)(2)(A) and (c)(2)(B) of the 2005 SFTA, which direct FDA to include in the sanitary food transportation regulations: (1) A list of nonfood products that the Secretary of Health and Human Services (the Secretary) determines may, if shipped in a bulk vehicle, render adulterated food that is subsequently transported in the same vehicle; and (2) a list of nonfood products that the Secretary determines 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. Some of the comments addressing this subject offered that lists that prohibit the transport of food and non-food items together would be illogical because they would create requirements for commercial food transportation that do not reflect how consumers privately transport food, wherein they transport food and non-food items together to their homes. One comment asserted that the simultaneous transportation of food and hazardous materials should be prohibited.

While certain combinations of non-food cargos and food cargos (either as a co-cargo or subsequent cargo) may

present the potential for adulteration of the food cargo under certain conditions of transportation, the likelihood of such adulteration is very situation specific. This is because the ability of a non-food product to adulterate a food product in either case is dependent upon, among other things: The construction of the vehicle; the nature and concentration of the non-food product and any contaminants therein contained; the manner and extent of cleaning and sanitizing operations between the cargos; the nature, subsequent processing, and intended use of the food cargo; the manner in which the food and non-food cargos are stored in the vehicle (for non-bulk vehicles); and the manner in which food and non-food cargos are packaged (for non-bulk vehicles). For this reason, we have tentatively concluded that we cannot identify any specific non-food product that may, under all circumstances, adulterate food subsequently hauled in a bulk vehicle, such that we could propose a list of such products in this proposed rule. We have also tentatively concluded that we cannot identify any specific non-food products that may, under all circumstances, adulterate food subsequently or simultaneously hauled in a non-bulk vehicle, such that we could propose a list of such products in this proposed rule. However, we have also tentatively concluded that guidance on how the specifics of the transportation operation affect the potential for non-food products to adulterate food products would be helpful to the transportation industry and intend to develop such guidance upon publication of this final rule. We request comment on these tentative conclusions.

Further, we recognize that within the bulk and non-bulk segments of the food transportation industry, carriers routinely transport non-food items in vehicles that subsequently or simultaneously (for non-bulk vehicles) haul food. Based upon the comments we received in response to the 2010 ANPRM, we believe that in many instances, shippers and carriers working together, e.g., through information sharing, establish procedures for transportation operations that adequately address any concerns that may exist about non-food prior and co-cargos. In other instances, transportation operations are carried out in accordance with various industry best practices guidelines that address non-food prior and co-cargos. This proposed rule, and the proposed preventive controls rules for human and animal food, will establish new requirements that will, respectively, provide for information disclosure between shippers and carriers and consideration of transportation practices within a facility's hazard analysis, that we tentatively conclude will be sufficient to enable shippers covered by this proposed rule and facilities covered by the proposed preventive controls rules to establish safe transportation practices for their bulk and non-bulk shipments where non-food prior or co-cargos are a consideration.

II. Legal Authority

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

The 2005 SFTA amended the Federal Food, Drug, and Cosmetic Act (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 directed us to issue regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food 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.

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, and new section 301(hh) in the FD&C Act (21 U.S.C. 331(hh)) to prohibit 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 proposed rule also derives from sections 402(a)(1), (a)(3), (a)(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)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. 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. The proposed rule includes requirements that are necessary to prevent food from being adulterated (either by becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source) during transportation operations. These requirements allow for the efficient enforcement of the FD&C Act.

III. Description of the Proposed Rule

We are proposing to establish new 21 CFR part 1, subpart O, entitled ''Sanitary Transportation of Human and Animal Food.'' The proposed rule would specify sanitary transportation practices to be used by shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food to ensure that food is not transported under conditions that may render the food adulterated.

A. Scope (Proposed § 1.900)

Proposed § 1.900 addresses who is subject to the requirements of subpart O. Proposed § 1.900(a) would provide that except for non-covered businesses as defined in proposed § 1.904 (who would not be subject to this rule as discussed

in section III.C of this document), the requirements of subpart O would apply to shippers, receivers, and carriers engaged in transportation operations for food whether or not the food is offered for or enters interstate commerce. Proposed § 1.900(b) would provide that the requirements of subpart O do not apply to shippers, receivers, or carriers when they are engaged in transportation operations of: (1) Food that is transshipped through the United States to another country; or (2) food that is imported for future export and that is neither consumed or distributed in the United States.

1. Other Persons Engaged in the Transportation of Food

Section 416(b) of the FD&C Act explicitly states that these regulations should address ''other persons'' engaged in the transportation of food. We considered what other entities could constitute ''other persons'' engaged in the transportation of food who are not shippers, receivers, or carriers and whether proposing requirements for ''other persons'' engaged in the transportation of food was necessary to ensure that food is not transported under conditions that may render the food adulterated. As part of that consideration we reviewed the comments to the 2010 ANPRM for any information that might suggest that applying the provisions of this proposed rule to such persons might substantially further the use of sanitary food transportation practices. After reviewing these comments and other information available to us about the transportation industry, and considering the definitions we are proposing for shippers, carriers, and receivers, we have tentatively concluded that there are not ''other persons'' engaged in the transportation of food whose function in food transportation would be expected to affect the sanitary condition of food, and as such, should be subject to the requirements of this rule. Therefore we are not proposing to subject persons other than shippers, receivers, and carriers to the requirements of this proposed rule. We request comment on whether any other persons should be subject to this proposed rule under the authority provided by section 416(b) of the FD&C Act. The comments should identify the specific function of the person in food transportation, explain how that person does not meet the definition of shipper, carrier, or receiver, describe how that person's actions may affect the sanitary condition of food, and describe the kinds of regulatory provisions that should be applied to that person.

2. Intrastate Activities

FDA tentatively concludes that the provisions in the proposed rule should be applicable to activities that are intrastate in character. The plain language of section 416(a)(2) of the FD&C Act defines the term ''transportation'' as any movement in commerce by motor vehicle or rail vehicle. Section 416(b) of the FD&C Act directs FDA 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. Section 416 does not include a limitation to interstate commerce. FDA seeks comment on whether the provisions should be applicable to activities that are intrastate in character.

3. Activities Outside the United States

This proposed rule sets forth sanitary transportation practices for shippers, carriers, and receivers who transport food that will be consumed or distributed in the United States. However, some food may enter the United States and be transported within the United States but not be consumed or distributed into the U.S. market. For example, some food is transshipped from a foreign country through the United States to a different country (e.g., food that is driven from Mexico through the United States into Canada). In addition, food may be imported into the United States, transported to a facility for further processing, and exported to another country without being consumed or distributed in U.S. commerce.

We have tentatively concluded that section 416 of the FD&C Act is not intended to apply to the transportation of food that is neither consumed nor distributed in the United States. Therefore, proposed § 1.900(b) would provide that the requirements of subpart O do not apply to shippers, receivers, or carriers when they are engaged in transportation operations of: (1) Food that is transshipped through the United States to another country; or (2) food that is imported for future export and that is neither consumed nor distributed in the United States.

However, the proposal would apply to the transportation operations of food that will be directly transported into the United States by motor or rail vehicle. By contrast, the requirements of this proposal would not apply to the transportation operations of food that may ultimately be intended for U.S. commerce, but will not be directly transported into the United States by motor or rail vehicle. For example, the requirements of this proposed rule would apply to a shipper and carrier who conduct a transportation operation abroad that includes direct shipment of the food into the United States by motor vehicle or rail vehicle (e.g., food that is shipped from Mexico by truck and that will enter the United States on that truck and be transported further within the United States). However, the requirements of this proposed rule would not apply to a shipper and carrier who conduct a transportation operation abroad for food that is ultimately intended for the United States, other than the direct shipment of the food to the United States by motor or rail vehicle (e.g., food that is shipped, carried, and received within China but that will ultimately be transported to the United States by air). As a further example, the requirements of this proposed rule would also apply to a person outside of the United States, such as an exporter, who ships food to the United States in an international freight container by oceangoing vessel or in an air freight container, and arranges for the transfer of the intact container in the United States onto a motor vehicle or rail vehicle for transportation in U.S. commerce, if that food will be consumed or distributed in the United States. We would consider this person to be a shipper under this proposed rule because he would be initiating a shipment of food by motor vehicle or rail vehicle, even if doing so from abroad, that would be entering U.S. commerce. If that shipper fails to comply with the requirements of this proposed rule and FDA determines that food shipped to the United States by that shipper may as a result be adulterated, such shipments of food would be subject to refusal of admission when offered for entry into the United States.

4. Other Requirements Applicable to Food Transportation

Proposed § 1.900 would also provide that the requirements of subpart O apply in addition to any other requirements of FDA that are applicable to food transportation. For example, FDA has established regulations setting forth current good manufacturing practices (CGMP) for medicated animal feeds in part 225 (21 CFR part 225), which include a provision in section 225.65 ''Equipment and cleanout procedures,'' that addresses requirements for the cleaning of equipment used in the distribution of medicated feeds to avoid

unsafe contamination of feeds with drugs. Similarly, FDA has established regulations addressing substances prohibited from use in animal food or feed in part 589 (21 CFR part 589), which include provisions 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.

B. Applicability (Proposed § 1.902)

Under section 402(i) of the FD&C Act (21 U.S.C. 342(i)), a food shall be deemed to be 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 2005 SFTA.

Proposed § 1.902(a) would provide that the criteria and definitions of subpart O apply in determining whether food is adulterated within the meaning of section 402(i) of the FD&C Act in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, or receiver engaged in the transportation of food under conditions that are not in compliance with subpart O.

Under section 301(hh) of the FD&C Act, the following act, and the causing thereof, is prohibited: 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 sanitary transportation practices prescribed by the Secretary under section 416. To clearly communicate that failure to comply with regulations established under section 416 of the FD&C Act is a prohibited act, proposed § 1.902(b) would provide that the failure by a shipper, carrier by motor vehicle or rail vehicle, or receiver engaged in food transportation operations to comply with the requirements of subpart O is a prohibited act under section 301(hh) of the FD&C Act.

C. Definitions (Proposed § 1.904)

Proposed § 1.904 would define ''adequate'' as that which is needed to accomplish the intended purpose in keeping with good public health practice. This proposed definition is identical to the definition for this term in the existing CGMP regulations (see 21 CFR 110.3(b)). We have retained this definition in the proposed updates to the CGMP provisions of the proposed preventive controls rule for human food and have also included the same definition in the CGMP provisions of the proposed preventive controls rule for animal food. Given the broad applicability of this term in describing essential principles and practices for the sanitary handling of food, we have tentatively concluded that using this term to express relevant requirements in this proposed rule, e.g., transportation equipment must be designed to be ''adequately'' cleanable, will be understood by industry and will be effective in ensuring that food is not transported under conditions that may render it adulterated. Several provisions of this proposed rule are comparable (see Table 1) to provisions of our CGMP regulations and reflect established principles of sanitary operations involving food, whether those operations are carried out in a food facility or in a food transportation operation. As a result, many firms are likely to already be in compliance with the proposed provisions of this rule.

TABLE 1—PROVISIONS OF THIS PROPOSED RULE THAT ARE COMPARABLE TO PROVISIONS OF FDA'S CGMP REGULATIONS

Provision	As proposed in this rule	Comparable to CGMP
§ 1.904	Defines ''adequate'' as that which is needed to accomplish the intended purpose in keeping with good public health practice.	21 CFR 110.3(b)—''Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.''
§ 1.906(b)	Requires that vehicles and transportation equipment be maintained in such a sanitary condition as to prevent the food that they transport from becoming filthy, putrid, decomposed, or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations.	21 CFR 110.40(a)—''All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained.''
§ 1.906(c)	Requires 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 be designed, maintained, and equipped, to maintain the food under temperature conditions that will prevent the rapid growth of undesirable microorganisms.	21 CFR 110.80(b)(6)—''Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act.''
§ 1.906(d)	Requires that each freezer and mechanically refrigerated cold storage compartment in vehicles or transportation equipment used in transportation operations for food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation be equipped with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.	21 CFR 110.40(e)—''Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to show the temperature accurately within the compartment . . . ''

TABLE 1—PROVISIONS OF THIS PROPOSED RULE THAT ARE COMPARABLE TO PROVISIONS OF FDA'S CGMP REGULATIONS—Continued

Provision	As proposed in this rule	Comparable to CGMP
§ 1.906(e)	Requires that vehicles and transportation equipment be stored in such 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.	21 CFR 110.35(e)—''Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.''
§ 1.908(a)(2)	Requires that responsibility for ensuring that transportation operations are carried out in compliance with all requirements of subpart O be assigned to competent supervisory personnel.	21 CFR 110.10(d)—''Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.''
§ 1.908(c)(1)	Requires that shippers and receivers provide vehicle operators who are expected to handle food not completely enclosed by a container during loading and unloading operations with access to a hand-washing facility that is convenient and that provides running water.	21 CFR 110.10(b)—''All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food.'' 21 CFR 110.10(b)(3)—''Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility . . .'' 21 CFR 110.37(e)—''Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature.''

Proposed § 1.904 would define ''animal food'' as food for animals other than man, and includes pet food, feed, and raw materials and ingredients. This definition is identical to the definition of ''animal food'' in the proposed preventive controls rule for animal food.

Proposed § 1.904 would define a ''bulk vehicle'' as 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. This proposed definition is taken directly from section 416(a)(1) of the FD&C Act (21 U.S.C. 350e(a)(1)). This definition differentiates a subset of motor vehicles and rail vehicles subject to this proposed rule, i.e., ''bulk vehicles,'' from other types of vehicles subject to this proposed rule, i.e., non-bulk vehicles such as trailers. As discussed in section III.E, we have proposed to establish several specific requirements applicable to transportation operations involving bulk vehicles to ensure that food is adequately protected from adulteration during such operations.

This proposed definition would include equipment used in food transportation because they are attached to and carried on a motor or rail vehicle, e.g., a cargo tank. We tentatively conclude that defining bulk vehicles as we have proposed would ensure that the provisions of this rule relating to bulk vehicles apply to all possible transportation operations in which food is hauled in bulk conveyances, ranging from tank trucks to cargo tanks.

Proposed § 1.904 would define a ''carrier'' as a person who owns, leases, or is otherwise ultimately responsible for the use of a motor vehicle or rail vehicle to transport food. This definition would further provide that the carrier is responsible for all functions assigned to a carrier in subpart O even if they are performed by other persons, such as a driver that is either employed or contracted by a trucking firm to operate the vehicle. Furthermore, a carrier may also be a receiver or a shipper if the person also performs the functions of those respective persons as defined in subpart O.

The transportation of food may be carried out in different ways that involve different entities. For example, a manufacturing facility that does not have its own private truck fleet, drivers, or contracted drivers may enter into a contract of carriage with a trucking company for the trucking company to physically transport a food shipment using the trucking company's vehicle to another facility designated in the contract. In another instance, a distributor who has possession of the food in a holding facility may operate leased vehicles to deliver food to his customers. In both of these examples, the entity ultimately responsible for the use of the vehicle that transports the food, i.e., the trucking company in the first case and the distributor in the second case, would be subject to the requirements applicable to the carrier under this proposed rule. In the second case, the distributor may also be subject to additional requirements applicable to shippers under this proposed rule due to his operation of the holding facility.

This proposed definition would provide that the carrier is responsible for all functions assigned to that person in subpart O, even if they are performed by other persons such as a driver that is employed or contracted by the carrier. Thus the carrier, being the entity ultimately responsible for the use of the vehicle to physically transport food, would be responsible for ensuring that a driver, who operates the vehicle, functions in a manner that enables the carrier to comply with all of his responsibilities under this proposed rule. For example, after a transportation operation, the carrier may under proposed § 1.908(d)(2), discussed in section III.E, provide a log of temperature measurements to the shipper to demonstrate that it has maintained temperature conditions during the transportation operation consistent with those specified by the shipper in accordance with proposed § 1.908(b)(3). In practice, the driver of the vehicle would likely be the person who compiles or retrieves this log from the temperature recording device; however it would be the responsibility of the carrier to ensure that the driver actually compiles or retrieves the log as

part of his duties during the transportation operation and makes it available to be provided to the shipper.

The definition of the term ''carrier'' acknowledges the potential distinction between the carrier, who is the entity responsible for the use of the vehicle, from the operator of the vehicle. The Federal Motor Carrier Safety Administration, part of DOT, makes a similar distinction in its federal motor carrier safety regulations (49 CFR part 390) which define a ''driver'' as any person who operates a commercial motor vehicle and specify that a driver could be employed by a motor carrier (49 CFR 390.5). These regulations also hold motor carriers responsible for, among other things, the oversight of drivers. We have acknowledged the potential for a distinction between the carrier and the driver for the purpose of placing the responsibilities assigned to the carrier under this proposed rule upon a single person. Further, we have tentatively concluded that placing these responsibilities on a single person will help to avoid any confusion regarding who is responsible for the requirements for carriers set forth in this proposed rule.

Proposed § 1.904 would define ''cross-contact'' to mean the unintentional incorporation of a food allergen as defined in section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)) into food, except animal food. We are proposing to establish essentially the same definition for the term ''cross-contact'' that we included in the proposed preventive controls rule for human food (see discussion in 78 FR 3646 at 3693), except that we are adding the term ''except animal food'' to our proposed definition because, as discussed in the preamble of the proposed preventive controls rule for animal food (78 FR 64736 at 64771, October 29, 2013), we are not aware of evidence indicating that foodborne allergens pose a significant health risk to animals, or to humans through handling animal food.

Proposed § 1.904 would define ''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. Further, we are proposing that the term ''farm'' includes 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. Our proposed definition of the term ''farm'' differs from the definition of a farm in § 1.227(b)(3) of this chapter, which is used to delineate which entities are required to register under section 415 of the FD&C Act. The reason why we are proposing to define a farm differently for the purposes of this proposed rule is discussed in our proposed definition for ''transportation operations'' later in this section.

Proposed § 1.904 would define ''food'' to mean food as defined in section 201(f) of the FD&C Act, which includes raw materials and ingredients. This definition is identical to the definition of ''food'' in the proposed preventive controls rules for human and animal food. To ensure that the reader understands the scope of food covered by this proposed rule, this definition provision would also state consistent with the definition of ''food'' in the FD&C Act, food includes animal food and food subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act [1] administered by the Food Safety and Inspection Service (FSIS) of the USDA.

FSIS carries out in-commerce surveillance activities to verify that entities whose business activities involve FSIS-regulated products prepare, store, transport, sell, offer for sale or transportation, import, and export such products in compliance with FSIS statutory and regulatory requirements. FSIS has issued guidance for the safe transportation and distribution of meat, poultry and egg products (Ref. 11), however, they do not have requirements that directly address transportation operations for these foods. This rulemaking will complement FSIS's efforts to promote the application of sanitary food transportation practices for FSIS-regulated meat, poultry, and egg products. We intend to work together with FSIS to facilitate this shared objective while carrying out our respective regulatory programs.

Proposed § 1.904 would define ''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. This proposed definition is used to designate a category of food that is subject to specific provisions of this proposed rule intended to ensure that such food is not potentially rendered adulterated during transportation because it is at increased risk of contamination due to being exposed to the environment. This definition provision includes examples of such containers such as an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. The definition also provides that this term does not include food transported in a bulk vehicle as defined in this proposed rule.

This approach is consistent with how we addressed unexposed refrigerated packaged foods in the proposed preventive controls rules for human and animal food. For instance in the proposed preventive controls rule for human food we stated that some of the requirements of that rule would not apply to facilities solely engaged in the storage of packaged foods not exposed to the environment (78 FR 3646 at 3713), and instead proposed to establish modified requirements for such foods that are TCS foods (78 FR 3646 at 3773). In that proposed rule we stated that we considered ''unexposed packaged food,'' to mean packaged food not exposed to the environment (78 FR 3646 at 3712).

In considering how unexposed packaged food should be addressed in the human preventive controls rule we recognized that in general, there are limited routes of contamination for unexposed packaged food due to the protective nature of the food's packaging (78 FR 3646 at 3713). The same was stated in the proposed preventive controls rule for animal food (provide FR cite when published). In this proposed rule, we recognize that the converse is true, i.e., we are recognizing that food not completely enclosed by a container is at greater risk of contamination during transportation, and as such, we tentatively conclude that it is appropriate to propose certain requirements that apply exclusively to such food.

Proposed § 1.904 would define ''microorganisms'' to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. Proposed § 1.904 would also specify that the term ''undesirable microorganisms'' includes 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. This proposed definition is identical to the definition for this term in the proposed preventive controls rules for human and animal food. Because they can adulterate food, we consider the types of microorganisms identified in this proposed definition to be of importance to sanitary transportation of foods as well as to the safe and sanitary production of human and animal food.

[1] FDA notes that, to prevent duplication of effort, its compliance policy is to inform FSIS when an apparent violation is encountered involving a meat or poultry product that has left a USDA inspected establishment (Ref. 12).

Proposed § 1.904 would define ''non-covered business'' as a shipper, receiver, or carrier engaged in transportation operations that has less than $500,000 in total annual sales.

Our proposed definition for a non-covered business is similar to one of the proposed definitions for a very small business in the proposed preventive controls rule for human food for which we requested comment (78 FR 3646 at 3701). Under that proposed rule a very small business would be subject to modified requirements that include provisions for an exemption from the requirements for hazard analysis and preventive controls. We are proposing to exclude these businesses from coverage under this rule to provide for comparable treatment of these firms between this proposed rule and the proposed preventive controls rules. Additionally, for firms that only function as carriers and thus would not be subject to the proposed preventive controls rules, excluding carriers with less than $500,000 in total annual sales from coverage by this proposed rule would treat carriers in a manner consistent with the treatment of shippers and receivers subject to this proposed rule. We estimate that not covering carriers with less than $500,000 in total annual sales would still result in an average of 97 percent of all food shipments by motor vehicle or rail being subject to this proposed rule. We note that a non-covered business is and will continue to be covered under the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether that business is included within the scope of this proposed rule. We are requesting comment on whether the foods that comprise the $500,000 in total annual sales should be limited in some way, such as to those subject to this rule or to any of the FSMA rules when finalized.

Proposed § 1.904 would define ''pest'' to mean any objectionable animals or insects including birds, rodents, flies, and larvae. This proposed definition is identical to the definition for this term in the proposed preventive controls rule for human food. That proposed rule also includes a discussion, which is relevant to this proposal, of some circumstances under which animals would not be considered ''objectionable'' (78 FR 3646 at 3721). We consider the types of pests identified in this proposed definition to be of importance to sanitary transportation of foods as well as to the safe and sanitary production of human and animal food.

Proposed § 1.904 would define ''receiver'' to mean any person who receives food after transportation, whether or not that person represents the final point of receipt for the food. This definition also states that a receiver may also be a carrier or a shipper if the person also performs the functions of those respective persons as defined in this proposed rule. Proposed § 1.904 would also provide that a receiver does not include an individual consumer or a person who receives or holds food on behalf of an individual consumer and who is not also a party to the transaction and who is not in the business of distributing food, e.g., such as a hotel concierge or the reception desk in an apartment building who is not holding the food for commercial purposes.

Within the transportation industry, shippers may direct goods to receivers in a single segment trip wherein the shipment proceeds directly to the ultimate consignee, or in multi-segment trips that proceed through intermediate destinations, such as a temporary storage point. Therefore, this proposed definition will provide that all persons who receive food after transportation, not just the ultimate consignee, are subject to the requirements applicable to receivers in this proposed rule.

Proposed § 1.904 would define ''shelf-stable food'' 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. We based this proposed definition on several inherently similar definitions of this term in the literature (Ref. 13) (Ref. 14) (Ref. 15) (Ref. 16). This definition provision would also provide some examples of shelf stable food, including canned juice, canned vegetables, canned meat, bottled water, and dry food items.

Proposed § 1.904 would define ''shipper'' to mean a person who initiates a shipment of food by motor vehicle or rail vehicle. This definition further provides that the shipper is responsible for all functions assigned to a shipper in subpart O 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. For example, a produce distributor (the shipper) may initiate a shipment of food by arranging for a carrier to pick up a shipment of fresh produce at a holding facility for transport by truck to a produce distribution facility hundreds of miles away. Employees of the holding facility who are not employed by the distributor may load the produce onto the truck. Under this proposed rule, the distributor would be responsible, e.g., through contractual arrangements, for ensuring that the employees of the holding facility visually inspect the vehicle for cleanliness and determine that it appears to be in appropriate sanitary condition for the transport of the food, as required by proposed § 1.908(b)(2), discussed in section III.E, and that all other requirements of this proposed rule are met. We believe that periodically reviewing and updating contractual relationships is a common and regular industry practice.

This definition also states that a shipper may also be a carrier or a receiver if the shipper also performs the functions of those respective persons as defined in subpart O, e.g., a supermarket chain may arrange for the shipment of fresh produce to be received at its distribution center.

We have defined the term ''shipper'' in this manner to place the responsibilities assigned to shippers, discussed in section III.E, upon a single person, the initiator of a transportation operation, as we expect this person to be knowledgeable about all factors concerning the food, e.g., its packaging and holding temperature requirements, relevant to its sanitary transport. We have tentatively concluded that defining shipper in this manner will ensure that food is not transported under conditions that may render it adulterated and also that placing these responsibilities on a single person will help to avoid any confusion regarding who is responsible for the requirements of a shipper set forth in this proposed rule.

Proposed § 1.904 would define ''small business'' to mean ''a business, subject to proposed § 1.900(a) (discussed in section III.A) employing 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 proposed § 1.900(a) having less than $25,500,000 in annual receipts, consistent with the size based standard that has been established by the U.S. Small Business Administration for truck transportation firms.'' The proposed limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility. For all persons subject to this rule except carriers by motor vehicle, we are proposing to establish the same definition for a small business as 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 part 121 for most food manufacturers. For carriers by motor vehicle, we are proposing to establish essentially the same definition for a

small business as the size based standard (expressed in terms of millions of dollars) that has been established by the U.S. Small Business Administration under 13 CFR part 121 for truck transportation firms. The definition of a small business affects what the compliance date is for such entities.

Proposed § 1.904 would define ''Time/Temperature Control for Safety Food (TCS Food)'' as a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. This proposed definition is identical to that for the term ''Potentially Hazardous Food (Time/Temperature Control for Safety Food)'' in the 2009 Edition of FDA's *Food Code* (Ref. 17) and this term, having the same meaning, is also used within the proposed preventive controls rules for human and animal food (78 FR 3646 at 3712 and 78 FR 64736 at 64768).

Proposed § 1.904 would define ''transportation'' as any movement of food in commerce by motor vehicle or rail vehicle. This proposed definition is identical to the definition of this term in section 416(a)(2) of the FD&C Act except that we added the words ''of food'' for clarity.

Proposed § 1.904 would define ''transportation equipment'' to mean equipment used in transportation operations, other than vehicles, e.g., bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, and loading and unloading systems and also state that transportation equipment would also include a railcar not attached to a locomotive or a trailer not attached to a tractor. We tentatively conclude that this definition, which encompasses all of the basic types of equipment that may be used in food transportation, is necessary to help ensure the safe transportation of food. The examples of transportation equipment in this definition are not all inclusive, but are broadly representative of the types of equipment used in food transportation as identified in the ERG report and in comments to the 2010 ANPRM.

Proposed § 1.904 would define ''transportation operations'' to mean all activities associated with food transportation that may affect the sanitary condition of food including the cleaning, inspection, maintenance, loading and unloading of, and operation of vehicles and transportation equipment. This proposed definition would further provide that transportation operations do not include any activities associated with the transportation solely of shelf stable food that is completely enclosed by a container, compressed food gases, or live food animals.

As noted previously in this section, section 416(a)(2) of the FD&C Act defines ''transportation'' to mean any movement in commerce by motor vehicle or rail vehicle. In establishing this definition of ''transportation operations,'' we intend to more precisely define the scope of certain requirements of this proposed rule by distinguishing between activities that occur in association with food transportation that may render the food adulterated and other activities that do not pose this potential. The requirements of this proposed rule would only apply to those activities that may render the food adulterated if carried out in an insanitary manner. An example of such an activity would be the transfer of juice from a bulk tank truck into a receiver's stationary storage tanks. An example of an activity that would not be considered to be a transportation operation under this proposed rule would be the filling of a vehicle's fuel tank while it is transporting food.

In addition, the proposed definition of transportation operations would exclude activities associated with the transportation of shelf stable food that is completely enclosed by a container, compressed food gases, and live food animals. We have tentatively concluded that shelf stable foods completely enclosed by a container are at little risk of adulteration during transportation. They do not require temperature control and as such, are not at risk of microbial spoilage or the growth of microorganisms of public health significance, and they are not directly exposed to the transportation environment due to their being fully enclosed by their container, e.g., a metal can, a glass or plastic bottle, or a sealed bag or box. Therefore, we have tentatively concluded that requirements for sanitary transportation practices do not need to apply to such foods.

Comments to the 2010 ANPRM (Ref. 18) (Ref. 19) stated that compressed food gases such as carbon dioxide used for carbonating beverages, are transported in cylinders or bulk containers or in bulk vehicles such as trailers or railcars that are dedicated to the transport of a single product. These comments also stated that compressed food gases do not support microbial growth and are transported under pressure in containers and vehicles that protect against chemical and physical contamination because they have no man-holes and only provide for exit and entry through valving. As such, we have tentatively concluded that compressed food gases are at little risk for adulteration during transport due to the manner in which they are transported and are proposing to exclude such foods from the scope of these requirements.

We are not aware of food safety concerns related to the transportation of live food animals intended for slaughter that could be addressed through the sanitary transportation practices set forth in this proposed rule. No comments to the 2010 ANPRM raised any such concerns. Furthermore, slaughter operations at facilities subject to FSIS jurisdiction are subject to requirements intended to minimize the risk of adulteration posed by the presence of contaminants on the external surfaces of live food animals. Therefore, we have tentatively concluded that sanitary transportation practices are not necessary to prevent live food animals from becoming adulterated during transportation, and are proposing to exclude such foods from the scope of these requirements.

We are specifically requesting comment on our tentative conclusion that shelf stable food that is completely enclosed by a container, compressed food gases, and live food animals should be excluded from the scope of this proposed rule.

Further, the proposed definition of transportation operations would exclude transportation activities for RACs that are performed by a farm. We use the term raw agricultural commodities as it is defined in section 201(r) of the FD&C Act. We discuss the meaning of the term in the proposed rule for preventive controls for human food (78 FR 3646 at 3678). Previously in this section, we proposed that, for the purposes of this proposed rule, the term ''farm'' means ''a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both'' and that the term ''includes 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.'' For purposes of this proposed regulation, a farm could be a facility that also performs activities other than the growing and harvesting of crops and the raising of animals; however, only transportation activities for raw agricultural commodities would be excluded from the proposed definition of transportation operations.

We note previously in this section that the definition of the term ''farm'' in this proposed rule differs from the definition of a farm in § 1.227(b)(3) of this chapter. The definition of a farm in

§ 1.227(b)(3) applies only to facilities that pack or hold food if the food used in such activities was grown, raised, or consumed on that farm or a farm under the same ownership. The definition in § 1.227(b)(3) was developed for the purposes of implementing the registration requirements of section 415 of the FD&C Act. However, as discussed further in the paragraphs that follow, we have tentatively concluded that 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 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, and therefore have concluded that a different definition of the term ''farm'' for the purposes of this proposed rule is necessary.

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 proposed rule. No comments to the 2010 ANPRM raised any such concerns. Specifically, we are not aware of instances in which insanitary conditions or practices (e.g., improper temperature control, improper equipment construction, inadequate equipment cleaning) with regard to transportation operations conducted by farms involving the transportation of RACs have contributed to foodborne illness. We note that this is the case 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 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 broadly suitable for this sector. Therefore, we have 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, and are proposing to exclude such foods from the scope of these requirements.

The proposed exclusion is intended to apply to the activities of farms, regardless of whether the farm is serving in the role of shipper, carrier, or receiver. We acknowledge 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. 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. 20). Building on industry experience we have tentatively concluded that the requirements of this proposed regulation should apply to such carriers with regard to the transportation of RACs from farms.

We are specifically requesting comment on our tentative conclusion 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. Further, we are requesting comment on whether the definition of ''transportation operations'' should include TCS raw agricultural commodities (e.g., sprouts, raw molluscan shellfish) because the temperature control requirements of these commodities warrant coverage under this proposed rule, and if so, what requirements would be appropriate.

Proposed § 1.904 would define ''vehicle'' to mean 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. We are proposing a broad definition of vehicle in order to encompass all of the types of motorized and rail conveyances that may be used in food transportation to ensure that all such conveyances are subject to the provisions of this proposed rule. Although a trailer is not motorized, we would consider a trailer to be a vehicle when attached to a tractor and used for food transportation because the trailer functions as part of the conveyance. Similarly, railcars would be considered to be vehicles when attached to a locomotive. The examples of vehicles in this definition are not all inclusive, but are broadly representative of the types of land conveyances used in food transportation as identified in the comments to the 2010 ANPRM.

D. Vehicles and Transportation Equipment (Proposed § 1.906)

Proposed § 1.906(a) would require that the design of vehicles and transportation equipment used in transportation operations, the materials used in their manufacture, and their workmanship be suitable and that they be adequately cleanable for their intended use to prevent the food that they transport from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations.

Comments we received in response to the 2010 ANPRM stated that vehicles and transportation equipment are generally made to meet industry and third party standards for sanitary fabrication, design, and construction. For example, a comment stated that standards for coatings may require that they maintain corrosion resistance, and be free of surface delamination, pitting, flaking, chipping, blistering, and distortion under conditions of intended use. However, vehicles and transportation equipment that are poorly designed can be a source of contamination of food during transport. For example, food contact surface coatings on vehicles or transportation equipment that are not corrosion resistant or are flaking or chipping, for example, could contaminate food transported in bulk, due to chemical contamination or by causing the food to become unfit, and would render the vehicles or equipment as not suitable for their intended use.

Similarly, vehicles and transportation equipment that are not adequately cleanable can be a source of contamination of food during transport. For example, wood containers used to hold raw meat or poultry during transportation typically cannot be brought to a sanitary condition to hold ready to consume produce during transportation due to the potential for the wood to retain contaminants such as harmful microorganisms in its porous structure (Ref. 21). Thus, wood containers used to hold ready to consume produce after their use to hold raw meat or poultry could be a source

of contamination of the produce and FDA would not consider such containers to be adequately cleanable for the transportation of produce following the transportation of raw meat or poultry.

We have tentatively concluded that proposed § 1.906(a) is consistent with best practices that have been established within the food transportation industry relative to vehicle and equipment design based upon the preceding discussion and the comments to the 2010 ANPRM.

Proposed § 1.906(b) would require that vehicles and transportation equipment be maintained in such a sanitary condition as to prevent the food that they transport from becoming filthy, putrid, decomposed, or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations. Vehicles and transportation equipment that are not maintained in a sanitary condition can become a source of contamination of food or of allergens being incorporated into food through cross-contact during transport (Ref. 1). For example, FDA would not consider equipment used in bulk food transfer operations, such as pumps and hoses, to be maintained in an appropriate sanitary condition if the equipment was not cleaned after its use in handling milk, because this failure could lead to the incorporation of milk (a major food allergen) through cross-contact into food that was subsequently handled on the equipment. We note that proposed § 1.906(b) would be consistent with measures routinely practiced within the juice industry to avoid the incorporation of allergens into juice by cross contact (Ref. 22).

Similarly, FDA would not consider pallets to be maintained in an appropriate sanitary condition if they are in such poor repair, e.g., jagged wood edges, that they could damage food packaging causing a loss of container integrity and increasing the potential that the food is directly contaminated. We note that proposed § 1.906(b) would also be consistent with pallet control measures practiced within the food transportation industry as described in a comment to the 2010 ANPRM which stated that pallets used within food distribution centers are cleaned and rotated or disposed of on a regular basis.

Furthermore, proposed § 1.906(b) is consistent with FDA's CGMP regulations in part 110 (21 CFR part 110) (see § 110.40(a) and Table 1) and the CGMP provisions of the proposed preventive controls rules for human and animal food that require that equipment and utensils in food plants be properly maintained. As such, proposed § 1.906(b) would similarly apply sanitary maintenance requirements to food transportation vehicles and equipment as such requirements have been and will continue to be applied to equipment and utensils that are used to produce food in facilities.

Proposed § 1.906(c) would require that vehicles and transportation equipment used in transportation operations for food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation (any food that requires time/temperature control either to ensure its safety or to prevent microbial spoilage, e.g., meat, poultry, seafood, raw seed sprouts, unpasteurized shell eggs, or pasteurized juice) be so designed, maintained, and equipped to be able to maintain the food under temperature conditions that will prevent it from supporting such microbial growth. As discussed previously, FDA is proposing in § 1.904 that the term ''undesirable microorganisms'' includes 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.

The use of vehicles and transportation equipment not designed, maintained, or otherwise equipped to maintain food under appropriate temperature conditions can, if used to transport TCS foods result in increased levels of microorganisms capable of causing human illness, and cause such foods to be adulterated. For instance, temperature control is used to minimize the growth of pathogens in TCS foods such as *Salmonella enteritidis* (SE) in unpasteurized shell eggs and *Listeria monocytogenes, Salmonella* spp., and other pathogens in other TCS foods (Ref. 17) (Ref. 23) (Ref. 24) (Ref. 25) (Ref. 26). Given this, we tentatively conclude that certain temperature controls are necessary to prevent TCS food from becoming adulterated during transportation.

In addition, the use of vehicles and transportation equipment not designed, maintained, or otherwise equipped to maintain food under appropriate temperature conditions can, if used to transport foods subject to microbial spoilage, result in food spoilage and cause such foods to be adulterated. For example, some foods that are pasteurized to ensure their safety are not processed to be shelf-stable. These pasteurized foods would still require refrigeration during transportation to prevent the spoilage of the food due to the growth of non-pathogenic spoilage microorganisms. For instance, pasteurized citrus juice (this term as used in this proposal excludes shelf-stable juice) requires refrigeration during distribution to control the growth of non-pathogenic spoilage microorganisms that are not killed by the pasteurization process, e.g., yeasts and lactobacilli (Ref. 27) (Ref. 28). Given this, we tentatively conclude that certain temperature controls are necessary to prevent food subject to microbial spoilage from becoming adulterated during transportation.

We continue to receive reports or otherwise learn of foods, such as meat and some seafood products, that require time/temperature control to ensure their safety, as well as foods subject to microbial spoilage if temperature abused, being transported in unrefrigerated vehicles not otherwise equipped, e.g., with insulated coolers and ice packs, to maintain the food under appropriate temperature conditions (Ref. 5) (Ref. 6) (Ref. 7) (Ref. 8). We would consider unrefrigerated vehicles or equipment used to transport foods requiring temperature control to prevent the growth or undesirable microorganisms to comply with proposed § 1.906(c) only if they incorporate design features such as thermal insulation for maintaining food in a chilled state or are otherwise equipped to maintain the food under appropriate temperature conditions, e.g., with insulated coolers and ice packs.

The intent of proposed § 1.906(c) is consistent with our CGMP regulations in part 110 (see § 110.80(b)(6) and Table 1) and the proposed preventive controls rules for human and animal food that require that food subject to these respective regulations that can support the rapid growth of undesirable microorganisms be held at temperatures that will prevent the food from becoming adulterated during prescribed operations. Proposed § 1.906(c) would apply appropriate holding temperature requirements to food transportation vehicles and equipment as such requirements have been and will continue to be applied to facilities in which food is produced.

Proposed § 1.906(d) would require that each freezer and mechanically refrigerated cold storage compartment in vehicles or transportation equipment used in transportation operations for food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation be equipped with an indicating thermometer, temperature-

measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment. This proposed requirement would provide a means by which the shipper, receiver or carrier, through checking the compartment temperature during the operation, can ensure as required by proposed § 1.908(a)(3)(iii) (discussed in section III.E), that the temperature conditions during the transportation operation are such that the operation meets the requirements of proposed § 1.908(a)(3) and are adequate to ensure that the food is not rendered adulterated during transportation. Furthermore, this proposed requirement would provide a means by which a shipper could verify before loading food that each freezer and mechanically refrigerated cold storage compartment or container offered by a carrier has been pre-cooled in accordance with information submitted by the shipper, as required by proposed § 1.908(b)(4) (discussed in section III.E). This proposed requirement would also provide a means by which officials carrying out transportation safety inspections can, along with other inspectional observations, assess whether the transportation operation is being carried out in accord with proposed § 1.908(a)(3) (discussed in section III.E).

The intent of proposed § 1.906(d) is consistent with FDA's CGMP regulations in part 110 (see § 110.40(e) and Table 1) and the proposed preventive controls rules for human and animal food that require that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to show the temperature accurately within the compartment. As such, proposed § 1.906(d) would establish requirements for food temperature displaying devices for food transportation vehicles and equipment as such requirements have been and will continue to be applied to facilities in which food is produced.

Proposed § 1.906(e) would require that vehicles and transportation equipment be stored in such 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. Vehicles and transportation equipment that harbor pests or are otherwise contaminated while they are stored can contaminate food during transport if the vehicles and equipment cannot be adequately cleaned before being used for the transport of food. For example, FDA would not consider trucks, railcars, or containers stored in such a manner that they could develop persistent rodent populations in food holding areas to meet the requirements of proposed § 1.906(e).

The requirements of proposed § 1.906(e) clearly represent a sanitary transportation practice and we have tentatively concluded that these requirements are necessary to ensure that food is not transported under conditions that may render it adulterated. Furthermore, the intent of this provision is consistent with our CGMP regulations in part 110 (see § 110.35(e) and Table 1) that recommend that cleaned and sanitized portable equipment with food-contact surfaces and utensils be stored in a location and manner that protects food-contact surfaces from contamination.

E. Transportation Operations (Proposed § 1.908)

1. General Requirements

Proposed § 1.908(a) would set forth general provisions and requirements applicable to transportation operations.

Proposed § 1.908(a)(1) would provide that the requirements of proposed § 1.908 apply to all shippers, carriers, and receivers engaged in transportation operations unless specifically stated otherwise. We have included this provision to make it clear that unless a requirement of proposed § 1.908 specifically only applies to shippers, receivers or carriers, the requirement applies to all of these persons.

Proposed § 1.908(a)(2) would require that responsibility for ensuring that transportation operations are carried out in compliance with all requirements of subpart O be assigned to competent supervisory personnel. Proposed § 1.908(a)(2) is intended to ensure that shippers, receivers, and carriers engaged in food transportation operations will identify the requirements they must meet under this proposed rule and establish accountability at the individual level for ensuring that transportation operations are carried out in compliance with those requirements and in a way that prevents food from becoming adulterated during transportation. This provision mirrors a longstanding provision in the current CGMP regulation regarding the manufacturing, processing, packing, or holding of human food (see § 110.10(d) and Table 1) and essentially equivalent provisions in the proposed preventive controls for both human and animal food, which require that competent supervisory personnel be assigned responsibility for ''assuring'' (or ''ensuring,'' in the case of the two proposed rules) compliance with the requirements of the regulations.

Proposed § 1.908(a)(3) would require that all transportation operations be conducted under such conditions and controls as are necessary to prevent the food that they are transporting from becoming filthy, putrid, decomposed, or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations.

This proposed provision sets forth circumstances under which we envision that food could be rendered adulterated as a result of contamination or insanitary conditions that could occur during a transportation operation. For example, if animal feed became contaminated by glass fragments during transport in an inadequately cleaned bulk vehicle, FDA would consider that the transportation operation was not conducted under conditions and controls necessary to prevent the food from being rendered injurious to animal health. Similarly, if a product such as shell eggs, which requires refrigeration during transportation to ensure its safety, was left unattended for several hours on a loading dock on a warm day, FDA would consider that the receiving stage of the transportation operation was not conducted under conditions and controls necessary to prevent the food from being rendered injurious to human health. Further, if pasteurized citrus juice became spoiled during transport due to inadequate refrigeration of the product, FDA would consider that the transportation operation was not conducted under conditions and controls necessary to prevent the food from becoming unfit for food.

Proposed § 1.908(a)(3)(i), (a)(3)(ii), and (a)(3)(iii) would identify specific actions that persons engaged in transportation operations must take to ensure that the operation complies with the requirements of proposed § 1.908(a)(3).

Proposed § 1.908(a)(3)(i) would require that persons take effective measures such as segregation or isolation to protect food from contamination during transportation operations by raw foods and non-food items in the same load. The failure to take effective measures, e.g., the proper loading of raw and ready to consume foods, to protect food from contamination during transportation

operations by raw foods and non-food items in the same load can lead to conditions, such as the dripping of raw poultry onto open containers of fresh produce, that could result in the adulteration of unprotected food by filth, chemical, or microbial contaminants (Ref. 3) (Ref. 5).

We received a number of comments to the 2010 ANPRM that asserted that food transporters routinely safely transport food and non-food items in the same load. We agree with these comments that this can be safely accomplished as long as appropriate practices, such as those that the industry has developed to ensure that food is adequately protected from contamination by non-food items on the same load, are consistently followed. These practices vary within the industry as discussed in the comments to the 2010 ANPRM. For example, in some operations, non-food items transported in the same load with food are placed in sealed containers with seamless bottoms. These non-food items are then placed on pallets that hold only non-food items. In other operations, non-food items may be directly stacked in their shipping boxes on pallets that hold only non-food items. In other operations, food and non-food items may be stacked on the same pallet, with the non-food items being positioned below the food items on the pallet so that if any containers of the non-food items were damaged or improperly sealed, their contents would not leak onto food. FDA would consider these practices to be effective in protecting food from contamination, as required by proposed § 1.908(a)(3)(i), if the non-food items are isolated by their packaging and the load is properly secured in the vehicle or shipping container. However, we would consider the transportation of food with non-food items that are not protectively packaged or that are loaded into a vehicle or a shipping container in a non-secured manner whereby the non-food item could contaminate food as a failure to take effective measures to protect food from contamination as proposed § 1.908(a)(3)(i) would require.

Further, as stated in the discussion of proposed § 1.906(c) in section III.D, we continue to receive or otherwise learn of reports of the improper loading of trucks carrying raw animal foods and ready to eat foods resulting in observable cross-contamination of ready to eat food items during transportation, e.g., the dripping of raw meat juices onto fresh produce (Ref. 4) (Ref. 5) (Ref. 7). For example, we would regard the loading of vehicles or portable containers in a manner that could allow for the contamination of ready to eat food by raw animal foods as a failure to take effective measures to protect food from contamination by raw foods as required by proposed § 1.908(a)(3)(i).

Proposed § 1.908(a)(3)(ii) would require that persons engaged in transportation operations take effective measures such as segregation, isolation, or other protective measures such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations.

The failure to take effective measures to protect foods that are exposed to the environment, that may be contacted by handlers of the shipment, or that directly contact a vehicle from contamination or cross-contact during transportation operations could result in the adulteration of the unprotected food by filth, chemical, or microbial contaminants or by allergens. We recognize that food transporters routinely safely transport foods in bulk vehicles and foods not completely enclosed by a container. We believe that this fact is substantially attributable to the practices the industry has developed as described in comments to the 2010 ANPRM to ensure that vehicles and containers used in the transport of such foods are cleaned and are in appropriate sanitary condition when offered for food transport and to ensure that sanitary procedures are employed during loading and unloading operations. However, we have tentatively concluded that persons engaged in transportation operations must also consider other factors related to their transportation operations to completely ensure that exposed or bulk-shipped foods are not adulterated during transport.

For example, a shipper of ready to consume fresh produce items that will not be completely enclosed by a container when shipped may, to protect the shipment, require by contractual arrangement that a carrier who intends to make additional pickups during the transportation operation only load other fresh produce items or items packaged in sealed containers onto the vehicle containing his shipment. To comply with proposed § 1.908(a)(3)(ii), the shipper and the carrier must ensure that such protective measures are taken in order to avoid contamination of the raw produce during transportation.

Furthermore, a driver of a vehicle transporting fresh produce items not completely enclosed by a container may be expected to handle containers during unloading. If during transport, the driver had to address a vehicle problem such as changing a flat tire, the driver's hands may have become soiled or contaminated with grease; in such a situation, this provision would require the driver to wash his or her hands before handling the containers of produce to reduce the potential for the food to become contaminated during handling.

Moreover, a firm that ships corn syrup by bulk tanker may use different carriers for their shipments, some of which may also haul milk and some of which only haul corn syrup. To ensure that milk, a food allergen, is not introduced into the corn syrup during transport through cross-contact, that shipper might establish different operational procedures for shipments to be transported by these respective carriers. For transportation operations using the carrier who also transports milk, the shipper could have the operator of each incoming tanker provide a wash ticket and also have the wash station operator apply a seal on access points to the tanker after cleaning. For the carrier that only hauls corn syrup, the shipper may choose to rely on the carrier's contractual assurance that only tankers dedicated to hauling corn syrup and cleaned at a mutually agreed frequency will be offered. The shipper would comply with proposed § 1.908(a)(3)(ii) if the shipper took measures, such as those discussed previously, to ensure that the corn syrup is not adulterated by contamination or cross-contact during transport. We note that, to facilitate the conduct of bulk transportation operations in a sanitary manner, proposed § 1.908(d)(4) and (d)(5), discussed in more detail in section III.E.4., would establish provisions regarding the disclosure to shippers of information about prior cargoes and subsequent vehicle cleaning by carriers that transport food in bulk vehicles.

Proposed § 1.908(a)(3)(iii) would require persons to ensure that food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation (see examples in the discussion of proposed § 1.906(c)) is transported in a manner, including the 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.

The provisions of this proposed rule and the proposed preventive controls rules for human and animal food are intended to function in a complementary manner to address the transportation of foods that require time/temperature control to control the growth of microorganisms that may cause illness.

The importance of maintaining temperature control during the transportation of TCS foods and foods subject to microbial spoilage if held under inadequate temperature control was addressed in the discussion of proposed § 1.906(c) in section III.D. For a TCS food that would be subject to either of the proposed preventive controls rules, if failure to provide adequate temperature control during transportation could result in a food safety hazard, in most cases, the owner, operator, or agent in charge of the facility that manufactures, processes, packs or holds the food would be responsible for establishing preventive controls for the food to prevent the occurrence of that hazard (78 FR 3646 at 3737, 3744, and 3773; 78 FR 64736 at 64784). Therefore, we have tentatively concluded that a person subject to either of the proposed preventive controls regulations would (when those regulations become final) be required to identify and take the steps necessary for that person to comply with proposed § 1.908(a)(3)(iii).

As previously noted, pasteurized citrus juice is an example of a non-TCS food that requires temperature control during distribution to control the growth of non-pathogenic spoilage microorganisms, which, in the case of juice, may not be killed by the pasteurization process. If such a food is not maintained under temperature conditions to prevent the food from undergoing microbial spoilage and becoming unfit for food, such food may become adulterated during transport. However, the specific temperature conditions necessary to prevent the food from undergoing microbial spoilage would depend upon the interaction of numerous factors concerning the food and its holding conditions that is sufficiently complex such that it is not possible to establish broadly applicable temperature conditions under which such foods must be held during transportation to prevent the microbial spoilage of the food. Therefore, we are not proposing to establish specific temperature requirements for non-TCS foods subject to proposed § 1.908(a)(3)(iii).

However, under proposed § 1.908(a)(3)(iii), persons subject to this proposed rule must provide adequate temperature control during transportation operations as necessary to control the growth of undesirable microorganisms. Persons engaged in transportation operations that result in the transportation of non-TCS food subject to microbial spoilage e.g., pasteurized juice, under conditions of inadequate temperature control, would not meet the requirements of proposed § 1.908(a)(3)(iii), and we may deem the food to be adulterated under section 402(i) of the FD&C Act in that the food has been transported under conditions that are not in compliance with the sanitary food transportation regulations.

With respect to frozen foods, in the preamble of the proposed preventive controls rule for human food (78 FR 3646 at 3774), FDA stated that 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. We noted that although there have been occasional problems with frozen food being subject to temperatures that allow some thawing in storage and distribution, we are not aware of situations in which frozen foods have been associated with the food becoming unsafe. Thus, we stated that we believe that it would be rare for a frozen food product to be a TCS food.

However, the same considerations discussed previously regarding the transportation of pasteurized juice apply to the transportation of frozen food. The transportation of frozen food under conditions of inadequate temperature control or temperature abuse whereby the food could undergo microbial spoilage would not comply with proposed § 1.908(a)(3)(iii), and we may deem the food to be adulterated under section 402(i) of the FD&C Act in that the food has been transported under conditions that are not in compliance with the sanitary food transportation regulations.

Finally, some foods that are typically transported under temperature control are not at risk of becoming adulterated if temperature control is not provided. An example of such a food would be fruit, such as bananas, that is transported under temperature control to delay ripening for marketability purposes. FDA would not consider bananas and other foods that are similar in this regard and typically transported under temperature control solely for marketability purposes to be food that can support the rapid growth of undesirable microorganisms in the absence of temperature control and these foods therefore would not be subject to proposed § 1.908(a)(3)(iii).

2. Requirements Applicable to Shippers

Proposed § 1.908(b) would set forth requirements applicable to shippers engaged in transportation operations.

Proposed § 1.908(b)(1) would require that the shipper 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 deemed necessary by the shipper, to ensure that the vehicle and equipment are 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. Proposed § 1.908(b)(1) would also provide that the information submitted by the shipper to the carrier is subject to the records requirements in proposed § 1.912(a).

Proposed § 1.908(b)(1) and similar requirements in this proposed rule (i.e., proposed § 1.908(b)(3), (d)(2), (d)(4), and (d)(5)) would address the provision of information by one party engaged in transportation operations to another party. Section 416(c)(1)(D) of the FD&C Act (21 U.S.C. 350e(c)(1)(D)) provides that, in issuing these regulations, the Secretary (and by delegation, FDA) must prescribe such practices as the Secretary determines appropriate relating to, among other things, information to be disclosed to a carrier by a person arranging for the transport of food and to a manufacturer or other person that arranges for the transportation of food by a carrier or furnishes a tank vehicle or bulk vehicle for the transportation of food. Proposed § 1.908(b)(1) establishes requirements for the information to be disclosed by a shipper to carrier that FDA has determined is necessary to ensure that food is not transported under conditions that would render the food adulterated. We discuss additional information sharing requirements for shippers and carriers in sections that follow.

Carriers in the food transportation industry commonly use standard procedures to deploy and prepare vehicles and transportation equipment to transport food. For example, comments to the 2010 ANPRM noted that thermally insulated tankers are used to haul foods that require temperature control. These tankers are typically designed and built to comply with industry standards that control the degree to which the temperature of the food will increase in a given amount of time. In addition, comments to the 2010 ANPRM stated that dry trailers used to haul non-refrigerated, fully packaged food items are swept or vacuum cleaned before being offered for loading. There are, however, circumstances in which a shipper may determine that specific procedures are necessary to prepare the vehicle or transportation equipment to ensure that they are in appropriate sanitary condition for the transport of a

particular food product. For example, shippers of fresh produce in non-enclosed containers may determine that a standard power washing procedure for a refrigerated trailer with a sanitization procedure is necessary to remove and treat any residues from a previous load that could contaminate the shipment. Shippers of animal feed may determine that special flushing procedures are necessary for bulk vehicles that have previously hauled medicated feed before being used for a feed shipment.

We have tentatively concluded that the identification by a shipper of the necessary sanitary requirements for vehicles and transportation equipment is essential for ensuring that the vehicle or transportation equipment to be provided by the carrier is appropriate for the intended transportation operation, particularly considering that certain types of foods, e.g., foods shipped in bulk or not completely enclosed by a container, may necessitate specific preparation procedures for the vehicle or transportation equipment. Proposed § 1.908(b)(1) would assign this responsibility to the shipper because we have tentatively concluded that the shipper is in the best position to know the characteristics of the food to be shipped that may necessitate the provision of specific features for the vehicle or transportation equipment, e.g., thermally insulated construction of a tank, or that may necessitate specific preparation steps by the carrier, e.g., a specific wash procedure, to ensure that the vehicle or transportation equipment is in appropriate sanitary condition for the transportation operation. We have also tentatively concluded that requiring the shipper to communicate this information to the carrier in writing is necessary to ensure that the shipper identifies the necessary sanitary requirements for the vehicle and equipment and to enable the carrier to take any necessary steps in deploying and preparing vehicles or transportation equipment for the operation.

Based upon comments we received in response to the 2010 ANPRM, we understand that in accordance with best industry practices, shippers and carriers frequently exchange information about requirements for vehicles, transportation equipment, and cleaning procedures. Accordingly, we do not believe that proposed § 1.908(b)(1) would require substantial efforts beyond those which are already common within the food transportation industry.

Given the importance of ensuring that vehicles and transportation equipment are in appropriate sanitary condition when offered for the transportation of food, proposed § 1.908(b)(1) would also provide that the shipper's written specification to the carrier of sanitary requirements for vehicles and transportation equipment is subject to the records requirements of proposed § 1.912(a) (discussed in section III.G).

Proposed § 1.908(b)(2) would require that, before loading food not completely enclosed by a container onto a vehicle or into transportation equipment, e.g., a shipping container, provided by a carrier, the shipper must visually inspect the vehicle or the transportation equipment provided by the carrier for cleanliness and determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food. The proposal would provide the following example of what constitutes ''appropriate sanitary condition for the transport of food'': the vehicle or transportation equipment is free of visible evidence of pest infestation and of debris, previous cargo, or dirt that could cause the food to become adulterated.

In the previous discussion of proposed § 1.908(a)(3)(ii) in this section we discussed the necessity to take effective measures during transportation operations to protect from adulteration foods that are not completely enclosed by a container and thus are exposed to potential contamination from the environment. Providing such protection depends in part upon ensuring that vehicles and transportation equipment in which such food will be transported are in adequate sanitary condition so that they will not become a source of contamination for the exposed food. We tentatively conclude that a pre-loading visual inspection by the shipper of the vehicle or transportation equipment provided by the carrier for cleanliness to determine that it is in appropriate sanitary condition for the transport of the food as would be required by proposed § 1.908(b)(2) is necessary to ensure that the transportation operation will be conducted in accord with sanitary transportation practices.

Several comments received in response to the 2010 ANPRM stated that pre-loading inspections are commonly carried out in transportation operations. One comment from a food retailers association stated that in such an inspection, for example, a trailer that exhibited any signs of mold, mildew, animal droppings, excess water, ice buildup, pest contamination or any holes, cracks or other breaches of the trailer itself that constituted conditions under which food may become contaminated would not generally be considered to be in an appropriate sanitary condition for the transport of food.

Proposed § 1.908(b)(3) would require that a shipper of 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, specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, the temperature conditions necessary during the transportation operation, including the pre-cooling phase, to ensure that the operation will maintain the temperature conditions and meet the requirements of proposed § 1.908(a)(3).

As previously noted in our discussion of proposed § 1.908(a)(3)(iii), various types of food require temperature control during transport either to prevent the food from becoming unsafe due to the growth of harmful microorganisms or to prevent the growth of non-harmful spoilage microorganisms. The shippers of such foods are generally expected to know the temperature control needs for these foods during transport. For example, our regulations for the prevention of SE in shell eggs during production, storage, and transportation in § 118.4(e) and for the refrigeration of shell eggs held for retail distribution in § 115.50(b)(2)) require eggs to be held and transported at a temperature not to exceed 45 °F (7 °C).

We tentatively conclude that specification by the shipper to the carrier of the temperature conditions necessary during the transportation operation, including the pre-cooling phase, is necessary to ensure that the operation will meet the requirements of proposed § 1.908(a)(3) with respect to the maintenance of appropriate temperature conditions for the food, and that the shipper is in the best position to identify the necessary temperature conditions because the shipper has the most knowledge and information about the food being offered for transport. We have also tentatively concluded, however, that such specification by the shipper would not be necessary for shipments of food in a thermally insulated tank because thermally insulated tanks are designed and built to limit the degree of temperature increase of a food in a given amount of time, and the shipper would specify the need for such a vehicle under the requirements of proposed § 1.908(b)(1). We have also tentatively concluded that requiring that the shipper make this communication to the carrier in writing would ensure that the shipper considers these temperature requirements for the food and explicitly communicates them to the carrier who can then implement the specified

temperature conditions during the transportation operation.

We expect that the information provided by shippers to carriers would identify appropriate holding temperatures for food to be shipped consistent with considerations about the food we have discussed in section III.D and in this section with respect to proposed §§ 1.906(c) and 1.908((a)(3)(iii). Shippers who would be subject to the proposed preventive controls rules for human food or animal food would know the appropriate holding temperatures for any food for which failure to adequately control temperature during transportation could make the food unsafe.

For non-TCS foods subject to microbial spoilage if not properly temperature controlled, as we noted previously in this section in the discussion of proposed § 1.908(a)(3)(iii), because of the complex interaction of factors that influence microbial spoilage in foods, we are not proposing to establish specific temperature requirements for non-TCS foods subject to proposed § 1.908(a)(3)(iii) and (b)(3). Under proposed § 1.908(b)(3), shippers of such foods would inform the carrier of the temperature control requirements for the food based upon their determination of the temperature conditions necessary to ensure that the product does not become adulterated due to the growth of spoilage microorganisms.

Based upon comments we received in response to the 2010 ANPRM, we understand that in accordance with best industry practices, shippers frequently inform carriers about temperature conditions necessary during transportation operations. Accordingly, proposed § 1.908(b)(3) should be consistent with efforts already commonly used within the food transportation industry.

Given the importance of ensuring that food is maintained under adequate temperature control during transportation, we tentatively conclude that the shipper should be able to demonstrate, through records, that it has specified, in writing to the carrier e.g., in a contract of carriage, the necessary temperature conditions for the food. The records will demonstrate that, within the shipper/carrier relationship, appropriate attention is given to maintaining the necessary temperature control during transportation operations to ensure that food does not become adulterated. Proposed § 1.908(b)(3) would also provide that the shipper's written specification to the carrier of the necessary temperature conditions for the food during the transportation operation is subject to the records requirements of proposed § 1.912(a) (discussed in section III.G).

Proposed § 1.908(b)(4) would require that, before loading food, a shipper of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation must verify that each freezer and mechanically refrigerated cold storage compartment or container has been pre-cooled in accordance with information submitted by the shipper as required by proposed § 1.908(b)(3).

In the previous discussions of proposed §§ 1.906(c) and 1.908(a)(3)(iii) in section III.D, we discussed the importance of providing temperature control during transportation operations for TCS foods and other foods subject to microbial spoilage, to ensure that these types of food do not become unsafe or otherwise adulterated. Providing adequate temperature control may depend in part upon the adequate pre-cooling of vehicles and containers into which the food will be loaded. If a refrigerated trailer has not been adequately pre-cooled at the time it is loaded with food, the temperature of the food may increase above levels necessary to ensure the safe and sanitary transport of the food until such time that the refrigeration unit brings the food to an acceptable temperature. Therefore, proposed § 1.908(b)(4) would require the shipper to conduct a pre-loading verification of a vehicle's or shipping container's pre-cooling to ensure that food is not transported under conditions that may render the food adulterated.

Based upon comments we received in response to the 2010 ANPRM, we understand that in accordance with best industry practices, pre-loading verification by shippers of the pre-cooling of refrigerated vehicles and containers is commonly carried out in transportation operations (although we understand that during such a verification check, the refrigeration system may be turned off when its doors are open, e.g., in humid conditions, to prevent water condensation on surfaces such as fiberboard packages that could be damaged by the water). Accordingly, we do not believe that the requirement placed on the shipper by proposed § 1.908(b)(4) would require substantial efforts beyond those which are already common within the food transportation industry.

Proposed § 1.908(b)(5) would provide that the shipper assumes the requirements applicable to the carrier in proposed § 1.908(d)(2)(i) (discussed later in this section) with respect to providing a demonstration to the receiver, if the shipper and carrier have agreed in writing pursuant to proposed § 1.908(d)(2)(ii) (also discussed later in this section) that the shipper is responsible for ensuring that the food was held under acceptable temperature conditions during transportation operations. Proposed § 1.908(b)(5) would also provide that the shipper assumes the corresponding records requirements applicable to the carrier under proposed § 1.908(d)(6)(ii) and proposed § 1.912(c) (also discussed later in this section).

We refer the reader to the discussion in this section of the requirement in proposed § 1.908(d)(2)(i) that the carrier 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. Proposed § 1.908(d)(2)(ii) would discharge the carrier from this requirement if the carrier and shipper agree, in writing and before transportation operations, that the shipper is responsible for monitoring the temperature conditions or otherwise assuring that the food was held under acceptable temperature conditions during the transportation operation.

In the circumstance addressed by proposed § 1.908(d)(2)(ii), e.g., a shipment by refrigerated rail car wherein the shipper controls the operation of the refrigeration equipment in a leased rail car, inasmuch as the shipper would be assuming responsibilities otherwise assigned to the carrier under this proposed rule, proposed § 1.908(b)(5) would make it clear that the shipper is also required to provide to the receiver, if requested, the specified demonstration that would have otherwise been provided by the carrier. Proposed § 1.908(b)(5) also makes it clear that the shipper assumes the corresponding records requirements that would otherwise be applicable to the carrier under proposed §§ 1.908(d)(6)(ii) and proposed § 1.912(b). Proposed § 1.908(b)(5) thus would ensure that the shipper is subject to the same requirements to provide information to the receiver, and the same corresponding records requirements as the carrier would otherwise be, in circumstances where the shipper has assumed a responsibility that would otherwise be borne by the carrier.

3. Requirements Applicable to Shippers and Receivers

Proposed § 1.908(c) would set forth requirements applicable to both shippers and receivers engaged in transportation operations.

Proposed § 1.908(c)(1) would require that shippers and receivers provide vehicle operators who are expected to handle food not completely enclosed by a container during loading and unloading operations with access to a hand-washing facility that is convenient and that provides running water. This would ensure that the operator's hands are not a source of contamination of food by providing facilities that are convenient and furnish running water. As noted in the discussion of proposed § 1.908(a)(3)(ii) previously in this section, a driver of a vehicle transporting food items not completely enclosed by a container may be expected to handle containers during unloading. If, for example, during transport, the driver had to change a tire, the driver's hands could become soiled or contaminated with grease such that it would be necessary for that driver to wash his hands before handling the containers of produce to reduce the potential for the food to become contaminated during handling. Proposed § 1.908(c)(1) would require the shipper or receiver to provide access to an adequate hand-washing facility if the driver is expected to handle the food being transported to ensure that the operator's hands are not a source of contamination of food.

Proposed § 1.908(c)(1) is consistent with our existing CGMP regulations which include a provision on cleanliness whereby persons working in direct contact with food must conform to hygienic practices (see § 110.10(b), (b)(3) and 110.37(e) and Table 1). These hygienic practices include washing hands thoroughly and sanitizing if necessary to protect against contamination with undesirable microorganisms (§ 110.10(b)(3)). This regulation also includes provisions that address the hand-washing facilities that must be available to personnel (see, e.g., § 110.37(e)). Furthermore, the proposed preventive controls rules for both human and animal food contain similar hygiene provisions for hand-washing facilities. For example, the CGMP provisions of both proposed preventive controls rules would establish a performance standard that would require that each plant provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food (human or animal), food-contact surfaces, or food packaging materials by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature (78 FR 3646 at 3723; 78 FR 64736 at 64774).

Proposed § 1.908(c)(2) would require that shippers and receivers of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation carry out loading and unloading operations under conditions that will prevent the food from supporting such microbial growth. During any period of temperature abuse foods that can support the rapid growth of undesirable microorganisms may experience conditions whereby they may develop increased levels of microorganisms capable of causing spoilage of the food, or if present, microorganisms that may cause human or animal illness. While some comments to the 2010 ANPRM stated that the docking areas of some shipping and receiving facilities are temperature monitored, a comment stated such temperature monitoring is not always practiced during loading and unloading operations for refrigerated and frozen foods. Nevertheless, FDA has tentatively concluded that the movement of these foods through non-temperature controlled loading and unloading areas would not put the food at risk of adulteration if the food is not held under conditions that may adversely affect the food's temperature for extended time periods. However, FDA would not consider staging and holding of any food capable of supporting the rapid growth of undesirable microorganisms in the absence of temperature control on a non-temperature controlled loading dock hours before a pickup is scheduled to be an acceptable handling practice for such food under proposed § 1.908(c)(2) because these conditions could cause the food to be rendered unsafe or otherwise adulterated.

4. Requirements Applicable to Carriers

Proposed § 1.908(d) would set forth requirements applicable to carriers engaged in transportation operations.

Proposed § 1.908(d)(1) would require that a carrier supply a vehicle and transportation equipment that meets any requirements specified by the shipper in accordance with proposed § 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.

In the discussion of proposed § 1.908(b)(1) previously in this section, we discussed the importance of the shipper specifying to the carrier the necessary sanitary requirements for vehicles and transportation equipment to ensure that the vehicle or equipment to be provided by the carrier is appropriate for the intended transportation operation. We discussed that we have tentatively concluded that the shipper is in the most appropriate person to specify these requirements because he would best know the characteristics of the food to be shipped and any specific steps that should be taken by the carrier to ensure that the vehicle or transportation equipment is in appropriate sanitary condition for the transportation operation and to ensure that the food does not become adulterated during transportation.

Because a vehicle that is not in appropriate sanitary condition when offered for the transportation of food can be a source of contamination of food during transport, we tentatively conclude that it is of equal importance to help ensure that food does not become adulterated during transportation that carriers provide vehicles and transportation equipment that meet the sanitary requirements specified by the shipper and are otherwise appropriate for the sanitary transportation of food. Therefore, proposed § 1.908(d)(1) would make the carrier responsible for providing a vehicle that is in appropriate condition for the transportation of food, including meeting any requirements specified by the shipper in accordance with proposed § 1.908(b)(1), to ensure that the food being transported will not become filthy, putrid, decomposed, or otherwise unfit for food, or be rendered injurious to health from any source during the transportation operation.

For example, a carrier would not be considered to be in compliance with this proposed provision if it offers a bulk vehicle intended for the transport of animal feed for loading if it had previously been used to transport medicated feed and the carrier had not performed a cleanout procedure established by the shipper to remove residues of the medicated feed from the vehicle.

Proposed § 1.908(d)(2) would establish requirements for carriers relevant to the maintenance of temperature control for foods subject to proposed § 1.908(b)(3) discussed previously in this section.

Proposed § 1.908(d)(2)(i) would require a carrier, once the transportation operation is complete, to demonstrate to the shipper and if requested, to the receiver, that the carrier maintained temperature conditions during the transportation operation consistent with those specified by the shipper in accordance with proposed § 1.908(b)(3). Proposed § 1.908(d)(2)(i) would further provide that this demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper. For

example, the carrier could present printouts of a time/temperature recording device or a log of temperature measurements taken at various times during the shipment.

As we noted in the discussion of proposed § 1.908(b)(3), the specification by the shipper to the carrier of the temperature conditions necessary during the transportation operation, including the pre-cooling phase, is important for ensuring the maintenance of appropriate temperature conditions for the food during the operation. Proposed § 1.908(b)(3) thus would require the shipper to make this specification to the carrier. Based upon comments we received in response to the 2010 ANPRM, we understand that shippers and carriers routinely exchange the type of information required by proposed § 1.908(b)(3) and furthermore, industry best practices have been developed for the maintenance of the cold chain.

Nonetheless, the lack of appropriate temperature control is a potential problem in food transportation as evidenced by concerns about improper temperature control of food products cited in the ERG report and the continuing reports we have received of food transported without proper temperature control (Ref. 3) (Ref. 4) (Ref. 5) (Ref. 6) (Ref. 7) (Ref. 8) (Ref. 9). In light of these concerns, we propose to include a mechanism by which the carrier must demonstrate to the shipper that food which may become adulterated if its temperature is not properly controlled during transportation operations was transported under acceptable temperature conditions. Proposed § 1.908(d)(2)(i) would require that a carrier demonstrate to the shipper, once the transportation operation is complete, that the carrier maintained temperature conditions during the transportation operation consistent with the shipper's specifications.

Proposed § 1.908(d)(2)(i) would further provide that the demonstration to be made by the carrier may be accomplished by any appropriate means agreeable to the carrier and shipper. This provision would allow the carrier to make this demonstration in different ways consistent with existing industry practices. For example, by agreement with a shipper of a TCS food, the carrier may use an onboard recording device to monitor compartment temperature in the vehicle during the transportation operation and provide the monitoring information to the shipper. Alternatively, by agreement with the shipper, the carrier may manually record the compartment temperatures in a log and provide the log to the shipper.

The proper temperature control of food subject to the rapid growth of undesirable microorganisms in the absence of temperature control during transportation is also of importance to receivers because the carrier's failure to provide the necessary temperature control for the food may result in receivers receiving and then offering adulterated food to consumers or other customers. Therefore, proposed § 1.908(d)(2)(i) would state that the carrier, upon request by the receiver, must demonstrate to the receiver that the carrier maintained temperature conditions during the transportation operation consistent with the shipper's specifications.

We recognize that in certain circumstances, a shipper may assume the responsibility for ensuring that food is held under acceptable temperature conditions during a transportation operation (Ref. 20). In such cases, proposed § 1.908(d)(2)(ii) would provide that a carrier is not subject to the requirements of proposed § 1.908(d)(2)(i) if the carrier and shipper agree in writing prior to the transportation operation that the shipper is 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. For example, in some cases the shipper may by agreement with the carrier arrange to have his own temperature monitoring device placed aboard the vehicle and recover the device upon delivery of the food.

In another example, a shipper of pasteurized juice to be transported a short distance may rely on: (1) His pre-loading inspection to establish that the vehicle was properly pre-cooled; and (2) the receiver's inspection of the food upon delivery. This arrangement would be an alternative to the carrier providing a demonstration to the shipper if the shipper has determined that this procedure would ensure that the food was transported under acceptable temperature conditions.

Thus, proposed § 1.908(d)(2) would establish a flexible mechanism compatible with existing industry practices whereby the carrier is responsible for demonstrating to the shipper that the carrier has met the shipper's specified temperature conditions unless the carrier and shipper agree, in writing, that the shipper will be responsible for monitoring the temperature conditions or otherwise assuring that the food was held under acceptable temperature conditions during the operation.

Proposed § 1.908(d)(2)(ii) further would require the carrier to provide the written agreement to the receiver, if requested. This provision provides a practicable means for a carrier to notify a receiver that the shipper has assumed responsibility for ensuring that the food was held under acceptable temperature conditions during the transportation operation, should the receiver request that a carrier provide the demonstration required by proposed § 1.908(d)(2)(i). As discussed previously in this section with respect to proposed § 1.908(b)(5), in such a situation, the shipper would assume the requirements otherwise applicable to the carrier in proposed § 1.908(d)(2)(i).

We tentatively conclude, and have thus specified in proposed § 1.908(d)(2)(ii) that the agreement between the carrier and shipper should be written because the agreement transfers responsibilities otherwise assigned to the carrier under this proposed rule to the shipper, and requiring the agreement to be written would appropriately document that transfer of responsibility. Proposed § 1.908(d)(2)(ii) further specifies that the written agreement is subject to the records requirements of § 1.912(b) of this subpart.

Proposed § 1.908(d)(3) would require that before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for the transportation of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control, a carrier must pre-cool each mechanically refrigerated freezer and cold storage compartment as specified by the shipper in accordance with proposed § 1.908(b)(3).

In the discussion of proposed § 1.908(b)(3) previously in this section, we discussed our tentative conclusion that requiring the shipper to specify to the carrier the temperature conditions necessary during the transportation operation, including the pre-cooling phase, was necessary for ensuring that the operation will meet proposed § 1.908(a)(3) with respect to the maintenance of appropriate temperature conditions for the food. The shipper is able to specify these requirements because it is in the best position to know the temperature control requirements of the food to be shipped to ensure that the food does not become adulterated due to the undesirable microorganism growth. Proposed § 1.908(b)(3) would thus make the shipper responsible for specifying these

temperature conditions to carrier in writing.

A vehicle or transportation equipment that is not adequately pre-cooled can, after loading, cause the food to exceed temperatures that are necessary to control microorganism growth. Therefore, proposed § 1.908(d)(3) would require the carrier to pre-cool each mechanically refrigerated freezer and cold storage compartment as specified by the shipper in accordance with proposed § 1.908(b)(3) before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for the transportation of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control. This proposed provision would only be applicable to vehicles or transportation equipment that maintain temperature control of food through the use of mechanically refrigerated freezers or cold storage compartments because for vehicles or transportation equipment that maintain temperature control by means other than mechanical refrigeration, e.g., thermally insulated bulk tankers, pre-cooling is not necessary to ensure temperature control of the food after loading.

Based upon comments we received in response to the 2010 ANPRM, we understand that in accordance with best industry practices, carriers in the industry generally pre-cool vehicles they intend to offer for the shipment of temperature controlled foods. Accordingly, we do not believe that the requirement placed on the carrier by proposed § 1.908(d)(3) will necessitate efforts beyond those which are already common within the food transportation industry.

Proposed § 1.908(d)(4) would require a carrier that offers a bulk vehicle for food transportation to provide information to the shipper that identifies the three previous cargoes transported in the vehicle, which is consistent with our understanding of current industry practice except that the shipper and carrier may agree in writing prior to transportation operations that the carrier will provide information that identifies fewer than three previous cargoes or that the carrier need not provide any such information if procedures have been established that would ensure that the bulk vehicle offered will be adequate for the intended transportation operation, e.g., if the carrier by contract will only offer bulk vehicles dedicated to hauling a single type of product. This provision is discussed after the description of proposed § 1.908(d)(5). Proposed § 1.908(d)(4) would also specify that the written agreement is subject to the records requirements of proposed § 1.912(b).

Proposed § 1.908(d)(5) would require a carrier that offers a bulk vehicle for food transportation to 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 prior to transportation operations that the carrier need not provide any such information, if procedures have been established 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 prior to loading food into the bulk vehicle. Proposed § 1.908(d)(5) would also specify that the written agreement is subject to the records requirements of proposed § 1.912(b).

Comments to the 2010 ANPRM stated that in transportation operations involving the bulk transport of human and animal food, shippers and carriers typically exchange information to ensure that the bulk vehicles will, when offered, be suitable for the operation. Shippers in some cases may need to know the identity of prior cargoes that were hauled in a bulk vehicle to determine whether they were of such a nature that they could affect their shipment in any manner that would either cause it to become adulterated or that would adversely affect its commercial value. Shippers may also need to know how the bulk vehicle was cleaned in order to determine that the cleaning procedure used was adequate to prepare the bulk vehicle for the transport of their product. As noted previously in this section in the discussion of proposed § 1.908(b)(1), in the bulk transport of animal feed, it may be necessary for the shipper to obtain assurance that specified cleanout procedures have been carried out for bulk vehicles that have previously hauled medicated feed.

A circumstance necessitating communication between shippers and carriers that might arise in the bulk transport of liquid non-dairy foods involves the need to ensure that vehicles that have previously hauled milk will not introduce allergens into non-dairy foods through cross contact. As noted in the discussion in this section of proposed § 1.908(a)(3)(ii), depending upon whether or not a bulk carrier uses its vehicles to transport milk, shippers might employ different procedures to establish the suitability of a bulk vehicle for the transport of their product. For example, if a carrier only provides vehicles dedicated to the hauling of a single product, e.g., juice, a shipper of juice would not need to know what the previous cargoes of a bulk vehicle were before loading its product into the vehicle. If, however, the carrier recently hauled milk in a bulk vehicle offered to the same shipper, milk residues that might remain in the bulk vehicle could contaminate subsequent shipments in the bulk vehicle. The shipper may need to know from the carrier that milk was hauled and may also need information about the most recent cleaning procedure for the tanker.

In practice, bulk carriers and shippers commonly establish mutually acceptable procedures concerning prior cargoes and cleanings, usually through contractual arrangements, to ensure that a bulk vehicle will be suitable for a transportation operation for which it will be offered. Such agreements may be based upon industry guidelines for bulk transport that set forth best practices for the hauling of particular commodities (Ref. 22) (Ref. 29). These guidelines may call for the use of dedicated vehicles for the transport of a particular commodity or may identify acceptable prior cargoes when the use of a dedicated vehicle is not necessary. These guidelines may also address acceptable cleaning procedures for the bulk vehicles.

While shippers and carriers commonly establish mutually acceptable procedures for bulk shipments prior to an actual transportation operation, there may be instances where such procedures have not been established and a shipper must obtain information from the carrier about prior cargoes and cleaning for a bulk vehicle at the time a vehicle is offered for his shipment to ensure that the condition of the bulk vehicle is adequate to ensure that the food is not adulterated during transportation.

To account for such situations, we tentatively conclude that the sanitary food transportation regulations should require that the carrier provide information to the shipper that identifies the prior cargoes and describes cleaning procedures for a bulk vehicle offered to the shipper. We also tentatively conclude that to provide flexibility consistent with existing practices, this proposed rule should allow for the shipper and carrier to mutually agree in writing to forgo the exchange of some or all of this information when it is not necessary to ensure that the bulk vehicle is adequate for the intended transportation operation.

For example, a shipper of juice and a carrier may mutually agree in writing that no information need be provided to the shipper about prior cargoes in the bulk vehicles if the carrier agrees to only offer bulk vehicles that exclusively haul juice. Similarly, if a carrier contractually agrees to use a cleaning procedure for bulk vehicles deemed suitable by the shipper, these parties could, under proposed § 1.908(d)(5), agree in writing that no information need be provided to the shipper about the cleaning of the vehicles.

Under proposed § 1.908(d)(4), the information to be provided by a carrier would identify the three previous cargoes hauled in a bulk vehicle. We have tentatively concluded that information about the three previous cargoes is sufficient to demonstrate to the shipper that the condition of the bulk vehicle is adequate to ensure that the food is not adulterated during transportation. We have based this tentative conclusion, in part, on two industry guidance documents, from a juice industry association and a broad food industry association, that contain recommendations that shippers obtain information from carriers identifying the three previous cargoes of a bulk vehicle (Ref. 22) (Ref. 29). We also note that we stated in a 1996 ANPRM published jointly with FSIS (61 FR 59372 at 59379) that we were considering requiring carriers of potentially hazardous foods (the designation used at that time for TCS foods) that are shipped in bulk to provide shippers with records that identify the last three cargoes for any conveyance being offered to the food shipper for use in transporting the food. However, comments to the 2010 ANPRM stated that other sectors of the food transportation industry, e.g., the animal feed transport sector, typically only exchange information about the immediate previous cargo of a bulk vehicle offered. We request comment on whether proposed § 1.908(d)(4) and (d)(5) are written with the flexibility to enable application across multiple sectors of the bulk human and animal food transportation industry and still accomplish its intended purpose of providing for information disclosure between carriers and shippers as necessary to establish that the condition of the bulk vehicle is adequate to ensure that the food is not adulterated during transportation. We also request comment on whether there are circumstances under which bulk carriers would also need to provide this information upon request to receivers about the condition of bulk vehicles to ensure that food is not adulterated during transportation.

We also note that additional requirements relevant to the bulk transport of human and animal food may apply to the owner, operator, or agent in charge of facilities that manufacture, process, pack, or hold food and are subject to the proposed preventive controls rules for human and animal food. For example, under the proposed preventive controls rule for human food, the owner, operator, or agent in charge of such a facility must evaluate known or reasonably foreseeable hazards in food, including any that may occur due to transportation practices.

We are requiring in proposed § 1.908(d)(4) and (d)(5) that the agreement required by those sections be written to appropriately document that a carrier and shipper have agreed to employ an alternative procedure available under these provisions.

Proposed § 1.908(d)(6) would require carriers to develop and implement specified written procedures subject to the records requirements of proposed § 1.912(b).

Proposed § 1.908(d)(6)(i) would require that the written procedures 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 proposed § 1.906(b).

The cleaning and inspection of a vehicle or transportation equipment is a fundamental element of sanitary food transportation and is necessary to ensure that food is not transported under conditions that may render it adulterated. As we have noted previously in this section in the discussion of proposed § 1.908(b)(1), carriers in the food transportation industry commonly use standard procedures to appropriately prepare vehicles and transportation equipment for the transportation of food. We also noted in that discussion that shippers may in some circumstances specify particular procedures to be used by carriers in the preparation of vehicles and transportation equipment. These types of cleaning procedures could be used in certain circumstances by a carrier to meet the proposed requirement for a written procedure. The proposed requirement that the procedures be written would help ensure that they are consistently applied, facilitate training on these procedures, and enable verification by FDA and other authorities.

Proposed § 1.908(d)(6)(ii) would require that the written procedures describe how the carrier will comply with the provisions for temperature control in proposed § 1.908(d)(2), discussed previously in this section. For example, the carrier's written procedures might state that the carrier will either provide data from a time/temperature recording device to a shipper or (upon request) receiver, or that it will provide the shipper with a receipt signed by the receiver noting the time of delivery, which in conjunction with the shipment's time of the departure (known by the shipper) and the shipper's verification of the vehicle's pre-cooling, would be sufficient for the shipper to know that the food was transported in accord with the shipment's specified temperature conditions. In practice, the carrier might use the first procedure for trips of several hours because data from a temperature recording device would demonstrate to the shipper or receiver that food's temperature was maintained in accord with the shipper's specification to the carrier. The carrier might use the second procedure for relatively short distance trips where the shipper or receiver can be assured that temperature control for the food according to his specifications was provided by knowing that the shipment was in transit only for a short period of time after departing his facility. The determination of the appropriate method would be made by the shipper.

A discussion of the importance of temperature control was previously provided in this section in the discussion of proposed § 1.908(d)(2). The proposed requirement that the procedures be written would help ensure that they are consistently applied, facilitate training on these procedures, and enable verification by FDA and other authorities.

Proposed § 1.908(d)(6)(iii) would require that the written procedures describe how the carrier will comply with the provisions for the use of bulk vehicles in proposed § 1.908(d)(4) and (d)(5), discussed previously in this section. A discussion of the importance of prior cargo information and bulk vehicle cleaning was previously provided in this section in the discussion of proposed § 1.908(d)(4) and (d)(5). The proposed requirement that the procedures be written would help ensure that they are consistently applied, facilitate training on these procedures, and enable verification by FDA and other authorities.

F. Training (Proposed § 1.910)

Proposed § 1.910 would establish training requirements for carriers. Proposed § 1.910(a) would require that carriers 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 proposed rule. Proposed § 1.910 would also require that this training be provided upon hiring and as needed thereafter.

We previously noted that the ERG report identified the lack of driver/employee training and/or supervisor/manager/owner knowledge of food safety and/or security as a problem area where food may be at risk for physical, chemical, or biological contamination during transport and storage (Ref. 9). Findings released in 2007 by the Michigan Department of Agriculture (Ref. 3) identified low driver awareness of safe food temperatures and inadequate food safety training of drivers as areas of concern in food transport. Also, as stated in the discussions of proposed §§ 1.906(c) and 1.908(a)(3)(i) in sections III.D and III.E, we continue to receive or otherwise learn of reports of foods such as meat and seafood products being transported under temperature abuse conditions (Ref. 5) (Ref. 6) (Ref. 7) (Ref. 8), and we have received reports in the 3 years since we established the Reportable Food Registry of animal feed becoming contaminated during transportation due to the insanitary condition of a vehicle (Ref. 2).

We recognize, based upon comments to the 2010 ANPRM, that food transporters commonly implement training programs for their personnel that address sanitary food handling. However, we also note that these identified areas of concern and recent problems involve practices that would be the carrier's responsibility under this proposed rule. This would indicate that there is a lack of consistent implementation of training in sanitary food handling practices among carriers in the food transportation industry. For this reason we are proposing training requirements for carriers in this proposed rule. We would envision that this training could be provided in half-day online format similar to training referred to as DOT HM 181 basic hazmat employee training, readily available in the private sector. The proposed training provision would require that the training be provided upon hiring and as needed thereafter. This would ensure that carrier personnel are knowledgeable about food safety issues and their responsibilities before they engage in transportation operations. It would also ensure that additional training is provided when needed; e.g., when a carrier's operations change substantially, or when the employee's performance indicates a need for additional training.

We have tentatively concluded that training needs for shippers and receivers would be most appropriately addressed through other regulations such as our CGMP regulations and our proposed preventive controls rules for human and animal food because these regulations and proposed rules contain provisions related to employee training for entities that would operate as shippers and carriers.

Section 110.10(c) of our CGMP regulations for human food provides guidance that personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Section 110.10(c) further recommends that food handlers and supervisors receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

Our proposed preventive controls rules for human and animal food include training requirements for individuals who perform or oversee specified functions, e.g., preparation of the food safety plan (78 FR 3646 at 3761 and 78 FR 64736 at 64750).

Proposed § 1.910(b) would require that carriers establish and maintain records that document required training of personnel. Such records would be required to include the date of the training, the type of training, and the person(s) trained. These records would be subject to the records requirements of proposed § 1.912 (discussed in section III.G). Given the importance of adequate training to the conduct of sanitary transportation operations by carriers, we tentatively conclude that this proposed rule should also require that carriers maintain records documenting that they have provided the required training to their personnel to enable the agency to verify compliance with the training requirement through inspection and records examination.

G. Records (Proposed § 1.912)

Proposed § 1.912 would establish requirements for the retention and availability of records applicable to shippers and carriers engaged in transportation operations. A discussion of the records we are requiring shippers and carriers to maintain and the necessity for the maintenance of such records is found in the respective discussions of proposed § 1.908(b)(1), (b)(3) and (d)(6) in section III.E.

Proposed § 1.912(a) would require that shippers retain records that demonstrate that they provide information as required by proposed § 1.908(b)(1) and (b)(3) as a regular part of their transportation operations for a period of 12 months beyond when the shipper is subject to any requirement to provide such information.

Proposed § 1.912(b) would require that carriers retain records of any written agreements required by proposed § 1.908(d)(2)(ii) and of the written procedures required by proposed § 1.908(d)(6) that describe cleaning, sanitizing and inspection procedures for vehicles and transportation equipment for a period of 12 months beyond when such agreements and procedures are in use in their transportation operations. Proposed § 1.912(c) would require that carriers retain training records required by proposed § 1.910(b) for a period of 12 months beyond when the person identified in any such records continues to perform the duties for which the training was provided.

The requirements of proposed § 1.912(a) through (c) would enable us to review records of the transportation operations of shippers and carriers during inspections for enforcement purposes and to assess compliance with the requirements of this proposed rule. In the case of records required by proposed § 1.912(a) and (b), we are proposing to require a retention period of 12 months to enable us to assess the recent operations of a shipper or carrier where it may be necessary to do so, e.g., in an investigation of a recent outbreak of foodborne illness.

Proposed § 1.912(d) would require that shippers and carriers make all records required by this proposed rule available to a duly authorized individual promptly upon oral or written request.

Proposed § 1.912(e) would require that all records required by this proposed rule 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, which must be kept in accordance with 21 CFR part 11.

Proposed § 1.912(f) would provide that except for the written procedures

required by proposed § 1.908(d)(6), offsite storage of records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. Proposed § 1.912(f) would also specify that the written procedures required by proposed § 1.908(d)(6) must remain onsite as long as the procedures are in use in transportation operations.

Providing for offsite storage of some records after 6 months would enable a facility with flexibility to comply with the proposed requirements for record retention while reducing the amount of space needed for onsite storage of the records without interfering with the purpose of record retention, because the records will be readily available.

Proposed § 1.912(f) also would provide that electronic records are considered to be onsite if they are accessible from an onsite location. Computerized systems within corporations can be networked, allowing for the sending and receiving of information in a secure fashion to all of the different facilities of that corporation worldwide. This type of system can be used to provide access at multiple locations to records from multiple plants or facilities.

Proposed § 1.912(f) is consistent with our Hazard Analysis and Critical Control Points (HACCP) regulations for seafood and juice. Our HACCP regulation for seafood provides for transfer of records if record storage capacity is limited on a processing vessel or at a remote processing site, if the records could be immediately returned for official review upon request (21 CFR 123.9(b)(3)). Our HACCP regulation for juice permits offsite storage of processing records after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review and considers electronic records to be onsite if they are accessible from an onsite location (21 CFR 120.12(d)(2)).

Proposed § 1.912(g) would provide that all records required this proposed rule are subject to the disclosure requirements under part 20 (21 CFR part 20). FDA's regulations in part 20, the Freedom of Information Act (FOIA) (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), and the FD&C Act, govern FDA's disclosures of information, including treatment of commercial confidential information (CCI) and trade secret information.

H. Waivers (Proposed §§ 1.914–1.934)

1. Statutory Authority

Section 416(d) of the FD&C Act provides the Secretary with the authority to waive any requirement under section 416 of the FD&C Act, which would include the requirements of this proposed rule, with respect to any class of persons, vehicles, food, or nonfood products, if the Secretary determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human and animal health and will not be contrary to the public interest. Section 416(d)(2) of the FD&C Act further provides that the Secretary shall publish in the **Federal Register** any waiver and the reasons for the waiver. Aside from section 416(d)(2), section 416 does not expressly prescribe the procedures for granting a waiver under section 416(d) or for revoking or amending a waiver that has already been granted under section 416(d).

2. Proposed Requirements

Consistent with the statutory provisions mentioned previously, we are proposing a process by which FDA will grant waivers from one or more requirements of subpart O on its own initiative or in response to a petition from an interested person, including information that must accompany such petitions, and the procedures and circumstances under which FDA may grant or deny such petitions, and modify or revoke any waivers that have already been granted. Waivers granted by FDA would be limited to the requirements of subpart O specified by FDA in the **Federal Register** notice announcing the waiver, and would have no effect on the application of other provisions of the FD&C Act or FDA regulations.

Proposed § 1.914 would provide that FDA may waive a requirement of subpart O with respect to any class of persons, vehicles, food, or nonfood products, if FDA determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and the waiver will not be contrary to the public interest. This proposed provision is identical to the standard set forth in section 416(d)(1) of the FD&C Act. Under this standard, a waiver could be granted with regard to a specific requirement or subset of requirements of subpart O or with regard to all requirements set forth in subpart O. Similarly, under this standard, a waiver could be granted with regard to any class of persons, vehicles, food, and/or nonfood products and the transportation operations in which they engage.

Proposed § 1.916 would provide that FDA will consider whether to waive a requirement of subpart O on FDA's own initiative or on the petition submitted under § 10.30 (21 CFR 10.30) by any person who is subject to the requirements of subpart O with respect to any class of persons, vehicles, food, or nonfood products. FDA would welcome requests for pre-petition consultations, including meetings, with interested persons to facilitate the development of petitions seeking a waiver of some or all of the requirements of subpart O, including data and information necessary to demonstrate that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and that the waiver will not be contrary to the public interest.

Proposed § 1.918 would provide that, in addition to the requirements set forth in § 10.30, the Statement of Grounds (which is addressed under § 10.30(b)) of a petition requesting a waiver must 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 subpart O to which the waiver would apply (proposed § 1.918(a)). In addition, the Statement of Grounds would also be required to 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 (proposed § 1.918(b)). Under these provisions, an interested person would be required to submit relevant and scientifically-valid information or materials specific to the requested waiver to demonstrate 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. This could include information about the nature of the food, the manner in which it is transported, the controls in place to mitigate any food safety issues, and government and/or non-government oversight of the transportation of the food.

Proposed § 1.920 establishes our presumption 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. We do not believe that

information exempt from disclosure under part 20 of this chapter is the type of information that FDA is requiring to be submitted in such a petition or that would be relevant in any comments submitted on such a petition. We also believe that providing full public access to this information is important to ensuring transparency and for the opportunity for other interested parties to offer comment on the petition. Therefore, we expect to make these submissions publicly available.

Proposed § 1.922 would establish 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 of the Office of Compliance, CFSAN, or the Director of the Office of Surveillance and Compliance, CVM, as the responsible official for responding to a request for a waiver from one or more requirements in subpart O.

Proposed § 1.924 would establish the general procedures applying to a petition requesting a waiver from one or more requirements in subpart O. Proposed § 1.924(a) would provide that the procedures sets forth in § 10.30 govern the process by which FDA responds to a petition requesting a waiver. Section 10.30 specifies the requirements for any citizen petition submitted by a person (including a petitioner who is not a citizen of the United States) to FDA. Proposed § 1.924(b) would establish that, under § 10.30(h)(3), we will publish a notice in the **Federal Register**, requesting information and views on the filed petition, including information and views from persons who could be affected by the waiver if the petition were to be granted (e.g., because the waiver would also apply to certain or all transportation operations performed by a person). Such persons could include those whose transportation operations are conducted under similar circumstances with similar procedures, processes, or practices as those addressed in the petition, or could include shippers, carriers, or receivers who are engaged in transportation operations of food that is similar or identical to a specific food addressed in the petition.

Proposed § 1.924(c) would establish that, under § 10.30(e)(3), FDA will respond to the petitioner in writing. Proposed § 1.924(c)(1) would establish that, 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. This action is required by section 416(d)(2) of the FD&C Act. Proposed § 1.924(c)(2) would establish that, if FDA denies the petition (including partial denials), FDA will explain the reason(s) for the denial in its written response to the petitioner. Under proposed § 1.924(d), we propose to 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). The provisions in proposed § 1.924 would ensure transparency in FDA's activities and decision-making, which allows the public to better understand the agency's decisions, increasing credibility and promoting accountability.

Proposed § 1.926 would provide that we may deny a petition requesting a waiver if it does not provide the information required under proposed § 1.918 (including the requirements of § 10.30), 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. For example, we would expect to deny a petition if the petitioner failed to submit data, information, or other materials to demonstrate that the requested waiver would not result in the transportation of food under conditions that would be unsafe for human or animal health.

Proposed § 1.928 would provide that if FDA, on its own initiative, determines that a waiver is appropriate, FDA will publish a notice in the **Federal Register** setting forth the waiver and the reasons for such waiver. Under certain circumstances, FDA may solicit public comment on a proposed waiver before making a final determination regarding whether to grant a waiver (as we have in this proposed rule, as discussed later in this section). However, under other circumstances, when FDA has 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, FDA may grant a waiver without first soliciting public comment. We have tentatively concluded that this process is sufficient for FDA granting a waiver on its own initiative because it is the process set forth in section 416(d)(2) of the FD&C Act.

Proposed § 1.930 would specify that a waiver granted by FDA becomes effective on the date that notice of the waiver is published in the **Federal Register**.

Under proposed § 1.932, we would be able to 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. For example, we may deem it necessary to modify terms and conditions of a waiver based on a review of updated scientific data or factual information related to the procedures, processes, or practices utilized by the transportation operations that are covered by the waiver.

Proposed § 1.934 would establish the procedures that apply if FDA determines that a waiver should be modified or revoked. Under proposed § 1.934(a), we would provide notice of such a determination as follows: (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 a petition should be modified or revoked; and (2) we will publish in the **Federal Register** a notice of our determination that a waiver should be modified or revoked. This notice will establish a public docket so that interested parties may submit written submissions on our determination. FDA requests comments on whether it should establish requirements for the timely submissions to the public docket, and if so, whether it should do so in the final rule or whether it would be more appropriate to address this issue in a guidance document.

Under proposed § 1.934(b), we would consider written submissions submitted to the public docket from interested parties.

Under proposed § 1.934(c), we would publish a notice of our final decision in the **Federal Register**. The effective date of the decision will be the date of publication of the notice.

We tentatively conclude that these provisions are necessary and appropriate not only to ensure transparency and accountability in FDA's activities and decisionmaking, but also to provide relevant parties with an opportunity for due process.

3. Potential Waivers

Under the standard set forth in section 416(d)(1) and proposed § 1.914, and as discussed further in the paragraphs that follow, we have tentatively determined that it would be appropriate to waive the applicable requirements of subpart O, 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.

• 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.

We intend 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 classes of persons from the applicable requirements of subpart O. We request comment regarding whether these 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.

a. Shippers, carriers, and receivers holding valid permits under the NCIMS Grade ''A'' Milk Safety Program, only when engaged in transportation operations involving Grade A milk and milk products. The NCIMS Grade ''A'' Milk Safety Program, participated in by all 50 States, the District of Columbia, and Puerto Rico, uses as its basic standard a model milk regulation, the Grade ''A'' Pasteurized Milk Ordinance (Grade ''A'' PMO) (Ref. 30) which incorporates provisions governing the production, storage, handling, processing, packaging, transportation, and sale of Grade ''A'' milk and milk products, including buttermilk and buttermilk products, whey and whey products, and condensed and dry milk products. Provisions of the Grade ''A'' PMO and the Grade ''A'' Milk Safety Program address milk tank trucks and operations involving them, including farm bulk milk pick-up tankers and milk transportation tanks used to transport Grade ''A'' milk and milk products in interstate commerce.

The Grade ''A'' PMO, and the state regulations modeled after the PMO, specifies that every milk producer, milk distributor, bulk milk hauler/sampler, milk tank truck, milk transportation company, and each milk plant, receiving station, transfer station, and milk tank truck cleaning facility operator shall hold a valid permit issued by an authorized regulatory agency, i.e., a State government agency. Furthermore, when any requirement of the Grade ''A'' milk safety program is violated, the permit holder is subject to the suspension of their permit. The Grade ''A'' PMO also specifies that each dairy farm, milk plant, receiving station, transfer station, and milk tank truck cleaning facility whose milk or milk products are intended for consumption within a state's jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances, shall be inspected/audited by the regulatory agency prior to the issuance of a permit and at specified intervals following the issuance of a permit.

We have tentatively determined that waiving the requirements of subpart O, if finalized as proposed, with respect to shippers, carriers, and receivers who hold valid permits and are inspected under the NCIMS Grade ''A'' Milk Safety Program, only when engaged in transportation operations involving Grade A milk and milk products, would not result in the transportation of food under conditions that would be unsafe for human or animal health and would not be contrary to the public interest. Specifically, we have determined that shippers, carriers, and receivers who hold permits and are inspected under the NCIMS Grade ''A'' Milk Safety Program, by complying with requirements that are identical to those set forth in the Grade ''A'' PMO, are using sanitary transportation practices to ensure that Grade A milk and milk products are not transported under conditions that may render such products adulterated. For example, under such requirements, trucks that transport milk from one milk plant to another must be sealed and temperatures of all milk and milk products must be verified for every tank truck load of milk or milk product received at these facilities. Further, all tank truck loads of milk or milk product that are shipped from Grade A facilities must include a shipping statement that includes, among other things, the seal numbers from the seals that were applied at the shipping plant and the temperature of the product upon loading. Based on our of analysis these, and other similar requirements, and the inspection and permitting processes that currently exist within the NCIMS Grade ''A'' Milk Safety Program, we have tentatively determined that the requirements of proposed subpart O, if finalized as proposed, would not be necessary to ensure that Grade A milk and milk products are not transported under conditions that may render such products adulterated. Accordingly, we are proposing to waive the requirements of subpart O, if finalized as proposed, with respect to shippers, carriers, and receivers who hold valid permits and are inspected under the NCIMS Grade ''A'' Milk Safety Program, only when engaged in transportation operations involving Grade A milk and milk products.

b. Food Establishments holding valid permits, only when engaged in transportation operations as receivers, or as shippers or carriers in operations in which food is relinquished to consumers after transportation from the establishment. For the purpose of establishing the scope of this potential waiver, we intend to define ''Food Establishment,'' using the definition set forth in the current edition of the Food Code (Ref. 17):

Food establishment means an operation that:

• Stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank; and

• Relinquishes possession of food to a consumer directly or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

The *Food Code* specifies that a person who operates a food establishment should hold a valid permit issued by the regulatory authority, i.e., a State government agency (Ref. 31). Only a food establishment operator who holds such a permit would fall within the scope of this potential waiver.

Food establishments, with the exception of establishments subject to the requirements of 21 CFR parts 1240 and 1250 that provide food to conveyances used to transport people, are generally subject to regulatory oversight, including permitting, by the more than 3,000 State, local, and tribal agencies that have primary responsibility to regulate the retail food and foodservice industries in the United States. These agencies are primarily responsible for the inspection and oversight of over 1 million food establishments that provide food directly to consumers. FDA assists these agencies and the industries they regulate by promoting the application of science-based food safety principles in retail and foodservice settings to minimize the incidence of foodborne illness. FDA publishes the *Food Code* to assist food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal model for regulating the retail and food service segment of the industry

(restaurants and grocery stores and institutions such as nursing homes). Local, State, tribal, and Federal regulators use the *Food Code* as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy. State codes patterned after the current or previous versions of the *Food Code* have been adopted in all 50 States. FDA also assists these regulators by providing scientifically-based guidance, training, program evaluation, and technical assistance.

FDA principally addresses aspects of sanitary food transportation relevant to retail food and food service operations through the provisions of the *Food Code* that address inspection and handling of food upon receipt to ensure that it does not appear to have been subject to contamination or temperature abuse. For example, since 1993 the *Food Code* has contained provisions addressing the temperature of TCS foods at the time they are received by a food establishment that would ensure that these foods are not received after transportation at temperatures at which the food could become unsafe (Ref. 32). In addition, provisions of the *Food Code* that address preventing food contamination and food holding temperatures for TCS foods or the use of time as a public health control, in the absence of temperature control, would apply to the transportation of foods from a food establishment to a site where the food would be relinquished to a consumer (Ref. 32).

We regard the regulatory programs of State and local agencies patterned upon the *Food Code* to be substantive, comprehensive, and effective in addressing food safety issues associated with retail food and food service operations and we intend to continue to operate through the Federal/State cooperative mechanism.

We have tentatively determined that waiving the requirements of subpart O, if finalized as proposed, with respect to food establishments holding valid permits, only when engaged in transportation operations as receivers, or as shippers and carriers for operations in which food is relinquished to consumers after transportation from the establishment, would not result in the transportation of food under conditions that would be unsafe for human or animal health and would not be contrary to the public interest. Specifically, we have determined that such food establishments, by complying with state requirements that are modeled after the Food Code, are using sanitary transportation practices to ensure that food is not transported under conditions that may render such products adulterated. We note that we are proposing this waiver only with respect to such food establishments when engaged in transportation operations as receivers and as shippers or carriers for operations in which food is relinquished to consumers after transportation from the establishment. If food establishments perform other functions that cause them to meet the definition of shipper and/or carrier under proposed § 1.904, e.g., transport food from a distribution facility to their establishment, any requirements under proposed subpart O that would apply to such entities as shippers and/or carriers would still be applicable and would not be waived.

As previously discussed in this section, we are proposing in § 1.934 to establish a procedure whereby FDA may revoke waivers with appropriate notice and comment.

IV. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed 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 Agencies 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, and other advantages; distributive impacts; and equity). We have developed a Preliminary Regulatory Impact Analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 33). We believe that the proposed rule will be a significant regulatory action as defined by Executive Order 12866. We request comments on the PRIA.

The summary analysis of benefits and costs included in this document is drawn from the detailed PRIA (Ref. 33) which is available at *http://www.regulations.gov* (Docket No. FDA–2013–N–0013) and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed rule does not cover any shipper, receiver or carrier with annual revenues of less than $500,000. Nevertheless, the Agency tentatively concludes that the final rule could have a significant economic impact on a substantial number of small entities covered by this proposed rule which would meet our proposed definition of a ''small business.''

C. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''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 $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA expects that this proposed rule will result in a 1-year expenditure that would meet or exceed this amount.

The analyses that we have performed to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995 are available to the public in the docket for this proposed rule (Ref. 33).

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been submitted to OMB for review under section 3507(d) of the Paperwork Reduction Act of 1995. FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the title ''Sanitary Transportation of Human and Animal Food.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

The analysis that FDA has performed in order to examine the impact of this proposed rule under the Paperwork Reduction Act of 1995, with estimates of the annual reporting, recordkeeping, and third-party disclosure burden, is available to the public in the docket for this proposed rule (Ref. 33).

VI. Analysis of Environmental Impact

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. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in *Executive Order 13132*. Section 4(a) of the Executive Order requires agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law 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 of the FD&C Act, or with a regulation issued under section 416 of the FD&C Act, 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 of the FD&C Act or a regulation issued under section 416 of the FD&C Act. Section 416(e) further provides that the express preemption provision applies to transportation that occurs on or after the effective date of regulations issued under section 416 of the FD&C Act. This express preemption provision would apply to the requirements of this proposed rule, when finalized.

VIII. Proposed Effective and Compliance Dates

While the current practices of many businesses are sufficient to satisfy some of the proposed requirements, some businesses will need to make at least some changes if the proposed rule is finalized. FDA tentatively concludes that it is appropriate to provide a sufficient time period following publication of the final regulation for entities to come into compliance. We proposed that any final rule under the 2005 SFTA become effective 60 days after publication in the **Federal Register**, with staggered compliance dates. FDA believes that it is reasonable to allow for 1 year after the date of publication of the final rule for businesses other than small businesses to come into compliance with the new requirements. FDA also believes that it is reasonable to allow for 2 years after the date of publication of the final rule for small businesses to come into compliance with the new requirements. FDA intends to work closely with the food transportation industry, extension and education organizations, and State partners to facilitate implementation of this rule. We request comment on our proposed approach to compliance dates.

IX. Request for Comments

We invite public comment on the matters specified in this document as well as any other matters concerning the proposed sanitary transportation of human and animal food regulations that are of interest. Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov*. (We have verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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29. National Food Processors Association, letter, ''Safeguarding Food From Contamination During Transportation,'' 1991.
30. FDA, ''Grade 'A' Pasteurized Milk Ordinance (2011 Revision),'' 2012.
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List of Subjects in 21 CFR Part 1

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be 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. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 333, 334, 335a, 343, 350c, 350d, 350e, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 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.

Vehicles and Transportation Equipment

Transportation Operations

Training

Records

Waivers

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, the requirements of this subpart apply to shippers, receivers, 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, 110, 118, 225, and 589).

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

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

(2) Food that is imported for future export and that is neither consumed nor distributed in the United States.

§ 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 (21 U.S.C. 342(i)) in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, 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, 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 (21 U.S.C. 331(hh)).

§ 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 (21 U.S.C. 321) 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 owns, leases, or is otherwise ultimately responsible for the use of a motor vehicle or rail vehicle to transport food. 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. 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.

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 means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' includes 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.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. *Food* includes animal food and food also subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

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.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term ''undesirable microorganisms'' includes 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.

Non-covered business means a shipper, receiver, or carrier engaged in transportation operations that has less than $500,000 in total annual sales.

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

Receiver means any person who receives food after transportation, whether or not that person represents the final point of receipt for the food. A receiver may also be a carrier or a shipper if the person also performs those functions as defined in this subpart. A receiver does not include an individual consumer or a person who receives or holds food on behalf of an individual consumer and who is not also a party to the transaction and who is not in the business of distributing food.

Shelf stable food means 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 juice, canned vegetables, canned meat, bottled water and dry food items such as rice, pasta, flour, sugar, and spices.

Shipper means a person who initiates a shipment of food by motor vehicle or rail vehicle. The shipper is 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. A shipper may also be a carrier or a receiver if the shipper also performs those functions as defined in this subpart.

Small business means a business subject to § 1.900(a) employing 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) having less than $25,500,000 in annual receipts.

Time/temperature control for safety (TCS) Food means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

Transportation means any movement of food in commerce by motor vehicle or rail vehicle.

Transportation equipment means equipment used in food transportation operations, other than vehicles, 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 solely of shelf stable food that is completely enclosed by a container, compressed food gases or live food animals. In addition, transportation operations do not include any transportation activities for raw agricultural commodities 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 filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations.

(b) Vehicles and transportation equipment must 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.

(c) 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.

(d) Each freezer and mechanically refrigerated cold storage compartment in vehicles or transportation 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 installed to show the temperature accurately within the compartment.

(e) 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.

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, and receivers engaged in transportation operations.

(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 filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations, including:

(i) Taking effective measures such as segregation or isolation to protect food from contamination by raw foods and non-food 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) For food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, ensuring that the food is transported in a manner, including the temperature conditions, such that the transportation operation meets the requirements of paragraph (a)(3) of this section.

(b) *Requirements applicable to shippers engaged in transportation operations.* (1) 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).

(2) Before loading food not completely enclosed by a container onto a vehicle provided by a carrier or into transportation equipment provided by a carrier, the shipper must visually inspect the vehicle or the transportation equipment provided by the carrier for cleanliness. The shipper must determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, e.g., it is free of visible evidence of pest infestation and of debris, previous cargo, or dirt that could cause the food to become adulterated.

(3) A shipper of 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, must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, the temperature conditions necessary during the transportation operation, including the pre-cooling phase, to ensure that the operation will maintain the temperature conditions and meet the requirements of paragraph (a)(3) of this section. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a).

(4) Before loading food, a shipper of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, must verify that each freezer and mechanically refrigerated cold storage compartment or container has been pre-cooled in accordance with information submitted by the shipper as required by paragraph (b)(3) of this section.

(5) 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).

(c) *Requirements applicable to shippers and receivers engaged in transportation operations.* (1) Shippers and receivers must provide vehicle operators who are expected to handle food not completely enclosed by a container during loading and unloading operations with access to a hand washing facility. The hand washing facility must be convenient and provide running water to enable vehicle operators to wash their hands and avoid contamination of food.

(2) Shippers and receivers of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation must carry out loading and unloading operations under conditions that will prevent the food from supporting such microbial growth.

(d) *Requirements applicable to carriers engaged in transportation operations.* (1) A carrier must supply a vehicle and transportation equipment that meets any requirements specified by the shipper in accordance with paragraph (b)(1) of this section 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.

(2) A carrier:

(i) 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). Such demonstration 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.

(ii) Is not subject to the requirement of paragraph (d)(2)(i) of this section if the carrier and shipper agree in writing, before transportation operations, that the shipper is 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. The carrier must provide the written agreement to the receiver, if requested. The written agreement is subject to the records requirements of § 1.912(b).

(3) 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 pre-cool each mechanically refrigerated freezer and cold storage compartment as specified by the shipper in accordance with paragraph (b)(3) of this section.

(4) 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. The shipper and carrier may agree in writing that the carrier will provide information that identifies fewer than three previous cargoes or that the carrier need not provide any such information if procedures have been established that would ensure that the bulk vehicle offered will be adequate for the intended transportation operation, e.g., if the carrier by contract, will only offer vehicles dedicated to hauling a single type of product. The written agreement is subject to the records requirements of § 1.912(b).

(5) 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. The written agreement is subject to the records requirements of § 1.912(b).

(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 (2) of this section, and;

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

Training

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

(a) 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 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 and carriers engaged in transportation operations?

(a) Shippers must retain records that demonstrate that they provide information to carriers as required by § 1.908(b)(1) and (3) as a regular part of their transportation operations for a period of 12 months beyond when the shipper is subject to any requirement to provide such information.

(b) Carriers must retain any written agreements required by § 1.908(d)(2)(ii) of this subpart and records of the written procedures required by § 1.908(d)(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 continues to perform the duties for which the training was provided.

(d) Shippers and carriers must make all records required by this subpart available to a duly authorized individual promptly upon oral or written request.

(e) 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, which must be kept in accordance with part 11 of this chapter.

(f) Except for the written procedures required by § 1.908(d)(6), offsite storage of records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The written procedures required by § 1.908(d)(6) 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.

(g) 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 FDA waive a requirement of this subpart?

FDA will waive any requirement of this subpart with respect to any class of persons, vehicles, food, or nonfood products, when FDA determines 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 FDA consider whether to waive a requirement of this subpart?

FDA will consider whether to waive a requirement of this subpart on FDA's 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 are 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 FDA 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 FDA follow when waiving a requirement of this subpart on FDA's own initiative?

If FDA, on its own initiative, determines that a waiver is appropriate, FDA will publish a notice in the **Federal Register** setting forth the waiver and the reasons for such waiver.

§ 1.930 When will a waiver granted by FDA become effective?

Any waiver granted by FDA will become effective on the date that notice of the waiver is published in the **Federal Register.**

§ 1.932 Under what circumstances may FDA modify or revoke a waiver?

FDA may modify or revoke a waiver if FDA determines 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 FDA determines 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.

Dated: January 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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