Preliminary Regulatory Impact Analysis for the proposed rule on Sanitary Transportation of Human and Animal Food (Docket No. FDA-2013-N-0013) under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 13563 and 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. FDA has developed a comprehensive preliminary regulatory impact analysis (PRIA); the PRIA is available at http://www.regulations.gov Docket No. XXXX, and is also available on FDA's website at (insert appropriate web address). This proposed rule has been designated an "economically" significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In general, this analysis exempts any firm estimated to have annual revenues less than $500,000. For produce farms that act as shippers or receivers, we exempt any farm with $25,000 or less

monetary value of food sold during the previous three year period[1]. However, the agency tentatively concludes that the proposed rule may have a significant economic impact on a substantial number of small entities.

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 this proposed rule may result in a 1-year expenditure that would meet or exceed this amount.

A. Need for Regulation

The need for the proposed regulation is to implement section 416(b) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) as added by section 7202 of the 2005 SFTA and to implement section 111(a) of FSMA which directs the Secretary of the Department of Health and Human Services (HHS) to promulgate the regulations described in section 416(b) of the FD&C Act. The regulation improves the sanitary transportation practices of shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport to better ensure they do not contain foodborne hazards that are injurious to the public health. The regulation enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to food safety problems after they occur.

[1] No railroads are estimated to have annual revenues under this threshold.

Private markets operating within the framework of the legal system promote the health and safety of consumers. Consumers want to avoid the risk of unsafe foods and producers, shippers, carriers, and receivers want to avoid the risk of damage to their brand name and reputation, and the large expense of lawsuits from injurious foods. Without regulatory consistency, the cost of monitoring adequate controls may reduce the ability of firms in a competitive market to efficiently control foodborne hazards.

Large scale outbreaks and product recalls are infrequently tied back to specific problems during transportation; however, it is well documented that incidents can occur during transportation that can result in injury or illness to consumers (Hennessy, et al 1996). Because monitoring can be costly, and the low probability that a consumer injury or illness will be tied to any particular shipment, carriers may underestimate the costs to society from shipping potentially hazardous foods. This proposed rule is intended to cover both interstate and intrastate-only transportation of food. However, as mentioned elsewhere in this analysis, data on intrastate-only transportation are not currently available to the Agency. Given this added uncertainty, we cannot rule out the possibility that firms engaging in food transportation may not currently invest in the optimal level of food safety practices, as outlined in this proposed rule, to ensure the safe transport of food. Furthermore, data are not available that would allow us to fully estimate current practices; therefore, costs may be underestimated. Nevertheless, the proposed requirements for training and records will facilitate better monitoring and greater assurance that food safety practices are followed.

B. Executive Summary

This proposed rule, if finalized, would implement regulations addressing the sanitary transportation of human and animal food, whether or not food is being offered for or enters interstate commerce. It establishes requirements for sanitary transportation practices applicable to shippers, carriers by motor vehicle and rail vehicle, and receivers. Specifically, these proposed requirements address design and maintenance of vehicles and transportation equipment; sanitary practices during transportation operations that apply to shippers, receivers, and carriers; training of carrier employees; records related to, for example, training, prior cargoes, temperature control, and written procedures; and waivers.

FDA does not have sufficient evidence at this point to fully quantify the costs and benefits of this regulation. We have data on many entities and shipments affected by the regulation, but very little quality data on baseline practices, or how baseline practices would change in response to the proposed regulation. Because of this data gap, we acknowledge that this analysis may overlook industry baseline practices that are not aligned with the requirements of this proposed rule.

Furthermore, while this proposed rule, if finalized, would cover intrastate food transportation, in addition to interstate transportation, data on entities, shipments, and baseline practices related to intrastate-only food transportation are not available to the Agency and are not included in this analysis. Based on largely anecdotal information available to the Agency in the form of guidance documents, industry best practices, and comments in response to the 2010 ANPRM, the industry's baseline practices appear to be largely in line with most of the requirements of the proposed regulation. The costs estimates are based in large part on assumptions that reflect this evidence.

This proposed rule is estimated to cover 83,609 entities. This number includes carriers engaged in food transportation, food (including animal) facilities, and USDA-inspected establishments. Total first year cost is estimated to be $149.1 million (with an average of $1,784 per covered firm), and total annual cost is estimated to be about $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 in part because we understand much of the proposed rule to reflect current industry practice. Nevertheless, later in this analysis we describe how 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.

Executive Summary Table: Estimated Costs and Benefits (in Millions of $)

	Initial Costs	Annual	Benefits
	$149.1	$30.1	Not quantified

Costs Annualized over 10 Years

	Costs	Benefits
3%	$44	Not quantified
7%	$46	

C. Coverage of the Analysis

Unless engaged in operations that are subject to a waiver, or not within the scope of this proposal, the requirements of this proposed rule would apply to shippers, receivers, and carriers engaged in the transportation operations of food (including animal food) whether or not the food is being offered for or enters interstate commerce. The requirements of this proposed rule would apply in addition to any other requirements that are applicable to the transportation of food, e.g., in 21 CFR Parts 1, 110, 118, 225 and 589.

Overview of Data and Estimates Used Throughout the Analysis

This section outlines some of the standard information and data used to inform estimates through the remainder of the analysis

Data sources

- Data provided by the U.S. Department of Transportation (DOT) is used to derive the total number of domestic motor carriers, the number of drivers they employ, and the number of trucks they operate to ship human and animal foods (DOT, 2012).

The 2007 Commodity Flow Survey is used to estimate the total number of food and feed shipments in the U.S. transported by truck and/or rail (U.S. Census Bureau, 2007).

- Railroad statistics provided by the Association of American Railroads (AAR) are used to estimate the number of rail traffic carriers (Association of American Railroards, 2013).

- Data provided by the Railinc is used to estimate a representative rail carload size using the total number of railroad shipments of farm produce, food and kindred products, and fresh fish and other marine products (Railinc Business Services Division, 2012). It is estimated that all 51 railroads in the 2010 Railinc data set were involved in food transportation. These 51 railroads were required to report to the DOT's Surface Transportation Board (STB) because in 2010, they terminated over 4,500 cars in shipments of any kind.

Estimated Shippers, Receivers, and Carriers Affected by this Rule

The estimated number of shippers, receivers, and carriers that would be affected by this proposed rule is presented in Table 1. We have estimated that shippers and receivers affected by this proposed rule include domestic facilities (manufacturers, warehouses, and wholesalers) that would be subject to either Subpart B or Subpart C of the preventive controls for human food proposed rule, domestic facilities subject to the preventive controls for animal food proposed rule, and USDA-inspected facilities.[2] A total of 97,646 facilities are estimated to be subject to either Subpart B or Subpart C of the preventive controls for human food proposed rule. However, this proposed rule will exempt any facility with less than $500,000 in sales annually; these exempt facilities total 57,411. Using data from Nationwide Survey of Food Industry Safety Practices (2011) it is estimated that approximately half of the remaining 40,235 facilities primarily handle commodities that will not be covered by this proposed rule (specifically, prepackaged food). Therefore, in the analysis of this proposed rule, the number of human food

[2] The data are not available that would allow the determination of those firms that would only be shippers or only be receivers.

facilities affected by this rule is reduced to 20,118. It is estimated that one facility is equal to one firm in this analysis.

This proposed rule also covers the transportation of meat and poultry products that have left USDA-inspected establishments. Therefore, meat processing facilities are also included in the analysis of provisions addressing the shipping or receiving of food. According to the 2007 Commodity Flow Survey (U.S. Census Bureau 2012), there are a total of 3,195 firms in the United States that process meat, and these firms operate a total of 3,817 establishments. Here, 783 of these firms (that operate 784 establishments), those domestic facilities with annual revenues of less than $500,000, are exempt from the requirements of this proposed rule, leaving 2,412 remaining firms (that operate 3,033 establishments), subject to this proposed rule..

Information on domestic facilities that manufacture, process, pack, or hold animal food or animal food ingredients comes from the Food Facilities Registration Database, and data from the U.S. Census. From this data, it is estimated that approximately 4,799 facilities that handle animal food have revenue greater than $500,000 annually, and will be subject to the requirements of this proposed rule[3].

The number of carriers is derived from DOT's Motor Carrier Identification Database (2012). In this dataset, information on cargo is self-reported; to the extent that carriers transport food which is not reported to DOT, the estimated number of food carriers will be underestimated. Furthermore, estimated affected firms may be underestimated because the DOT data set excludes firms that are engaged solely in intrastate commerce, while this proposed rule covers both interstate and intrastate

[3] Exempting animal food facilities that generate less than $500,000 annually will eliminate 1,488 facilities from coverage of this proposed rule.

commerce. Data is not currently available that would allow estimation of intrastate-only carriers. Comment is requested on the number of intrastate-only carriers in the United States.

In 2012, there were a total of approximately 534,810 active interstate freight motor carriers registered with DOT that carried food or non-food items in the United States, the District of Columbia, and the Commonwealth of Puerto Rico. All firms requiring a vehicle for interstate commerce are required to register with DOT. These firms transported a total of 30 different cargo classifications, both food and non-food. These cargo categories are not mutually exclusive; the same carrier may engage in transportation of more than one food and non-food cargo category. From this pool of 534,810 motor carriers, it is estimated that 55,717 transport food and would be affected by this proposed rule, with 10,536 of these firms handling bulk foods. The 107,629 truck carriers with annual revenue of less than $500,000 are exempt from this proposed rule, leaving the remaining 55,717 trucking firms subject to this proposed rule.

It is estimated that a total of 563 railroads will be subject to the requirements of this proposed rule. STB classifies railroads based on their annual operating revenues. Rail carriers affected by this proposed rule consist of seven Class I railroads, 23 regional, or Class II, railroads, and 339 local, or Class III, railroads. Furthermore, the AAR (2009) defines Switching and Terminal (S&T) railroads as 194 railroads that primarily provide switching and/or terminal services. Rather than point-to-point transportation, they usually perform pick-up and delivery services within a port or industrial area, or move traffic between other railroads. In total, it is estimated that 563 railroads are affected by the requirements of this proposed rule. To the extent that these railroads may not handle

commodities covered by this rule, estimations of rail carriers will be overstated. The Agency requests comment on the number of firms that will be affected by this proposed rule.

Table 1-- Estimated Numbers of Affected Shippers, Receivers, and Carriers

	Number of Firms
Human Food Facilities	20,118
USDA-inspected establishments	2,412 (3,033)
Animal Food Facilities	4,799
Carriers—Trucking	55,717
Carriers-Rail	563
Total Estimated Affected Firms (establishments)	**83,609(84,230)**

Estimated Number of Refrigerated Trucks

Information from DOT (2012) is used to estimate the number of refrigerated trucks in the United States and the firms that own them. This data set was constructed by the DOT using information collected on DOT form MCS-150. The DOT data do not provide the number of refrigerated trucks per firm, but provides the total number of trucks operated by a motor carrier and self-reported cargo categories for each firm. Since these data are self-reported, it is possible these numbers of refrigerated trucks and affected firms may be underestimated because firms may transport refrigerated foods that do not get reported to DOT. Furthermore, the DOT data do not include trucks involved in intrastate-only transport. To the extent that trucks exist that operate intrastate-only, this

data is underestimated. However, data do not exist that would allow the estimation of any underreporting factor nor is data available that would allow us to estimate trucks that operate intrastate-only. Using available data, it is estimated that a total of 416,716 refrigerated trucks are involved in food transportation in the U.S, and these trucks are operated by 68,916 firms. After subtracting out refrigerated trucks operated by firms exempt from the requirements of this proposed rule (those carriers with less than $500,000 annual revenue), 383,424 refrigerated trucks (operated by 23,507 firms) are covered by this proposed rule. Comment is requested on the number of refrigerated trucks that transport food in the U.S, particularly those that operate intrastate-only.

Estimated Number of Food Shipments

The total number of food shipments used in cost calculations in this analysis is estimated using the 2007 Commodity Flow Survey (U.S. Census Bureau 2012). Information does not exist that would allow the calculation of the number of times each product changes vehicles during transportation; therefore, in this analysis, it is estimated that that each food product is on a vehicle one time and also that it is shipped without any other products on the same vehicle at the same time. To the extent that products are shipped more than once, for example, from a producer to a distribution center and then from a distribution center to a retailer, these shipment estimates are understated. However, some food products may travel only once before being transformed into other product. For example, after wheat is shipped from a farmer to a mill, it becomes flour which is then transported to its next destination. Furthermore, multiple products may be shipped simultaneously on the same truck; here these are estimated as separate shipments, which may result in an overestimate the number of shipments presented in this analysis. Information is not available to refine these estimates further, but the under- and

overestimation described above may approximately offset each other. Comment is requested on estimations regarding food shipments used in this analysis.

Food Shipments by Truck

It is estimated that this proposed rule will affect a total of 52.1 million truck-related shipments of food annually. The number of shipments is calculated as the number of trucks needed to haul the total tonnage of each food commodity (by 4-digit SCTG code). The total annual total shipped weight of each commodity is then divided by the size of a representative load. Again, to the extent that for each commodity there is only an estimation of a single one-way haulage of a truckload, estimates of the total number of loads may be underestimated.[4]

Among truck-only shipments, we estimate that approximately 51.5 million shipments will be covered by this proposed rule. These 51.5 million truck-only shipments exclude shipments of shelf-stable fully packaged commodities and shipments of Grade A milk products that we approximate as 90 percent of milk and cream shipments. For the truck-and-rail mode, it is estimated that approximately 25 percent of

[4] Since food commodities are transported by both truckload (TL) and less-than-truckload (LTL), the size of a truckload is estimated using a weighted combination of TL and LTL. The share of LTL loads for each commodity is calculated using 2007 Commodity Flow Survey data for 2-digit SCTG categories (U.S. Census Bureau). The definition provided by the American Trucking Association is used to distinguish between TL and LTL, that is, loads of over 10,000 pounds are considered TL (ATA, 2012). The weight of TL is then calculated using the Pert distribution with a minimum load of 10,000 pounds and a typical load of 46,000 pounds (Thompson, et al., 2002). Based on information available to the agency, the maximum gross weight is estimated at 49,000 pounds (Freund 2014)The maximum gross vehicle weight of 80,000 pounds for a single tractor-trailer is regulated by the Federal Highway Administration (Federal Highway Administration, DOT). The weight of LTL is defined by the Pert distribution with a minimum load of 1 pound, a typical load of 1,323 pounds, and a maximum load of 10,000 pounds. The average LTL load is approximated as 1,323 pounds (600kg), the size of a standard pallet. The Pert distribution is commonly used in cases such as this, when data are sparse.

truckloads (i.e. of all truck portions of truck-and-rail trips) are covered by the proposed rule, with our best estimate of 516,525 truckloads[5].

Shipments by rail

It is estimated that 3,324,140 rail carloads will be covered by this proposed rule. These 3,324,140 covered rail carloads account for approximately 86 percent of all food rail carloads. These rail carloads don't include shipments of shelf-stable fully packaged commodities and shipments of Grade A milk products. Covered shipments include rail shipments by both rail and truck-and-rail modes. For rail-only shipments, it is estimated that there are about 3,187,640 shipments of covered food annually. In addition, it is estimated there are about 136,500 annual shipments relating to the rail portion of each truck-and-rail trip that are also covered by this proposed rule.

In order to calculate these numbers, for each food commodity (i.e. each 4-digit SCTG code) shipped by rail or truck-and-rail modes, total annual shipped weight is

[5] As discussed in the preamble of the proposed rule, Grade A milk products and shelf-stable fully-packaged foods are not covered by the proposed rule. As discussed more extensively elsewhere in this analysis, we used the 2007 U.S. Commodity Flow Survey shipped tonnage data for each transportation mode to calculate the number of shipments as the number representative truckloads needed to haul the annual tonnage of each food commodity (by 4-digit SCTG code). For each food commodity, we divide the annual shipped weight by the representative truckload size, which is approximated using Pert distribution (see description elsewhere in the analysis).
Not every shipment of food commodity or food product, however, is potentially covered by the proposed rule. For example, SCTG 0631 'Pasta, including stuffed, canned, frozen, or dried, and couscous;' it may include transportation of shelf-stable canned pasta that is not covered by the proposed rule and also transportation of fresh or frozen pasta that is covered by the proposed rule. With some help from FDA experts, we further transform our estimates of the number of shipments to fit the proposed rule description (e.g., shelf-stable food, bulk food, TCS food, etc.), so that only shipments relevant to a specific provision are included in cost estimates for that provision. We assign one or more of the following rule reference categories to each food commodity: TCS food, shelf-stable food, bulk food, food that in the absence of temperature control during transportation can support the rapid growth of undesirable microorganisms, etc. We then approximate the share of potentially covered shipments for each provision.
Finally, we estimate the share of shipments that are conducted only by those food carriers that have annual revenues of over $500,000 because the proposed SFTA covers only those carriers. Based on SBA data for the entire trucking industry (SBA, 2007), we estimate that 94.81% of all shipments are conducted by truck carriers with over $500,000 in annual revenues.

divided by the size of a rail carload. Estimates of the total number of railroad shipments may be underestimated to the extent that each representative rail carload is estimated as a single one-way trip. According to 2007 Commodity Flow Survey data for 2-digit SCTG categories (U.S. Census Bureau 2012), for most food commodities the share of rail carloads that are less than full is below 1 percent, meaning that most rail carloads of food are full loads[6].

Table 2 –Annual shipments, by transportation mode, covered by this proposed rule

Mode	**Shipments**
Truck Only	51,573,616
Truck Portion (of Truck and Rail)	516,525
Total Truck Shipments	**52,090,140**
Rail Only	3,187,640
Rail Portion (of Truck and Rail)	136,500

[6] The following information is used to estimate the size of a rail carload. Based on the reporting to the U.S. Surface Transportation Board, in 2010, Railinc has processed 580,928 Waybills of U.S., Canadian and Mexican origin submitted by 51 major railroads operating on the U.S. territory (Railinc Business Services Division, 2012 p. 5). Each Waybill corresponds to a separate railroad contract that includes multiple rail carloads. Railinc reports that 63,327 of these Waybills were food-related, including 21,038 Waybills for farm products, 67 Waybills for fish and marine products, and 42,222 Waybills for food and kindred products. According to the Railinc data, 180,571,623 tons of farm products were transported using 1,989,267 rail carloads; 65,800 tons of fish and other marine products – using 2,680 rail carloads; 130,752,745 tons of food and kindred products – using 1,895,485 rail carloads. Thus, for each of these three food cargo categories, this Railinc data is used to estimate the average size of a *food-category-specific* rail carload as total annual tonnage divided by the number of rail carloads.

Next, using the Pert distribution (commonly used when data are sparse) and the calculated three *food-category-specific* rail carload sizes, we estimate the size of a rail carload. We estimate this number based on the notion that Grade A milk products are not transported by rail. According to the USDA/USDOT Study of Rural Transportation Issues, in 2007, the average capacity of a single carload in the United States was 102.8 tons ((USDA), 2010). We use this number as the maximum rail carload size in the Pert distribution. We use and average between 90.77 and 68.98 tons, or 79.86 tons as the mode rail carload size in the Pert distribution. Since the data shows that an average rail carload size for fish and marine products was 24.55 tons, we use this number as the minimum rail carload size in the Pert distribution.

Total Rail Shipments	**3,324,140**

Covered Shipments by Type, as Referenced in the Proposed Rule

For the purposes of estimating cost of individual provisions, available shipment information is separated into categories addressed by this proposed rule. In addition, given that some provisions of the proposed rule cover both shipments of bulk food and shipments of food that is not completely covered by a container during transport, we add together all shipments in these two categories. After combining all representative loads across all transportation modes, we estimate that the total number of combined loads for bulk food, food that is not completely covered by a container, and certain shelf stable foods is about 54 million.

Proposed § 1.908(b)(4) is a requirement placed on refrigerated carriers and covers shipments that require temperature control. These shipments include shipments of frozen food and food that that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation. According to data from DOT (2012), it is estimated that there are a total of about 9.2 million shipments of food that can support the rapid growth of undesirable microorganisms annually. After combining all representative loads across all transportation modes, the total number of temperature-controlled shipments equals about 17.6 million.

Persons engaged in the transportation of food

Truck drivers

The Commercial Motor Safety Act of 1984 establishes minimum national standards that States must ensure their drivers meet when receiving a Commercial

Driving License (CDL). The goal of the Act is to ensure that drivers that operate large trucks and buses are qualified to do so. Depending on a class of the CDL license, CDL drivers are licensed to drive a single or combined vehicle of over 26,001 pounds (Class A or B), or a vehicle that transports 16 or more passengers or hazardous materials (Class C) (U.S. Federal Motor Carrier Safety Administration). Non-CDL drivers are drivers that don't fall into any of the above operating class categories, or are otherwise exempt by statute or waiver; they typically operate smaller vehicles and/or are still in training towards receiving their CDL license. It is estimated that the covered 55,717 motor carrier firms operate a total of 1.14 million trucks and employ 190,185 non-CDL truck drivers and 1 million CDL truck drivers.

Railroad Employees

Based on industry information from the AAR (2009) and the data from Railroad Retirement Board (2012), in 2010 Class I, II, and III railroads employed a total of 240,460 employees. The data show that Class I rail traffic carrier firms employ 193,853 employees, or 81 percent of the total number of employees in the railroad industry. All other railroads employ 46,607 employees, or 19.38 percent of the total number of employees in the railroad industry.

Current Industry Practices

The food transportation industry has developed its own guidelines and best practices addressing dedication of vehicles, cleaning of vehicles, cold chain, loading and

unloading, training and recordkeeping. Existing industry guidelines are diverse because they address transport of different commodities. Table 3 outlines some practices by commodity and Table 4 outlines practices by conveyance type.

For example, grain is delivered to mills by truck, rail or barge, and flour leaves by truck and rail. The practices used by mill operators[7] to ensure that vehicles are sanitary are those consistent with practices for low safety risk foods. These practices generally include the following: ongoing vehicle maintenance, thorough cleaning and inspection of vehicles prior to loading, washing of vehicles on a fixed schedule, training of employees on appropriate loading and unloading procedures, use of appropriate packaging such as one-way pallets and totes, use of self-audits and/or third party audits to ensure conformance with these practices. The types of information currently disclosed to mill operators generally include the following: vehicle inspection records; vehicle wash records; loading records; seal verification records; and bill of lading verification records. These records are disclosed via e-mail, fax, or hand delivery by the operator of the vehicle. The records kept by mill operators generally can include the following: vehicle inspection records, vehicle wash records, loading records, seal verification records, bill of lading verification records, employee training records, and audit reports.

According to comments submitted by the National Tank Truck Carriers (NTTC), standard records of communicated information include (1) the basic bill of lading (product, shipper, customer, quantity and weight), (2) wash tickets and (3) other documentation prepared for a specific product or destination, such as invoice, the Bio-

[7] This description is based on ANPRM comments by the North America Miller's Association.

Terrorism Sheet, or the Certificate of Analysis. The railroad industry uses waybills instead of bills of lading. The recordkeeping retention standards among the industry vary widely; however the most common retention standard for most documents is two years, which is the length of time that records required to be kept by section 414 of the FD&C Act must be retained.

Trucking firms have developed best practices for loading and unloading procedures, vehicle inspections and maintenance, personnel training, cleaning and sanitation practices, and pallet control. Table 3 provides examples of guidelines developed by the industry. For example, the Food Industry Transportation Coalition (2003) has developed special voluntary bulk over-the-road food tanker transportation and security guidelines. This guidance recommends exchanging information between a shipper and a carrier about the last three prior cargoes, wash ticket, and documentation that supports the tanker's conversion from non-food to food grade. Bulk liquid haulers typically follow guidelines developed by the Juice Product Association (2012). For tank trailers, NTTC has developed a special Tank Truck Cleaning Facility Audit Form (NTTC 2009).

The Association of American Feed Control Officials has developed best management practices, including transportation, for animal feed and feeds ingredients (AAFCO 2002). The American Feed Industry Association (AFIA) has the Safe Feed/Safe Food voluntary 3rd party certification program that sets comprehensive standards for non-medicated feed and ingredients ((AFIA), 2004). Among other things, this program establishes some cleanout and inspection guidelines as well as addresses sealing and prior hauls.

Although there are no formal industry procedures for temperature control, American Frozen Foods Institute and the Frozen Food Handling and Merchandizing Alliance suggest a written protocol for carrier to follow if loss of refrigeration occurred during food transport (Frozen Food Handling and Merchandizing Alliance, revised 2009). The Safe Quality Food Institute of the Food Marketing Institute also addresses food transportation practices (Safe Quality Institute of the Food Marketing Institute, 2012).

For products transported by refrigerated trailers, suggested equipment and equipment maintenance requirements are provided by the Refrigerated Transportation Foundation (RTF) Classification System guidelines and the American Trucking Association's (ATA) guidelines. The American Frozen Food Institute recommends that that all vehicles that transport frozen food be equipped with an appropriate temperature monitoring device, a temperature recorder and, where appropriate, time/temperature indicators to accurately measure the temperature inside the cargo area of the vehicle (Frozen Food Handling and Merchandizing Alliance 2009). The dial or reading element of the device should be mounted in a readily visible location that can be conveniently read from outside the cargo area.

Cleaning procedures in the trucking industry differ depending whether the vehicle is private or for-hire. *Private* carriers establish their own internal standards. *For-hire* carriers follow procedures dictated by their customer (the shipper). In addition, industry associations establish industry guidelines. Cleaning procedures also depend on the conveyance type, for example, tank trailers vs. bulk trailers. Table 3 provides descriptions of some of existing industry practices and guidelines for cleaning conveyances according to their type. These practices include, for example, routine power-washing of refrigerated

trucks and broom sweeping or vacuuming of dry vans. Dry vans are rarely power-washed because they typically have wooden floors and power-washing may potentially cause contamination. The most common method of evaluating non-tanker cleanliness of conveyances is visual inspection prior to loading. For products transported in the tank trailers, the type of cleaning process, including time, temperature, detergents, and drying process, may vary according to product.

According to the National Truck Tank Carriers, liquid food products are transported either in food grade Type 304 or similar stainless steel tank trailers and dry bulk products are transported in pneumatic aluminum trailers. Both the tank trailer and the dry bulk tailor serves as the package for the transported food. By design of the vehicle, all components of the trailers, such as pumps, gaskets, and hoses, are specified for food grade service. Aluminum pneumatic bulk tank trailers that are used for dry bulk products such as flour or sugars are loaded and unloaded by air flow. Tank trailers that are used by the dairy industry are built to meet special 3-A SSI sanitary standards, including pumps and fittings. Food grade tank trailers and pneumatic bulk trailers are single compartment packages and there is no simultaneous transportation of different food products. With certain cleaning procedures tank trailers may be used for sequential transport of both food and some non-food. Bulk juice products may be transported sequentially with other food grade products only and Model Tank Wash Guidelines guidance also identifies foods that are not permitted in tankers that transport juice.

Outside of tank trailers, most trucks haul food and non-food simultaneously and sequentially, as it is not economically feasible to have dedicated conveyances for food. Typically, the tank truck driver must show a wash ticket to the shipper at pickup,

showing that the tanker has been cleaned prior to being dispatched to haul the shippers load. The wash ticket often lists three previous cargoes, seal numbers, date of cleaning, cleaning chemicals, etc.

The railroad industry does not have standards for car cleaning. Instead it is the responsibility of the shipper to set requirements and perform a loading inspection. The National Oilseed Processors Association (NOPA), for example, reports adequacy of cleaning railcars and trucks used for transporting crude vegetable oil is verified with inspection forms, where appropriate.

Shippers request specific types of rail cars and identify temperature and lading requirements. Shippers can clean or reject an unsuitable car. AAR sees refrigeration failure as the biggest risk in transporting food. Current practices on temperature monitoring include physical monitoring, remote monitoring (satellite), alarms, shipper recording devices, inspections with record keeping. Many refrigerated units have alarm systems that provide an alert if a unit is not operating properly. The rail industry does not limit simultaneous or sequential transport of non-foods if they are not sources of contamination. Using standard transportation classification codes (STCC), railroad carriers keep records of cars that haul loads such as municipal solid waste, ruminant protein, and other potential contaminants that are prohibited to be used for sequential food hauls. They also keep refrigeration inspection and seal records; railroad records are subject to STB recordkeeping requirements.

Table 3-Selected Existing Industry Guidelines by Food Category

Product	**Industry Standards and Best Practices**
Food products in general	a) Best practices developed by the Retail Industry

	Leaders Association (RILA) b) FMI SQF Code, a HACCP-Based Supplier Assurance Code for the Food Industry (2012)
All foods transported by tank trucks (e.g. bulk grain, grain products, liquid foods such as juice, dairy, oils and shortening, dressings, mayonnaise, condiment sauces, etc.)	a) Bulk Over-the-Road Food Tanker Transportation and Security guidelines (2003) b) Tank Truck Cleaning Facility Audit Form (NTTC, 2009) c) 3-A sanitary standards (3-A SSI) for vehicle design applicable all food-hauling tankers;
Juice by tanker	a) Model Tank Wash Guidelines for Juices (2012) – includes Kosher guidelines
Milk and other dairy	a) Milk Transport Security System is being developed by the University of Kentucky b) Best practices: a Post Schwan addition of in facility kill step for dairy usage of dedicated tankers.
Vegetable oils	a) National Oilseed Processors Association's (NOPA) Railcar Sealing Best Management Practices Policy
Grains, feed and feed ingredients, flour and other grain and oilseed products	a) NGFA/NAMA Facility Risk-Assessment and Security Guide (2009) b) NGFA Voluntary Best-Management Practices for Transportation under FDA's existing BSE Rule (2011)
Meat, meat products and scraps	a) North American Rendering Industry Code of Practice (2010)
Frozen foods	a) American Frozen Foods Institute and the Frozen Food Handling and Merchandizing Alliance guidelines (2009)
Animal feed (medicated feed)	a) AFIA Safe Feed/Safe Food voluntary 3rd party certification program (2004) b) AAFCO Best Management Practices (2002)
Leafy Greens	a) Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain (2006)
Produce	a) NAPTWG Produce Transportation Best Practices (2012)

Table 4- Safe food transportation industry best practices

Conveyance type	Description	Frequency
Truck Trailers, Refrigerated trailers (reefers)	Typical procedure is high-pressure water wash to achieve visual cleanliness.	As needed

	It is common to wash trailer interior with detergent, rinse, then spray with water and a common bleach solution (100 ppm) and let final application air dry.	Once a week
Refrigerated Trailers for *higher risk products* such as frozen food and meat	Washed with sanitizer or soap, or at least hot water to kill any pathogens.	Varies
Trailers dedicated to transporting *lower risk dry products*	Swept out with a broom, vacuumed and rinsed out only when an odor is present.	As needed
Bulk and Non-bulk vehicles	Cleanliness is assessed through visual inspection For bulk vehicles, cleanliness may also be evaluated with swab testing, ATP bioluminescence or other inspection methods.	Prior to loading The wash certificate (or copy) must be made available prior to destination inspection and unloading (except when industry practice allows for periodic washout of repeated shipments of same material)
Non-dairy food, food grade liquid cargo tanks	At a minimum, steam, hot or cold water, detergent (where appropriate), caustic (according to customer's specification), air drying. Apply seals after cleaning and prior loading. For dry bulk, all lines should be disassembled and cleaned separately; aerating pads and dust collectors should be inspected and cleaned; internal loading tube should receive a separate cleaning; drying phase	Depends on a specificity of a product

	should use filtered air. Separate requirements for conversion of trailers from non-food to food service vehicles.	
Tanker Trucks	Are cleaned according to the Tanker Wash Guidelines (JPA). Tank Truck Cleaning Facility Audit Form (NTTC) is completed. Visual inspection cleaning assessment.	As advised. With certain cleaning procedures stainless steel tank trailers are used for both food and some non-food transport.
Medicated feeds and prohibited mammalian products	Depends upon conveyance and product transported. Sequencing and flushing procedures also are used to avoid cross-contamination.	Varies, as needed
Transfer hoses and pipes	Established protocols	As specified
Railroad cars (grains, oilseeds, processed commodities and other agricultural products)	Carrier-specific procedures, depending on the product. Sealing rail cars is considered a best management practice (issued by NOPA)	As instructed by the shipper

D. Regulatory Options

1. No new regulatory action (baseline)
2. Require the provisions of this proposed rule as they apply to carriers only **(**Proposed §1.906, §1.908(d), §1.910, and §1.914)
3. Require the provisions of this proposed rule, but exempt firms with annual revenues of less than $500,000.
4. Require the provisions of this proposed rule, but allow no exemptions to firms based on size, and include farms within the option's scope.

1. Option 1: No New Regulatory Action (baseline)

The first option is no new regulatory action. We include it here because OMB cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. It is assumed that there are zero costs and benefits associated with this and it serves as the baseline against which other options will be measured for assessing costs and benefits

Option 2: Require the Provisions of this Proposed Rule as they Apply to Carriers Only (Proposed §1.906, §1.908(d), §1.910, and §1.914)

Under this option, the proposed rule would consist of provisions that apply to carriers only. Shippers and receivers of human and animal food would not be covered under this provision. This option would cover 55,717 trucking carriers and 563 rail carriers, or 56,280 firms.

Under this option, the proposed rule would consist of

- Proposed §1.906, outlining requirements for vehicles and transportation equipment (design and maintenance of vehicles and equipment);
- Proposed §1.908(d), outlining requirements for carriers engaged in food transportation (supply of vehicle specified by shippers, demonstration of temperature conditions, pre-cooling of vehicle, documentation of previous three cargoes and most recent cleaning [bulk vehicles only], written procedures addressing cleaning and sanitizing of vehicles, temperature control, and use of bulk vehicles);
- Proposed §1.910, outlining training of carrier employees and related recordkeeping;

- Proposed §1.914, waivers.

However, by eliminating requirements applicable to shippers and receivers, the following controls would not be included in the rule:

- Proposed §1.908(b), which requires written sanitation requirements for vehicle and transportation equipment, and assurances that carriers are aware of sanitation requirements;
- Proposed §1.908(b)(2), requiring visual inspection of vehicle or container for cleanliness;
- Proposed §1.908(b)(3), requiring written specifications of temperature conditions;
- Proposed §1.908(b)(4), verification of precooling;
- Proposed §1.908(c), requiring access to hand washing, loading and unloading operations carried out under conditions that will prevent food from supporting microbial growth; Proposed §1.912, certain recordkeeping requirements.

Under this option, the total number of covered carriers would be 56,280, as opposed to the total of 83,609 firms (that operate 84,230 establishments) covered in Option 3. As with the other options, this option also covers intrastate-only food transportation for which we do not have data; therefore, these firm numbers are underestimated. Under this option total first year cost is about $107.2 million (consisting of $79.8 million in administrative costs), and annual costs are $27.3 million.

This option was not chosen because, despite controls required by other FSMA proposed rules (human and animal preventive controls), excluding shippers and receivers from coverage would introduce gaps in the supply chain that would leave food being transported vulnerable to all forms of adulteration. The 2005 SFTA directed FDA to

develop requirements for shippers, carriers, and receivers engaged in transportation operations to ensure that food is not transported under conditions that may render the food adulterated. Carriers aren't expected to be aware of all food safety hazards, depend on shippers for instructions in how to handle food being shipped, and do not have control over food at all points during transportation that could result in adulteration. For example, it is necessary for shippers to instruct carriers about how transportation operations should be carried out to ensure that hazards that may occur for their particular foods are avoided. Therefore, FDA has concluded that it is necessary to require that shippers, carriers, and receivers use sanitary transportation practices when transporting food.

Option 3: The Proposed Rule

Summary of the Major Provisions of the Proposed Rule

The proposed rule would implement regulations addressing the sanitary transportation of food (human and animal food) that establish criteria and definitions that would apply in determining whether food is adulterated within the meaning of section 402(i) of the FD&C 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 under conditions that are not in compliance with the sanitary food transportation regulations. As provided by the 2005 SFTA, transportation would be defined in the regulations as any movement (of human or animal 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. Specifically, the proposed rule would address or establish requirements

for: vehicles and transportation equipment; transportation operations; training; records; and waivers.

The required sanitary transportation practices include numerous provisions consistent with established best practices concerning cleaning, inspection, maintenance, loading and unloading of, and operation of conveyances and transportation equipment, that have been developed over the years within the food transportation industry to ensure that food is transported under the conditions and controls necessary to prevent contamination and other safety hazards.

A principal emphasis of the proposed rule would be to ensure that persons engaged in the transport 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 not completely enclosed within its container but would not require the same prior to loading foods such as canned food items, which are at little risk of contamination during transport. The proposed rule would also require that persons engaged in the transportation of foods that require temperature control to ensure their safety, or to prevent spoilage, e.g., meats, poultry, raw seed sprouts, unpasteurized in-shell eggs, take actions to ensure the integrity of the transportation cold chain such as the pre-cooling of the conveyance by the carrier with subsequent verification by the shipper before the food is loaded onto the vehicle. Additionally for foods that require temperature control for these reasons, the proposed rule would require that carriers demonstrate to shippers that they have maintained appropriate temperature control for the food during transportation. The proposed rule would also establish procedures for the disclosure to shippers, by

carriers, of information about previous cargoes hauled in bulk conveyances to be offered for the transportation of food and the intervening cleaning of those conveyances.

The proposed rule would also establish requirements for training for carrier personnel engaged in transportation operations including a requirement for records that document the training. The proposed rule would also establish requirements for records that describe cleaning procedures used for conveyances and equipment and records that document that shippers, carriers and receivers provide or receive certain types of information necessary to the conduct of transportation operations in accord with sanitary principles.

Administrative Costs

In addition to the other provisions of this proposed rule, each firm engaged in food transportation, whether a carrier, shipper, or receiver, will incur costs to learn about the requirements of this proposed rule. We estimate that, for any firm affected by this proposed rule, whether a shipper, receiver, or carrier, an operations manager (for facilities or carriers) will spend 8 hours to review and assess the requirements[8]. In addition, it is estimated that a legal analyst will also spend 8 hours analyzing the requirements of this proposed rule.[9] Because the data do not exist that would allow us to determine if a facility would not ever transport food, we include the entire universe of facilities in the estimates here, exempting those firms with annual revenues less than $500,000.

Estimated administrative costs are presented in Table 5. Wage rates are taken

[8] For the purpose of this analysis, administrative costs are estimated only for covered firms. Because exempt firms are not required to engage in any activity to attest to their exempt status, or engage in any other activity, it is estimated that, if there is any administrative cost related to exempt firms, it is minimal.

[9] In the Preventive Controls proposed rule, it was estimated that 40 hours would be spent reviewing the rule. Because this rule only addresses transportation of food, and not the production of food, this estimate was reduced to 8 hours per manager and lawyer.

from the May 2012 BLS Occupational Employment Statistics for a General and Operations manager; and lawyers; and include overhead, which is assumed to equal 50 percent of base wages. It is estimated that wages will be consistent across firm type. Note that, for USDA establishments, it is estimated that the review will take place at the establishment level by an operations manager and at the firm level by a lawyer. Note that total costs are rounded to the nearest dollar. We acknowledge the uncertainty in these estimates and request comment on the administrative costs of this rule.

Table 5 –Administrative costs

Human Food Facilities				
Managers	**Hours**	**Total Hours**	**Wage**	**Total Cost**
20,118	8	160,944	$82.83	$13,330,992
Legal	**Hours**	**Total Hours**	**Wage**	**Total Cost**
20,118	8	160,944	$94.40	$15,193,114
USDA-inspected facilities				
Managers	**Hours**	**Total Hours**	**Wage**	**Total Cost**
3,033	8	24,264	$82.83	$2,009,787
Legal	**Hours**	**Total Hours**	**Wage**	**Total Cost**
2,412	8	19,296	$94.40	$1,821,542
Animal Food Facilities				
Managers	**Hours**	**Total Hours**	**Wage**	**Total Cost**
4,799	8	38,392	$82.83	$3,180,009
Legal	**Hours**	**Total Hours**	**Wage**	**Total Cost**
4,799	8	38,392	$94.40	$3,624,205
Rail Carriers				
Managers	**Hours**	**Total Hours**	**Wage**	**Total Cost**
563	8	4,504	$82.83	$373,066
Legal	**Hours**	**Total Hours**	**Wage**	**Total Cost**
563	8	4,504	$94.40	$425,178
Trucking Carriers				
Managers	**Hours**	**Total Hours**	**Wage**	**Total Cost**
55,717	8	445,736	$82.83	36,920,313
Legal	**Hours**	**Total Hours**	**Wage**	**Total Cost**
55,717	8	445,736	$94.40	$42,077,478

	Total Hours	**1,342,712**	**Total Cost**	**$42,077,478**

Costs Related to Requirements for Vehicles and Transportation Equipment (Proposed § 1.906)

Proposed § 1.906 outlines requirements for vehicles and transportation equipment used in the transportation of food. Proposed § 1.906(a) states that vehicles and transportation equipment must be designed and of such material and workmanship as to be adequately cleanable. It is estimated that it is common business practice for vehicles and equipment to be adequately cleanable. Furthermore, based on information available to the Agency, in the form of guidance documents, industry best practices, comments in response to the 2010 ANPRM, it is estimated that this proposed requirement will not impose any additional cost on to the food transportation industry. Therefore, no additional cost is estimated for this proposed provision.

Proposed § 1.906(b) states vehicles and transportation equipment must be maintained in an appropriate sanitary condition to prevent the food that they are transporting from becoming unfit for food, becoming contaminated by filth or undesirable microorganisms, or potentially being rendered injurious to health from any source during transportation. It is estimated that this is a common business practice in food transportation. Furthermore, any cost of this provision is estimated to be covered by the training requirement of § 1.910(a). Therefore, no additional cost is estimated for this proposed provision.

Proposed § 1.906(c) states that in the case of food that can support the rapid growth of undesirable microorganisms, e.g., those of public health significance and those that subject food to decomposition, vehicles and transportation equipment must be designed

and maintained, or otherwise equipped, to be able to maintain the food under temperature conditions that will prevent it from supporting such microbial growth. Based on information available to the Agency, in the form of guidance documents, industry best practices, comments in response to the 2010 ANPRM, it is estimated that this proposed requirement will not impose any additional cost on to the food transportation industry. To the extent that this may result in extra training for employees, it is estimated that the cost of this proposed provision will be covered by § 1.910(a). Therefore, no additional cost is estimated for this proposed provision. Proposed § 1.906(d) states each freezer and mechanically refrigerated cold storage compartment within vehicles or within transportation equipment used for the transport of food that can support the rapid growth of undesirable microorganisms must be equipped with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

According to information available to the Agency, including best practices, comments in response to the 2010 ANPRM, and knowledge of those familiar with industry practices (Vache 2013), it is estimated that the use of thermometers, or other temperature measuring or recording devices, is widespread in trucking, due to the risk of degraded product or growth of undesirable organisms. However, because data on intrastate-only food transportation is not available to the Agency, it is possible that not all trucks or cold storage compartments have temperature measuring or recording devices. To acknowledge this possibility, cost related to this proposed provision is estimated using data on the estimated number refrigerated trucks in the food transportation industry. From the estimate of 383,424 refrigerated trucks estimated to be covered by this

proposed rule, , for the purposes of this analysis, we assume 1 percent of these, or 3,834, will require the installation of temperature measuring or recording devices. Based on information available to the Agency (Vache 2013), temperature measuring or recording devices can range in cost from $5-$23.50, with a mean of $14.25. Therefore, it is estimated that cost to comply with this proposed provision will cost about $54,638 (3,834 x $14.25 = $54,638). Based on information available to the Agency, it is common practice, in rail transport, to transfer refrigerated trailers and containers from truck tractors and chassis (Vache 2013), to railroad flatcars. The railroad delivers the trailers and containers to an intermodal rail yard, and they are removed from the flatcars and are sent by truck for final delivery. Therefore, it is estimated that this proposed provision will not impose any new cost on rail carriers. Comment is requested on possible costs of this proposed provision.

Proposed § 1.906(e) states vehicles and transportation equipment must be stored in such manner as to prevent the conveyances or transportation equipment from harboring pests or becoming contaminated in any other manner that could result in food that they are transporting becoming unfit for food, becoming contaminated by filth or undesirable microorganisms, or potentially being rendered injurious to health from any source during transportation operations, or the equipment shall be cleaned prior to use. It is estimated that practices aligned with this provision include, for example, keeping doors closed, keeping the equipment free from rodents, and any other common sense practice that would ensure that vehicle condition does not result in contaminated food. According to information available to the Agency, including best practices, comments in response to the 2010 ANPRM, and those knowledgeable of industry practices, it is estimated that this

proposed requirement will not impose any additional cost on to the food transportation industry.

Costs Related to Requirements for Transportation Operations (Proposed § 1.908)

Proposed § 1.908 outlines requirements for shippers, carriers or receivers and would require that the responsibility for ensuring that transportation operations are carried out in compliance with all requirements in this proposed rule be clearly assigned to competent supervisory personnel.

Proposed § 1.908(a)(3)(i) requires that transportation operations must include taking effective measures to protect food from contamination by raw foods and non-food items in the same load. Furthermore, proposed § 1.908(a)(3)(ii) requires shippers, carriers, and receivers to take effective measures to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations. It is estimated, for both proposed §§ 1.908(a)(3)(i) and (ii), firms can make any needed adjustments in loading practices through proper training. That is, it is assumed that safe and unsafe loading practices are equally costly; with the only additional cost that of training employees to use safe practices. We acknowledge the possibility that costs are slightly underestimated here. For example, it is possible smaller truckloads may result from aligning practices with this proposed provision, or that there may be slight differences in the time it takes to load a food shipment. However, data are not available to allow the confirmation of these results or the associated cost. Because no data exist that would allow the estimation of the difference in loading times before and after training, it is assumed that, once trained, additional time to perform safe loading

practices could be somewhat, if not completely, mitigated, if we hold the size of the food load constant. Therefore, it is estimated that any cost related to these provisions will be covered by costs estimated for proposed § 1.910(a). No additional costs are estimated. The uncertainty and simplicity of this estimate is acknowledged and comment is requested on the cost of proposed §§ 1.908(a)(3)(i) and (ii), including comments on the cost of enacting these safer practices.

Proposed § 1.908(a)(3)(iii) requires that food that can support the rapid growth of undesirable organisms in the absence of temperature control during transportation is transported in a manner, including proper temperature conditions, that meets the requirements of paragraph (a)(3). In the case of a refrigerated truck that has, for example, a broken temperature indicating device, this provision would allow the Agency to take action against the carrier. Therefore, no additional cost is estimated for this proposed provision.

Requirements for shippers engaged in transportation operations

Proposed § 1.908(b) outlines requirements that apply to shippers engaged in transportation operations. It is possible that these requirements will result in costs for at least some shippers engaged in transportation operations.

Proposed § 1. 908(b)(1) requires shippers to specify, in writing, all necessary sanitary requirements for the vehicle and transportation equipment (e.g., a shipping container) to be provided by the carrier to ensure that the vehicle is in appropriate sanitary condition for the transportation of the food. This is a disclosure of information that is subject to the records requirements of proposed § 1.912(a). It is estimated that

shippers affected by this proposed requirement include domestic facilities (manufacturers, warehouses, and wholesalers) that would be subject to either Subpart B or Subpart C of the preventive controls for human food proposed rule , USDA inspected establishments, as well the estimated facilities that handle animal food (21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 211 . Furthermore, it is estimated this provision will affect shipments of bulk food, food not completely covered by a container, and certain shelf stable foods.[10] The preventive controls for human food proposed rule does not have specific requirements that would allow us to estimate that the burden of proposed § 1.908(b)(1) is covered by that regulation.

According to information available to FDA, it is believed that it is common business practice for the shipper to specify the necessary condition of the vehicle or equipment conveyance. However, it is possible that not all shippers have practices entirely aligned with this requirement; therefore it is estimated that this could be a new requirement for some shippers. Information is not available that would allow precise estimation the percentage of shippers for whom this would be a new requirement, whether interstate or intrastate. To acknowledge the possible cost for the purposes of this analysis, here we assume that this requirement could be a new practice for 1 percent of affected shippers, and 1 percent of shipments. We acknowledge the uncertainty in this estimate and request comment on practices related to this requirement.

For firms with practices not already aligned with this proposed requirement, there could be a one-time cost of developing requirements, and an annual cost of disclosing

[10] As discussed elsewhere in the preamble, the Agency anticipates that the transportation of most shelf stable foods will not fall within the scope of this proposed rule; however, there are some shelf stable foods that will continue to be covered by this proposed rule; for example, those shelf stable foods that are not also fully packaged (dried fish, as an example) .

these requirements to a carrier. In Table 6, it is estimated that the one-time burden consists of the development of one written document per shipper, and that each document takes 30 minutes for a cargo and freight agent to develop (BLS 2012).

The annual burden of this proposed requirement is based on the estimated annual numbers of bulk shipments, shipments of food not completely enclosed by a container, and shipments of certain shelf stable foods covered by this proposed rule, which total about 54 million annually. The one-time cost to develop a written document is about $4,169, and the cost related to the annual information disclosure is estimated at about $1.32 million, as shown in Table 6. Note that resulting numbers of firms and related costs are rounded to the nearest firm and dollar, respectively, and also note that the total first year cost is the one-time burden of developing requirements, plus the annual cost (in the first year), of disclosure of these requirements, or $4,169 + 1,320,629 = $1,324,798.

Note that total costs are rounded to the nearest dollar. The uncertainty of these estimations is acknowledged, and we request comment on the practices and cost of proposed § 1.908(b)(1).

Table 6 – Estimated Cost of § 1.908(b)(1)

One Time Burden				
Firms	**Hourly Burden to Develop Written Document**	**Total One-Time Hours**	**Hourly Wage**	**Total One Time Cost**
273 (273.29)	0.5	136.65	$30.51	**$4,169**
Annual Burden of Information Disclosure				
Estimated Affected Shipments	**Hourly Burden to Generate Written Description**	**Total Annual Hours**	**Hourly Wage***	**Total Annual Cost**

541,064	0.08	43,285	$30.51	**$1,320,629**

Proposed § 1.908(b)(2) requires shippers before loading food not completely enclosed in a container, to visually inspect the vehicle or container for cleanliness and determine that it appears to be in appropriate sanitary condition for the transportation of the food. Based on information available to the Agency, in the form of guidance documents, industry best practices, comments in response to the 2010 ANPRM, it is estimated that this proposed requirement is not likely to impose large costs on the food transportation industry. However, no data exist that would allow the precise percentage of shippers for whom this would be a new requirement, and no data exist that would allow an estimation of this possible cost on intrastate-only food transportation. To acknowledge any possible cost of this proposed requirement, estimates are made based on an assumption that 1 percent of shipments, both rail and trucking, of food not completely enclosed by a container during transport. The wage is based on that of a Cargo and Freight Agent (BLS 2012) and it is estimated that inspection will take 10 minutes for each shipment. These estimates are presented in Table 7, and note that resulting numbers of shipments and related costs are rounded to the nearest shipment and dollar, respectively.

Table 7 –Estimated cost of § 1.908(b)(2)

Shipment type	**Shipments**	**Estimated Time**	**Total Hours**	**Wage**	**Total Cost**
Truck	122,723	0.2	24,544.50	$30.51	$748,853
Rail	1,832	0.2	366.41	$30.51	$11,179
				Total Cost	**$760,032**

Proposed § 1.908(b)(3) requires, in the case of food that can support the rapid growth of undesirable microorganisms, shippers to specify, in writing, to carriers the temperature conditions necessary during the transportation operation, including the pre-cooling phase. This proposed requirement does not apply to a carrier who transports the food in a thermally insulated tank. This is a disclosure of information is subject to the records requirements in proposed § 1.912(a).

It is estimated that this cost will be borne by shippers of food that can support the rapid growth of undesirable microorganisms. Here it is estimated that this will be a per shipment cost. According to information available to FDA, it is estimated that there is an annual average of about 9.27 million shipments (covered by this proposed rule) of food that can support the rapid growth of undesirable microorganisms. While it is not known how many shippers have practices already aligned with this requirement, for the purposes of this analysis, we assume here that this could be a new requirement for shippers of 1 percent of these shipments, or about 93,000 shipments of food that can support the rapid growth of undesirable microorganisms, as shown in Table 8. Furthermore, it is estimated that each record will take 0.08 hours (approximately five minutes) for a cargo and freight agent to generate, at a wage rate of $30.51 per hour (BLS 2012), for an annual cost of $226,498. Note that the affected shipments are rounded to the nearest number, and total cost is rounded to the nearest dollar. The uncertainty of these calculations is acknowledged and comments are requested regarding any potential costs of this proposed provision.

Table 8 – Annual cost of proposed § 1.908(b)(3)

Estimated Shipments		

Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
92,455	0.08	7,396.39	$30.51	$225,664
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
342	0.08	27.33	$30.51	$ 834
			Total Cost	**$226,498**

Proposed § 1.908(b)(4) requires shippers of food requiring temperature control to verify that each freezer and mechanically refrigerated cold storage compartment or container has been pre-cooled as necessary. It is estimated that this will be a per shipment cost. According to data from the Department of Transportation and the Department of Commerce (2012), it is estimated that there are an annual total of about 17 million shipments of food requiring temperature control. While it is not known how many shippers have practices already aligned with this requirement, for the purposes of this analysis, we assume here that this could be a new requirement for shippers of 1 percent of these shipments, as shown in Table 9. Furthermore, it is estimated that each record will take five minutes for a cargo and freight agent to generate, at a wage rate of $30.51 per hour (BLS 2012). Note that shipment calculations are rounded to the nearest number and cost is rounded to the nearest dollar. The uncertainty of these calculations is acknowledged and comments are requested regarding any potential costs of this proposed provision.

Table 9 –Estimated Cost of § 1.908(b)(4)

Estimated Shipments		

Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
175,816	0.08	14,065.29	$30.51	$429,132
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
549	0.08	44	$30.51	$1,341
			Total Cost	**$430,473**

Proposed § 1.908(b)(5) states that the shipper assumes the requirements applicable to the carriers in § 1.908(d)(2)(i) with respect to providing a demonstration to the receiver if the shipper and carrier have agreed in writing that the shipper is responsible for ensuring that the food was held under acceptable temperature conditions during transportation operations. It is not known how many shippers already have agreements in place or would choose to create an agreement as a result of this proposed rule. However, for the purposes for this analysis, we assume that 1 percent of shippers (food facilities, USDA inspected establishments, and animal food facilities covered by this proposed rule) may need to generate a written agreement as a result of this proposed requirement to cover, for example, satellite monitoring or "black box" temperature monitoring performed by shippers. Firm calculations are rounded to the nearest number and cost is rounded to the nearest dollar. As shown in Table 10, this one-time cost is estimated at about $2,000.

Table 10 –Estimated cost of § 1.908(b)(5)

One Time Cost					
Shipper Type	**Number of Firms**	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
Human Food Facilities	201	0.25	50.30	$30.51	$1,535
USDA-inspected facilities	24	0.25	6.03	$30.51	$184
Animal Food Facilities	48	0.25	11.9975	$ 30.51	$366
				Total Cost	**$2,085**

Requirements for shippers and receivers engaged in food transportation

Proposed § 1.908(c) outlines requirements for shippers and receivers. Proposed § 1.908(c)(1) requires that shippers and receivers must provide vehicle operators who expect to handle food not completely enclosed by a container during loading and unloading operations with access to a hand washing facility with running water to enable vehicle operators to wash their hands and avoid contamination of food. For the shippers and receivers that are covered by the preventive controls proposed regulations (21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 211, it is estimated that this requirement will not impose any additional cost, as it is estimated that these entities will have adequate hand washing facilities in place. Furthermore, it is estimated that this would not impose additional cost onto those shippers and receivers that are not covered by the preventive

controls proposed regulation, because this proposed requirement could be met by giving vehicle operators access to any available hand washing facility. If it is the case that no hand washing facilities are immediately available, it is estimated that the truck driver would not participate in the loading or unloading process. The Agency acknowledges the simplicity and uncertainty of this estimation and requests comments on any burden resulting from this proposed provision.

Proposed § 1.908(c)(2) requires, for the transportation of food that can support growth of undesirable microorganisms, that shippers and receivers must carry out loading and unloading operations under conditions that will prevent the food from supporting such microbial growth. For the shippers and receivers that are covered by the produce or preventive controls proposed regulations (21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 211), it is estimated that this requirement will not impose any additional cost, as it is estimated that these entities will have adequate practices in place. For those shippers and receivers that are not covered by the preventive controls or produce rules, it is estimated that the cost of this proposed provision will be covered by the training requirement of proposed § 1.910(a). No additional cost is estimated.

Requirements for carriers engaged in food transportation

Proposed § 1.908(d) outlines requirements for carriers engaged in food transportation. Proposed § 1.908(d)(1) states that carriers must supply vehicle and transportation equipment that meet any requirements specified by the shipper and is otherwise appropriate to ensure that the food transported will not become unfit for food.

We estimate that it is common practice for carriers to provide vehicle and transportation equipment that meets any requirements of shippers, due to the strong

business incentive to do so. Therefore, we do not estimate an additional cost on industry for this requirement. We seek comment on the potential costs imposed by this requirement.

Proposed § 1.908(d)(2)(i) states that, carriers must, once the transportation operation is complete, demonstrate to the shipper (and to the receiver, if requested) that any specified temperature conditions during the transportation operation were maintained. This could be accomplished by any means agreeable to the carrier and shipper such as printouts of time/temperature recording device. This demonstration is subject to the records requirements in § 1.912(c). This cost estimation is presented in Table 11; it is estimated that this demonstration will take five minutes per operation, measured here in shipments requiring temperature control that are estimated to need this demonstration (1 percent of estimated annual temperature controlled shipments). Note that shipment calculations are rounded to the nearest number and total cost is rounded to the nearest dollar.

Table 11 – Annual cost of proposed § 1.908(d)(2)(i)

Estimated Shipments				
Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
175,816	0.08	14,065	$30.51	$429,132
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
549	0.08	44	$30.51	$1,341
			Total Cost	**$430,473**

Proposed § 1.906(d)(2)(ii) states that carriers are not subject to the requirement of proposed § 1.908(d)(2)(i) if the carrier and shipper agree in writing that the shipper is responsible for monitoring temperature conditions during the transportation operation. This cost is covered by the estimated cost related to proposed § 1.908(b)(5), which states that the shipper assumes the requirements of proposed § 1.906(d)(2)(ii), if the shipper and carrier have a written agreement to that effect. No additional cost is estimated.

Proposed § 1.908(d)(3) states that a carrier must pre-cool each mechanically refrigerated freezer and cold storage unit as specified by the shipper. It is estimated that this provision affects refrigerated units used in trucking and the truck portion of intermodal (truck and rail) transport and is a per temperature controlled shipment cost. The cost is estimated based on wages for CDL and non-CDL drivers (including overhead) who spend four hours pre-cooling trucks, and a fuel cost based on four gallons of diesel fuel at the national average as of August, 2013 ($3.90 per gallon).[11] Please note that no data are available that would inform estimates of fuel usage; we ask for comment on fuel usage related to pre-cooling. It is estimated that pre-cooling is a general practice among refrigerated carriers; however, given the lack of data on current industry practices, and the uncertainty surrounding practices among intrastate-only carriers, cost is estimated based on precooling of 1 percent of transported refrigerated shipments, which number about 17.5 million annually. Of this 1 percent, we estimated that 87 percent are handled by drivers with commercial drivers' licenses, and the remaining 13 percent are handled

[11] Drivers with commercial driver's licenses will drive any type of vehicle which has a gross vehicle weight rating (GVWR) of 26,001 lb. (11,793 kg) or more for commercial use, or transports quantities of hazardous materials that require warning placards under Department of Transportation regulations, or that is designed to transport 16 or more passengers, including the driver. This includes (but is not limited to) tow trucks, tractor trailers, and buses.

by drivers without commercial drivers' licenses. Fuel cost is estimated at $15.60 per shipment ($3.90 per gallon x 4 gallons = $15.60). Please note that the shipment calculations are rounded to the nearest number and cost is rounded to the nearest dollar. The estimated cost of this proposed provision is shown in Table 12. The uncertainty of these calculations is recognized and comment is requested regarding the costs of this proposed provision.

Table 12 –Estimated Cost of § 1.908(d)(3)

Shipments handled by CDL drivers	**Hours**	**Total Hours**	**Wage**	**Total Wage**	**Fuel Cost Per Shipment**	**Total Cost**
152,960	4	611,840.24	$29.10	$17,804,551	$15.60	$20,190,728
Shipments handled by non-CDL drivers	**Hours**	**Total Hours**	**Wage**	**Total Wage**	**Fuel Cost Per Shipment**	**Total Cost**
22,856	4	91,424.40	$24.48	$2,238,069	$15.60	$2,594,625
					Total Cost	**$22,785,352**

Proposed § 1.908(d)(4) states that carriers offering bulk vehicles for food transportation must provide written documentation to the shipper that identifies the three previous cargoes transported on the vehicle. The shipper and carrier may agree that the carrier will provide documentation that identifies fewer than three previous cargoes or that the carrier need not provide any documentation at all.

The cost of this proposed requirement is a function of a one-time cost of the number of bulk carriers that may have informal agreements in place but do not have a

written agreement in place, and a fraction of annual estimated bulk shipments where this documentation may not already be provided. There are 10,536 trucking firms (that are covered by this proposed rule) that transport bulk food. In addition, it is estimated that there are a total of 563 rail carriers in the United States. Information is not available that would allow us to determine if there are any rail carriers that do not ever carry bulk shipments; therefore, these calculations are based on the universe of rail carriers in the available data. Furthermore, data is not available that would allow the precise calculation of the number of those carriers, whether trucking or rail, that would develop agreements as a result of this proposed regulation.

For the purposes of this analysis, and to acknowledge possible cost related to intrastate-only transportation, we assume that this proposed requirement would result in 1 percent of estimated trucking and rail firms that may transport bulk to develop agreements, that each of these firms will develop one agreement, and that this proposed requirement would affect 1 percent of shipments. The uncertainty of these estimations is acknowledged. The Agency requests comment on the potential costs of this proposed requirement. This cost estimate is presented in Table 13. While the one-time cost consists of the development of an agreement, the total first year cost is the sum of the one-time cost and the annual cost (in the first year), or $847 + $792,765 = $793,612. Note that carrier and shipment calculations are rounded to the nearest number, and cost is rounded to the nearest dollar.

Table 13 –Estimated cost of § 1.908(d)(4)

Estimated Carriers			

Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
105	0.25	26.3	$30.51	$804
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
6	0.25	1.41	$30.51	$43
			Total Cost	**$847**
Estimated Shipments				
Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
304,516	0.08	24,361.24	$30.51	$743,261
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
20,282	0.08	1622.55	$30.51	$49,504
			Total Cost	**$792,765**

Proposed § 1.908(d)(5) states that a carrier who offers a bulk vehicle for food transportation must provide to the shipper written documentation of the most recent cleaning of the bulk vehicle, except when a shipper and carrier agree in writing that the carrier need not provide any documentation because of, for example, any contractual agreement to use a specified cleaning procedure.

The cost of this proposed requirement is a function of a one-time cost of the estimated number of bulk carriers that may have informal agreements in place but do not have a written agreement in place, and a fraction of annual estimated bulk shipments where this documentation may not already be provided. There are 10,536 trucking firms (covered by this proposed rule) that transport bulk food. In addition, it is estimated that there are a total of 563 rail carriers in the United States. Information is not available that would allow us to determine if there are any rail carriers that do not ever carry bulk shipments; therefore, these calculations are based on the universe of rail carriers in the available data. Furthermore, data is not available that would allow the precise calculation of the number of those carriers, whether trucking or rail, that would develop agreements as a result of this proposed regulation. For the purposes of this analysis, and to acknowledge possible cost related to intrastate-only transportation, we assume that this proposed requirement would result in 1 percent of estimated trucking and rail firms that may transport bulk to develop agreements, and that each of these firms will develop one agreement, as shown in Table 14, and that this agreement would affect (or be a new disclosure for) 1 percent of all bulk shipments. While the one-time cost consists of the development of an agreement, the total first year cost is the sum of the one-time cost and the annual cost (in the first year), or $847 + $792,765 = $793,612. Note that carrier and shipment calculations are rounded to the nearest number, and cost is rounded to the nearest dollar. . The uncertainty of these estimations is acknowledged. The Agency requests comment on the potential costs of this proposed requirement.

Table 14 –Estimated Cost of § 1.908(d)(5)

Estimated Carriers				
Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
105	0.25	26.3	$30.51	$804
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
6	0.25	1.41	$30.51	$43
			Total Cost	**$847**
Estimated Shipments				
Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
304,516	0.08	24,361.24	$30.51	$743,261
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
20282	0.08	1622.55	$30.51	$49,504
			Total Cost	**$792,765**

Proposed § 1.908(d)(6)(i) states that carriers must develop written procedures that specify practices for cleaning, sanitizing, if necessary, and inspecting vehicles. The written procedures are subject to the records requirements in proposed § 1.912(b).

This is estimated to be a per carrier record. According to data from the Department of Transportation, it is estimated that there are 55,717 motor carriers in the U.S. that transport food and would be affected by this proposed rule. Furthermore, there are about 563 rail carriers in the U.S. that are covered by this proposed rule. A one-time cost for document development will be calculated if the carrier is not estimated to have practices in alignment with this proposed requirement. Information is not available to determine to what extent the generation of this record is a common business practice among carriers, particularly intrastate only carriers. Therefore, for the purposes of this analysis, calculations are made based on the assumption that 1 percent of carriers will develop new written procedures as a result of this this proposed requirement. These estimations are presented in Table 15. Note that carrier and shipment calculations are rounded to the nearest number and cost is rounded to the nearest dollar. The wage is based on that of a first line supervisor of transportation and material-moving vehicle operators (BLS 2012).

Table 15 –Estimated Cost of Proposed § 1.908(d)(6)(i)

Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
557	2	1,114.34	$39.98	$44,551
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
6	2	11.26	$39.98	$450
			Total Cost	**$45,001**

Proposed § 1.908(d)(6)(ii) requires carriers to develop and implement written procedures that describe how they will comply with the provisions for temperature control. This is estimated to be a per refrigerated carrier record and the cost of this proposed requirement is estimated the same way as the burden for proposed § 1.908(d)(6)(i). Similarly, information is not available to determine to what extent the generation of this record is a common business practice among carriers, particularly intrastate only carriers. Therefore, for the purpose of this analysis, calculations are made based on the assumption that 1 percent of estimated refrigerated carriers will develop written procedures as a result of this this proposed requirement. These estimations are presented in Table 16, firms calculations are rounded to the nearest number and total cost is rounded to the nearest dollar. While the wage is again based on that of a first line supervisor of transportation and material-moving vehicle operators (BLS 2012), the hourly burden is estimated to be two hours.

Table 16–Estimated cost of proposed § 1.908(d)(6)(ii)

Estimated Carriers				
Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
235	2	470.14	$39.98	$18,796
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
6	2	11.26	$39.98	$450

			Total Cost	**$19,246**

Proposed § 1.908(d)(6)(iii) requires carriers to develop and implement written procedures that describe how they will comply with the provisions for the use of bulk vehicles as described in § 1.908(d)(4) and (5). This is estimated to be a per bulk carrier requirement. Again, it is estimated that there are 10,536 motor carriers in the U.S. that transport bulk food and would be subject to the requirements of this proposed rule. Furthermore, there are about 563 rail carriers in the U.S. that are covered by this proposed rule. A one-time cost for document development will be calculated if the carrier is not estimated to have practices in alignment with this proposed requirement. Information is not available to determine to what extent the generation of this record is a common business practice among carriers, particularly intrastate only carriers. Therefore, for the purposes of this analysis, calculations are made based on the assumption that 1 percent of carriers will develop written procedures as a result of this this proposed requirement. These estimations are presented in Table 17 and firm calculations are presented rounded to the nearest number and cost is rounded to the nearest dollar.

Table 17--Estimated Cost of Proposed § 1.906(d)(6)(iii)

Estimated Carriers				
Truck	**Hourly Burden**	**Total**	**Wage**	**Total**

		Hours		**Cost**
105	2	210.72	$39.98	$8,425
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
6	2	11.26	$39.98	$450
			Total Cost	**$8,875**

Costs Related to Training

Proposed § 1.910(a) states 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. Proposed § 1.910(b) states carriers must establish and maintain records documenting the training described in § 1.910(a). Such records must include the date of training, the type of training, and the person(s) trained. These records are subject to the records requirements of § 1.912(c).

It is estimated that training costs will consist of one time costs to train any workers not estimated to be trained in accordance with the requirements of this proposed rule, and annual costs attributable to retraining or employee turnover. The hourly burden is based on a half day (four hour) training course that can be accessed via the internet. For the purposes of this analysis, we assume that all employees will have internet access. The total cost per worker is estimated as the average cost of the course plus four hours'

wages. The cost of the course here is $50, estimated by averaging the cost of sample Department of Transportation courses on hazardous materials. Comment is requested on the format and length of training that will be necessary as a result of this training requirement.

While information regarding recommended employee training is available via industry guidance documents, empirical data are not available to the Agency to precisely estimate how widespread training practices are within the industry. In addition, there is no information available regarding training of employees of intrastate-only carriers.

The estimated number of truck drivers employed by firms affected by the proposed rule in the United States is about 1.2 million, consisting of about 190,185 truck drivers without commercial driver's licenses, and about 1 million drivers with commercial driver's licenses.[12] For the purposes of this analysis, it is estimated that 1 percent of drivers (both CDL and non-CDL drivers) will require training in the first year, and 1 percent annually to address turnover and retraining. The wage for drivers with commercial drivers is based on that of a Heavy and Tractor-Trailer Truck Driver and, for those drivers without commercial driver's licenses, the wage is based on that for a Light Truck or Delivery Services Drivers (BLS 2012). Wages include 50 percent overhead.

Data on the number of rail employees that may need training in food safety is not available to the Agency, nor is data available on the number of employees who may come

[12] Drivers with commercial driver's licenses will drive any type of vehicle which has a gross vehicle weight rating (GVWR) of 26,001 lb. (11,793 kg) or more for commercial use, or transports quantities of hazardous materials that require warning placards under Department of Transportation regulations, or that is designed to transport 16 or more passengers, including the driver. This includes (but is not limited to) tow trucks, tractor trailers, and buses.

into any contact at all with transported food. In the data description, it is estimated that 206,796 rail employees may be affected by this proposed rule. For the purposes of this analysis, we assume that 1 percent will require training in the first year, and 1 percent annually, to address retraining and employee turnover. Wages are based on Rail Transportation Workers, all other, and include overhead (BLS 2012). The cost of proposed § 1.910(a) is presented in Table 18. All employee calculations are rounded to the nearest number, and total cost is rounded to the nearest dollar. The uncertainty of these estimates is acknowledged, and comment is requested on potential costs related to proposed § 1.910(a).

Table 18 -- Training Costs of Proposed § 1.910(a)

Costs from training--Motor Carriers						
First Year						
Truck Drivers	**Employees**	**Hours**	**Total Hours**	**Wage**	**Average Cost of Course**	**Total Cost**
CDL Drivers	10,316	4	41,262.48	$29.10	50	$1,716,519
non-CDL Drivers	1,902	4	7,607.40	$24.48	50	$281,322
					Total Cost	**$1,997,841**
Annual						
Truck Drivers	**Employees**	**Hours**	**Total Hours**	**Wage**	**Average Cost of Course**	**Total Cost**
CDL Drivers	10,316	4	41,262.48	$29.10	50	$1,716,519

non-CDL Drivers	1,902	4	7,607.40	$24.48	50	$281,322
					Total Cost	**$1,997,841**
Costs from training--Rail Carriers						
First Year	**Employees**	**Hours**	**Total Hours**	**Wage**	**Average Cost of Course**	**Total Cost**
Rail	2,068	4	8271.84	$39.62	50	$431,128.
Annual	**Employees**	**Hours**	**Total Hours**	**Wage**	**Average Cost of Course**	**Total Cost**
	2,068	4	8271.84	$39.62	50	$431,128
					Total First Year Cost	**$2,428,969**
					Total Annual Cost	**$2,428,969**

*As outlined earlier in the analysis, it is estimated that costs related to training also cover any retraining needed to align carriers with the requirements of proposed § 1.906(b) (sanitary maintenance of vehicles), § 1.906(c) (design and maintenance of vehicles), and § 1.908(c)(2) (loading and unloading operations).

Proposed § 1.910(b) states carriers must establish and maintain records documenting the training described in § 1.910(a). Such records must include, but are not limited to, the date of training, the type of training, and the person(s) trained. Wages are estimated on the First-Line Supervisors of Transportation and Material-Moving Machine and Vehicle Operators (BLS 2012), including overhead. It is estimated it will take 10 minutes (0.2 hour) for the supervisor to generate the record of training, regardless of whether the

worker is employed by a rail or motor carrier, or whether the training takes place in the first year, or annually. The estimated costs of this proposed requirement is in Table 19.

Table 19 –Estimated Costs of Proposed § 1.910(b)

Recordkeeping Costs --Motor Carriers				
First Year				
Employees (CDL + non-CDL)	**Hours per Record**	**Total Hours**	**Wage**	**Total Cost**
12,217	0.2	2,443.49	$39.98	$97,691
Annual				
Employees (CDL+ non-CDL)	**Hours per Record**	**Total Hours**	**Wage**	**Total Cost**
12,217	0.2	4,506.18	$39.98	$97,691
Recordkeeping Costs --Rail Costs				
First Year				
Employees	**Hours Per Record**	**Total Hours**	**Wage**	**Total Cost**
2,068	0.2	413.592	39.98	$16,535
Annual				
Employees	**Hours Per Record**	**Total Hours**	**Wage**	**Total Cost**
2,068	0.2	413.592	39.98	$16,535
			Total First Year Cost	**$114,226**
			Total Annual Cost	**$114,226**

Records

Proposed § 1.912 addresses requirements related to records and retention of records that apply to shippers and carriers engaged in food transportation. Proposed §

1.912(a) states that shippers must retain records that demonstrate they provide information to carriers as required by §§ 1.908 (b)(1) and (b)(3). It is estimated that this requirement could be met by having a contract or letter on file with the shipper that outlines an agreement between the shipper and carrier to provide such information. In the analysis of the cost of § 1.908 (b)(1), it is assumed that 1 percent of shippers – that is, animal food facilities, human food facilities, and meat facilities—would begin providing information to carriers regarding necessary sanitary requirements. Therefore here it is estimated that that same 1 percent of shippers will generate an agreement to keep on file that outlines the agreement to provide written sanitary requirements to carriers. Similarly, in § 1.908 (b)(3), it is assumed that 1 percent of shipments of food that can support the rapid growth of undesirable organisms in the absence of temperature control during transportation will result in disclosure of necessary temperature conditions by shippers. Therefore, it is estimated that 1 percent of shippers will generate an agreement to keep on file. As shown in Table 20, the total one-time cost of proposed § 1.912(a) is about $31,000, at a wage of $30.51, and 30 minutes to generate each agreement.

Table 20 – Estimated Cost of § 1.912(a)

One-Time Burden, with Respect to Records in 1.908(b)(1)				
Shippers	**Hourly Burden**	**Total hours**	**Hourly Wage**	**Total Cost**
273	0.5	136.64	$30.51	$4,169
One Time Burden, with Respect to Records in 1.908(b)(3)				
Shippers	**Hourly Burden**	**Total Hours**	**Hourly Wage**	**Total Cost**
273	0.5	136.64	$30.51	$4,169
			Total Cost	**$8,33**

Proposed § 1.912(b) states that carriers must retain records of the written agreements required by §1.908(d)(2)(ii) and 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. It is estimated that carriers will be able to retain records of written agreements and procedures using existing electronic methods; therefore, no cost is estimated for this proposed requirement. Proposed§ 1.912(c) states that carriers must retain training records required by § 1.910(b) for a period of 12 months beyond when the employee identified in the records continues to perform the respective duties. It is estimated that carriers will be able to retain records of written procedures using existing electronic methods; therefore, no cost is estimated for this proposed requirement.

Proposed § 1.912(d) states that shippers and carriers must make all records required by this subpart available to a duly authorized individual and proposed § 1.912(e) states that all records must be kept as original records, true copies, or electronic records. It is estimated that these proposed requirements will not impose additional costs on carriers as it is estimated that any carrier engaged in the transportation of food will have electronic or other storage methods in place that would allow shippers and carriers to fulfill the requirements of these proposed provisions. No cost is estimated.

Table 21 presents costs related to recordkeeping over all provisions of the proposed codified. As shown, the one-time cost related to recordkeeping is estimated to be $203,634 with annual costs of about $3.6 million. This does not include costs related to waiver petitions; these costs are estimated later in the analysis.

Table 21- Recordkeeping Summary

One Time Costs					
Codified Provision	**Number of Records**	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
1.908(b)(1)	273	0.5	137	$30.51	$4,169
1.908(b)(5)	273	0.25	68	$30.51	$2,085
1.908(d)(4)	111	0.25	28	$30.51	$847
1.908(d)(5)	111	0.25	28	$30.51	$847
1.908(d)(6)(i)	563	2	1,126	$39.98	$45,001
1.908(d)(6)(ii)	241	2	481	$39.98	$19,246
1.908(d)(6)(iii)	111	2	222	$39.98	$8,875
1.910(b)	14,285	0.2	2,857	$39.98	$114,226
1.912(a)	547	0.5	273	$30.51	$8,338
				Total Cost	**$203,634**
Annual Cost					
Codified Provision	**Number of Records**	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
1.908(b)(1)	541,064	0.08	43,285	$30.51	$1,320,629
1.908(b)(3)	92,797	0.08	7,424	$30.51	$226,498
1.908(d)(2)(i)	176,365	0.08	14,109	$30.51	$430,473
1.908(d)(4)	324,797	0.08	25,984	$30.51	$792,765
1.908(d)(5)	324,797	0.08	25,984	$30.51	$792,765
1.910(b)	14,285	0.2	2,857	$39.98	$114,226
				Total Cost	**$3,677,356**

Waivers

Under proposed § 1.914, entities may request waivers from the requirements of this rule that may be granted if FDA determines that the waivers 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. Proposed § 1.916 states that FDA will consider a waiver when the conditions for a waiver are met on FDA's own

initiative or on the petition submitted under § 10.30. Proposed § 1.918 describes requirements in a petition requesting a waiver in addition to those requirements under § 10.30, and proposed § 1.920 and § 1.922 address publically available information in the petition application process.

The petition process in § 10.30 is approved and its burden estimated under OMB Control Number 0910-0183. The petition burden is estimated for an average of 24 hours per submission; this is estimated to cover a wide range of possible subject matter, including those additional requirements outlined in proposed § 1.918. However, because this proposed rule, when finalized, will add to the current annual estimate of petitions under § 10.30, the number of new submitted petitions and related cost must be estimated here.

It is not known how many waivers will be submitted to the Agency as a result of this rule, in the first year or annually. In addition, it is not known whether these firms would be shippers, receivers, or carriers. However, for the purposes of this analysis, it is assumed that six petitions will be submitted in the first year and then two petitions annually. It is also estimated that the submission will require one lawyer to spend an average of 24 hours (per the estimate for § 10.30) writing the petition at a wage of $94.40, including overhead (BLS 2012). The estimated cost of submitting petitions for waivers is presented in Table 22.

Table 22—Cost of Waiver Petitions

First Year Cost				
Number of Recordkeepers	**Hourly Burden**	**Total Hours**	**Wage**	**Total First**

				Year Cost
6	24	144	$94.40	$13,594
Annual Cost				
Number of Recordkeepers	**Hourly Burden**	**Total Hours**	**Wage**	**Total Annual Cost**
2	24	48	$ 94.40	$4,531

Benefits

The proposed rule addresses how human and animal food is transported and handled during transport by motor vehicle or rail vehicle,[13] minimizing potential hazards in human and animal food. The proposed rule requires shippers, carriers by motor vehicle or rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated.

To achieve these objectives, the proposed rule requires shippers, carriers by motor vehicle or rail vehicle, and receivers engaged in the transportation of human and animal food, to reevaluate existing or establish new written practices related to sanitation, temperature control, product isolation and/or segregation to protect against cross-contamination, information disclosure (e.g., about prior cargo), training, and recordkeeping. Conducting a systematic evaluation of the potential hazards related to

[13] The proposed rule establishes requirements only for shippers, receivers, and carriers by motor vehicle or rail transportation mode. Shipments of food by any other transportation mode such as by air, water, etc. are not covered by the proposed rule.

their activities helps shippers, carriers by motor vehicle or rail vehicle, and receivers identify the potential risks to human and animal health from their current practices associated with food transportation. Identifying sources of potential hazards allows shippers, carriers, and receivers to develop prevention-focused safety systems related to food transport. Increasing the stringency of requirements for food and feed transportation, an important part of the food supply chain, would maintain public confidence in the safety of human and animal foods and protect human and animal health.

As mentioned elsewhere in this analysis, we do not either expect large scale changes in practices as a result of the provisions in this proposed rule, or large benefits to accrue. However, to the extent that benefits from this proposed rule will accrue, they will be related to reduced risk of adulteration associated with transportation by motor vehicle or rail vehicle of human and animal food ingredients and food products. Specifically, reducing the probability of adulteration of human and animal food associated with unsafe transportation practices would (1) reduce the risk of serious illness and death to humans and animals, (2) reduce the risk of adverse health effects to humans handling contaminated food and feed, and (3) reduce the risk of consuming human food derived from animals that consumed feed contaminated during transport.

Data are not currently available that would allow us to quantify benefits from this proposed rule. In the sections that follow, we present a model that would aide in quantifying benefits, should the data become available. The discussion consists of the following parts: 1) potential hazards related to food transportation; 2) data needs and current availability; 3) probability of adverse health events; 4) effects of hazards on health resulting from violations of proposed requirements; and 5) potential reduction of

risk. We acknowledge any uncertainties with this model and request data that would allow the estimation of benefits of this proposed rule as well as comments on ways to improve the model.

1. Potential Hazards Related to Transportation of Human and Animal Food

For the purposes of this analysis, we assume there are two types of situations that may result in foodborne illness due to product that was contaminated or amplified during transport. Here, these situations are labeled Type A and Type B. Type A situations are those transportation practices which increase the riskiness of already contaminated product, for example, bacteria growth due to improper temperature inside the vehicle. A Type B situation is one where contamination is introduced during transport, for example, from inadequate cleaning of the vehicle after previous cargo or improper segregation of food transported in a not fully enclosed container.

Codex defines a food hazard as a biological, chemical, physical or radiological agent that is capable of causing an adverse health effect (FAO 2007). We believe that Type A situations occur due to prior contamination of the product with biological or chemical agents, while Type B situations occur due to contamination with either biological, chemical, physical or radiological agent during transport. Either Type A or Type B situations will result in a food product that is risky to human and/or animal health.

Who is at risk of an adverse health effect from a hazard and the severity of such an effect depends on the type of hazard and the probability that the presence of the hazard in a particular food will cause the adverse health effect. For example, *Salmonella* spp., a commonly identified biological hazard in human and animal foods, primarily affects

humans that handle affected food or consume affected food without proper cooking. While *Salmonella* spp. may be present on the food product before transportation resulting in risky product, the proposed rule is only concerned with benefits associated with reduction of those *Salmonella* spp. cases that are linked to transportation, that is, either Type A or B situations. As an example of contamination of food with chemical hazard, cross-contact of a product or ingredient containing food allergen with another product due to improper cleaning of the transportation vehicle creates a risk of adverse health effects for the humans and animals that consume the adulterated food. Foreign substances such as metal, glass or plastic fragments are types of physical hazards in human and animal food.

Furthermore, the probability of the presence of hazard does not automatically translate into the probability of an adverse health effect that is evaluated in the benefits section of the proposed rule. As discussed elsewhere, the proposed rule addresses only hazard risks from Type A or Type B situations, that is, either new food risks introduced during transport or an increase in existing food risks caused by inadequate handling during transport. In addition, biological hazards, even if linked to Type A or B situations, can sometimes be reduced to safe levels by adequate cooking and handling procedures, reducing the probability of an adverse health effect. These biological hazards, however, can also be amplified by inadequate cooking and handling, increasing the probability of an adverse health effect. In certain cases, a known presence of some physical agents can also be reduced to safe levels by adequate prepping procedures, for example, sieving.

2. Data Needs and Data Availability for estimation of Benefits

If the appropriate data were available, benefits from the proposed rule could be calculated for each hazard type using the following formula (Equation 1):

$$Benefits = P_{E\ per\ load} * N_{loads} * D_{per\ E} * R_{H\%} \quad (1)$$

$P_{E\ per\ load}$ - Probability of an adverse health event resulting from Type A or B situations, per representative load (i.e. per shipment);

N_{loads} - Number of representative loads (i.e. shipments);

$D_{per\ E}$ - Damage caused by an event – the estimated value of adverse health effect to humans or animals resulting from Type A or B situations;

$R_{H\%}$ - Percent of reduction of probability of adverse health events from Type A or B situations, expressed as a share of $P_{E\ per\ load}$.

2.1. Probability of an Adverse Health Event

By an event with probability $P_{E\ per\ load}$ we imply a risky product that resulted from a Type A or B situation has not been detected and removed prior to handling or consumption and caused an adverse health effect for humans or animals. Although there are no recent large outbreaks that have been tied to transportation of food, as section 2.3 discusses, there are a number of reported food-related illnesses for which the exact food product or handling practice that resulted in illness have not been identified. An occurrence of food contamination during transport or conditions that may lead to amplification of existing contamination during transport is needed to calculate the probability of an adverse heath effect $P_{E\ per\ load}$.

The data on vehicle inspections in regard to food safety should ideally come from a database on the number of random State or federal food safety inspections of vehicles

that carry food. It is our understanding that, currently, unless potential problems are suspected in the food transportation operations of interstate carriers which would need to be addressed by Federal authorities, States are more likely to conduct any specific food safety inspections of transportation vehicles. That is, it is our understanding that State authorities conduct occasional rather than systematic random inspections. Thus, unless States receive information, such as an anonymous tip about a food-related violation linked to a vehicle on-route, State authorities rarely conduct random inspections of food vehicles. (Pittman, Eric, email to Katie Vierk)

For example, one such incident occurred in Indiana, where a trooper had noticed liquid leaking from the back of a truck transporting food. This incident resulted in more than 200 pounds of contaminated food headed to central Indiana restaurants destroyed by the State because of unsafe handling and cross contamination during transport (TheINDYchannel.com, 2013)[14]. The data from this and similar reports, therefore, is biased toward revealing only contaminated food vehicles among the vehicles inspected and, therefore, use of this data may overestimate the probability of an adverse health effect from a Type A or B situation.

A limited number of food vehicle inspections by certain State authorities did result in finding conditions of food contamination during transport that may have led to adverse health effects. Unfortunately, these cases of unsafe food transport are typically

[14] The Indiana State Department of Health (ISDH) has authority for inspection, embargo, and condemnation of food in transport (Indiana State Department of Health 2014). Similar programs do not exist in other states, and in the case of Indiana, this proposed regulation could complement the state action by enforcing a training requirement on the carrier. Similarly, if a carrier in Indiana were cited for loading food not completely enclosed by a container onto a dirty truck, we could complement the state action by inspecting the carrier and reviewing their SOPs (required records under this proposed rule for vehicle cleaning.

reported as a total number of detected violations during a specific enforcement operation rather than a share of violations in the total inspected food vehicles. For example, Michigan State Police Motor Carrier Officers conducted a series of inspections in 2006 and found 22 cases of unsafe food transport (Michigan State Police Motor Carrier Devision, 2007). Most violations that may lead to adverse health effects were found with smaller box trucks, while large semitrailers had little or no areas of concern (Michigan Department of Agriculture, Gerald Wojtala, 2006). Typical violations included temperature violations such as improper refrigeration or a lack of refrigeration that resulted in improper internal food temperature; cross-contamination such as juices from raw poultry dripping onto open boxes of produce and other surfaces; lacking of food labels and source information; improper packaging such as re-usage of old cardboard boxes; lack of vehicle security – 42 percent of trucks didn't have security or locks; and pest activity (e.g., insect egg mass on ducks, bugs on Bok Choy; inadequate segregation; insanitary storage such as roof leaks and mold on walls, etc.). Table 23 provides a summary of enforcement efforts by selected states.

Table 23. Summary of Enforcement Operations of Safe Food Transport Conducted by Selected States, 2006

Authority	Duration	Number of cases that may lead to adverse health effects
Michigan State Police Motor Carrier Officers and Michigan State Department	na	22 cases
Illinois State Police, Indiana State Police, and Ohio State Highway Patrol	3 days	5 truckloads of spoiled food
Troopers from Michigan, Indiana and Illinois (a multi-state operation)	na	6 shipments

Another potential data source for the probability of an adverse health effect $P_{E|per\ load}$ comes from detecting a hazard related to food transportation by anyone other than federal or State authorities. These data could come from inspection reports of inspections conducted by a final consumer or by anyone in the food's supply chain: final receivers such as retailers, intermediate receivers such as warehouses, or manufacturers if a transported food product is intended to be used as an ingredient. Much of this information is proprietary or is limited in scope. For example, in the railroad industry, rail cars that are used for shipping certain potentially contaminating commodities (e.g., municipal waste, protein derived from ruminants, etc.) are identified and prohibited from being used for the transportation of food. In addition, shippers can reject a rail car if they find it unsuitable for ensuring safety of food products (Ref. Public Comment to the 2010 ANPRM by the Association of American Railroads).

In addition, if consumers or producers detect food contamination or are the victim of a foodborne illness and report it to the FDA, the case record will be in FDA's CFSAN Adverse Events Reporting System (CAERS) or Reportable Food Registry (RFR). The issue on hand becomes to be able to separate cases that are related to adverse health effects from a type A or B situation from the rest of the cases in these FDA databases, which is often difficult to do ex-post transportation.

2. 2. The Number of Shipments

We estimate N_{loads}, the number of representative loads (i.e. shipments) affected by the proposed rule, as a sum of 52.1 million truck-related and 3.3 million rail-related

representative loads, or a best estimate of about 55.4 total loads.[15] The section on the costs of the proposed rule discusses the number of representative loads in more detail.

2.3. Effects of Hazards from Violations of the Proposed Rule on Human and Animal Health

Limited data is available for the variable $D_{per\text{-}E=}$ from equation 1, damage caused by an event of adverse health effect to humans or animals that resulted from a Type A or B situation. The damage can be measured by a combination of both direct and indirect costs. These costs include, but are not limited to, costs of outbreaks related to food transportation, including costs associated with illnesses, recalls, and additional inspections. . We request comment on any available data sources documenting food transportation-related adverse health events.

Adulteration of human and animal food during transport, if undetected and not removed before consumption, can cause final consumers to incur direct costs of treating consequent illnesses, sometimes until the end of their lifetime. The economic impact of these events include the medical and veterinarian costs to treat individuals, companion animals, or food animals that became ill after consuming the contaminated food. Society also bears the indirect costs of pain and suffering and of lost human capital associated with the ill or deceased individuals. Animal food adulterated during transport causes companion animal owners and livestock producers to incur direct costs of treating consequent illness.

[15] The size of a load is different for trucks and railcars. The size of a *representative* truckload changes slightly depending on a product shipped; it typically has an average weight of about 16-17 tons. A *representative* railcar load also changes slightly depending on a product shipped and has an average weight of about 72-74 tons.

The available data show that between 1998 and 2008, CDC received 13,405 reports of foodborne disease outbreaks that resulted in 273,120 reported cases of illness, 9,109 hospitalizations, and 200 deaths (June 28, 2013 p. 1). Out of 13,405 outbreak reports, in only 7,724 (58 percent) outbreaks was a food or ingredient implicated; and then only 3,264 outbreaks were assigned to one of 17 predefined food commodity categories, that is, were traced to a specific food. The CDC database does not specify if the contaminated food or ingredient was traced to inadequate transportation practices. Thus, unless the FDA were able to trace a contaminated food to inadequate transportation practices, adverse health effects from these 3,264 outbreaks could be linked to any known cases related to food transport. Furthermore, for the 42 percent of the outbreaks, the violative food has never been determined, creating the possibility that at least in some of these 5,681 outbreaks, hazards could have been related to improper food handling during food transport.

According to CDC, *Salmonella* spp. remains one of the major biological hazards that can cause illness in humans who consume and handle the food.[16] The 1994 national outbreak of *Salmonella* enteritidis infections from Schwan's ice-cream, for example, was traced to inadequate cleaning of tanker trucks leading to cross-contamination of the ice cream with that of the prior cargo, liquid eggs. This outbreak affected an estimated 224,000 people (Hennessy 1996). Having safer food transportation systems in place would reduce the risk that contaminated products reach final consumers. Reducing the

[16] According to the CDC symptoms of *Salmonella* spp. infection occur 12 to 72 hours after infection and include diarrhea, fever, and abdominal cramps. Normally the acute symptoms of *Salmonella* spp. infections last for four to seven days and often do not require treatment. Certain groups, such as the elderly, children and persons with compromised immune systems can be more susceptible to severe illness and need hospitalization. Although rare, death can occur if the *Salmonella* infection spreads to other parts of the body (CDC, Center for Disease Control and Prevention).

risk that consumers handle contaminated human and animal food and feed would reduce the risk of *Salmonella* spp. and other foodborne infections. The public health benefit of fewer *Salmonella* spp. infections would be the value of avoided illness and deaths. We lack information about the number, type, and severity of human illness specifically attributable to improper transportation practices that would allow us to estimate the burden of these illnesses[17]. FDA's Reportable Food Registry (RFR) reports that between 2009 and 2012, there were seven animal outbreak cases that were traced to inadequate transportation practices (FDA). One case reported to the RFR described livestock feed contaminated by glass particles; improper cleaning of the transport truck was likely responsible. Two animal outbreak cases were linked to metal shavings in feed that resulted in the deaths of three calves and affected many more. The remaining cases were attributed to chemical contamination from prior cargo: fertilizer (urea) or ingredients in the feed intended for other types of animals. The proposed rule would decrease the potential risk from such physical hazards.

Finally, adulteration of both human and animal food during transport can trigger expensive recalls that may lead to product shortages and higher food costs. Improper sanitation of transportation vehicles for human and animal food and ingredients can promote the growth of fungi or bacteria. Fungi release toxins, e.g., aflatoxin, that can be harmful to humans and animals that consume contaminated food and feed. Products found to contain such toxins or bacterial contamination would likely be recalled.

[17] As an example of the economic costs of such illnesses, if the 3,264 cases of CDC-identified foodborne illness were, for example, Salmonella cases linked to unsanitary transportation practices, economic costs could be large. Taking the 3,264 and adjusting for the possibility of underreporting, we get a total of 3,264 x 26.1 = 85,190 potential illnesses (of course, assuming these cases are all transportation-related, using multipliers from Scallan, et al (2011). The total potential cost (using an average cost of illness estimated in the produce safety proposed rule) is then 85,190 x $4,622 = $393.7 million.

Minimizing hazards that food would become adulterated during transport could reduce some of the recalls of animal food and costs of additional food vehicle inspections for safety.

2.4. The Reduction in Probability of an Adverse Health Effect

The product of the first three variables of equation 1 represent the baseline damages related to contaminated food as a result of inadequate food transportation by motor vehicle or rail vehicle. The last variable of equation 1, $R_{H\%}$, is the percent of reduction in the probability of adverse health events that would result from the proposed rule. This variable represents the share of total damages that can be reduced as a result of the proposed rule – the benefits of the proposed rule.

To estimate this variable we would need data on reduction in food contamination (and therefore foodborne illness) as the result of transporters having written practices related to sanitation, appropriate temperature control, product isolation and/or segregation to protect against cross-contamination, information disclosure (e.g., about prior cargo), training, and recordkeeping. While there is very little information on these preventive controls as related to food transportation specifically, we could use as proxies information on how effective these types of controls are in the food industry in general (see Docket No. FDA-2011-N-0920 Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food available at http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0920 . The available evidence, including with respect to general practices in the food industry and their effectiveness at reducing contamination, is sparse. We request comment on the

availability of data that on the role of preventive controls related to food transportation in minimizing the risk of foodborne hazards.

3. Summary of Potential Benefits

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 identified but not quantified. Because no complete data exists to precisely quantify the likelihood of food-related violation 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. Nevertheless, we have described how improved food transportation systems can 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.

Summary of Costs and Benefits of the Proposed Rule

Summary of Costs

Table 24 summarizes the costs of the proposed rule by provision, in the first year and annually. The first year costs are estimated at $149.1 million, and annual costs are estimated at $30.1 million, with average costs (over all covered firms) of $1,784 in the first year and $360 annually. Total costs, annualized over a 10-year time horizon, are $46 million with a 7 percent discount rate or $44 million with a 3 percent discount rate. Note that much of the cost estimated is related to administrative costs, training, precooling of refrigerated trucks, and records. The data are not available which would allow us to estimate wide changes in industry practices. As mentioned elsewhere in this analysis, we do not expect widespread changes in industry practices as a result of the requirements of this proposed rule, if finalized. However, administrative measures will help ensure

uniform practices across hazardous shipments, reducing the possibility of a sanitation failure. Nevertheless, we acknowledge the gap between the costs and benefits of this proposed rule and request comments on ways to refine our estimates.

Table 24 -- Summary of Costs

Provision	First Year Cost	Annual Cost
Costs related to vehicles and transportation equipment		
§ 1.906(a)	0	0
§ 1.906(b)	0	0
§ 1.906(c)	0	0
§ 1.906(d)	54,638	0
§ 1.906(e)	0	0
Costs related to requirements for transportation operations		
§ 1.908(a)(3)(i)	0	0
§ 1.908(a)(3)(ii)	0	0
§ 1.908(a)(3)(iii)	0	0
Costs related to requirements for shippers engaged in transportation operations		
§ 1.908(b)(1)	$1,324,798	$1,320,629
§ 1.908(b)(2)	$760,032	$760,032
§ 1.908(b)(3)	$226,498	$226,498
§ 1.908(b)(4)	$430,473	$430,473
§ 1.908(b)(5)	$2,085	0
Costs related to requirements for shippers and receivers engaged in food transportation		
§ 1.908(c)(1)	0	0
§ 1.908(c)(2)	0	0
Costs related to requirements for carriers engaged in food transportation		
§ 1.908(d)(1)	0	0
§ 1.908(d)(2)(i)	$430,473	$430,473
§ 1.908(d)(2)(ii)	0	0
§ 1.908(d)(3)	$22,785,352	$22,785,352
§ 1.908(d)(4)	$793,612	$792,765
§ 1.908(d)(5)	$793,612	$792,765
§ 1.908(d)(6)(i)	$45,001	0
§ 1.908(d)(6)(ii)	$19,246	0

§ 1.908(d)(6)(iii)	$8,875	0
Costs related to training		
§ 1.910(a)	$2,428,969	$2,428,969
§ 1.910(b)	$114,226	$114,226
Additional costs related to		
records		
§ 1.912	$8,338	0
Costs related to waivers		
§ 1.914	$13,594	$4,531
Administrative Cost	$118,955,684	0
Total	**$149,195,505**	**$30,086,713**
Catering to Passenger Air and Rail	**$8,922**	**$1,800**

Transportation Related to Catering of Passenger Air and Rail

This proposed rule covers shippers, receivers, and carriers engaged in the transportation of food. As outlined in this analysis, it is estimated that these entities include rail, trucking, and facilities. However, it cannot be ruled out that this proposed rule may also affect shipments related to catering of passenger air and rail. Information regarding shipments, vehicles, and practices of these firms are not available to the Agency; therefore, these entities are not included in the overall analysis of this rule. In addition, given that much of the food shipped to and handled by passenger air and rail consist of prepackaged food and beverages (which is shelf-stable food completely enclosed by its container), it is estimated that much of this transportation will not be covered by this proposed rule, if finalized. However, in order to acknowledge any cost that these firms may incur as a result of the requirements of this rule, average first year and annual costs are applied to these firms. It is assumed that one major passenger rail

firm and four major air caterers may be affected by this rule; no firms would be exempted because of size. Average first year costs are $149.1 million/83,609 firms = about $1,784 and average annual costs are $30.08 million/83,609 firms= about $360. Therefore 5 firms x $1,784 = $8,922 in the first year, and 5 firms x $360 = $1,800 annually. The uncertainty of these estimations is acknowledged. The Agency requests comment on how this proposed rule may affect passenger air and rail catering.

Summary of Benefits

Data are not available that would allow quantification of benefits of the proposed rule. If the data were available benefits are unlikely to be greater than estimated costs given that costs related to modified sanitation practices are minimal. However, this proposed rule, if finalized, could still result in a reduction of possible future cases of contamination associated with transportation of human or animal food by motor or rail vehicle. We believe sanitation practices that are uniform across the food transportation industry could reduce the future risks of recalls, adverse health effects related contamination during transport, and adverse health effects related contamination introduced before transport but amplified during transport due to inappropriate sanitation. Improved safety of food transportation can also reduce losses of food and feed ingredients and products related to unsafe transportation practices. The reduction of contamination associated with food transportation by motor vehicle or rail vehicle can then decrease the risk to humans and animals consuming this food. It can also decrease the risk to humans handling potentially contaminated food and feed. This in turn can generate social benefits in the form of potential improvements in public health.

Option 4: Require all provisions of this proposed rule, but allow no exemptions to firms based on size, and include farms within the option's scope.

The proposed rule analyzed in Option 3 exempts from coverage those firms with annual revenues of less than $500,000 (farms are outside the scope of the proposed rule). Under Option 4, no exemptions would be allowed based on size and all farms are included within the scope of the option.[18]

All provisions of the proposed rule would remain in place; however, the total number of covered firms would increase to 1,312,473, of which 163,909 are carriers (truck and rail), as opposed to 83,609 firms (that operate 84,230 establishments, of which 56,280 are carriers), covered in Option 3. As with the proposed rule analyzed in Option 3, this option also covers intrastate-only food transportation for which we do not have data; therefore, these firm numbers are underestimated. In addition, total costs increase significantly under this option, with a first year cost of about $775.7 million (consisting of $743 million in administrative costs), and annual costs of $31.7 million.

This option was not chosen because, despite the increased firm coverage and related total cost, we would not expect this increase in coverage to yield a substantial increase in benefits. It is believed that the intent of this regulation can still be met even with an exemption for firms, as outlined in Option 3, the proposed rule, as it will still cover an average of 97% of annual domestic shipments addressed in specific provisions of the proposed rule, with significantly less cost overall.

[18] Note that, under this option, farms include produce and non-produce farms, with non-produce farms including corn, soybeans, hay, wheat, sorghum, and rice. These estimates include about 900,000 non-produce farms.

Economic Effects on Small Entities

a. Regulated entities.

i. Number of small entities affected.

It is estimated that shippers and receivers affected by this proposed rule include: domestic human food facilities that primarily handle commodities covered by this proposed rule and have annual revenues of greater than $500,000. Animal food facilities with annual revenues greater than $500,000; motor carriers engaged in food transportation with annual revenues of greater than $500,000; USDA-inspected facilities with annual revenues of greater than $500,000; and all railroad carriers.

FDA, for purposes of this proposed rule-making, has defined a small food facility as having annual revenue less than $500,000; a small USDA inspected establishment as having annual revenue less than $500,000; a small animal food facility as having annual revenue less than $500,000; a small trucking carrier as having annual revenue less than $500,000; and a small railroad as a railroad with operating annual revenues of under $250 million for three consecutive years (in $1991), adjusted for inflation.

The Small Business Administration (SBA) defines farms involved in crop production as "small" if total revenue is less than $750,000 annually. In the economic analysis of the published proposed produce safety rule, it was estimated that 95 percent of all farms that grow covered produce are small by Small Business Administration standards. Using SBA definitions, small food facilities, for both human and animal food, are defined as those facilities with fewer than 500 employees. Therefore, under that definition, about 19,883 human food facilities estimated to be affected by this rule are small, and 4,799 animal food facilities estimated to be affected by this rule are small.

The SBA defines motor carriers as small if total revenues are less than $25.5 million annually. Under that definition, 53,202 motor carrier firms are considered small. Facilities that are inspected by USDA, regardless of commodity, are defined by SBA as small if they have fewer than 500 employees. Under that definition, 2,267 of these facilities are considered small. Finally, SBA defines line haul railroads (providing point to point transport) as small if they have fewer than 1,500 employees. It is estimated that about 544 of these railroads are small by SBA standards.

ii. Costs to small entities. The average first year cost is estimated to be about $1,784 for firms covered by this proposed rule. The average annual cost is estimated to be about $360 for firms covered by the proposed rule.

3. Regulatory Options

If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. Section 418(n)(1)(B) of the FD&C Act requires FDA to define the term "small business."

a. Exemption for small entities.

One possible approach to reduce the impact on small entities would be to exempt all small entities from the rule. This proposed rule already provides exemptions for firms based on size. That is, this proposed rule exempts firms having revenues of less than $500,000 annually. This exemption results in 20,118 human food facilities, 2,412 USDA-inspected facilities, 4,799 animal food facilities, 55,717 trucking carriers, and 563 rail carriers covered by this proposed rule. While it is acknowledged that providing an

exemption for small firms, as outlined in this proposed rule, may lead to an increase in risk related to insanitary food transportation practices (because of the connection of insanitary food transportation practices to small scale food transportation), we believed that the intent of this regulation can still be met, as it will still cover approximately 97 percent of annual domestic shipments addressed in specific provisions of the proposed rule, with significantly less cost. It is possible that this exemption could be more extensive. For example, exempting firms that make less than $1 million annually would result in fewer firms covered by the rule; however, we believe such an expansion would result in a greater risk of food becoming adulterated during transport due to insanitary food transportation practices. However, we seek comment on the exemption for small firms.

b. Longer compliance periods.

Small entities may find it more difficult to learn about and implement the proposed requirements than it will be for large entities. Lengthening the compliance period provides some regulatory relief for small businesses by allowing small businesses to take advantage of increases in industry knowledge and experience in implementing these regulations. A longer compliance period will allow additional time to learn about the requirements of the rule and implement appropriate practices consistent with the proposed requirements, and set up record keeping. It will also delay the impact of the annual costs of compliance.

Therefore, FDA would give motor carriers having less than $25.5 million in annual receipts that do not also ship or receive food two years to comply with these

requirements and would give other carriers, shippers and receivers employing fewer than 500 persons 2 years to comply. A breakdown of firms falling under the proposed three year compliance period is presented in Table 27. Shippers and receivers include human food facilities, animal food facilities, and USDA-inspected facilities[19]. Note that 80,695 out of an estimated 83,609 total covered firms, or about 97 percent, will fall under this two year compliance period.

While this proposed rule offers 2 year compliance periods for the firms meeting these conditions, it is possible that a longer compliance period could be chosen for these firms. For example, it is possible that a 3 year compliance period could be chosen for motor carriers with less than $25.5 million in revenue and other carriers, shippers and receivers employing less than 500 persons. While doing so would delay the cost of complying with this proposed rule, if finalized, it would also delay any benefits that would accrue as a result of a longer compliance period. We seek comment on these proposed implementation periods and comment is requested on the number of small firms that will be affected by these implementation periods.

Table 26 -- Firms, by compliance period

	2 Year Compliance
	Motor Carriers With Less Than $25.5 million in annual revenue, and any firm with <500 employees
Motor Carriers	53,202

[19] Note we assume that all animal food facilities covered by this rule have less than 500 employees. It is possible that some of these facilities have more than 500 employees, for example, if there are multi-establishment firms. However, information do not exist that would allow the estimation of any multi-establishment animal food firms.

Shippers/Receivers	26,949
Rail	544
Total	80,695

FDA will continue to evaluate the impact of this rule, if finalized, on smaller firms and will consider taking appropriate steps to mitigate those impacts, where it is possible to do so without reducing safety. Further, FDA will publish guidance small entity compliance guides, which will help inform and educate small businesses on the requirements of the rule. We plan to use these guides, to the extent feasible, as a vehicle to identify areas where compliance could be achieved via flexible approaches that would mitigate the financial impact while preserving the public health benefits of the rule. Stakeholder participation and comment on these documents will be solicited and considered.

4. Description of Recordkeeping and Recording Requirements

The Regulatory Flexibility Act requires a description of the recordkeeping required for compliance with this final rule. The records requirements of this final rule include written procedures and records pertaining to: 1) sanitary requirements for vehicle and transportation equipment; 2) temperature specifications 3) temperature recordings 4) documentation of previous cargoes; 5) most recent cleaning; 6) procedures for cleaning and sanitizing; 7) procedures for complying with temperature controls; 8) procedures for use of bulk vehicles; 8) training; and 9) waivers, when appropriate.

F. Summary

FDA tentatively finds that, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), this final rule will have a significant economic impact on a substantial number of small entities.

G. Paperwork Reduction Act of 1995

This final rule contains information collection requirements 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) (PRA). The title, description, and respondent description of the information collection requirements are given in the following paragraphs, including estimates of the one-time burdens of establishing records regarding sanitary requirements for vehicle and transportation equipment; temperature control monitoring; temperature recordings; agreements regarding documentation of previous cargoes; procedures for cleaning and sanitizing; procedures for complying with temperature controls; procedures for use of bulk vehicles; training; and submission of waiver petitions, when appropriate. Annual burdens of records related to sanitary and temperature requirements, temperature readings during transportation operations, previous cargoes, cleaning of bulk vehicles, and annual training are also estimated. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Sanitary Transportation of Human and Animal Food

Description: This new collection of information will be performed by shippers, receivers, and carriers of human and animal food. The records requirements of this

proposed rule include records pertaining to: sanitary and temperature requirements, temperature during transportation operations, previous cargoes, cleaning of bulk vehicles, training, and written procedures. In addition, this proposed rule includes submission requirements pertaining to waiver petitions, when appropriate.

FDA has concluded that recordkeeping and submissions are necessary for the success of the food transportation operation. Records of actions taken due to each requirement are essential for manufacturers to implement this rule effectively. Further, records and reports are essential for FDA to be able to determine whether a firm is in compliance with the rule.

Analysis of Burden Estimates Resulting from this Proposed Rule

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

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

The total one-time estimated burden imposed by this collection of information is 5,363.82 hours (5,219.82 recordkeeping hours + 144 submission hours). The total annual estimated burden imposed by this collection of information is 119,690.72 hours (119.642.72 recordkeeping hours+ 48 submission hours). There are no capital costs or operating and maintenance costs associated with this collection of information. FDA estimates that firms will be able to fulfill recordkeeping requirements with existing record systems; that is, FDA estimates that it will not be necessary for firms involved in food transportation to invest in new recordkeeping systems.

One-time burdens are estimated for establishing records regarding sanitary requirements for vehicle and transportation equipment; temperature control monitoring;

temperature recordings; agreements regarding documentation of previous cargoes; procedures for cleaning and sanitizing; procedures for complying with temperature controls; procedures for use of bulk vehicles; training; and submission of waiver petitions, when appropriate. These one-time and annual burdens are presented in Table 1.

Note that there are two numbers presented in the column labeled "Number of Recordkeepers". In the economic analysis of this proposed rule, cost estimations were estimated based on a percentage of, for example, shippers that may have to change behavior as a result of this proposed rule, or shipments that would have new records associated with them. Calculating percentages of firms or shipments often resulted in fractions; these numbers were rounded to the nearest whole number to be presented in the analysis. However, hourly burdens were calculated based on the original calculations. In order to facilitate multiplying across the burden table, and to ensure that the hourly burdens presented here are consistent with the burdens presented in the economic analysis of this proposed rule, the rounded numbers are presented, with the fractions in parentheses. The hourly burdens are calculated using the numbers in parentheses.

The one-time cost of developing written specifications regarding necessary sanitation requirements, as required by proposed § 1.908(b)(1), is estimated at the shipper level. It is estimated that one recordkeeper for each of about 273 (273.29) firms will spend 30 minutes developing written specifications regarding sanitation requirements. Therefore, .5 hour x 273.29 firms = 136.65 one time hours for proposed § 1.908(b)(1), as shown in line 1.

The one-time cost of developing an agreement (such as a contract) to establish responsibility for temperature monitoring as required by proposed § 1.908(b)(5) is

estimated at the shipper level. It is estimated that one recordkeeper for each of about 273 (273.29) firms will spend 15 minutes developing a written agreement regarding temperature monitoring. Therefore, .25 hour x 273.29 firms = 68.32 one time hours for proposed § 1.908(b)(5), as shown in line 2.

The one-time cost of development an agreement (such as a contract) to establish responsibility for disclosure of previous cargoes as required by proposed § 1. 908(d)(4), is estimated at the bulk carrier level. It is estimated that one recordkeeper for about 111 firms (110.99) will spend 15 minutes developing an agreement. Therefore, .25 hour x 110.99 = 27.75 one time hours for proposed § 1. 908(d)(4), as shown in line 3.

The one-time cost of development of an agreement (such as a contract) regarding disclosure of recent cleaning of bulk vehicles, as required by proposed § 1.908(d)(5), is estimated at the bulk carrier level. It is estimated that one recordkeeper for about 111 firms (110.99 will spend 15 minutes developing an agreement. Therefore, .25 hour x 110.99 = 27.75 one time hours for proposed § 1.908(d)(5), as shown in line 4.

The one-time cost of development of written procedures related to cleaning and sanitation, as required by proposed § 1.908(d)(6)(i), is estimated at the carrier level. It is estimated that one recordkeeper for about 563 firms (562.80) will spend 2 hours developing written procedures. Therefore, 2 hours x 562.80 = 1,125.60 one time hours for proposed § 1.908(d)(6)(i), as shown in line 5.

The one-time cost of development of written procedures related to temperature control, as required by proposed § 1.908(d)(6)(ii), is estimated at the refrigerated carrier level. It is estimated that one recordkeeper for about 241 firms (240.70) will spend 2

hours developing written procedures. Therefore, 2 hours x 240.70= 481.40 one time hours for proposed § 1. 908(d)(6)(ii), as shown in line 6.

The one-time cost of development of written procedures related to bulk vehicles, as required by proposed § 1.908(d)(6)(iii), is estimated at the bulk carrier level. It is estimated that one recordkeeper for about 111 firms (110.99) will spend 2 hours developing written procedures. Therefore, 2 hours x 110.99= 221.98 one time hours for proposed § 1. 908(d)(6)(iii), as shown in line 7.

The one-time cost of establishing training records, as required by proposed § 1.910(b), is estimated at the employee level. It is estimated that one recordkeeper per employee will establish a record for about 14,285 workers (14,285.43), and this will take 10 minutes (.2 hours) for each worker. Therefore, .2 hour x 14,285.43= 2,857.09 one time hours for proposed § 1. 910(b), as shown in line 8.

The one-time cost of establishing records pertaining to disclosure of information, as required by proposed § 1.912(a), is estimated at the firm level. It is estimated that one recordkeeper will establish a record at a total of about 547 firms (546.58), and this will take 30 minutes (.5 hour) for each record. Therefore, .5 hour x 546.58= 273.29 one time hours for proposed § 1.912(a), as shown in line 9.

The total one-time hourly recordkeeping burden is 5,219.82 hours.

The annual cost of disclosing necessary sanitation requirements, as required by proposed § 1.908(b)(1), is estimated at the shipment level. It is estimated that one recordkeeper for each of about 541,064 shipments (541,063.93) will spend 5 minutes

disclosing sanitation requirements. Therefore, .08 hour x 541,063.93 shipments = 43,285.11 annual hours for proposed § 1.908(b)(1), as shown in line 10.

The annual cost of disclosing necessary temperature conditions, as required by proposed § 1.908(b)(3), is estimated at the shipment level. It is estimated that one recordkeeper for each of about 92,797 shipments (92,796.5) will spend 5 (.08 hour) minutes disclosing necessary temperature conditions. Therefore, .08 hour x 92,796.5 shipments = 7,423.72 annual hours for proposed § 1.908(b)(3), as shown in line 11.

The annual cost of disclosing temperature, as required by proposed § 1.908(d)(2)(i), is estimated at the shipment level. It is estimated that one recordkeeper for each of about 176,365 shipments (176,365.39) will spend 5 (.08 hour) minutes disclosing temperature. Therefore, .08 hour x 176,365.39 shipments = 14,109.23 annual hours for proposed § 1.908(d)(2)(i), as shown in line 12.

The annual cost of disclosing previous cargoes, as required by proposed § 1.908(d)(4), is estimated at the shipment level. It is estimated that one recordkeeper for each of about 324,797 bulk shipments (324,797.32) will spend 5 (.08 hour) minutes disclosing sanitation requirements. Therefore, .08 hour x 324,797.32 shipments = 25,983.792 annual time hours for proposed § 1. 908(d)(4), as shown in line 13.

The annual cost of disclosing recent cleaning of bulk vehicles, as required by proposed § 1.908(d)(5), is estimated at the shipment level. It is estimated that one recordkeeper for each of about 324,797 bulk shipments (324,797.32) will spend 5 (.08 hour) minutes disclosing recent cleaning of bulk vehicles. Therefore, .08 hour x

324,797.32 shipments = 25,983.79 annual hours for proposed § 1.908(d)(5), as shown in line 14.

The annual cost of training records, as required by proposed § 1.910(b), is estimated at the worker level. It is estimated that one recordkeeper for each of about 14,285 workers (14,285.43) will spend 10 minutes (.2 hour) minutes completing records related to annual training . Therefore, .2 hour x 14,285.43 shipments = 2,857.09 annual hours for proposed § 1.910(b), as shown in line 15.

The annual hourly recordkeeping burden is 119,642.72 hours.

The one-time and annual hourly burdens related to submission of waiver burdens (proposed § 1.914) are presented in Table 2. This proposed requirement rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in § 10.30 have been approved under OMB control number 0910-0183 (General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions).

In the first year, it is estimated that one recordkeeper from each of a total of 6 firms will each spend 24 hours submitting a waiver petition to FDA. Therefore, 6 waiver petitions x 24 hours = 144 one-time hours for proposed § 1.914, as shown in line 1. Annually, it is estimated that one recordkeeper from each of a total of two firms will spend 24 hours submitting a waiver petition to FDA. Therefore, two waiver petitions x 24 hours = 48 annual hours for proposed § 1.914, as shown in line 2.

Table 1 –First Year Only and Annual Recordkeeping Burdens

First Year Only Hourly Burden						
	21 CFR Section	**Number of Recordkeepers**	**First Year Frequency of Recordkeeping**	**Total Records**	**Hours Per Record**	**Total Hours**
1	**Written Sanitation Requirements 1.908(b)(1)**	273 (273.29)	1	273.29	0.50	136.65
2	**Agreement establishing responsibility for temperature monitoring 1.908(b)(5)**	273 (273.29)	1	273.29	0.25	68.32
3	**Agreement regarding disclosure of previous cargoes 1.908(d)(4)**	111 (110.99)	1	111	0.25	27.75
4	**Agreement regarding disclosure of bulk vehicle cleaning 1.908(d)(5)**	111 (110.99)	1	110.99	0.25	27.75
5	**Written procedures, cleaning and sanitation 1.908(d)(6)(i)**	563 (562.80)	1	562.80	2.00	1,125.60
6	**Written procedures, temperature control 1.908(d)(6)(ii)**	241 (240.70)	1	240.70	2.00	481.40
7	**Written procedures, bulk**	111 (110.99)	1	110.99	2.00	221.98

	vehicles 1.908(d)(6)(iii)					
8	**Training Records 1.910(b)**	14,485 (14,285.43)	1	24,601.05	0.20	2,857.09
9	**Records pertaining to disclosure of informaiton 1.912(a)**	2,062 (2,061.92)	1	3,003.28	0.50	1,030.96
					First Year Only Hourly Recordkeeping Burden	**5,219.82**
Recurring Hourly Burden						
	21 CFR Section	**Number of Recordkeepers**	**Annual Frequency of Recordkeeping**	**Total Records**	**Hours Per Record**	**Total Hours**
10	**Sanitation Requirements 1.908(b)(1)**	541,064 (541,063.93)	1	541,063.93	0.08	43,285.11
11	**Necessary temperature conditions 1.908(b)(3)**	92,797 (92,796.5)	1	92,796.5	0.08	7,423.72
12	**Temperature disclosure 1.908(d)(2)(i)**	176,365 (176,365.39)	1	176,365.39	0.08	14,109.23
13	**Disclosure of previous cargoes 1.908(d)(4)**	324,797 (324,797.32)	1	324,797.32	0.08	25,983.79
14	**Disclosure of bulk cleaning**	324,797 (324,797.32)	1	324,797.32	0.08	25,983.79

	1.908(d)(5)					
15	**Training Records 1.910(b)**	14,285 (14,285.43)	1	14,285.43	0.2	2,857.09
					Annual Hourly Recordkeeping Burden	**119,642.72**

Table 2 –First Year and Annual Submission Burden

Estimated First Year Only Submission Burden						
	21 CFR Section	Number of Recordkeepers	First Year Frequency of Recordkeeping	Total Records	Hours Per Record	Total Hours
1	§ Waiver Petitions 1.914	6	1	6	24	144
Estimated Annual Submission Burden						
	21 CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Records	Hours Per Record	Total Hours
2	Waiver Petitions § 1.914	2	1	2	24	48

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