DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Sanitary Transportation of Human and Animal Food

Docket No. FDA-2013–N–0013

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Planning
Office of Policy, Planning, and Legislation
Office of the Commissioner

Executive Summary

This final rule implements requirements addressing the sanitary transportation of human and animal food. It establishes requirements for sanitary transportation practices applicable to shippers, carriers by motor vehicle and rail vehicle, loaders, and receivers. Specifically, these finalized requirements address design and maintenance of vehicles and transportation equipment; sanitary practices during transportation operations that apply to shippers, receivers, loaders, and carriers; training of carrier employees; and records related to, for example, training, and written procedures. Through improved data, information acquired through public comment, and an expert elicitation we have estimated expected costs of this final rule. Annualized costs over the first ten years of implementation of this final rule at seven percent are expected to be $117 million ($113 million at three percent). FDA does not have sufficient data or evidence to fully quantify the benefits of this regulation.

Table of Contents

I. Introduction and Summary

A. Introduction

FDA has examined the impacts of the final 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 preliminary regulatory impact analysis (PRIA); the PRIA is available at http://www.regulations.gov Docket No. FDA–2013–N–0013, and is also available on FDA's website at (http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm). This final 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. A non-covered business means a shipper, loader, receiver, or carrier engaged in transportation operations that has less than $500,000 in sales, adjusted for inflation, on a three year rolling basis. Furthermore, this final rule defines small business as one subject to §1.900(a) employing fewer than 500 persons except that for carriers by motor vehicle that are not also shippers

and/or receivers, this term would mean a business subject to §1.900(a) having less than $27,500,000 in annual receipts. The agency tentatively concludes that the final 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 (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule to result in a 1-year expenditure that would meet or exceed this amount.

Need for Regulation

The need for the 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 establishes sanitary transportation requirements for shippers, carriers by motor vehicle or rail vehicle, loaders, and receivers to prevent the adulteration of human or animal food. Therefore, this regulation enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to food safety problems after they occur.

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

shippers (who are likely manufacturers), 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 food product recalls are infrequently tied back to specific problems during transportation; however, it is well documented that incidents can occur during transportation that result in injury or illness to consumers, and that such injury or illness can be as severe as those caused by unsafe food production practices (Ref 1). 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 insanitary food transportation practices.

B. Summary of Costs and Benefits

This final rule is estimated to cover 108,810 entities. This number includes carriers engaged in food transportation and food (including animal food) facilities, and property transaction brokers. Total annualized costs are estimated to be $112.5 million using a three percent discount rate, and $116.6 million using a seven percent discount rate.

We received many comments regarding the lack of benefits estimated in the proposed rule. This feedback has been considered; however, we lack sufficient data to quantify the potential benefits of the final 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 final rule to reduce potential adverse health effects in humans or animals. Furthermore, while we expect some changes in behavior (in the form of safer practices as a result of aligning with this final rule where needed), we do not anticipate large scale changes in practices, with the exception of training, as a result of the requirements of this final rule, in part because we understand much of the rule to reflect current industry practice.

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

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

C. Comments on the Preliminary Regulatory Impact Analysis and Our Responses

FDA's proposed rule "Sanitary Transportation of Human and Animal Food" (79 FR 7006) was published on February 5, 2014 and its comment period ended July 30, 2014. We prepared a preliminary regulatory impact analysis in connection with the proposed rule. In the following paragraphs, we describe and respond to the comments we received on our economic analysis. While we have numbered each comment to distinguish them from each other, the number is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

(Comment 1) We received many public comments that addressed, in general terms, the estimated costs presented in the regulatory impact analysis of the proposed

rule. Several comments said that the total and average costs appeared to be underestimated. Several comments stated that the number of firms were underestimated in the PRIA (83,609) and that the per firm cost of the rule will "almost certainly" exceed the $1,784 estimated in the analysis of the proposed rule.

(Response 1) These comments did not provide any information that would aide in revising our cost estimates. The cost per firm presented in the PRIA was intended to be an average over all the costs of the rule, which were itemized in the Summary of Costs. However, in response to changes made to the regulatory text, as well as comments received from the public and improved data we have obtained, we have revised our cost estimates for this regulation. Furthermore, based on improved data and feedback from public comments, we have adjusted the number of covered firms upward, from 83,609 to 108,810.

(Comment 2) One comment stated that the analysis of the proposed rule did not itemize costs for the average per firm costs while another stated that we did not distinguish between the costs of railroads and the costs to motor vehicle firms.

(Response 2) The PRIA did present average cost per firm in the both the Executive Summary and Summary of Cost. In this RIA, average cost estimates are presented for carriers (separating costs to railroads from those of motor vehicle carriers) and all other firms in the analysis to provide a more accurate sense of costs to individual firms as a result of the provisions of this final rule.

(Comment 3) A commenter stated that the assumption used in the PRIA that one facility is equal to one firm resulted in an underestimate of the number of facilities in the analysis. Furthermore, this comment stated, because the terms "firm" and "facility" were

used interchangeably, the number of non-covered facilities were overestimated.

(Response 3) This assumption that one facility is equal to one firm was used in the analysis of the proposed rule because of our inability to determine the number of facilities owned by a given firm. While the commenter did not provide any additional data that would allow us to estimate the extent to which these assertions may have been true, in this RIA, we were able to utilize improved data that would allow us to distinguish firms from facilities, thus providing more accurate cost estimates. While the comment did not provide us with any data that would have allowed us to verify the number of non-covered facilities, estimates of these facilities are not used for any cost estimates.

(Comment 4) Several commenters stated that other entities in the supply chain were not considered in the analysis to be affected by the rule. Specifically, these comments stated that the proposed rule did not include brokers, but the rule will still have a substantial impact on the business operations of those entities.

(Response 4) We acknowledge that these entities (third party brokers) were omitted from the PRIA and acknowledge that these entities may incur costs as a result of aligning practices with the final rule. In this economic analysis, we employ improved data that include these firms, including them in the cost estimates of applicable provisions of the final regulatory text. In this analysis, these firms are included in estimates of administrative costs, and costs related to carrier requirements.

(Comment 5) A commenter stated that the number of firms estimated in the PRIA, 83,609, appeared to be either inaccurate or reflect a lack of understanding of the cold supply chain. Furthermore, due to the definition of non-covered business, thousands of entities would not be covered by this rule that also participate in the transportation of

human or animal food. Thus, a rule covering some entities, but not all entities that haul food may not provide any benefit.

(Response 5) This comment did not provide any data which would allow us to revise our estimates of firms affected by this rule and did not further elaborate as to why the estimate of 83,609 was incorrect. However, in the analysis of this final rule, we now include estimates of third party brokers and improved estimates of carriers. Other estimates, such as the number of affected facilities, have been updated to reflect the most current available data. In total, 108,810 entities are estimated to be covered by this final rule. Furthermore, while the revenue threshold for non-covered business remains at $500,000, we believe the intent of this regulation can still be met, as it will cover approximately 95 percent of annual domestic shipments addressed in specific provisions of the rule, with significantly less cost than if there were no threshold for non-covered firms.

(Comment 6) A commenter stated that this rule should exclude official establishments operating under FSIS inspection from the final regulation, stating that applying the rule to the transportation of poultry products would create confusing, duplicative requirements.

(Response 6) While this comment is not directed at the PRIA, this rule excludes shippers, loaders, receivers or carriers when they are engaged in transportation operations of food while the food is located in food facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act. However, FDA does have the authority to regulate these foods once

outside of these facilities. USDA's Food Safety and Inspection Service (FSIS) does not have requirements that directly address transportation operations for these foods once they leave USDA inspected facilities, and this rulemaking will complement FSIS's efforts to promote the application of sanitary food transportation practices for FSIS-regulated meat, poultry, and egg products.

(Comment 7) We received several comments requesting that transfers of human and animal food between facilities operating under the ownership of the same legal entity be exempted from the requirements of the final rule, with commenters stating that this rule would be burdensome and costly for intracorporate transfers. One comment stated that, in lieu of what would be excessive recordkeeping requirements for these firms, a standard operating procedure should suffice.

(Response 7) Final §1.908(a)(5) has been added to this final rule, which allows for written procedures as an alternative to many requirements for shippers, receivers, loaders, and carriers which are under the ownership or operational control of a single legal entity. We acknowledge that firms transporting food under such an arrangement were not acknowledged in the analysis of the proposed rule. Aside from not being addressed in the requirements of the proposed rule, we did not have information that would allow us to estimate either the number of firms operating or food shipped under such an arrangement. We have since obtained estimates of the percentage of food shipments transported under a single legal entity and provide those cost estimates in the discussion of §1.908(a)(5).

(Comment 8) One commenter stated that the additional cost of sanitation to small railroad carriers would be burdensome, $150 for a simple box car. Sanitizing represents

additional cost due to the necessary steam cleaning, which is not a common practice among small railroads. The comment stated that proposed §1.906(a) should clarify that this requirement is not putting additional requirements on rail cars that are already suitable and adequately cleanable.

(Response 8) We have taken this comment into consideration and, because this provision (final §1.906(a)) is intended, as revised in the final rule, to align with current industry practices, we do not estimate any additional cost to industry as a result of this requirement. The comment's estimate of $150 per railcar for sanitation has not been used to revise cost in this RIA.

The definition of "carrier" in this final rule has been amended such that a carrier means a person who physically moves food in commerce, so railroads are covered. However, in the final rule, we have given some responsibilities that were on carriers in the proposed rule to shippers. Carriers may assume those duties, per written agreement with shippers, but would only do so if they are able to take on the responsibilities. While we do not have data that would allow us to estimate how often this would occur, we expect this to be infrequent.

(Comment 9) A comment stated that requirements would increase the cost of transporting food by 15 percent, which was not reflected in the PRIA, due to the need to clean or sanitize containers. This comment further stated facilities to perform these tasks are not widespread enough throughout the country to be efficient and would be extremely cost prohibitive for industry.

(Response 9) We acknowledge the lack of information available to us when estimating costs for proposed §1.906(b); it was estimated the proposed requirement for

vehicles and transportation equipment to be maintained in a sanitary condition was current industry practice. As a result of comments we received, this requirement has been amended and final §1.906(b) states that vehicles and transportation equipment are to be maintained in a sanitary condition for their intended use, which we believe reflects current industry practice; therefore, we do not estimate any additional cost to industry as a result of this requirement.

(Comment 10) A commenter stated that the estimate of the temperature recording device provided in the PRIA, $14.25, was underestimated, saying that this estimate could not include any type of automated device that measures and records time versus temperature data. Other comments provided alternative estimates of costs of these devices.

(Response 10) We acknowledge the uncertainty of our estimates and lack of information regarding the practices and procedures potentially affected by proposed § 1.906(d), which required indicating thermometers in vehicles or transportation equipment used for food that could support the rapid growth of microorganisms. As a result of comments received, this proposed requirement has been eliminated from the final rule.

(Comment 11) We received several comments addressing the costs related to the requirements of § 1.908(b). One commenter stated it would take some time and effort to comply with the requirements of § 1.908(b); these efforts would not be cost neutral. Two comments stated that proposed § 1.908(b)(1), which required shippers to specify, in writing, all necessary sanitary requirements for the vehicle and transportation equipment (e.g., a shipping container), would impose a burdensome recordkeeping requirement that would not provide any benefit, and that this burden was not properly accounted for.

(Response 11) We acknowledge the uncertainty of the estimates in the analysis of

the proposed rule; data were not available at the time that would have allowed a more precise estimate of cost. As a result of comments, § 1.908(b), specifically § 1.908(b)(1), has been amended to require one-time notification unless the design requirements and cleaning procedures required for sanitary transport change based upon a change in the type of food being transported, or the shipping conditions, which we believe will reduce cost to industry. Furthermore, firms engaging in intracorporate transfers of food are not subject to this requirement, which further reduces cost. Finally, we used improved and updated estimates of firms that may have to align practices with this final requirement. These estimates are presented in the discussion of final § 1.908(b)(1).

(Comment 12) We received several comments expressing concern that the proposed requirements regarding temperature control, for example proposed § 1.908(b)(3), could result in an increase in rejected loads, due to the perceived lack of quality of the food, even absent evidence pointing to contamination. Some of these comments stated that the potential increase in cargo claims represent a cost to industry that was not discussed in the PRIA. Comments stated that transportation temperature requirements are often established to maintain optimal product quality and are more stringent than those required for product safety. If a food fails to meet a temperature limit established for quality requirements yet meets all temperature requirements identified for safety, then the food should not be considered adulterated. Another comment stated that the carrier or receiver would also not know what to do with the transported food, which may be perfectly safe and unspoiled despite having been temporarily exposed to temperatures exceeding quality specifications. In addition, other comments expressed concern that the malfunction of a recording device, or a missed temperature reading,

rather than actual food safety practices, could increase the cost of production and increase waste. These issues could lead to significant economic loss, with no food safety benefit.

(Response 12) We acknowledge that the possibility of increased cargo claims was not taken into consideration when estimating costs for the proposed rule. We have taken these comments into consideration and, as a result, have amended the temperature control requirements for this final rule in order to align with current industry practice, thus eliminating the potential for increases in rejected loads (and associated costs), due to the perceived lack of quality of the food, even absent evidence pointing to contamination, because of a failure to meet a temperature limit established for quality. For example, final § 1.908(b)(2) requires a shipper of food requiring temperature control for safety to specify in writing to a carrier, except for a carrier who transports food in a thermally insulated tank, an operating temperature, unless a shipper takes other measures in accordance with 1.908(b)(5). We believe these requirements are aligned with current industry practice and will prevent economic losses due to cargo claims as described by comments received.

(Comment 13) Several comments addressed proposed §1.908(c), which required shippers and receivers to provide access to a hand washing facility for drivers engaging in loading and unloading operations of food that can support rapid microbial growth. In general, these comments stated that the proposed requirement to provide drivers with access to hand washing facilities would add cost without offering any added benefit, with one comment stating that this requirement, if finalized, would result in capital costs of $1,000,000.

(Response 13) In the analysis of the proposed rule, we did not estimate any cost

associated with this provision, as it was estimated that drivers would access any existing hand washing facility. However, there was uncertainty surrounding this assumption and we acknowledge the lack of data that was available to us in making this estimate. However, this final rule has eliminated the requirement for drivers to have access to hand washing facilities.

(Comment 14) We received many comments regarding the cost of proposed § 1.908(d)(2)(i)), which required demonstration of temperature conditions during a shipment. In general, these comments all stated that this provision, if finalized, would impose a much greater, and likely unrealistic, economic burden on industry than was estimated in the PRIA and several comments shared estimates of these potential costs. The comments stated that these costs can include adoption of a method of monitoring and recording temperatures during shipment, purchase of equipment, implementation of those systems, and the costs of downloading data. One comment stated that, although most carriers have temperature data on temperature controlled shipments, this data is not readily available and easily retrievable without incurring significant costs. Furthermore, as another comment stated, if the proposed requirement were finalized, far more than the one percent of industry estimated in the economic analysis would have to incur these costs. Another comment stated that, while "reefer" trailers are generally equipped with thermometers, they do not ordinarily create any kind of permanent printout record to be shown to the receiver. The comment emphasized that any requirement to have this would put unnecessary burdens on industry, particularly small firms. One comment stated that the current practice is for such records to be provided only if there is an indication of a problem (i.e., signs of temperature abuse) upon receipt of the load.

(Response 14) We acknowledge the lack of data available to us when estimating the cost of this proposed requirement. However, as a result of public comment, this requirement has been amended (final § 1.908(e)(2)) to require this demonstration of temperature conditions only if requested by the shipper or receiver and in a way agreeable to the shipper and carrier, which can include measurements of ambient temperature. We believe this is aligned with current industry practices and is not estimated to represent new cost to industry.

(Comment 15) A comment stated that mandatory precooling would increase costs by a total of "at least $250,000 to $750,000 over a single year". Even among smaller carriers, the comment stated that this requirement would increase costs by $5,000 to $10,000. In addition, the comment stated that there would be a "proportionate increase in equipment maintenance and replacement costs," but the comment did not estimate these costs.

(Response 15) We acknowledge the lack of information available to us when estimating the costs of proposed § 1.908(d)(3) and we appreciate feedback regarding this provision. These estimates, while informative, were not explained further, making them difficult to confirm. Furthermore, the claim that the precooling would lead to proportionate increases in maintenance and replacement costs were not accompanied by cost estimates or any further information that would inform our revised estimates. However, as a result of feedback from industry and improved data relating to the current rate of precooling as well as the number of refrigerated shipments, we have revised our estimates for compliance with final § 1.908(e)(3). These estimates are presented in the discussion of that provision.

(Comment 16) One commenter stated that proposed § 1.908(d)(4), requiring carriers offering bulk vehicles for food transportation to provide written documentation to the shipper that identifies the three previous cargoes transported on the vehicle, would be overly burdensome. Another comment stated that the estimated cost of this requirement did not include the cost of implementing industry wide software changes for railroads, as tracking this information is not current industry practice.

(Response 16) These comments did not provide any data to allow us to calculate this burden, and we acknowledge the simplicity of our assumptions in the estimates of the cost related to this provision. However, as a result of the feedback from industry, this provision has been amended (final § 1.908(e)(4)) to require carriers in bulk to provide information, on the last previous cargo, only when the carrier and shipper have a written agreement that the carrier is responsible in whole or part, for sanitary conditions during transportation operations, and only if requested by the shipper. We believe this provision is aligned with current industry practice.

(Comment 17) A commenter stated that proposed § 1.908(d)(5), which required carriers to provide information to shippers describing the most recent cleaning of bulk vehicles, would be beyond the current capabilities of railroads. The comment stated that compliance with this requirement would likely require expensive investments to track this information, as this is not current industry practice.

(Response 17) This comment did not provide any data that would allow us to estimate this burden. However, as a result of feedback from industry, this provision has been amended (final § 1.908(e)(5)) to require carriers in bulk to provide information describing the most recent vehicle cleaning, only when the carrier and shipper have a

written agreement that the carrier is responsible in whole or part, for sanitary conditions during transportation operations, and only if requested by the shipper. This provision is believed to be aligned with current industry practice.

(Comment 18) We received many comments regarding the proposed training requirements of § 1.910. In general, these comments expressed concern regarding the potential costs and some of these comments included cost estimates. One comment stated that, while current training allows drivers the knowledge to properly transport food, it warned that an increase or extension of those requirements could substantially increase cost for companies. A comment stated that a one size approach to training would be burdensome to those carriers who have little to no contact with the products itself. Furthermore, the comments provided average turnover rates for drivers ranging from 92 percent to 100 percent, further adding to the burden related to training. A commenter stated that the average carrier with 20 trucks could have increased training and reporting costs of $48,000 annually, given the industry driver rate of turnover. Another commenter stated that, even with a minimum wage of $7.25/hour, training the 5,000 drivers they hired last year would cost $36,250 as a result of these training requirements. One comment suggested that half day long training, as estimated in the PRIA, seems unnecessary, while another estimated that four hour training would cost in excess of $60,000 in initial labor hours alone. This same comment suggested that, while all of this firm's drivers were trained in the safe handling of food, the development of training materials would be an additional cost. Another comment stated that driver training in the food transportation industry was already adequate.

(Response 18) Carriers who agree to bear responsibility for sanitary conditions during transportation can tailor their training to suit their needs to minimize additional cost burden. For example, if a firm does not haul refrigerated foods, it would not be expected to be trained on good temperature control practices. Some rail lines do not have a contractually designated responsibility to manage the temperature control process during transportation, so they would not be expected to be trained. Furthermore, the estimate of a half day (four hour) long training session presented in the PRIA was intended to represent a hypothetical training session; the proposed rule did not prescribe length of training. Final § 1.910 does not prescribe length of training, only that training is required. In this RIA, training costs have been revised to reflect new information regarding current practices, use wage rates appropriate for drivers employed by covered carriers and are based on one hour of a driver's time, using materials that are free of cost to the carrier. These estimates are presented in the discussion of final § 1.910.

(Comment 19) One commenter stated that requiring firms to retain records for one year would not benefit those along the supply chain and would be unnecessarily burdensome.

(Response 19) This comment does not describe how the 12 month retention requirement would be burdensome. This final rule reduces the total number of records related to sanitary food transport, which will reduce cost to industry relative to what would be incurred as a result of the proposed rule. Furthermore, the regulatory language provides a wide range of options on how these records must be kept. We estimate that firms will maintain electronic records, which further reduces cost.

(Comment 20) One commenter stated that many facilities would have to add .5

FTE to their permanent staff just to meet the recordkeeping requirements of the proposed rule.

(Response 20) This comment did not provide additional information to support that claim. While we have considered these comments, because of the reduced recordkeeping requirements of the final rule, we have not adjusted our recordkeeping cost modeling beyond updating firm numbers and wages.

(Comment 21) We received many comments regarding the records requirements of proposed §1.912(e) regarding the proposed requirement to keep electronic records in accordance with 21 CFR Part 11. All of these comments stated this proposed requirement would be very burdensome for firms, with several stating that the requirement would be overly cumbersome and add significant costs without adding any food safety benefit.

(Response 21) These comments did not provide estimates of cost related to Part 11 compliance; however, we acknowledge that the PRIA did not estimate costs related to compliance with 21 CFR Part 11 due to the lack of information available to us. However, the requirements of final §1.912(g) state that that records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in §11.3(b)(6) are exempt from Part 11. Therefore, no cost is estimated in this economic analysis with respect to Part 11 compliance.

(Comment 22)We received several comments regarding the benefits discussed in the PRIA. They were all general in nature and expressed concerns about the lack of quantifiable benefits attributable to the regulation. For example, one commenter stated that there is no systemic problem that justifies imposing additional regulations above and beyond current industry practices. Another commenter stated that, because benefits are

not quantifiable, the need for the rule is in doubt, while yet another commenter points out that the lack of benefit to the rule reflects that the goal of the proposed rule is already being met by industry.

(Response 22) None of these comments provided information that would allow us to quantify the benefits of this final rule. However, identifying sources of potential hazards allows shippers, carriers, loaders and receivers to develop prevention-focused safety systems related to food transport. Given that incidents that occur during transportation can result in injury or illness to consumers as severe as those caused by unsafe food production practices, increasing the stringency of requirements for food and feed transportationwould maintain public confidence in the safety of human and animal foods and protect human and animal health.

(Comment 23) One comment expressed appreciation regarding the ability of industry to diverge from certain proposed requirements, such as those for bulk shipments, by contractual agreement. This comment stated that reflects a practical understanding of the way business is conducted and how flexibility is essential because of the highly complex nature of the transportation chain. This comment went on to state that FDA should permit flexibility to allow businesses to enter into contractual agreements allocating the responsibilities for shippers, carriers, and receivers to other parties.

(Response 23) While this comment did not address the PRIA specifically, it does allow us to estimate that contractual agreements, such as those addressed in § 1.908(b)(3), are common business practice. No additional cost to industry is estimated for such agreements.

II. Final Regulatory Impact Analysis

A. Coverage of the Analysis

Unless engaged in operations that are subject to a waiver, or not within the scope of this regulation, the requirements of this final rule would apply to shippers, loaders, 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 final 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 throughout 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 (Ref 2).

- Only firms with total annual revenues of more than $500,000 on a three year rolling basis are covered by this final rule. We estimate the industry share of covered motor carrier firms using data from the U.S. Census Bureau (Ref 3).

- We estimate the number of covered broker firms with annual revenues greater than $500,000 on a three year rolling basis and the number of establishments

associated with these firms using the U.S. Census Bureau data for these firms and the Small Business Administration's estimates based on this data (Ref 3, 4, 5).

- The 2012 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 (Ref 5).

- Railroad statistics provided by the Association of American Railroads (AAR) are used to estimate the number of rail traffic carriers (Ref 6).

- 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 (Ref 7). 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 because in 2010, they terminated over 4,500 cars in shipments of any kind (Ref 8).

Estimated Shippers, Loaders, Receivers, and Carriers Affected by this Rule

The estimated number of shippers, loaders, receivers, and carriers that would be affected by this rule is presented in Table 1. We have estimated that shippers, loaders, and receivers affected by this rule include domestic facilities (manufacturers, warehouses, and wholesalers) that would be subject to either Subpart B or Subparts B and C of the preventive controls for human food final rule, and domestic facilities subject to the preventive controls for animal food final rule.

A total of 71,113 firms that operate 88,501 total facilities (manufacturing facilities, refrigerated storage, and non-refrigerated storage) are estimated to be subject to

either Subpart B or Subparts B and C of the preventive controls for human food final rule. However, this rule will exempt any shipper, loader, or receiver with less than $500,000 in sales annually; this will exempt 28,606 firms that operate 28,969 facilities. Using data from Nationwide Survey of Food Industry Safety Practices (Ref 9) it is estimated that approximately half of the remaining 12,103 manufacturing firms (that operate 19,036 facilities) and 28,179 non-refrigerated storage firms (operating 37,502 facilities) primarily handle commodities that will not be covered by this rule (specifically, food that is completely enclosed in a container that does not require temperature control for safety). In this analysis we estimate that all 2,205 refrigerated storage firms (that operate 2,994 facilities) will be affected by this final rule. Therefore, in the analysis of this rule, the total number of human food firms and facilities affected by this rule are reduced to 22,346 and 31,263, respectively[1].

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 4,068 facilities that handle animal food have revenue greater than $500,000 annually, and will be subject to the requirements of this rule[2].

[1] As discussed in the responses to comments, this final rule excludes shippers, loaders, receivers or carriers when they are engaged in transportation operations of food while the food is located in food facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act. Therefore, USDA inspected facilities, which were included in our estimates of affected firms in the PRIA, are not included here. We do not expect these facilities to incur any indirect costs as a result of this final rule.

[2] Exempting animal food facilities that generate less than $500,000 annually will eliminate 1,248 facilities from coverage of this proposed rule. We do not have the information that would allow us to distinguish the number of firms from the number of facilities; therefore, it is estimated that one firm is equal to one facility. Furthermore, we are unable to eliminate any animal food facility that may only handle animal food that is in a container and does not require temperature control for safety. Therefore, our estimates of covered animal food facilities may be overestimated.

Information on third party brokers that engage in food transportation comes from the U.S. Census (Ref 5) and Small Business Administration (Ref 4)[3]. Using this data, it is estimated that approximately 7,335 brokerage firms that operate 13,618 establishments (firms that operate multiple offices) have annual revenue greater than $500,000 and are covered by this final rule.

The number of carriers is derived from DOT's Motor Carrier Identification Database (Ref 2). 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. The final rule is intended to cover both intrastate and interstate transport. However, we were not able to include any estimates of intrastate only carriers in the PRIA. We did not receive any comments that specifically addressed the number of intrastate only carriers that should be included in the analysis. Nevertheless, here we estimate both the number of interstate and intrastate-only motor carriers.[4]

By mid-2013, there were a total of approximately 534,810 active interstate and 302,465 active intrastate-only motor carriers registered with DOT that carried a total of 30 different cargo classifications, food or non-food, in the United States, the District of Columbia, and the Commonwealth of Puerto Rico. 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 motor carriers, it is estimated that a total of 74,487 motor

[3] In this arrangement, for the purposes of this final rule, warehouses and other holding facilities that may engage with third party brokers are referred to as loaders.

[4] Reporting for intrastate-only carriers is voluntary and only some states collect this information. In this analysis, we used DOT estimates of active intrastate-only carriers for our estimates.

carriers (55,717 interstate and 18,770 intrastate-only) transport food and would be affected by this final rule, with 13,415 of these firms (10,536 interstate and 2,879 intrastate-only) handling bulk foods. To the extent that these motor carriers handle food that is not subject to the requirements of the rule, estimates of motor carriers will be overstated.

It is estimated that a total of 574 railroads will be subject to the requirements of this final rule. To the extent that these railroads handle food not covered by this rule, estimates of rail carriers will be overstated.

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

	Number of Firms (Facilities)
Brokers	7,335 (13,618)
Human Food Firms (Facilities)	22,346 (31,263)
Animal Food Facilities	4,068
Carriers—Trucking	74,487
Carriers-Rail	574
Total Estimated Affected Firms	**108,810**

Estimated Number of Food Shipments

While we did not receive any comments on the estimates of food shipments in the proposed rule, here we present updated estimates based on newer and improved data available to the Agency.

The total number of food shipments used in cost calculations in this analysis is estimated using the 2012 Commodity Flow Survey provided by the U.S. Census Bureau (Ref 5). We estimate that the total number of shipments covered by this final rule is

82,724,650 (80,421,836 truck shipments and 2,302,814 rail shipments). 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 of the number of shipments presented in this analysis. Information is not available to refine these estimates further, but the under- and overestimate described above may approximately offset each other.

Food Shipments by Truck

It is estimated that this final rule will affect a total of 82.7 million truck-related shipments of food annually[5]. 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 annual total shipped weight of each commodity is then divided by the size of a

[5] In the PRIA, estimated truck shipments totaled 52.1 million. The difference in estimates is likely attributable to the following: The total tonnage of food shipped by truck has increased from that estimated using 2007 Commodity Flow Survey (1,657 million tons of food from 2012 data compared to 1,273 million tons of food estimated from 2007 data); improved estimates of temperature-controlled shipments, as 2012 was the first year in which the Census started collecting data on temperature-controlled shipments, eliminating the need to approximate the exact share of these shipments transported by truck; and a simplified estimate of the size of a representative shipment by truck

representative load. Again, to the extent that for each commodity there is only an estimate of a single one-way haulage of a truckload, estimates of the total number of loads may be underestimated.[6]

In order to estimate only the shipments of food subject to the requirements of the rule by firms covered by this rule, we estimate that the number of representative loads (shipments) that these covered firms conduct annually is proportional to the average industry revenue share for that firm's size group. We estimate that 94.8 percent of the total industry revenues are earned by trucking firms with annual revenues of over $500,000. That is, we estimate that these firms covered by the rule also conduct about 95 percent of all shipments.

Shipments by rail

It is estimated that 2.3 million rail carloads will be covered by this final rule. These rail carloads don't include shipments of food totally enclosed by a container that do not require temperature control for safety, including frozen foods, and shipments of Grade A milk products because these shipments are outside the scope of this regulation.

[6] Since food commodities are transported by both truckload (TL) and less-than-truckload (LTL), we use the definition provided by the American Trucking Association to distinguish between TL and LTL; loads of over 10,000 are considered TL (Ref 10).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 2012 Commodity Flow Survey data for 2-digit SCTG categories (Ref 5). 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 (Ref 11). Based on information available to the agency, the maximum gross weight is estimated at 49,000 pounds (Ref 12). The maximum gross vehicle weight of 80,000 pounds for a single tractor-trailer is regulated by the Federal Highway Administration (Ref 13). The weight of LTL is defined by the Pert distribution with a minimum load of one 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.

In order to calculate these numbers, for each food commodity (i.e. each 4-digit SCTG code) shipped by rail, total annual shipped weight is 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 2012 Commodity Flow Survey data for 2-digit SCTG categories (Ref 5), 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[7].

Covered Shipments by Type, as Referenced in the Final Rule

For the purposes of estimating cost of individual provisions, available shipment information is separated into categories addressed by this final rule. Specifically, this final rule addresses:

- Food requiring temperature control for safety (this would exclude frozen food and some refrigerated shipments)[8];
- Bulk food
- Food not completely enclosed by a container.

[7] 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 2013, Railinc has processed 641,193 Waybills of U.S., Canadian and Mexican origin submitted by 49 major railroads operating on the U.S. territory (Ref 7). According to this Railinc data, 14,201,502 tons of farm products were transported using 1,989,267 rail carloads; 93,080 tons of fish and other marine products- using 4,560 rail carloads; 128,819,680 tons of food and kindred products – using 1,994,829 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. We estimate that these food-category-specific rail carload sizes equal 74, 20.41, and 64.58 tons respectively.

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 of grain in the United States was 102.8 tons (Ref 14). 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 20.41 tons, we use this number as the minimum rail carload size in the Pert distribution.

[8] Our shipment estimates may be overestimated to the extent that estimated refrigerated shipments in this RIA include some non-covered, but difficult to estimate shipments of food, such as refrigerated fruit juices.

Persons engaged in the transportation of food

Truck drivers

The Motor Carrier Safety Act of 1984, as amended, 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) (Ref 15). 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. We estimate the number of interstate and intrastate-only drivers using information from DOT (Ref 2). It is estimated that the covered motor carrier firms employ 703,507 non-CDL truck drivers and 1,518,705 million CDL truck drivers, for a total of 2,222,212 drivers.

Railroad Employees

Based on industry information from the Railroad Retirement Board (Ref 16), Class I, II, and III railroads employed a total of 203,928 employees. The data show that Class I rail traffic carrier firms employ the majority of these workers (180,117 employees).

Current Industry Practices

We presented a summary of what we understood to be current industry practices in the PRIA, based on information from industry guidance documents. This information

has not changed; therefore, we direct the reader to the PRIA for that discussion.

B. Regulatory Options

1. No new regulatory action (baseline)
2. Require the provisions of this final rule as they apply to carriers only **(**§1.906, §1.908(a) and (e), §1.910, §1.912, and 1.914)
3. Require the provisions of this final rule, exempting firms with annual revenues of less than $500,000.

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 estimated 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. Please see Option 3 for a discussion of baseline food transportation practices as they relate to the final rule.

Option 2: Require the Provisions of this Final Rule as they Apply to Carriers Only (Final §1.906, §1.908(a) and (e), §1.910, §1.912, and §1.914)

Under this option, the final rule would consist of provisions that apply to carriers only. Shippers, loaders, and receivers of human and animal food would not be covered under this provision.

Under this option, the final rule would consist of

- Administrative costs
- Final §1.906, outlining requirements for vehicles and transportation equipment (design and maintenance of vehicles and equipment);
- Final §1.908(a), outlining requirements for transportation operations;
- Final §1.908(e), outlining requirements for carriers engaged in food transportation (supply of appropriate vehicle, demonstration of temperature conditions (if requested), pre-cooling of vehicle, written procedures addressing cleaning and sanitizing of vehicles and temperature control);
- Final §1.910 and 1.912, outlining training of carrier employees and related recordkeeping; and
- Final §1.914, waivers.

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

- Final §1.908(b)(1), which requires written sanitation requirements for vehicle and transportation equipment, and assurances that carriers are aware of sanitation requirements;
- Final §1.908(b)(2), requiring written specifications of temperature conditions;
- Final §1.908(c), pre-loading determination by the loader that vehicle and transportation equipment are in appropriate sanitary condition; and
- Final §1.908(d), requiring receivers to assess that the food was not subject to significant temperature abuse.
- Final 1.908(e)(6)(iii), requiring carriers to demonstrate how they will comply, at the request of a shipper, with provisions regarding identifying previous cargo and describing the most recent cleaning of a bulk vehicle.

This option was not chosen because, despite controls required by other FSMA rules (human and animal preventive controls), excluding shippers, loaders, and receivers from coverage would introduce gaps in the supply chain that would leave food being transported vulnerable to potential adulteration. The provisions identified above as ones that would be excluded from the rule are some of the most important provisions for safe food transport, particularly provisions related to previous cargo and cleaning of bulk vehicles.

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 proper operating temperature for transport of foods that require temperature control for safety and to let them know what procedures are necessary when transporting bulk cargo. Under a carrier-only rule, the burden of acquiring instructions would fall onto the carrier, who almost certainly would not have functional knowledge of food safety, such as appropriate refrigeration temperatures for various commodities. For example, comments from the railroad industry stated that "a railroad carrier's involvement in the transportation of food is limited to moving cars between origin and destination." In order to address concerns expressed by the railroad industry with regard to their role in transport activities, we would need to change the definition of carrier from the definition in this final rule to include some entities now considered shippers. Further, covering carriers only would add a significant burden on carriers to acquire information that they likely would not have ready access to, and would be likely to result in a rule that would be at least as costly as Option 3, the

final rule, and possibly more costly. This cost would be due to the need to develop and implement information systems that these firms do not already have in place, as well as train personnel who do not already have the knowledge to acquire and manage this information, all while still leaving gaps in the safe transport supply chain that could leave shipments of food vulnerable to adulteration.

Finally, the 2005 SFTA directed FDA to develop requirements for shippers, carriers, and receivers and other persons engaged in transportation operations to ensure that food is not transported under conditions that may render the food adulterated. Consequently, the final rule covers the persons that Congress thought most vital to ensuring the sanitary transportation of human and animal food.

Therefore, FDA has concluded that it is necessary to require that shippers, loaders, carriers, and receivers use sanitary transportation practices when transporting food.

Option 3: The Final Rule

Summary of the Major Provisions of the Final Rule

The final 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, loader 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

final rule would also establish requirements for sanitary transportation practices applicable to shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers. Specifically, the final 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 final rule is 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 final rule requires that persons engaged in the transportation of foods that require temperature control for safety take actions to ensure the integrity of the transportation cold chain such as the pre-cooling of refrigerated trucks by the carrier, when necessary, with subsequent verification by the loader per § 1.908(c)(2). Additionally, for foods that require temperature control for safety, and if carriers agree to take on these responsibilities, the final rule requires that carriers demonstrate to receivers and shippers, if requested, that they have maintained appropriate temperature control for the food during transportation. It also establishes procedures for the disclosure to shippers, by carriers, per mutual agreement between the parties, of information about the last previous cargo hauled in bulk conveyances to be offered for the transportation of food and the intervening cleaning of those conveyances.

The final rule also establishes requirements for training for carrier personnel engaged in transportation operations, including a requirement for records that document the training. The final rule establishes 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 conduct transportation operations in accord with sanitary principles. Finally, this rule establishes requirements for standard operating procedures for shippers which address the sanitary condition of vehicles and equipment, previous cargo, and temperature controlled foods.

Cost estimates in this final RIA are presented to the dollar throughout the analysis. This is simply to avoid any large scale rounding errors, and should not be viewed as an indication of precision in the estimates themselves. In the Summary of Costs, estimated costs are rounded to the nearest thousand.

Administrative Costs

In addition to the other provisions of this final rule, each firm engaged in food transportation, whether a carrier, shipper, loader, or receiver, will incur costs to learn about the requirements of this final rule. We estimate that, for any firm affected by this final rule, whether a shipper, loader, receiver, or carrier, an operations manager (for facilities or carriers) will spend two hours to review and assess the requirements[9]. In addition, it is estimated that a legal analyst will also spend two hours analyzing the requirements of this final rule.

[9] 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.

To be conservative, we include the entire universe of railroads; however, a railroad is only affected by this final rule if it agrees with the shipper to take on certain responsibilities that would otherwise fall to the shipper. We did not receive comments from the public on our estimate of administrative costs in the proposed rule. However, we have adjusted our estimates to reflect updated wages and firm numbers, and a refined estimate of the time needed to review the provisions of the final rule applicable to a given firm[10].

Estimated administrative costs are presented in Table 2. For human food facilities and brokers, the number of managers and lawyers differ from each other. In our data for these types of businesses, one firm can own more than one facility. We do not have data that would allow us to determine if one animal food manufacturing firm owns more than one facility. We assume that the final rule will be reviewed by a one lawyer for each firm, and one manager at each facility. Because one firm can own more than one facility, the number of managers is greater than the number of lawyers. For each railroad and trucking carrier, we assume the final rule will be reviewed by one manager and one lawyer.

Wage rates are taken from the May 2014 BLS Occupational Employment Statistics for a General and Operations manager and lawyers (Ref 17, 18) and include overhead, which is estimated to equal 100 percent of base wages. It is estimated that wages will be consistent across firm type. Note that total costs are rounded to the nearest

[10] For example, we estimate that carriers will only review those provisions applicable to carriers. Furthermore, because we also believe this final rule largely codifies current industry practice, our estimates of administrative costs have been adjusted downward from eight hours per manager or lawyer to two hours per manager or lawyer. Note that this is not the same as saying two hours per firm. For example, if a firm consists of a single facility (as our estimates of animal facilities, railroads, or trucking carriers), then a lawyer and a manager will each spend two hours learning the final rule, for a total of four hours for that firm. If a firm has more than one establishment, the total hours for that firm will increase. For example, if a food manufacturing firm has two establishments, then a lawyer and two managers would spend two hours each learning the final rule, for a total of six hours.

dollar.

Table 2 –Administrative Costs

Human Food Facilities				
Managers	**Hours**	**Total Hours**	**Wage**	**Total Cost**
31,263	2	62,526	$112.70	$7,046,680
Legal	**Hours**	**Total Hours**	**Wage**	**Total Cost**
22,346	2	44,692	$128.34	$5,735,771
Animal Food Facilities				
Managers	**Hours**	**Total Hours**	**Wage**	**Total Cost**
4,068	2	8,136	$112.70	$916,927
Legal	**Hours**	**Total Hours**	**Wage**	**Total Cost**
4,068	2	8,136	$128.34	$1,044,174
Rail Carriers				
Managers	**Hours**	**Total Hours**	**Wage**	**Total Cost**
574	2	1,148	$112.70	$129,380
Legal	**Hours**	**Total Hours**	**Wage**	**Total Cost**
574	2	1,148	$128.34	$147,334
Trucking Carriers				
Managers	**Hours**	**Total Hours**	**Wage**	**Total Cost**
74,487	2	148,974	$112.70	$16,789,370
Legal	**Hours**	**Total Hours**	**Wage**	**Total Cost**
74,487	2	148,974	$128.34	$19,119,323
Third Party Brokers				
Managers	Hours	Total Hours	Wage	Total Cost
13,618	2	27,236	$112.70	$3,069,497
Lawyer	Hours	Total Hours	Wage	Total Cost
7,335	2	14,60	$128.34	$1,882,748
	Total Hours	**460,442**	**Total Cost**	**$55,881,205**

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

Final § 1.906 outlines requirements for vehicles and transportation equipment used in the transportation of food. Final § 1.906(a) states that vehicles and transportation

equipment must be designed and of such material and workmanship as to be adequately cleanable for their intended use to prevent food from becoming unsafe. 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, and comments in response to the 2010 Advance Notice of Proposed Rulemaking (ANPRM) and the proposed rule, it is estimated that this requirement will not impose any additional cost on to the food transportation industry. Therefore, no additional cost is estimated for this requirement.

Final § 1.906(b) states vehicles and transportation equipment must be maintained in an appropriate sanitary condition for their intended use to prevent the food that they are transporting from becoming unsafe. It is estimated that this is a common business practice in food transportation. To the extent that this may result in extra training for employees, it is estimated that the cost of this requirement will be covered by the training requirement of § 1.910(a). We received no public comments on these assumptions; therefore, no additional cost is estimated for this requirement.

Final § 1.906(c) states that, in the case of food requiring temperature control for safety, vehicles and transportation equipment must be designed and maintained and equipped, as necessary, to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations. Based on information available to the Agency, in the form of guidance documents, industry best practices, and comments in response to the 2010 ANPRM, it is estimated that this 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 requirement will be

covered by § 1.910(a). We received no public comments on these assumptions; therefore, no additional cost is estimated for this requirement.

Final § 1.906(d) 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 for which it will be used becoming unsafe during transportation operations. 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 unsafe 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 was estimated in the PRIA that this requirement would not impose any additional cost on to the food transportation industry. We received no public comments that would lead us to change these cost assumptions; therefore, no additional cost is estimated for this requirement.

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

Final § 1.908 outlines requirements that apply to transportation operations. Final § 1.908(a)(1) states that, unless stated otherwise, requirements apply to shippers, carriers, loaders, or receivers and § 1.908(a)(2) would require that the responsibility for ensuring that transportation operations are carried out in compliance with all requirements in this final rule be clearly assigned to competent supervisory personnel.

Final § 1.908(a)(3)(i) requires that transportation operations must include taking effective measures (such as segregation, isolation, or the use of packaging) to protect food from contamination by raw foods and non-food items in the same load.

Furthermore, final § 1.908(a)(3)(ii) requires shippers, carriers, loaders, and receivers to take effective measures (segregation, isolation, or other protective measures like hand washing) to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations. It is estimated, for both §§ 1.908(a)(3)(i) and (ii), firms can make any needed adjustments in loading practices through proper awareness training. That is, it is estimated that safe and unsafe loading practices are equally costly; with the only additional cost being that of training employees to use safe practices. We acknowledge the possibility that costs may be underestimated here. For example, it is possible smaller truckloads may result from aligning practices with this requirement, 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. Furthermore, we received no public comments that would lead us to change these assumptions.

Because no data exist that would allow the estimate of the difference in loading times before and after training, it is estimated 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 final § 1.910(a) (training). We received no comments questioning our assumptions for this provision and no additional costs are estimated.

Final § 1.908(a)(3)(iii) requires that effective measures to ensure that food requiring temperature control for safety is transported under adequate temperature control. In the case of a refrigerated truck that has, for example, a non-functional refrigeration system,

this provision would allow the Agency to potentially consider the food unsafe, and possibly take action against the carrier. We received no public comments on the economics of this provision; therefore, no additional cost is estimated for this requirement.

Final § 1.908(a)(4) states that the type of food e.g., animal feed, pet food, human food, and its production stage, e.g. raw material, ingredient, or finished food, must be considered in determining the necessary conditions and controls for the transportation operation. We do not estimate any cost associated with this requirement due to the strong business incentive for firms to take these characteristics into account when transporting them.

Final § 1.908(a)(5) states that shippers, receivers, and carriers which are under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of paragraphs (b), (d), and (e) of this section may conduct transportation operations in conformance with common, integrated, written procedures that ensure the sanitary transportation of food consistent with the requirements of 1.908. These written procedures are subject to the records requirements in § 1.912(d).

As outlined in the preamble to this final rule, we received many comments addressing what was characterized as “intra-corporate” or “intra-company” shipments, and this provision is a response to those comments. While these non-economic comments stressed the need to avoid redundant recordkeeping for such shipments, none of the comments provided any information that would allow us to determine the number of firms that would be affected by this provision, the number of shipments that would be affected, or the savings in cost that would result.

Through an expert elicitation performed under contract with RTI (Ref 19), we attempted to acquire estimates of the number of shipments that could be considered "intracorporate" or "intra-company." This yielded a range of estimates, with the average being 34 percent. Here we use this percentage to estimate the number of shippers, carriers, loaders, and receivers that are under the ownership or operational control of a single legal entity. For the purpose of this analysis, we estimate that firms that are under the ownership or operational control of a single legal entity will not include railroads or brokers. Based on these assumptions, we estimate that 34,306 (34 percent of 100,901; that is 108,810 total firms minus 574 railroads and 7,335 third party brokers) firms would be considered integrated. We acknowledge the simplicity of this estimate. According to public comments we received, it is generally considered common practice for firms to have these procedures in place. To account for the possibility that not all of these estimated firms have these written procedures in place, we estimate that 10 percent of these 34,306 firms, or 343, would generate written procedures in response to this provision. Given the need to generate a document that addresses procedures that ensure sanitary transportation from shipper to receiver, we estimate these written procedures will take a first line supervisor two hours to generate at a wage rate of $55.32 (including 100 percent overhead), for a total of $37,957 for §1.908(a)(4), as shown in Table 3.

Table 3 – Estimated Cost of §1.908(a)(5)

Firms	**Hours**	**Wage**	**Total Cost**
343	2	$55.32	$37,957

Final § 1.908(a)(6) states that if a shipper, loader, receiver or carrier becomes aware of an indication of a possible material failure of temperature control or other

conditions that may render the food unsafe during transportation, the food shall not be sold or otherwise distributed, and these persons must take appropriate action, including, as necessary, communication with other parties, to ensure that the food is not sold or otherwise distributed, unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe. It is estimated that this requirement is aligned with current industry practice and does not represent new cost. Therefore, no costs are estimated related to final § 1.908(a)(6).

Requirements for shippers engaged in transportation operations

Final § 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. Furthermore, third party brokers, if they act as shippers, will incur shipper responsibilities and it is possible that these requirements will result in costs for at least some of these firms.

Final § 1.908(b)(1) requires shippers to specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the vehicle and transportation equipment, including any specific design specifications and cleaning procedures, to ensure that the vehicle is in appropriate sanitary condition for the transportation of the food, unless the shipper takes other measures in accordance with paragraph (b)(3) of this section. One-time notification shall be sufficient unless the design requirements and cleaning procedures desired by the shipper change based on the type of food being transported, or the conditions of shipment, in which case the shipper shall so notify the carrier in writing before the shipment. This is a disclosure of information that is subject to the records requirements of § 1.912(a).

It is estimated that shippers affected by this requirement include covered domestic manufacturing facilities (warehouses are not included as they are estimated to fill the role of loader in this analysis) that would be subject to either Subpart B or Subparts B and C of the preventive controls for human food final rule, as well as the estimated facilities that handle animal food (4,068), minus those firms that engage in integrated shipping (that is, those engaging in intracorporate shipments), plus third party brokers. The preventive controls for human food final rule does not have specific requirements that would allow us to estimate that the burden of final § 1.908(b)(1) is covered by that regulation. Therefore, we estimate 9,518 human food facilities + 4,068 animal facilities = 13,586 total facilities. Subtracting 34 percent of these to account for facilities that are estimated to have written procedures in place per § 1.908(a)(5) as an alternative to meeting the requirements of paragraph (b) leaves 13,586- 4,619 = 8,967 total estimated facilities that could be affected by this requirement. There are 13,618 brokers that could also be affected by this requirement, for a total of 22,585 total facilities.

In the PRIA, we estimated that, while it is common business practice for the shipper to specify the necessary condition of the vehicle or equipment conveyance, it was possible that not all shippers have practices entirely aligned with this requirement; therefore it was estimated that this could be a new requirement for some shippers (one percent of shippers and one percent of shipments).

However, as a result of information made available to FDA through a contract with RTI (Ref 19), we are adjusting our estimates. Information acquired from the expert elicitation yielded wide estimates of this practice. Estimates of the percentage of firms that engage in this information dissemination ranged from less than ten percent to 100

percent, with one expert stating that larger firms would be more likely to engage in this practice than smaller firms. For the purposes of this analysis, we take the average of these estimates, 55 percent, and apply that to the total number of facilities potentially affected by this provision, 22,585. Therefore, 22,585 – 12,422 = 10,163 estimated firms that will need to align practices with this requirement.

For firms with practices not already aligned with this requirement, there could be a one-time cost of developing and disclosing requirements, and an annual cost of disclosing these requirements to a carrier to account for changing requirements based on variations in food shipments. We have no information that would allow us to estimate the number of carriers used by each shipper or the number of different types of food facilities would ship. For simplicity, we estimate one facility would generate one set of relatively simple to assemble written specifications. In Table 4, 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, at a wage of $42.28 (including 100 percent overhead) (Ref 20).

The annual burden of this requirement is based on the estimated annual number of shippers that would adjust written specifications based on any changes in requirements. We have no way of estimating the number of shippers or brokers that would have to begin notifying carriers based on variations in foods shipped. However, to account for the possibility that this may happen some of the time, we estimate that one percent of total estimated facilities potentially affected by this requirement would incur an annual cost, or 22,585 *.01 = 226. The one-time cost to develop a written document is about

$214,849 and the annual cost is estimated at about $4,774 as shown in Table 4. Note that resulting numbers of firms and related costs are rounded to the nearest firm and dollar.

Table 4 – Estimated Cost of § 1.908(b)(1)

One Time Burden				
Facilities	**Hourly Burden to Develop Written Document**	**Total One-Time Hours**	**Hourly Wage***	**Total One Time Cost**
10,163	0.5	5,082	$42.28	$214,849
Annual Burden of Information Disclosure				
Firms	**Hourly Burden to Generate Written Description**	**Total Annual Hours**	**Hourly Wage***	**Total Annual Cost**
226	0.5	113	$42.28	$4,774

Final § 1.908(b)(2) requires shippers, in the case of food that requires temperature control to prevent the food from becoming unsafe under the conditions of shipment to specify, in writing, to carriers and to the loader when necessary, an operating temperature as necessary for the transportation operation, including, if necessary, the pre-cooling phase, unless the shipper takes other measures in accordance with 1.908(b)(5). This requirement does not apply to a carrier who transports the food in a thermally insulated tank. One-time notification shall be sufficient unless a factor, e.g. the conditions of shipment, changes necessitating a change in the operating temperature, in which case the shipper shall so notify the carrier in writing before the shipment. This disclosure of information is subject to the records requirements in § 1.912(a).

We do not have information that would allow us to narrow our estimates of shippers to those firms that would only ship food that requires temperature control to prevent the food from becoming unsafe under the conditions of shipment. Therefore, the

estimates of cost here are calculated in a way similar to § 1.908(b)(1).

It is estimated that shippers affected by this requirement include covered domestic manufacturing facilities (warehouses are not estimated to be included as they are estimated to fill the role of loader in this analysis) that would be subject to either Subpart B or Subparts B and C of the preventive controls for human food final rule, as well as the estimated facilities that handle animal food (4,068), minus those firms that engage in integrated shipping (that is, those engaging in estimated to have written procedures in place per § 1.908(a)(5) as an alternative to meeting the requirements of paragraph (b), plus third party brokers. The preventive controls for human food final rule does not have specific requirements that would allow us to estimate that the burden of final § 1.908(b)(2) is covered by that regulation. Therefore, we estimate 9,518 human food facilities + 4,068 animal facilities = 13,586 total facilities. Subtracting 34 percent of these to account for facilities that engage in intracorporate shipping leaves 13,586- 4,619 = 18,967 total estimated facilities that could be affected by this requirement. There are 13,618 brokers that could also be affected by this requirement, for a total of 22,585 total facilities.

For facilities with practices not already aligned with this requirement, there could be a one-time cost of developing and notifying carriers (and loaders, if necessary) of the condition of shipment, and an annual cost of notifying carriers (and loaders, if necessary) of the condition of shipment to account for changing requirements. We have no information that would allow us to estimate the number of carriers used by each shipper of food that requires temperature control. For simplicity, we estimate one facility would generate one set of written specifications and that these specifications are relatively

simple to assemble. In Table 5, 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, at a wage of $42.28 (including 100 percent overhead) (Ref 20).

While we did not receive any comments that specifically addressed our assumptions or estimates of cost of proposed § 1.908(b)(2), as a result of a modification to the regulatory text that allows for one-time notification, as well, as information made available to FDA through a contract with RTI (Ref 19), we are adjusting our estimates. Information acquired from the expert elicitation yielded wide estimates of the practice of this type of information dissemination. Estimates of the percentage of firms that engage in this information dissemination were, in general, high (75-100 percent), with one expert stating that larger carriers would provide written specification. Another expert said, regardless of size, these specifications would be oral. For the purposes of this analysis, to account for the possibility that this requirement would be a new requirement for some shippers, we estimate this would be a new cost for 25 percent of shippers affected by this requirement.

The annual burden of this requirement is based on the estimated annual number of shippers that would adjust written specifications based on any changes in requirements. We have no way of estimating the number of shippers or brokers that would have to begin notifying carriers (or loaders, if necessary) based on variations in shipping condition. However, to account for the possibility that this may happen some of the time, we estimate that one percent of total estimated facilities potentially affected by this requirement would incur an annual cost, or 22,585 *.01 = 226. The one-time cost to

develop a written document is about $214,849 and the annual cost is estimated at about $4,774 as shown in Table 5. Note that resulting numbers of firms and related costs are rounded to the nearest firm and dollar.

Table 5 – Estimated cost of § 1.908(b)(2)

One Time Burden				
Facilities	**Hourly Burden to Develop Written Document**	**Total One-Time Hours**	**Hourly Wage***	**Total One Time Cost**
5,646	0.5	2,823	$42.28	$119,362
Annual Burden of Information Disclosure				
Firms	**Hourly Burden to Generate Written Description**	**Total Annual Hours**	**Hourly Wage***	**Total Annual Cost**
226	0.5	113	$42.28	$4,774

.

Final § 1.908(b)(3) states that a shipper must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food. Measures to implement these procedures may be accomplished by the shipper or undertaken by the carrier or another party covered by the rule, under a written agreement subject to the records requirements of § 1.912(a).

This provision was not in the proposed rule; therefore, we did not receive comments about the related cost in the PRIA. It is not known how many shippers (estimated here to be human and animal food facilities minus the estimated number of facilities that operate under the same legal entity and who are estimated to have written procedures in place per § 1.908(a)(5) as an alternative to meeting the requirements of paragraph (b)) already have these simple and easy to assemble written procedures in

place. Therefore, we estimate that 50 percent of estimated affected firms will each spend 30 minutes to align current practices with these requirements. That is, (9,518+4,068) – 4,619 = 8,967 and 8,967 * .50 = 4,483 firms. Firm calculations are rounded to the nearest number, hourly calculations are rounded to the nearest tenth of an hour, the wage is estimated for a Cargo and Freight Agent, including 100 percent overhead (Ref 20), and the first year only cost is rounded to the nearest dollar. As shown in Table 6, this one-time cost is estimated at about $94,779.

Table 6 –Estimated cost of § 1.908(b)(3)

One Time Cost				
Facilities	Hourly Burden To Develop	Total Hours	Wage	Total Cost
4,483	.5	2,466	$42.28	$94,779

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

This provision was not in the proposed rule; therefore, we did not receive comments about the related cost in the PRIA. It is not known how many shippers (estimated here to be human and animal food facilities minus the estimated number of facilities that operate under the same legal entity who are estimated to have these simple and easy to assemble written procedures in place per § 1.908(a)(5) as an alternative to meeting the requirements of paragraph (b)) already have these written procedures in

place. Furthermore, we do not have information that would allow us to narrow the estimate of affected firms to those that would only ship food in bulk. Therefore, we estimate that 50 percent of estimated affected firms will each spend 30 minutes to align current practices with these requirements. That is, (9,518+4,068) – 4,619 = 8,967 and 8,967 * .50 = 4,483 firms. Firm calculations are rounded to the nearest number, hourly calculations are rounded to the nearest tenth of an hour, the wage is estimated for a Cargo and Freight Agent, including 100 percent overhead (Ref 20), and the first year only cost is rounded to the nearest dollar. As shown in Table 7, this one-time cost is estimated at about $94,779.

Table 7 –Estimated cost of § 1.908(b)(4)

One Time Cost				
Facilities	Hourly Burden To Develop	Total Hours	Wage	Total Cost
4,483	.5	2,466	$42.28	$94,779

Final § 1.908(b)(5) states that shippers of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures, subject to the records requirements of § 1.912(a), to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or undertaken by the carrier or another party subject to the rule, under a written agreement subject to the records requirements of § 1.912(a) and must include measures equivalent to those specified for carriers under § 1.908(e)(1)-(3).

This provision was not in the proposed rule; therefore, we did not receive comments about the related cost in the PRIA. It is not known how many shippers

(estimated here to be human and animal food facilities minus the estimated number of facilities that operate under the same legal entity and not subject to paragraph (b)) already have these simple and easy to assemble written procedures in place. Furthermore, we do not have information that would allow us to narrow the estimate of affected firms to those that would only ship food that requires temperature control for safety. Therefore, we estimate that 50 percent of estimated affected firms will each spend 30 minutes to align current practices with these requirements. That is, (9,518+4,068) – 4,619 = 8,967 and 8,967 * .50 = 4,483 firms. Firm calculations are rounded to the nearest number, hourly calculations are rounded to the nearest tenth of an hour, the wage is estimated for a Cargo and Freight Agent, including 100 percent overhead (Ref 20), and the first year only cost is rounded to the nearest dollar. As shown in Table 8, this one-time cost is estimated at about $94,779.

Table 8 –Estimated cost of § 1.908(b)(5)

One Time Cost				
Facilities	Hourly Burden To Develop	Total Hours	Wage	Total Cost
4,483	.5	2,466	$42.28	$94,779

Requirements for loaders engaged in transportation operations

Final § 1.908(c) outlines requirements for loaders.

Final § 1.908(c)(1) requires that, before loading food not completely enclosed by a container onto a vehicle or into transportation equipment, the loader must determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transportation of the food, considering, as appropriate, specifications provided by the shipper in accordance with § 1.908(b)(1). Based on information available to the Agency,

in the form of guidance documents, industry best practices, and comments in response to the 2010 ANPRM, it is estimated that this requirement is not likely to impose large costs on the food transportation industry. However, no data exist that would allow us to calculate the precise percentage of loaders for whom this would be a new requirement.

In the PRIA, our estimates were based on an assumption that one percent of shipments, for both rail and trucking, of food not completely enclosed by a container during transport, would be affected by the provision (there are 12.8 million of these shipments transported by trucks, and about 16,000 transported by rail). The wage is based on that of a Cargo and Freight Agent, including 100 percent overhead (Ref 20), and it is estimated that inspection will take 10 minutes for each shipment. We did not receive comments on this specific provision of the proposed rule; therefore, we are keeping these basic assumptions intact. We are uncertain how often railroads are "loaders"; however, to be conservative and to acknowledge any potential cost to the railroad industry, we include estimates of railroad shipments here.

These estimates are presented in Table 9, and note that resulting numbers of shipments and related costs are rounded to the nearest shipment and dollar, respectively.

Table 9 –Estimated cost of § 1.908(c)(1)

Shipment type	Shipments	Estimated Time	Total Hours	Wage	Total Cost
Truck	128,480	0.2	25,696	$42.28	$1,086,427
Rail	160	0.2	32	$30.51	$1,355
				Total Cost	**$1,087,782**

Final § 1.908(c)(2) states that, before loading food that requires temperature control for safety the loader must verify, considering, as appropriate, specifications provided by the shipper in accordance with § 1.908(b)(2), that each mechanically

refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, as necessary, and meets other sanitary conditions for food transportation. While we received many comments about temperature control in general, we received none that specifically addressed the costs of the verification of cold storage compartment preparation.

In the PRIA, it was estimated this provision may be a new activity for one percent of shipments, both rail and truck. While rail shipments will only be affected if a railroad meets the definition of "loader" in this final rule, to be conservative, we include estimates of rail shipments here. According to data from the Census (Ref 5), it is estimated that there are an annual total of about 18.8 million shipments of food requiring temperature control. Furthermore, it is estimated that it will take a cargo and freight agent five minutes for each verification at a wage rate of $42.28 per hour, including 100 percent overhead (Ref 20). Note that shipment calculations are rounded to the nearest number and cost is rounded to the nearest dollar.

Table 10 –Estimated Cost of § 1.908(c)(2)

Estimated Shipments				
Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
188,850	0.08	15,198	$42.28	$638,767
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
336	0.08	27	$42.28	$1,137
			Total Cost	**$639,905**

Requirements for receivers engaged in food transportation

Section § 1.908(d) outlines requirements for receivers engaged in food

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

While we received many comments about temperature controlled shipments in general, these provisions were not included in the proposed regulatory language; therefore, we do not have any comments that address the cost of this specific requirement. For the purposes of this analysis, we estimate that this is a common practice, due to the strong business incentive to verify temperature and confirm there are no signs of temperature abuse. However, it is possible that this may be a new practice for some receivers. This is estimated as a per shipment cost. We estimate that there are 18.8 million truck shipments and 33,621 rail shipments of food that require temperature control annually. Subtracting 34 percent of these shipments to account for firms who are estimated to have written procedures in place per § 1.908(a)(5) as an alternative to meeting the requirements of paragraph (d) leaves 12.4 million truck shipments and 22,190 rail shipments. For the purposes of this analysis, we estimate this may be a new requirement for receivers of one percent of these shipments and that the temperature abuse assessment may take a Cargo and Freight Agent (Ref 20) 15 minutes per shipment, which we believe is an adequate amount of time to perform a basic temperature check.. The wage includes 100 percent overhead.

Table 11 –Estimated Cost of § 1.908(d)

Estimated Shipments		

Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
124,641	0.25	31,160	$42.28	$1,317,458
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
222	0.25	55	$42.28	$2,345
			Total Cost	**$1,319,803**

Requirements for carriers engaged in food transportation

Final § 1.908(e) outlines requirements for carriers engaged in food transportation, when carriers and shippers have a written agreement that carriers are responsible for sanitary conditions during transport. Final § 1.908(e)(1) states that carriers must ensure that vehicles and transportation equipment meets any shipper's specifications and are otherwise appropriate to ensure that the food transported will not become unsafe.

In the PRIA, we estimated 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. Furthermore, we did not receive any comments that questioned this assumption or provided any additional information that would lead us to revise our assumption for this provision. Therefore, we do not estimate an additional cost on industry for this requirement.

Final § 1.908(e)(2)) states that, carriers must, once the transportation operation is complete, and if requested by the receiver, provide the operating temperature specified by the shipper in accordance with §1.908(b)(2); and if requested by the shipper or receiver, demonstrate that any specified operating temperature conditions during the transportation operation were maintained, in accordance with § 1.908(b)(2). This could be

accomplished by any means agreeable to the carrier and shipper such as presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment. Final § 1.908(e)(2) reflects current business practice according to public comments; therefore, no cost is estimated for this requirement.

Final § 1.908(e)(3) states that a carrier must pre-cool each mechanically refrigerated cold storage unit as specified by the shipper before offering a vehicle or transportation equipment for use for the transportation of food that requires temperature control for safety under the conditions of shipment as specified by the shipper in accordance with paragraph (b)(2).

Under contract with RTI (Ref 19), industry experts provided us with estimates regarding industry practices related to precooling. These experts estimated that the rate of precooling is high, with estimates ranging from 90-100 percent, or an average of 95 percent. In addition, these experts estimated that it would take from 45 minutes to two hours to precool a refrigerated unit, and this would use about one gallon of fuel per hour.

As in the analysis of the proposed rule, it is estimated that this provision affects refrigerated units used in trucking transport and is a per temperature controlled shipment cost. Therefore, the cost is estimated based on wages for CDL and non-CDL drivers (including 100 percent overhead) who spend 1 hour pre-cooling trucks, and a fuel cost based on 1.4 gallons of diesel fuel at the national average as of April 2015, $2.794 per gallon (Ref 21, 22, 23).[11]

[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

In the PRIA, cost was estimated based on precooling of one percent of transported refrigerated shipments. Based on the comments and information obtained from RTI, we adjust these estimates to five percent of affected refrigerated shipments (subtracting those transported by firms estimated to have written procedures in place per § 1.908(a)(5) as an alternative to meeting the requirements of paragraph (d)) which number about 12.4 million annually. That is, five percent of 12.4 million shipments, or about 623,206 shipments. Of this five percent, we estimated that 87 percent are handled by drivers with commercial drivers' licenses, and the remaining 13 percent are handled by drivers without commercial drivers' licenses. Fuel cost is estimated at $3.91 per shipment ($2.794 per gallon x 1.4 gallons = $3.91). 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 provision is shown in Table 12.

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

Shipments handled by CDL drivers	**Hours**	**Total Hours**	**Wage**	**Total Wage**	**Fuel Cost Per Shipment**	**Total Cost**
542,189	1	5421,89	$40.32	$21,861,074	$3.91	$23,981,901
Shipments handled by non-CDL drivers	**Hours**	**Total Hours**	**Wage**	**Total Wage**	**Fuel Cost Per Shipment**	**Total Cost**
81,017	1	81,017	$32.56	$2,637,907	$3.91	$2,954,812
					Total Cost	**$26,936,714**

to transport 16 or more passengers, including the driver. This includes (but is not limited to) tow trucks, tractor trailers, and buses.

Final § 1.908(e)(4) states that, if requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the last previous cargo transported on the vehicle. In the proposed rule, this requirement was for the carrier to provide information to the shipper that identifies as many as three previous cargoes transported on the vehicle. In response to public comment, this requirement has been revised to require carriers to provide information on the last previous cargo only on request. Because we believe this is aligned with current industry practice and because a carrier would not agree to take this responsibility from the shipper unless it had the information, we estimate this does not represent new cost to industry[12].

Final § 1.908(e)(5) states that, if requested by the shipper, 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. In the proposed rule, this requirement stated that a carrier who offers a bulk vehicle for food transportation must always provide to the shipper written documentation of the most recent cleaning, 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. In response to public comment, this requirement has been revised and, because we believe this is aligned with current industry practice and because a carrier would not agree to take

[12] Under contract with RTI (Ref 19), we obtained estimates provided by industry experts regarding industry practice. These experts stated that is was not common practice to provide information on the three previous cargoes; rather it was common practice to have information on the last one or two cargoes.

this responsibility from the shipper unless it had the information, we estimate this does not represent new cost to industry[13].

Final § 1.908(e)(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 final § 1.912(b). This provision is unchanged from the proposed rule. While we did not receive specific comments on the cost of the proposed provision, we did, under contract with RTI (Ref 19), obtain expert opinion on the practices related to this provision. These experts provided us with a variety of opinions on current industry practice: less than 50 percent of carriers have these written specifications in place; carriers only have specifications when backhauling; only shippers and consignees have specs, since carriers generally just provide a clean trailer; specifications are actually a mix of written and oral specifications, depending on the size of the fleet (if fleet>50, these would be written); or this is not common practice at all, specifications are oral and generally very poor.

As a result of this new information, we adjust our cost estimates from the proposed rule. This is estimated to be a per carrier record. According to data from the Department of Transportation, it is estimated that there are 74,487 motor carriers in the U.S. that transport food and would be affected by this rule (Ref 2). Furthermore, there are about 574 rail carriers in the U.S. that are covered by this rule (Ref 6). A one-time cost for document development will be calculated if the carrier is not estimated to have practices

[13] Under contract with RTI (Ref 19), we obtained estimates provided by industry experts regarding industry practice. These experts stated that "most" carriers provide this because shippers usually require it; but an exact estimate was not provided. In addition, shippers and receivers usually have written protocols regarding cleaning carriers have to meet.

in alignment with this requirement. The variation in expert opinion makes it difficult to estimate a precise number; however, for the purposes of this analysis, calculations are made based on the assumption that 50 percent of motor carriers, or 37,244, will develop new written procedures as a result of this this requirement. While this rule potentially covers 574 railroads, they are subject to these requirements only to the extent that they agree to take on these responsibilities from the shipper. Since we do not know how often that is the case, but believe it is infrequent, we maintain the assumption from the PRIA that one percent of rail carriers, or about six, will develop new written procedures. We also estimate that these written procedures will be relatively detailed; therefore, we estimate two hours per document. These estimates are presented in Table 13. 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 and includes 100 percent overhead (Ref 24).

Table 13 –Estimated Cost of § 1.908(d)(6)(i)

Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
37,244	2	74,487	$55.32	$4,120,621
Rail	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
6	2	11.48	$55.32	$635
			Total Cost	**$4,121,256**

Final § 1.908(e)(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 requirement is estimated the same way as the burden for § 1.908(e)(6)(i). This provision is unchanged from the proposed rule, except in the final rule the carrier must agree in writing to assume these responsibilities for the shipper. While we did not receive specific comments on the cost of the proposed provision, we did, under contract with RTI (Ref 19), obtain expert opinion on the practices related to this provision. These experts generally believed that it was common practice for carriers to have these written procedures. However, one noted that the requirement to record temperatures was not commonly part of this. As a result of this information, we do not estimate cost for this final provision.

Final § 1.908(e)(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(e)(4) and (5). This provision is unchanged from the proposed rule, except in the final rule the carrier must agree in writing to assume these responsibilities for the shipper. To be conservative, we estimate that carriers will agree to assume these responsibilities some of the time. While we did not receive specific comments on the cost of the proposed provision we did, under contract with RTI (Ref 19), obtain expert opinion on the practices related to this provision. These experts provided mixed responses: some thought it was uncommon for carriers to have these procedures, and one noted that carriers would follow the requirements of the shipper or

receiver. Others believed it was a common practice for carriers to have these written specifications in place.

This is estimated to be a per bulk carrier requirement. Again, it is estimated that there are 13,415 motor carriers in the U.S. that transport bulk food and would be subject to the requirements of this rule. Furthermore, there are about 574 rail carriers in the U.S. that are covered by this rule. A one-time cost for document development will be calculated if the carrier is not estimated to have practices in alignment with this requirement. Because we received varying opinions on industry practices, for the purposes of this analysis, calculations are made based on the estimate that 50 percent of carriers will develop written procedures as a result of this this requirement. While this rule potentially covers 574 railroads, they are subject to these requirements only to the extent that they fall under the definition of a carrier. Since we do not know how often that is the case, but believe it is infrequent, we maintain the assumption from the PRIA that one percent of rail carriers, or about six, will develop new written procedures. We also estimate these procedures will require some detail; therefore, we estimate two hours per document. These estimates are presented in Table 14 and firm calculations are presented rounded to the nearest number, wages include 100 percent overhead, and cost is rounded to the nearest dollar.

Table 14--Estimated Cost of Final § 1.906(e)(6)(iii)

Estimated Carriers				
Truck	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
6,708	2	13,415	$55.32	$742,118

Rail	Hourly Burden	Total Hours	Wage	Total Cost
6	2	11.48	$55.32	$635
			Total Cost	**$742,753**

Costs Related to Training

Final § 1.910(a) states carriers, when the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or part, for the sanitary conditions during transportation operations, must provide adequate training to personnel engaged in transportation operations that provides an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems and the responsibilities of the carrier under this part. The training must be provided upon hiring and as needed thereafter.

Final § 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).

Under contract with RTI, we obtained expert opinion on training of carrier personnel (truck drivers) (Ref 19). While respondents were, in general, reluctant to provide exact estimates (with one exception), they did provide general comments about training. For example, for tank trucks, training is very specific to the commodity that is being hauled. A few respondents stated that the numbers of drivers currently receiving training is low (one estimated the rate to be 25 percent), with one of these respondents

stating that the need to train drivers is limited because drivers are only allowed to do basic checks, such as checking seals or monitoring temperature.

Regardless of whether or not there is driver contact with food, training is required for firms that accept the responsibility for sanitary conditions during transportation. Often rail lines do not enter into agreements with shippers to be responsible for sanitary conditions during transportation, so employees of those rail lines would not be expected to be trained.

In the PRIA, we estimated that training costs would consist of one time costs to train any workers not estimated to be trained in accordance with the proposed requirements, and annual costs attributable to retraining or employee turnover. We did not receive any comments that would lead us to revise these assumptions; therefore, we continue to employ this approach for this final rule. However, based on feedback from industry, we amend our previous approach to estimating training cost in one major way. As outlined in the responses to comments, public comment expressed concern regarding the potential costs of the proposed training requirements, stating that a one size approach would be burdensome, and that a four hour long training (as estimated in the PRIA) for each worker would be especially costly. Therefore, in this final RIA, we estimate cost as one hour of a worker's time for awareness training, which includes 100 percent overhead. While in the PRIA, we estimated four hours of training at a cost of $50 per worker (truck or rail) for the course, the training materials are now estimated to have no cost to the carriers.

Based on the varied comments we received, it is difficult to estimate how many drivers would need training as a result of this requirement, although it is likely to be

greater than the one percent estimated for the PRIA. Furthermore, we estimate that, while turnover in the industry may be high, it is likely that a large proportion of this turnover represents truck drivers who move between carriers; however, we don't have information that would allow us to accurately estimate the number of drivers moving between firms (Ref 25). For the purposes of this analysis, truck drivers are divided into two large groups, CDL and non-CDL drivers, to account for differences in drivers' wages. As outlined in the data discussion, it is estimated that this final rule will affect approximately 2,222,212 truck drivers (1,518,705 CDL; 703,507 non-CDL).

Training Costs for Drivers

As shown in Table 12, the estimated first year cost of training is based on 75 percent of the total number of truck drivers covered by the rule requiring awareness training as a result of this requirement. The cost is simply one hour of wages per worker. We do not know the precise rate of turnover in this industry; however, based on comments from the public and from experts, it is likely to be very high. For the purposes of this analysis, annual training costs are based on an assumption of 90 percent of the first year estimate of drivers in need of training (Ref 25, 26). Otherwise, the annual training costs are estimated in the same manner as in the first year. Here, we estimate that training costs, current practices, and turnover rates are consistent across all carrier firms. The first year and annual costs of training these refrigerated carrier drivers are presented in Table 15.

Table 15 – Cost of Training Truck Drivers

First Year					
Truck Driver	Drivers Needing	Hours of	Total Hours	Wage	Total Cost

Type	Awareness Training	Training			
CDL	1,139,029	1	1,139,029	$40.32	$45,925,639
non-CDL	527,630	1	527,630	$32.56	$17,179,641
				Total Cost in the First Year	**$63,105,280**
Annual					
CDL	1,025,126	1	1,025,126	$40.32	$41,333,075
non-CDL	474,867	1	474,867	$32.56	$15,461,677
				Total Annual Cost	**$56,794,752**

It is estimated that costs related to training also cover any retraining needed to align carriers with the requirements of final § 1.906(b) (sanitary maintenance of vehicles), and § 1.906(c) (design and maintenance of vehicles), and § 1.908(a)(3)(i),(ii) (loading practices).

Training of Rail Workers

Railroads are only impacted by this final rule to the extent that they agree via contract to take on the responsibility for sanitary conditions during transportation. We have no empirical data on the number of railroads that would enter into such a contract or allow us to estimate the number of rail employees that may need training in sanitary transportation of food; however, we expect these numbers to be very small. In the data description, it is estimated that total 203,928 total rail employees may be affected by this final rule. In the PRIA, we estimated that one percent will require training in the first year, and one percent annually, to address retraining and employee turnover. To acknowledge any possible cost to the railroad industry, we use this estimate here. Wages are based on Rail Transportation Workers (all other), and include 100 percent overhead (Ref 27). Here we estimate the same cost of training as with drivers (one hour of wages

using materials that are of no cost to railroads). These costs are presented in Table 16. All employee calculations are rounded to the nearest number, and total cost is rounded to the nearest dollar.

Table 16 –Training Costs of Railroad Employees

First Year				
Number of Employees	**Number of Hours**	**Total Hours**	**Wage**	**Total Cost**
2,039	**1**	**2,039**	**$57.64**	**$117,544**
Annual				
Number of Employees	**Number of Hours**	**Total Hours**	**Wage**	**Total Cost**
2,039	**1**	**2,039**	**$57.64**	**$117,544**

Summary of Costs Related to § 1.910(a)

Total costs of § 1.910(a) in the first year are estimated to be $63.2 million and total annual training costs are estimated to be $56.9 million. The summary of training costs for drivers and railroad employees are presented in Table 17.

Table 17 –Summary of estimated cost of § 1.910(a)

First Year		
	Employees	Cost
Drivers	1,666,659	$63,105,280
Railroad Employees	2,039	$117,544

	Total	**$63,222,824**
Annual		
Drivers	1,499,993	$56,794,752
Railroad Employees	2,039	$117,544
	Total	**$56,912,296**

Final § 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 (Ref 24), including 100 percent overhead. It is estimated it will take five minutes (0.08 hour) for the supervisor to generate the record of training (for example, to print off a certificate of completion), 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 cost of this requirement is in Table 18.

Table 18 –Estimated Costs of § 1.910(b)

Recordkeeping Costs --Motor Carriers				
First Year				
Employees (CDL + non-CDL)	**Hours per Record**	**Total Hours**	**Wage**	**Total Cost**
1,666,659	0.08	133,333	$55.32	$7,375,966
Annual				
Employees (CDL+ non-CDL)	**Hours per Record**	**Total Hours**	**Wage**	**Total Cost**
1,499,993	0.08	119,999	$55.32	$6,638,369
Recordkeeping Costs --Rail Costs				
First Year				

Employees	**Hours Per Record**	**Total Hours**	**Wage**	**Total Cost**
2,039	0.08	163	$55.32	$9,025
Annual				
Employees	**Hours Per Record**	**Total Hours**	**Wage**	**Total Cost**
2,039	0.08	163	$55.32	$9,025
			Total First Year Cost	**$7,384,991**
			Total Annual Cost	**$6,647,395**

Records

Final § 1.912 addresses requirements related to records and retention of records that apply to shippers, receivers, loaders, and carriers engaged in food transportation. Final § 1.912(a)(1) states that shippers must retain records that demonstrate they provide specifications and operating temperatures to carriers as required by §§ 1.908(b)(1) and (b)(2) for a period of 12 months beyond the termination of the agreements with the carriers. 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. Furthermore, it is estimated these records could be kept in electronic form using existing methods. In the analysis of the cost of § 1.908(b)(1), it is estimated that 28,867 shippers – that is, animal food facilities and human food manufacturing facilities, along with third party brokers, would begin providing information to carriers regarding necessary sanitary requirements. Therefore, it is estimated that that same 28,867 shippers will generate a simple document to keep on file outlining the agreement to provide written sanitary requirements to carriers. This is estimated as a one-time cost.

In § 1.908(b)(2), the final rule directs shippers to provide to carriers and, as necessary, loaders notification of necessary temperature conditions. It is not possible to determine how many different shippers handle these shipments of food requiring temperature control; therefore, it is conservatively estimated that 25 percent of shippers (that is, manufacturing facilities) will generate an agreement to keep on file. As shown in Table 19, the total one-time cost of § 1.912(a) is about $762,810, at a wage of $42.28 (including 100 percent overhead), and 30 minutes to generate each agreement.

Table 19 – 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**
28,867	0.5	3,431	$42.28	$610,248
One-Time Burden, with Respect to Records in 1.908(b)(2)				
Shippers	**Hourly Burden**	**Total Hours**	**Hourly Wage**	**Total Cost**
7,217	.5	3,608	$42.28	$152,562
			Total Cost	**$762,810**

Final § 1.912(a)(2) states that shippers must retain records of written agreements and the written procedures required by § 1.908(b)(3), (4), and (5), for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations. Final § 1.912(b) states that carriers must retain records of the written procedures required by § 1.908(e)(6) for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations. Final§ 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 stops performing the respective duties. Final § 1.912(d) states any person subject to this rule must retain any

other written contracts/agreements assigning duties in compliance with this rule for a period of 12 months beyond when the agreements are in use in their transportation operations. Final § 1.912(e) states that shippers, receivers, loaders, and carriers which operated under a single legal entity in accordance with the provisions of § 1.908(a)(4) must retain records of their written procedures for a period of 12 months beyond when the procedures are in use in their transportation operations. Final § 1.912(f) states that shippers, receivers, loaders, and carriers must make all records required by this subpart available to a duly authorized individual upon request, and § 1.912(g) states that all records must be kept as original records, true copies, or electronic records. It is estimated that carriers will be able to retain records of written agreements and procedures using existing storage or electronic methods, and will be able to retrieve them upon request; therefore, no cost is estimated for these requirements. In addition, we estimate that required retention time for these records is consistent with current business practices; therefore, no cost is related to records retention.

Final § 1.912(h) states that records that are established or maintained to satisfy the requirements of this part are exempt from the requirements of part 11 of this chapter. This provision was added in response to public comment and consistent with other FSMA rulemakings; no new cost is associated with this provision. Final § 1.912(i) states that, except for the written procedures required by § 1.908(e)(6)(i), offsite storage is permitted if such records can be retrieved within 24 hours of request for official review. Written procedures required by § 1.908(e)(6)(i) must remain onsite as long as the procedures are in use. Finally, § 1.912(j) states that all records required by this subpart are subject to the disclosure requirements under part 20 of this chapter. It is estimated that these

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 firms to fulfill the requirements of these provisions.

Table 20 presents costs related to recordkeeping over all provisions of the regulation. As shown, the one-time cost related to recordkeeping is estimated to be $24.3 million with annual costs of about $29.3 million. This does not include costs related to waiver petitions.

Table 20- Recordkeeping Summary

One Time Costs					
Regulatory Provision	**Number of Records**	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
1.908(a)(5)	343	2	686	$55.32	$37,957
1.908(b)(1)	10,163	0.5	5,082	$42.28	$214,849
1.908(b)(2)	5,646	.5	2,823	$42.29	$119,362
1.908(b)(3)	4,483	0.5	2,242	$42.28	$94,779
1.908(b)(4)	4,483	.5	2,242	$42.28	$94,779
1.908(b)(5)	4,483	.5	2,242	$42.28	$94,779
1.908(e)(6)(i)	37,249	2	74,498	$55.32	$4,121,256
1.908(e)(6)(iii)	6,713	2	13,426	$55.32	$742,753
1.910(b)	1,668,698	0.08	133,496	$55.32	$7,384,991
1.912(a)	36,084	0.5	18,042	$42.28	$762,810
				Total Cost	**$13,548,952**
Annual Cost					
Regulatory Provision	**Number of Records**	**Hourly Burden**	**Total Hours**	**Wage**	**Total Cost**
1.908(b)(1)	226	0.5	113	$42.28	$4,774
1.908(b)(2)	226	0.5	113	$42.28	$4,774
1.910(b)	1,502,032	0.08	120,163	$55.32	$6,647,395
				Total Cost	**$6,656,943**

Waivers

Under § 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. Final § 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. Final § 1.918 describes requirements in a petition requesting a waiver in addition to those requirements under § 10.30, and final § 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 § 1.918. However, because this rule 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, loaders, or carriers. However, for the purposes of this analysis, it is estimated 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 $128.34, including 100 percent overhead (Ref 18). The estimated cost of submitting petitions for waivers is presented in Table 21.

Table 21—Cost of Waiver Petitions

First Year Cost				
Number of Recordkeepers	**Hourly Burden**	**Total Hours**	**Wage**	**Total First Year Cost**
6	24	144	$128.34	$18,481
Annual Cost				
Number of Recordkeepers	**Hourly Burden**	**Total Hours**	**Wage**	**Total Annual Cost**
2	24	48	$128.34	$6,160

Benefits

We presented a full discussion of potential benefits in the PRIA. This information has not changed; therefore, we direct the reader to the PRIA for that analysis (http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm416394.htm). A summary of this information is provided in the Summary of Costs and Benefits.

III. Summary of Costs and Benefits of the Final Rule

Summary of Costs

Table 22 summarizes the costs of the final rule by provision, in the first year and annually. The costs of the rule presented in this table are rounded to the nearest thousand. Average costs are based on the rounded costs of the regulatory provisions and are rounded to the nearest hundred. The first year costs are estimated at $162.7 million, and annual costs are estimated at $93.5 million. Note that much of the cost estimated is related to administrative costs, training, precooling of refrigerated trucks, and records. While we expect only some adjustments in industry practices as a result of the

requirements of this final rule, administrative measures will help ensure uniform practices across the riskiest shipments of food, reducing the possibility of a sanitation failure.

Table 22 -- Summary of Costs of Final Rule

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)	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
§ 1.908(a)(4)	0	0
§ 1.908(a)(5)	$38,000	0
§ 1.908(a)(6)	0	0
Costs related to requirements for shippers engaged in transportation operations		
§ 1.908(b)(1)	$215,000	$5,000
§ 1.908(b)(2)	$119,000	$5,000
§ 1.908(b)(3)	$95,000	$0
§ 1.908(b)(4)	$95,000	$0
§ 1.908(b)(5)	$95,000	0
Costs related to requirements for loaders		
§ 1.908(c)(1)	$1,088,000	$1,088,000
§ 1.908(c)(2)	$640,000	$640,000
Costs related to requirements for receivers engaged in food transportation		
§ 1.908(d)	$1,718,000	$1,718,000
Costs related to requirements for carriers engaged in food transportation		
§ 1.908(e)(1)	0	0
§ 1.908(e)(2)(i)	0	0
§ 1.908(e)(2)(ii)	0	0
§ 1.908(e)(3)	$26,937,000	$26,937,000
§ 1.908(e)(6)(i)	$4,121,000	$0
§ 1.908(d)(6)(ii)	$0	0
§ 1.908(d)(6)(iii)	$743,000	0
Costs related to training		
§ 1.910(a)	$63,223,000	$56,912,000
§ 1.910(b)	$7,385,000	$6,647,000

Additional costs related to records		
§ 1.912	$763,000	0
Costs related to waivers		
§ 1.914	$18,000	$6,000
Administrative Cost	$55,881,000	0
Total Costs	**$162,786,000**	**$93,560,000**
Average Cost Per Carrier (Trucking and Rail)	**$1,800**	**$1,200**
Average Cost Per Railroad	**$700**	**$200**
Average Cost for All Other Firms	**$700**	**$100**

In Table 23, the net present value of total rounded costs, that is, the present value of the aggregated rounded costs for the first ten years, is $865 million discounted at three percent, and $721 million discounted at seven percent. Total costs, annualized over a 10-year time horizon, are $117 million with a 7 percent discount rate or $113 million with a 3 percent discount rate.

Table 23-- Net Present Value and Annualized Costs of Final Rule

Net present value at 3 percent	$865 million
Net present value at 7 percent	$721 million
Annualized costs at 3 percent over 10 years	$113 million
Annualized costs at 7 percent over 10 years	$117 million
Annualized cost per carrier at 3 percent	$1,400
Annualized cost per carrier at 7 percent	$1,500
Annualized cost for all other firms at 3 percent	$182
Annualized cost for all other firms at 7 percent	$200

Summary of Benefits

Data are not available that would allow quantification of benefits of the final rule. If the data were available, benefits are unlikely to be greater than estimated costs given the lack of foodborne illnesses that have been traceable to unsanitary food transportation practices in recent years. However, we believe that, by ensuring that persons engaged in

the transportation of food that is at the greatest risk for contamination during transportation follow appropriate sanitary transportation practices, this final rule could reduce the future risks of recalls and adverse health effects related to contamination during, or previous contamination amplified during transport, by ensuring that transportation practices do not create food safety risks. Practices that create such risk include failure to properly refrigerate food requiring temperature control for food safety, the inadequate cleaning of vehicles between loads, and the failure to otherwise properly protect food during transportation. This final rule builds on current safe food transportation best practices and is focused on ensuring that persons engaged in the transportation of food that is at the greatest risk for contamination during transportation follow appropriate sanitary transportation practices.

Improved safety practices 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.

Uncertainty and Sensitivity Analysis of Costs

The uncertainty in this regulatory impact analysis is primarily related to the changes in industry practices that must occur in order for firms (carriers, shippers (including brokers), receivers, and loaders) to align with the requirements of this final rule. Where it was possible to state that we believed a requirement would not result in new cost for industry, we did so.

However, because of the variations in some responses from experts regarding industry practices, along with the overall lack of specific data provided by public comments, estimated costs in this analysis should be considered part of a range of possible costs. For example, it is possible that the percentage of carrier employees needing training is greater than 75 percent in the first year; however, it is not possible to estimate by how much. Because of the variation in estimates provided by our experts, it is also possible that the percentage of workers needing training is less than 75 percent; again, it is not possible to estimate by how much. It is also possible that firms have already made improvements to sanitary transportation practices since the publication of the proposed rule, which would (if not motivated by anticipation of this rule being finalized) cause our estimates of costs here to be overestimated. Because our point estimates, where we have them, are based on widely varying feedback, we do not believe we can say what a precise minimum or maximum estimate of total cost would be here. Therefore, to acknowledge this uncertainty, estimated rounded costs as presented in Table 22 are varied by 25 percent and are rounded to the nearest million.

Table 24-- Sensitivity Analysis of Costs (in millions)

	Low Estimate	High Estimate
Range of rounded first year costs	$122	$203
Range of rounded annual costs	$70	$117
Annualized at 3 percent	$84	$87
Annualized at 7 percent	$141	$146

Economic Effects on Small Entities

a. Regulated entities.

i. Number of small entities affected.

It is estimated that shippers, carriers, loaders, and receivers affected by this final rule include: domestic human food facilities that primarily handle commodities covered by this final 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; and railroad carriers with annual revenues of greater than $500,000.

FDA, for purposes of this rule-making, has defined a small business as one employing fewer than 500 persons except for motor vehicle carriers that are not also shippers and/or receivers. For these carriers, small business is defined as having less than $27.5 million in annual receipts, adjusted for inflation. The baseline year for calculating the adjustment for inflation is 2014.

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 29,351 human food facilities estimated to be affected by this rule are small, and 4,068 animal food facilities estimated to be affected by this rule are small. A small third party broker is also defined as having fewer than 500 employees; under this definition, 7,129 of the covered firms (operating 13,608 establishments) are small. The SBA defines motor carriers as small if total revenues are less than $27.5 million annually. Under that definition, 71,365 covered motor carrier firms 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 504 railroads are small by SBA standards.

ii. Costs to small entities. The annualized cost per carrier is estimated to be about $1,400 at three percent ($1,500 at seven percent) and $182 at three percent ($200 at seven percent) for all other firms covered by this rule. The data do not exist that would allow us to differentiate costs based on our definition of small; therefore, we estimate firms face identical costs regardless of size.

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.

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, and this final rule does provide exemptions for firms based on size. That is, this final rule exempts firms having revenues of less than $500,000 annually. This exemption results in 21,244 human food firms (operating 29,766 facilities), 7,335 brokerage firms (operating 13,618 establishments), 4,068 animal food facilities, 74,487 trucking carriers, and 574 rail carriers remaining covered by this rule, and these firms handle 95 percent of annual domestic shipments of food subject to the requirements of the rule.

It is possible that this exemption could be more extensive. For example, exempting firms that make less than $1 million annually would be consistent with the threshold in the Preventive Controls rules, which we otherwise believe would be a desirable endpoint, except for the difference between the two rules in the percentage of industry activities that would not be covered. Because we are not aware of any data

suggesting that food transported by smaller firms presents a lesser or greater risk, on a per-serving basis, than food transported by larger firms, we believe it is appropriate to assume that the risk is the same. Therefore, we assume that an increase in the percentage of shipments not covered by this rule constitutes an increase in overall risk. We estimated, in the proposed rule, that exempting firms with less than $500,000 total annual sales would result in excluding about 3% of shipments from coverage by this rule. We have since recalculated that the percentage of exempted shipments would be about 5% with a $500,000 exemption. Exempting firms with less than $1,000,000 total annual sales would result in excluding about 10% of shipments from coverage.

We weighed the cost to this category of small businesses against the risk of adulteration, and determined that excluding 5% of shipments from coverage by this rule was more appropriate than excluding 10% of shipments. Limiting excluded shipments to 5% would expose less food to any potential risk arising from non-coverage by this rule (i.e., reduce risk) and is consistent with the impact of exemption cutoffs in other food safety rulemakings. For example, the Preventive Controls rules excluded from coverage less than 0.6 percent of food. Three to five percent of non-coverage is near the limit of what we deemed to be appropriate for a food safety rule. Exempting firms with less than $1,000,000 in annual revenue would cause the amount of non-covered shipments to increase by more than three-fold from the amount we had envisioned under the proposed rule and twice what we are finalizing. We have determined that that would be inconsistent with the preventive control mandate in FSMA and SFTA

b. Longer compliance periods.

Small entities may find it more difficult to learn about and implement the requirements of this final rule 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 requirements, and set up record keeping. It will also delay the impact of the annual costs of compliance.

Therefore, FDA is giving motor carriers having less than $27.5 million in annual receipts that do not also ship or receive food, two years to comply with these requirements. Other carriers, loaders, shippers and receivers employing fewer than 500 persons also have 2 years to comply with this final rule. A breakdown of firms falling under the two year compliance period is presented in Table 25. Shippers, loaders, and receivers include human food facilities, animal food facilities, and third party brokers[14]. Note that 100,262 out of an estimated 108,810 total covered firms, or about 92 percent, will fall under this two year compliance period.

Table 25 -- Firms, by compliance period

	2 Year Compliance

[14] Note we estimate 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 does not exist that would allow the estimate of any multi-establishment animal food firms.

	Motor Carriers With Less Than $27.5 million in annual revenue, and any firm with <500 employees
Third Party Brokers (Facilities)	7,355 (13,618)
Motor Carriers	71,365
Shippers/Receivers/Loaders (Facilities)	20,968 (29,351)
Rail	574
Total Firms	100,065

FDA will publish 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.

References

1. Hennessy, Thomas W., M.D., Craig W. Hedberg, Ph.D., Laurence Slutsker, M.D., M.P.H., Karen E. White, M.P.H., John M. Besser-Wiek, M.S., Michael E. Moen, M.P.H., John Feldman, B.S., William W. Coleman, M.S., Larry M. Edmonson, M.P.H., Kristine L. MacDonald, M.D., M.P.H., and Michael T. Osterholm, Ph.D., M.P.H. "A National Outbreak of Salmonella Enteritidis Infections from Ice Cream." 1996. The New England Journal of Medicine, 334:1281-1286. http://www.nejm.org/doi/full/10.1056/NEJM199605163342001#t=article (accessed January 14, 2014).
2. United States Department of Transportation. Motor Carrier Identification Database. 2013.
3. Small Business Administration, Office of Advocacy. "Employer Firms, Establishments, Employment, Annual Payroll, and Receipts by Receipts Size of Firm and Major Industry, 2007". 2007. http://www.sba.gov/advocacy/849/12162 (accessed September 6, 2012).
4. Small Business Administration. "Small business size standards matched to North American Industry Classification System" 2012.http://www.sba.gov/content/table-small-business-size-standards (accessed November 3, 2013).
5. United States Census Bureau**.** 2012 Commodity Flow Survey. *American Fact Finder.* 2012. http://factfinder.census.gov/faces/nav/jsf/pages/searchresults.xhtml?refresh=t. (accessed June 9, 2015).
6. Association of American Railroads. "Railroad statistics" 2014.https://www.aar.org/StatisticsAndPublications/Documents/Documents/Forms/Allitems.aspx. (accessed March 3, 2015)
7. Railinc Business Services Division. "Reference guide for the 2010 surface transportation board carload waybill sample" 2012. http://www.stb.dot.gov/stb/industry/econ_waybill.html (accessed November 3, 2013).
8. Surface Transportation Board, United States Department of Transportation. "FAQs" 2013. http://www.stb.dot.gov/stb/faqs.html (accessed November 4, 2013)
9. Eastern Research Group. "2010 Nationwide Survey of Food Industry Safety Practices, Draft final report". January 10, 2011. Contract No. 223-01-2461, task order 7.
10. American Trucking Association. "American Trucking Trends 2012". 2012. Arlington,VA .
11. Thompson, James F., Brecht, Patrick E. and Hinsch, Tom." Refrigerated trailer transport of perishable products" University of California, Agricultural and Natural Resources, Publication 21614, 2002.
12. Freund, Deborah, email to Olu Ajayi, Brian Routhier, and Luke Loy, regarding food shipment weights, January 16, 2014.
13. Federal Highway Administration, United States Department of Transportation . "Freight Management and Operations".http://ops.fhwa.dot.gov/freight/sw/overview/index.htm" (accessed July 10, 2013).
14. United States Department of Agriculture and United States Department of Transportation. "Study of Rural Transportation Issues" April 2010. http://www.ams.usda.gov/RuralTransportationStudy.

15. United States Department of Transportation. “Motor Carrier Identification Report, MS-150”. http://www.fmcsa.dot.gov/documents/forms/r-l/MCS-150-Instructions-and-Form.pdf (accessed December 12, 2012).
16. United States Railroad Retirement Board. “Total Employment by State, Class of Employer and Last Railroad Employer, 2010”. May 10, 2012. http://www.rrb.gov/act/Yearly_Data.asp (accessed February 15, 2013)
17. Bureau of Labor Statistics. *Occupational Employment and Wages, 11-1021 General and Operations Managers*. May 2014, Washington, DC.http://data.bls.gov/cgi-bin/print.pl/oes/current/oes111021.htm. (accessed May 7, 2015)
18. Bureau of Labor Statistics. *Occupational Employment and Wages, 23-1011 Lawyers*. May 2014, Washington, DC. http://data.bls.gov/cgi-bin/print.pl/oes/current/oes231011.htm. (accessed May 7, 2015)
19. RTI International. “Food Safety During Transportation, Final Report”. September 2014. Contract HHSF-223-2007-10273G, task order 18.
20. Bureau of Labor Statistics. Occupational Employment and Wages, 43-5011 Cargo and Freight Agents. May 2014, Washington, DC. http://data.bls.gov/cgi-bin/print.pl/oes/current/oes435011.htm. (accessed May 7, 2015)
21. Bureau of Labor Statistics. Occupational Employment and Wages, 53-3032 Heavy and Tractor-Trailer Truck Drivers. May 2014, Washington, DC. http://data.bls.gov/cgi-bin/print.pl/oes/current/oes533032.htm. (accessed May 7, 2015)
22. Bureau of Labor Statistics. Occupational Employment and Wages, 53-3033 Light Truck or Delivery Services Drivers. May 2014, Washington, DC. http://data.bls.gov/cgi-bin/print.pl/oes/current/oes533033.htm. (accessed May 7, 2015)
23. United States Energy Information Administration. “Petroleum & Other Liquids: Gasoline and Diesel Fuel Update” August, 2013. http://www.eia.gov/petroleum/gasdiesel/ (accessed August 21, 3013)
24. Bureau of Labor Statistics. Occupational Employment and Wages, 53-1031 First-Line Supervisors of Transportation and Material-Moving Machine and Vehicle Operators. May 2014, Washington, DC. http://data.bls.gov/cgi-bin/print.pl/oes/current/oes531031.htm. (accessed May 7, 2015)
25. Badkar, Mamta. “There’s a Huge Shortage of Truck Drivers in America – Here’s Why the Problem is Only Getting Worse”. Business Insider. August 4, 2014. http://www.businessinsider.com/americas-truck-driver-shortage-2014-7 (accessed June 22, 2015).
26. Cassidy William B. “US Truck Driver Shortage Getting Worse, Turnover Figures Show”. Journal of Commerce. April 1, 2015. http://www.joc.com/trucking-logistics/labor/us-truck-driver-shortage-getting-worse-turnover-figures-show_20150401.html (accessed 06/22/2015).
27. Bureau of Labor Statistics. Occupational Employment and Wages, 53-4099 Rail Transportation Workers, All Others. May 2014, Washington, DC.http://data.bls.gov/cgi-bin/print.pl/oes/current/oes534099.htm. (accessed May 7, 2015)