Sanitary Transportation Disclosure, Recordkeeping and Reporting Requirements for Human and Animal Food

0910-NEW
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SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA or we) is proposing to establish requirements for shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. This action is part of our larger effort to focus on prevention of food safety problems throughout the food chain and is part of our implementation of the Sanitary Food Transportation Act of 2005 (2005 SFTA) and the FDA Food Safety Modernization Act of 2011 (FSMA).

The 2005 SFTA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), in part, by creating a new section 416 of the FD&C Act (21 U.S.C. 350e). Section 416(b) of the FD&C Act directed us to issue regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use prescribed sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. Section 416(c) of the FD&C Act specifies that we shall prescribe those practices that we determine are appropriate relating to: (1) Sanitation; (2) packaging, isolation, and other protective measures; (3) limitations on the use of vehicles; (4) information to be disclosed to carriers and to manufacturers; and (5) recordkeeping. Section 416(c) of the FD&C Act also states that the regulations are to include a list of nonfood products that may, if shipped in a bulk vehicle, render adulterated food that is subsequently transported in the same vehicle and a list of nonfood products that may, if shipped in a motor vehicle or rail vehicle (other than a tank vehicle or bulk vehicle), render adulterated food that is simultaneously or subsequently transported in the same vehicle. Section 111(a) of FSMA, directed us to issue these sanitary transportation regulations.

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

section 416. FDA's authority for this proposed rule also derives from sections 402(a)(1), (a)(3), (a)(4), and 701(a) of the FD&C Act (21 U.S.C. 371(a)).

On February 5, 2014, FDA published in the Federal Register a proposed rule to establish regulations at part 1 (21 CFR part 1), subpart O, entitled "Sanitary Transportation of Human and Animal Food" (79 FR 7005) (the Sanitary Transportation proposed rule). The proposed rule, if finalized as proposed, would require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. The goal of the proposed rule is to ensure that transportation practices do not create food safety risks. Practices that create such risk include failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food during transportation. The proposed rule builds on current safe food transport practices and is focused on ensuring that persons engaged in the transportation of food that is at the greatest risk for contamination during transportation follow appropriate sanitary transportation practices. It otherwise would allow the transportation industry to continue to use best practices concerning cleaning, inspection, maintenance, loading and unloading of, and operation of vehicles and transportation equipment, that it has developed to ensure that food is transported under the conditions and controls necessary to prevent contamination and other safety hazards.

If the rule is finalized as proposed, persons engaged in the transportation of food would be required to implement measures to prevent contamination or microbial spoilage during transportation, including training, and to maintain records concerning their compliance with the rule. The proposed rule would also establish procedures for affected persons to request a waiver of any requirement.

We request OMB approval for the following proposed collection of information requirements:

21 CFR 1.908(b)(1) – Third Party Disclosure *(Shipper to Carrier)*
Would require shippers to specify to the carrier, in writing, all necessary sanitary requirements for the carrier's vehicle and transportation equipment.

21 CFR 1.908(b)(3) – Third Party Disclosure *(Shipper to Carrier)*
Would require shippers of foods subject to temperature control requirements to specify to the carrier, in writing, the temperature conditions necessary during the transportation operation.

21 CFR 1.908(b)(5) – Third Party Disclosure *(Shipper to Receiver)*
If the shipper and carrier have agreed in writing under § 1.908(d)(2)(ii) that the shipper is responsible for ensuring that the food was held under acceptable temperature conditions during transportation operations, would require the shipper to assume the requirements applicable to the carrier in § 1.908(d)(2)(i) with respect to providing a demonstration to the receiver.

21 CFR 1.908(b)(5) – Recordkeeping *(Shipper)*
If the shipper and carrier have agreed in writing under § 1.908(d)(2)(ii) that the shipper is responsible for ensuring that the food was held under acceptable temperature conditions during

transportation operations, would require the shipper to assume the corresponding records requirements of §§ 1.908(d)(6)(ii) (develop and implement written procedures for maintaining appropriate temperature conditions during the transportation operation) and 1.912(b) (retain records of any written agreements).

21 CFR 1.908(d)(2)(i) – Third Party Disclosure *(Carrier to Shipper)*
Would require carriers of food subject to temperature control requirements to demonstrate to shippers and, upon request, to receivers that they have maintained temperature conditions during the transportation operation consistent with those specified by the shipper in accordance with § 1.908(b)(3).

21 CFR 1.908(d)(2)(i) – Recordkeeping *(Carrier)*
Would require carriers to retain records that demonstrate that they have maintained appropriate temperature conditions during the transportation operation (printouts of a time/temperature recording device or a log of temperature measurements taken during the shipment).

21 CFR 1.908(d)(2)(ii) – Third Party Disclosure *(Carrier to Receiver)*
Would require carriers, which have agreed in writing with the shipper that the shipper is responsible for monitoring the temperature conditions during the transportation operation, to provide the written agreement to receivers, upon request.

21 CFR 1.908(d)(4) and (5) – Third Party Disclosure *(Carrier to Shipper)*
Would require carriers that offer a bulk vehicle for food transportation to provide information to shippers about the three previous cargoes transported in the vehicle and the most recent cleaning of the vehicle, except as provided.

21 CFR 1.908(d)(6) – Recordkeeping *(Carrier)*
Would require carriers to develop and implement written procedures that specify its practices for cleaning, sanitizing, and inspecting vehicles and transportation equipment; its practices for maintaining temperature conditions during the transportation operation consistent with those specified by the shipper; and, if the carrier offers a bulk vehicle, its practices for identifying and communicating to the shipper the three previous cargoes transported in the vehicle and the describes the most recent cleaning procedure used on the bulk vehicle, except as provided.

21 CFR 1.910 – Recordkeeping *(Carrier)*
Would require carriers to provide training to personnel engaged in transportation operations, upon hiring and as needed thereafter; would require carriers to establish and maintain records documenting the training; would set forth the information that must be included in the records.

21 CFR 1.912(a) – Recordkeeping *(Shipper)*
Would require shippers to retain records that demonstrate that they provide information to carriers as required by § 1.908(b)(1) and (3) as a regular part of their transportation operations for a period of 12 months beyond when the shipper is subject to any requirement to provide such information.

21 CFR 1.912(b) and (c)– Recordkeeping *(Carrier)*
Would require carriers to maintain records of any written agreements required by §§ 1.908(d)(2)(ii) and of the written procedures required by § 1.908(d)(6), for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations; would require carriers to maintain records of personnel training required by § 1.910(b), for a period of 12 months beyond when the person identified in any such records continues to perform the duties for which the training was provided.

21 CFR 1.912(d) through (g) – Recordkeeping (*Access to Records and Record Retention)*
Would require all records required by subpart O to be available for official review promptly upon oral or written request; would set forth the requirements for copies and electronic records; would set forth the permitted timing and the access requirements for offsite storage of records, except written procedures required by § 1.908(d)(6), which must remain onsite as long as the procedures are in use in transportation operations; and, would set forth that all records required by subpart O are subject to the disclosure requirements under part 20 (21 CFR part 20).

21 CFR 1.916 – Reporting
Would require any person seeking a waiver of a requirement in subpart O to submit a petition under § 10.30 (21 CFR 10.30).

21 CFR 1.918 – Reporting
Would set forth the information that must be included in the Statement of Grounds in a petition requesting a waiver, in addition to the requirements set forth in § 10.30.

2. Purpose and Use of the Information Collection

The potential exists for food to be transported under conditions that expose the food to the risk of contamination or other safety hazards such as microbial spoilage associated with improper temperature control. The Sanitary Transportation proposed rule, if finalized as proposed, would establish requirements for sanitary transportation practices for food to prevent contamination or spoilage.

Proposed Disclosure and Recordkeeping Requirements

Written procedures, disclosures and recordkeeping are necessary for the success of the proposed prevention measures. Without them, shippers and carriers would not be able to implement the contamination and spoilage prevention measures effectively and receivers and food safety inspectors would not be able to determine whether the proposed requirements were followed.

The rule would require shippers to disclose in writing to carriers the sanitary requirements for vehicles as well as temperature requirements for foods requiring appropriate temperature control. The proposed rule would require carriers to disclose to shippers and receivers records demonstrating that they have maintained appropriate temperature control during the transportation operation. Carriers would also be required to disclose to shippers using

bulk transportation services the previous cargoes hauled in the bulk vehicle and the intervening cleaning of the vehicle. Carriers would be required to develop and implement written procedures that specify its practices for cleaning, sanitizing and inspecting equipment, as well as its practices for training personnel engaged in food transportation operations. Shippers and carriers would be required to establish and maintain recordkeeping as noted in each of the proposed provisions listed in Section 1 of this document.

Written procedures, disclosures and records would be compiled and retained onsite by shippers and carriers and examined there periodically by FDA inspectors. Documents are essential for shippers, carriers, receivers, and food safety inspectors to be able to determine whether food is adulterated because it has been transported under conditions that are not in compliance with the proposed sanitary food transportation regulations. Shippers, carriers, receivers, FDA and other regulatory officials will use the written procedures, disclosures and records that would be required by the proposed rule to assess the risk of contamination of food or microbial spoilage.

Proposed Reporting Requirements

As noted above, proposed §§ 1.916 and 1.918 would require that any person seeking a waiver of the requirements for written procedures, disclosures and records submit a petition under § 10.30. The information the person would be required to submit includes a description of the waiver requested, including the persons, vehicles, food, or nonfood product(s) to which the waiver would apply and the requirement to be waived; and information demonstrating that the waiver, if granted, would not result in the transportation of food under conditions that would be unsafe for human or animal health or otherwise be contrary to the public interest. FDA would use the information to determine whether to grant the waiver, and whether to impose conditions if a waiver is granted.

Description of Respondents: The respondents to this proposed information collection are domestic and foreign shippers and carriers of human and animal food (except fully packaged shelf-stable foods, live food animals and raw agricultural commodities (RACs) when RACs are transported by farms) except those engaged in food transportation operations that have less than $500,000 in total annual sales. Respondents are from the private sector (for profit businesses).

3. Use of Improved Information Technology and Burden Reduction

Proposed Disclosure and Recordkeeping Requirements

Firms are free to use whatever forms of information technology may best assist them in preparing written procedures, making written disclosures, retaining the appropriate records and making these available to regulatory officials. The proposed rule does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. However, because the proposed rule exempts very small firms with less than $500,000 in total annual sales FDA estimates that 100% of the respondents will use electronic means to fulfill the proposed disclosure and recordkeeping requirements.

Proposed Reporting Requirements

Firms seeking a waiver must file a Citizen Petition under 21 CFR 10.30. FDA has established a docket on www.regulations.gov for the electronic submission of citizen petitions. The docket number established for this purpose is FDA-2013-S-0610. We estimate that 100% of waiver requests will be filed electronically.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency that collects this information. There is no duplication of recordkeeping requirements. Proposed § 1.904 would define "food" to mean food as defined in section 201(f) of the FD&C Act, which includes raw materials and ingredients. This definition is identical to the definition of "food" in the proposed preventive controls rules for human and animal food. To ensure that the reader understands the scope of food covered by this proposed rule, this definition provision would also state consistent with the definition of “food” in the FD&C Act, food includes animal food and food subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act administered by the Food Safety and Inspection Service (FSIS) of the USDA. FDA notes that, to prevent duplication of effort, its compliance policy is to inform FSIS when an apparent violation is encountered involving a meat or poultry product that has left a USDA inspected establishment (FDA 2005).

FSIS carries out in-commerce surveillance activities to verify that entities whose business activities involve FSIS-regulated products prepare, store, transport, sell, offer for sale or transportation, import, and export such products in compliance with FSIS statutory and regulatory requirements. FSIS has issued guidance for the safe transportation and distribution of meat, poultry and egg products (FSIS 2005), however, they do not have requirements that directly address transportation operations for these foods. This rulemaking will complement FSIS's efforts to promote the application of sanitary food transportation practices for FSIS-regulated meat, poultry, and egg products. We intend to work together with FSIS to facilitate this shared objective while carrying out our respective regulatory programs.

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

5. Impact on Small Businesses or Other Small Entities

FDA estimates that, among firms analyzed in the RIA, ninety-eight percent (98%) of shippers/receivers and ninety-five percent (95%) of carriers are small businesses. FDA proposes to assist small businesses by exempting *very* small firms with less than $500,000 in total annual sales and providing staggered compliance dates for other small businesses. FDA believes that it is reasonable to allow for 1 year after the date of publication of the final rule for businesses other than small businesses to come into compliance with the new requirements. FDA also believes

that it is reasonable to allow for 2 years after the date of publication of the final rule for small businesses to come into compliance with the new requirements. Proposed § 1.904 would define "small business" to mean "a business, subject to proposed § 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 proposed § 1.900(a) having less than $25,500,000 in annual receipts, consistent with the size based standard that has been established by the U.S. Small Business Administration for truck transportation firms."

6. Consequences of Collecting the Information Less Frequently

Proposed Disclosure and Recordkeeping Requirements

Disclosure and recordkeeping will occur on an occasional basis. Written procedures, written disclosures, and records of actions taken due to each provision are essential for firms to implement the contamination and spoilage prevention measures effectively. Without the procedures, disclosures and records, shippers, carriers, receivers, and food safety inspectors would be unable to assess the risk of contamination of food or microbial spoilage and FDA would be unable to determine whether food is adulterated because it has been transported under conditions that are not in compliance with the proposed sanitary food transportation regulations.

Proposed Reporting Requirements

Reporting will occur on an occasional basis. Only those firms seeking the waiver provided for in §§ 1.916 and 1.918 will submit information to FDA. If the collection is not conducted, the waiver will not be available to interested firms.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA provided an opportunity for public comment on the information collection provisions of the proposed rule, which published in the Federal Register of February 5, 2014 (79 FR 7005). The proposed rule requested that comments be submitted directly to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB).

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The proposed rule does not contain an assurance of confidentiality with regard to the procedures, disclosures, recordkeeping or petitions for waiver. Firms seeking the waiver provided for in proposed §§ 1.916 and 1.918 would submit a citizen petition to the publicly available docket on www.regulations.gov. However, records that may be consulted during FDA inspections are subject to FDA's regulations on the release of information, 21 CFR part 20. Confidential commercial information is protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). To the extent 21 CFR 20.64 applies, the FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the burden for this information collection as follows:

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection in two parts: a recordkeeping burden, in Table 1; and a reporting (submission) burden, in Table 2. Specific calculations are discussed below, while numbers in each table have been rounded to the nearest whole number.

The estimated hourly recordkeeping burden is 5,219.82 one-time hours and 119,642.72 annual hours. Furthermore, the estimated one-time submission burden is 144 hours and the annual submission burden is 48 hours, for a total estimated hour burden of 125,054.54. FDA estimates the recordkeeping burden for this information collection as follows:

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

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

The one-time cost of development an agreement (such as a contract) to establish responsibility for disclosure of previous cargoes as required by proposed § 1. 908(d)(4), is estimated at the bulk carrier level. It is estimated that one recordkeeper for about 111 firms

(110.99) will spend 15 minutes developing an agreement. Therefore, .25 hour x 110.99 = 27.75 one time hours for proposed § 1.908(d)(4), as shown in line 3.

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

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

The one-time cost of development of written procedures related to temperature control, as required by proposed § 1.908(d)(6)(ii), is estimated at the refrigerated carrier level. It is estimated that one recordkeeper for about 241 firms (240.70) will spend 2 hours developing written procedures. Therefore, 2 hours x 240.70= 481.40 one time hours for proposed § 1.908(d)(6)(ii), as shown in line 6.

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

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

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

The total one-time hourly recordkeeping burden is 5,219.82 hours. By rounding individual numbers to the nearest whole number, the burden is estimated to be 5,222 hours.

The annual cost of disclosing necessary sanitation requirements, as required by proposed § 1.908(b)(1), is estimated at the shipment level. It is estimated that one recordkeeper for each of about 541,064 shipments (541,063.93) will spend 5 minutes disclosing sanitation requirements. Therefore, .08 hour x 541,063.93 shipments = 43,285.11 annual hours for proposed § 1.908(b)(1), as shown in line 10.

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

The annual cost of disclosing temperature, as required by proposed § 1.908(d)(2)(i), is estimated at the shipment level. It is estimated that one recordkeeper for each of about 173,365 shipments (176,365.39) will spend 5 (.08 hour) minutes disclosing temperature. Therefore, .08 hour x 176,365.39 shipments = 14,109.23 annual hours for proposed § 1.908(d)(2)(i), as shown in line 12.

The annual cost of disclosing previous cargoes, as required by proposed § 1.908(d)(4), is estimated at the shipment level. It is estimated that one recordkeeper for each of about 324,797 bulk shipments (324,797.32) will spend 5 (.08 hour) minutes disclosing sanitation requirements. Therefore, .08 hour x 324,797.32 shipments = 25,983.79 annual time hours for proposed § 1.908(d)(4), as shown in line 13.

The annual cost of disclosing recent cleaning of bulk vehicles, as required by proposed § 1.908(d)(5), is estimated at the shipment level. It is estimated that one recordkeeper for each of about 324,797 bulk shipments (324,797.32) will spend 5 (.08 hour) minutes disclosing recent cleaning of bulk vehicles. Therefore, .08 hour x 324,797.32 shipments = 25,983.79 annual hours for proposed § 1.908(d)(5), as shown in line 14.

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

The annual hourly recordkeeping burden is 119,642.72 hours. By rounding individual numbers to the nearest whole number, the burden is estimated to be 119,643.

Table 1 –Estimated First Year Only and Annual Recordkeeping Burdens

First Year Only						
	Proposed 21 CFR Section/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
1	**Written Sanitation Requirements 1.908(b)(1)**	273 (273.29)	1	273	0.50	137
2	**Agreement establishing responsibility for temperature monitoring 1.908(b)(5)**	273 (273.29)	1	273	0.25	68
3	**Agreement regarding disclosure of previous cargoes 1.908(d)(4)**	111 (110.99)	1	111	0.25	28
4	**Agreement regarding disclosure of bulk vehicle cleaning 1.908(d)(5)**	111 (110.99)	1	111	0.25	28
5	**Written procedures, cleaning and sanitation 1.908(d)(6)(i)**	563 (562.80)	1	563	2.00	1,126
6	**Written procedures, temperature control 1.908(d)(6)(ii)**	241 (240.70)	1	241	2.00	482
7	**Written procedures, bulk vehicles 1.908(d)(6)(iii)**	111 (110.99)	1	111	2.00	222
8	**Training Records 1.910(b)**	14,485 (14,285.43)	1	14285	0.20	2,857
9	**Records pertaining to disclosure of information 1.912(a)**	547	1	547	0.50	274
First Year Only Hourly Recordkeeping Burden						5,222

Recurring Recordkeeping Burden						
	Proposed 21 CFR Section/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
10	**Sanitation Requirements 1.908(b)(1)**	541,064 (541,063.93)	1	541,064	0.08	43,285
11	**Necessary temperature conditions 1.908(b)(3)**	92,797 (92,796.5)	1	92,797	0.08	7,424
12	**Temperature disclosure 1.908(d)(2)(i)**	176,365 (176,365.39)	1	176,365	0.08	14,109
13	**Disclosure of previous cargoes 1.908(d)(4)**	324,797 (324,797.32)	1	324,797	0.08	25,984
14	**Disclosure of bulk cleaning 1.908(d)(5)**	324,797 (324,797.32)	1	324,797	0.08	25,984
15	**Training Records 1.910(b)**	14,285 (14,285.43)	1	14,285	0.2	2,857
Annual Hourly Recordkeeping Burden						119,643

The one-time and annual hourly burdens related to submission of waiver petitions (proposed § 1.914) are presented in Table 2.

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

Table 2 –First Year and Annual Reporting Burden

Estimated First Year Only Reporting Burden						
	Proposed 21 CFR Section/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1	§ Waiver Petitions 1.914	6	1	6	24	144
Estimated Annual Reporting Burden						
	Proposed 21 CFR Section/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
2	Waiver Petitions § 1.914	2	1	2	24	48

This proposed rule also refers to previously approved collections of information found in FDA regulations. The collections of information in § 10.30 have been approved under OMB control number 0910-0183.

b. Annualized Cost Burden Estimate

We estimate that the burden of this information collection results in a total of 125,054.54 hours annually. The salary that a company will pay an employee to respond to the information collection is considered a cost burden. We estimate that three types of respondent employees will be responsible for information collection: cargo and freight agents; first-line supervisors of transportation and material-moving machine and vehicle operators; and, managerial or professional employees such as plant managers, food safety specialists, and in-house legal counsel. We base our estimate of the wage rates on the Bureau of Labor Statistics, Occupational Employment Statistics, May 2012, National Industry-Specific Occupational Employment and Wage Estimates. Wages are increased by 50 percent to account for overhead.

Table 3–Cost Burden Estimate			
First Year Only			
Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Cargo and Freight Agent	533.76	$30.51	$16,285.02
First-Line Supervisors of Transportation and Material-Moving Machine and Vehicle Operators	4,686.06	$39.98	$187,348.67
Managerial or Professional Employees	144	$94.40	$13,593.60
Total			$217,227.29 ($72,409.06 annualized)
Annual Costs			
Cargo and Freight Agent	116,785.64	$30.51	$3,563,129.88
First-Line Supervisors of Transportation and Material-Moving Machine and Vehicle Operators	2,857.09	$39.98	$144,226.45
Managerial or Professional Employees	48	$94.40	$4,531.20
Total			$3,711,887.53

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA's review of the retained records would generally occur as part of its routine or for cause inspection activities. FDA estimates that its review of the retained records would take five hours per inspection. FDA estimates the hourly cost for review and evaluation to be $43.09 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2014. To account for overhead, this cost is increased by 100 percent, making the total cost $86.18 per hour. Thus, FDA estimates the cost to the Federal Government for the review of records to be $430.90 per review ($86.18/hour x 5 hours). Assuming that FDA reviews records for 100 inspections per year, FDA estimates that the total annual cost to the Federal Government would be $43,090 ($430.90 x 100 inspections).

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

No comprehensive tabulation of the data resulting from this information collection is planned or anticipated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Approval to not display the expiration date of OMB approval is not being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

Bureau of Labor Statistics. *Occupational Employment and Wages, 43-5011 Cargo and Freight Agents*. May 2012, Washington, DC. http://data.bls.gov/cgi-bin/print.pl/oes/current/oes435011.htm. (accessed July 26, 2013)

Bureau of Labor Statistics. *Occupational Employment and Wages, 53-1031 First-Line Supervisors of Transportation and Material-Moving Machine and Vehicle Operators*. May 2012, Washington, DC. http://data.bls.gov/cgi-bin/print.pl/oes/current/oes531031.htm. (accessed April 1, 2013)

Bureau of Labor Statistics. *Occupational Employment and Wages, 23-1011 Lawyers*. May 2012, Washington, DC. http://data.bls.gov/cgi-bin/print.pl/oes/current/oes231011.htm.

FDA, "Compliance Policy Guide Sec. 565.100 FDA Jurisdiction Over Meat and Poultry Products," 2005.

FSIS, "FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry, and Egg Products. 2005. http://www.fsis.usda.gov/shared/PDF/Transportation_Security_Guidelines.pdf (accessed on September 9, 2013).