Sanitary Transportation of Human and Animal Food

OMB Control No. 0910-0773
RIN 0910-AG98

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA or we) is establishing 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 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)).

The rule requires 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 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 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 allows 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.

As finalized, persons engaged in the transportation of food are required to implement measures to prevent contamination or microbial spoilage during transportation, including training, and to maintain records concerning compliance with the rule. The rule also establishes procedures for affected persons to request a waiver of any requirement.

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. This final rule establishes requirements for sanitary transportation practices for food to prevent contamination or spoilage and provides for information collection to support these requirements. FDA will use the information to determine compliance with the regulatory requirements of the rule thereby protecting the food supply and helping to ensure the public health.

Description of Respondents: Respondents the 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

The information collection requirements under the rule solicit what the agency believes is the minimal information necessary. We believe that all respondents will use electronic means to

fulfill the information collection requirements. Additionally, firms seeking a waiver under 21 CFR 10.30 may submit electronically.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency collecting the information. Under the rule, "food" is defined consistent with section 201(f) of the FD&C Act, which includes raw materials and ingredients. This definition also 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. 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, however, it does not have requirements that directly address transportation operations for these foods. This rulemaking complements 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 final rule implementing the 2005 SFTA and FSMA to operate in conjunction with other rules promulgated 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.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that, among firms analyzed, ninety-eight percent (98%) of shippers/receivers and ninety-five percent (95%) of carriers are small businesses. Under the rule, we have attempted to assist small businesses by exempting *very* small firms with less than $500,000 in total annual sales and by providing staggered compliance dates for other small businesses. The rule defines "small business" to mean a business employing fewer than 500 persons, except that for carriers by motor vehicle that are not also shippers and/ or receivers the term means a business having less than $25,500,000 in annual receipts, consistent with the size-based standard established by the U.S. Small Business Administration for truck transportation firms. FDA believes it is reasonable to allow 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 it is reasonable to allow 2 years after the date of publication of the final rule for small businesses to come into compliance with the new requirements.

6. Consequences of Collecting the Information Less Frequently

Disclosure and recordkeeping occur as the regulations require while reporting occurs only occasionally. We believe this collection schedule imposes the minimum burden on respondents in fulfilling the requirements of the rulemaking.

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

The final rule published in the Federal Register on April 6, 2016 (81 FR 20091). In accordance with 5 CFR 1320.8(d), FDA provided an opportunity for public comment on the information collection provisions in its proposal, which published in the Federal Register of February 5, 2014 (79 FR 7005). Comments received in response to the proposed rule were considered by the agency, are addressed in the final rule, and are included in the rulemaking docket FDA-2013-N-0013.

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

This regulation does not specify confidentiality. However, records that may be reviewed during FDA inspections are subject to FDA regulations on the release of information in 21 CFR Part 20. Confidential commercial information is protected from disclosure under FOIA in accordance with section 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20. To the extent that § 20.64 applies, we 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

12 a. Annualized Hour Burden Estimate

The information collection includes recordkeeping, reporting, and third-party disclosure requirements as discussed here:

Recordkeeping

Table 1 – Estimated First Year and Annual Recordkeeping Burden

First Year Only						
	Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
1	Written procedures for integrated operation; 1.908(a)(4)	343	1	343	2	686
2	Written procedures to ensure sanitary condition of vehicles; 1.908(b)(3)	4,483	1	4,483	0.5	2,242
3	Written procedures to ensure that previous cargo does not make food unsafe; 1.908(b)(4)	4,483	1	4,483	0.5	2,242
4	Written procedures to ensure that food is transported under adequate temperature control; 1.908(b)(5)	4,483	1	4,483	0.5	2,242
5	Written procedures, cleaning and sanitation; 1.908(e)(6)(i)	37,249	1	37,249	2	74,498
6	Written procedures bulk vehicles; 1.908(e)(6)(iii)	6,713	1	6,713	2	13,426
7	Training records; 1910(b)	1,668,698	1	1,668,698	.08	133,496
First Year Only Hourly Recordkeeping Burden						228,832

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
8	Training Records; 1.910(b)	1,502,032	1	1,502,032	.08	120,163
Annual Hourly Recordkeeping Burden						120,163

The estimated hourly recordkeeping burden is 228,832 one-time hours (76,277.33 annualized one-time hours), and 120,163 annual hours.

The one-time cost of developing written procedures regarding integrated transportation operations, as required by § 1.908(a)(4), is estimated at the shipper level. It is estimated that about 343 recordkeepers will each spend 2 hours (one-time) developing written procedures

related to integrated transportation operations, as required by § 1.908(a)(4). Therefore, 343 x 2 = 686 (686.13) one-time hours, as presented in line 1.

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

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

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

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

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

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

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

for § 1.910(b), as shown in line 8. Thus, the estimated annual hourly recordkeeping burden is 120,163 hours.

Reporting

Table 2 –First Year and Annual Reporting Burden

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

In the first year, we estimate that one recordkeeper from each of a total of 6 firms will spend 24 hours submitting a waiver petition to FDA. Therefore, 6 waiver petitions x 24 hours = 144 one-time hours, as shown in line 1. Annually, we estimate 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, as shown in line 2.

Third party disclosure

Table 3—Third Party Disclosure Burden

Estimated First Year Only Third-Party Disclosure Burden						
	21 CFR Section	No. of Recordkeepers	First Year Frequency of Recordkeeping	Total Records	Hours Per Record	Total Hours
1	Written Sanitary Specifications 1.908(b)(1)	10,163	1	10,163	0.5	5,082 (5,081.57)
2	Notification of operating temperature 1.908(b)(2)	5,646	1	5,646	0.5	2,823 (2,823.13)
3	Records pertaining to disclosure of information 1.912(a)	36,084	1	36,084	0.5	18,042 (18,041.88)
TOTAL						25,947 (25,946.57)

Estimated Annual Third-Party Disclosure Burden						
	21 CFR Section	No. of Recordkeepers	First Year Frequency of Recordkeeping	Total Records	Hours Per Record	Total Hours
4	Sanitary Specifications 1.908(b)(1)	226	1	226	0.08	18 (18.07)
5	Operating temperature conditions 1.908(b)(2)	226	1	226	0.5	113 (112.93)
TOTAL						131 (130.99)

The one-time cost of developing written sanitary specifications necessary for transportation, as required by § 1.908(b)(1), is estimated at the shipper level. It is estimated that one recordkeeper for each of about 10,163 firms will spend 30 minutes developing written sanitary specifications. Therefore, 0.5 hour x 10,163 firms = 5,082 (5,081.57) one-time hours for § 1.908(b)(1), as shown in line 1.

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

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

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

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

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 4–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 retained records will generally occur as part of its routine or for-cause inspection activities. Because these activities are covered by existing resource allocations we are estimating zero cost to the Federal government.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

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.