Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types (2015-2025)

0910-NEW

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   The statutory basis for the U.S. Food and Drug Administration's (FDA) conducting this survey is the Public Health Service (PHS) Act [42 USC 243, Section 311(a)] which requires that the FDA provide assistance to state and local governments relative to the prevention and suppression of communicable diseases. Responsibility for carrying out the provisions of the Act relative to food protection was transferred to the Commissioner of Food and Drugs in 1968 (21 CFR 5.10(a)(2) and (4)). Additionally, the Federal Food, Drug, and Cosmetic Act [21 USC 301 et seq] and the Economy Act [31 USC 1535] require the FDA to provide assistance to other federal, state, and local government bodies.

   This study provides FDA with a solid foundation for developing and maintaining a national retail food program model that can be used by federal, state, local, and tribal agencies to:

   - Identify essential food safety program performance measurements.
   - Assess strengths and gaps in the design, structure, and delivery of program services.
   - Establish program priorities and intervention strategies focused on reducing the occurrence of foodborne illness risk factors.
   - Create a mechanism that justifies program resources and allocates them to program areas that will provide the most significant public health benefits.

2. Purpose and Use of the Information Collection

   The information gathered from this survey is used to:

   - Assist the FDA with developing retail food safety initiatives and policies focused on the control of foodborne illness risk factors – preparation practices and employee behaviors most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors to foodborne illness outbreaks at the

retail level. (i.e. Food from Unsafe Sources, Poor Personal Hygiene, Inadequate Cooking, Improper Holding/Time and Temperature, and Contaminated Equipment/Protection from Contamination).

- Identify retail food safety work plan priorities and allocate resources to enhance retail food safety nationwide.
- Track changes in the occurrence of foodborne illness risk factors in retail and foodservice establishments over time.
- Inform recommendations to the retail and foodservice industry and state, local, tribal, and territorial regulatory professionals on reducing the occurrence of foodborne illness risk factors.

3. Use of Improved Information Technology and Burden Reduction

This survey involves collection of information related to the behaviors and practices of food employees. In order to accurately document food employee behavior, the FDA data collectors must be physically located in the establishments during hours of operation. Data is gathered through interviewing, actual observations, and record reviews. All information will be entered into a web-based data platform. The interface will support the manual entering of data, as well as the ability to upload a fillable PDF. The web-based platform will also be accessible to state, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies.

For the 2015-2016 data collection, FDA plans to pilot the use of handheld technology for collecting the data on-site during the data collection visits. FDA plans to roll out the use of handheld tablet computers to all data collectors in time for the 2017-2018 risk factor study in restaurants. Approximately 25 percent of the data collectors will enter data using hand held technology.

FDA will minimize burden by conducting the data collection during normal hours of operation and in a manner that is customary with routine inspections performed by the establishments' normal regulatory authorities.

4. Efforts to Identify Duplication and Use of Similar Information

There are no other nationally representative estimates of the occurrence of foodborne illness risk factors in retail and foodservice establishments. Some State and local regulatory authorities have conducted risk factor surveys within their jurisdictions; however, these studies do not provide a nationally representative sample. Thus, no comparable data have been collected by other Federal, State, or local regulatory agencies or industry.

FDA and CDC compared and contrasted our various retail food studies and surveillance systems [i.e. FDA's Foodborne Illness Risk Factor Study, CDC's EHS-Net Food Safety Studies, CDC's National Outbreak Reporting System (NORS), and CDC's National Voluntary Environmental Assessment Information System (NVEAIS)] relative to the following:

- Purpose and objectives.
- Intended use of the data.
- How the data informs and influences the food protection efforts of the sister agency.
- The specific food establishments included.
- Data collection and sampling methods.

We used this information to evaluate the feasibility of combining some or all of the survey questions into a single study or surveillance system. Our determination was that each of these studies and/or surveillance systems collects unique, but related, information that is vital to informing policy and intervention strategy development to reduce foodborne illness at the retail level. Differences, especially in regards to sampling and data collection methods, are necessary to ensure the objectives of the studies and/or surveillance systems are achieved. Consequently, we feel that combining these studies or surveillance systems would jeopardize the data and limit their utility.

CDC and FDA will conduct joint annual reviews of the data collected through our various data collections systems. These reviews will be used to determine if changes are needed to future information collections to ensure the data collected are optimal to meet our collective needs and missions to reduce foodborne illness.

5. Impact on Small Businesses or Other Small Entities

Of the 2,400 respondents in this survey, 1,200 will be from small businesses. FDA will minimize burden by conducting the data collections during normal hours of operation and in a manner that is customary with routine inspections performed by the industry operator's respective regulatory authority. The information being requested has been held to the absolute minimum required for the intended use of the data.

6. Consequences of Collecting the Information Less Frequently

The 2015-2016 data collection will provide the baseline measurement and is the subject of this ICR. A minimum of three data points is needed to determine statistically significant trends in improvement or regression over time; thus, FDA intends to conduct follow-up data collections in 2019-2020 and 2023-2024 (which will be posted in the Federal Register in future renewals). If the data collections are conducted less frequently or not at all, the data will have less statistical power and the Agency will be unable to measure trends of improvement or regression in foodborne illness risk factor occurrence over time. This lack of information will impede FDA's ability to formulate Agency retail food safety policies, initiatives, and work plan priorities based on sound science. In addition, the lack of information will hamper FDA's ability to allocate resources in a strategic and efficient manner based on the specific needs of our stakeholders. Lastly, without this information, FDA will be unable to recommend targeted intervention strategies to assist the retail and foodservice industry and State, local, and tribal regulators with reducing foodborne illness risk factors. The study is part of the Agency's mission critical work to reduce foodborne illnesses. There are no legal obstacles to reduce the burden.

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

   There are no special circumstances for 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 published a 60 day notice for public comment in the FEDERAL REGISTER of December 17, 2014 (79 FR 75158). No comments were received.

   Efforts to Consult with Representatives from Industry on the Proposed Information Collection

   The current 10-year study builds on the design of a previous 10-year risk factor study that included three separate data collections. At the completion of each of the three previous data collections in 1998, 2003, and 2008, results were shared via presentations to small groups and established committees made up of retail food and restaurant industry leaders. Feedback was obtained on the study design and the reporting of the results. This feedback helped to inform the process of designing the current 10-year study.

   FDA seeks input from industry stakeholder groups, among others, for enhancing the effectiveness of the nation's food safety system. FDA has established a partnership with food safety leaders from the foodservice industry and separate partnership with leaders from the retail food store industry. These partnerships provide an opportunity for FDA personnel to meet with industry leaders three times a year to discuss ways to best achieve our food safety objectives. During these meetings, FDA provides the partnership members with regular updates on the Risk Factor Study and seeks suggestions for improving the study design and for optimizing access to the food establishments. For example, the industry partnership groups provided recommendations for improving the introductory letter describing the purpose and burden of the study. In addition, industry partnership groups provided recommendations for phrasing some of the interview questions so they are asked in a manner that will be clear to the person in charge.

   In addition, key industry committees were made aware of FDA's plan to update the study design and proceed with the 2013-2014 baseline data collection. These groups included the National Restaurant Association's Quality Assurance Executive Study Group, the National Council of Chain Restaurants' Food Safety Task Force and the FMI Food Protection Committee.

   These groups raised no issues following the 2013-2014 baseline data collection.

   Efforts to Consult with Representatives of Other Federal Programs on the Proposed Information Collection

The results of the FDA Retail Risk Factor Study have impact on the following Federal agencies: USDA- Food Safety and Inspection Service (FSIS), USDA- Food and Nutrition Service (FNS), and the CDC. Specifically:

- The results of the study can assist FSIS in their efforts to assure the safety of meat and poultry, as the study will reflect on practices at retail that can directly impact the survival and proliferation of pathogens in these products. The results may assist FSIS target resources to the retail sector where training and/or enforcement action on meat and poultry handling practices are most needed.
- The USDA Food and Nutrition Service has used the results of the previous studies to call attention to key food safety practices in school cafeterias and direct research funds to institutions that can provide operators with appropriate educational materials.
- CDC conducts and funds research that seeks a better understanding of the prevalence and prevention of the transmission of disease via food, including several studies as part of its EHS-Net program that targets foodservice operations. FDA has kept and will continue to keep key CDC staff informed of the plans for and results of the Risk Factor Study so that areas in which our concurrent studies reinforce or run counter to one another can be analyzed and appropriate prevention-based messages developed.

While FDA's data collections are not targeting establishments operating on Federal installations, any Federal agency that has responsibility for the oversight of foodservice or retail food store operations could derive benefit from the results of this Retail Risk Factor Study. Organizations such as the Indian Health Service, the National Park Service, the Bureau of Prisons, and the branches of the Department of Defense can gain insight into which foodborne illness risk factors present the greatest challenge for control and the potential value of certain intervention strategies.

9. Explanation of Any Payment or Gift to Respondents

There will be no payments to the respondents.

10. Assurance of Confidentiality Provided to Respondents

FDA will collect the following information associated with the establishment's identity: establishment name, street address, city, state, zip code, county, industry segment, and facility type. The establishment identifying information is collected to ensure the survey is not duplicative. Other information related to the nature of the operation, such as seating capacity and number of employees per shift, will also be collected. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study. Operators of the establishments visited are informed that the information collected will not be reported in a manner that allows for the name or location of the establishment to be connected to any specific observations that are made.

When an inspector is assigned a specific firm, the inspector will conduct the survey and log the information into a secure web-based platform in FoodSHIELD using secure FDA computers. This tracking system, explained in A.3, will remove the completed establishment from the list of possible establishments so that the random generator will

not include the establishment when finding the next assignment. The establishment identifying information will be kept electronically as well as in hard copy form at the FDA district offices associated with the inspections and will not be published.

FDA will seek assistance from its privacy officers to develop an appropriate system of records notice and privacy impact assessment, as appropriate.

The privacy of the establishment and the individual responding on behalf of the establishment will be provided to the extent permitted by law.

11. Justification for Sensitive Questions

There are no sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The burden for this collection of information is as follows. For each data collection, the respondents will include: (1) The person in charge of the selected facility type (whether it be a healthcare facility, school, or supermarket/grocery store); and (2) the program director (or designated individual) of the respective regulatory authority. In order to provide the sufficient number of observations needed to conduct a statistically significant analysis of the data, FDA has determined that 400 data collections will be required in each of the three facility types. Therefore, the total number of responses will be 2,400 (400 data collections × 3 facility types × 2 respondents per data collection).

The burden associated with the completion of Sections 1 and 3 of the form is specific to the persons in charge of the selected facilities. It includes the time it will take the persons in charge to accompany the data collectors during the site visit and answer the data collectors' questions. The burden related to the completion of Section 2 of the form is specific to the program directors (or designated individuals) of the respective regulatory authorities. It includes the time it will take to answer the data collectors' questions and is the same regardless of the facility type.

To calculate the estimate of the hours per response, FDA will use the average data collection duration for similar facility types during FDA's 2008 Risk Factor Study (Ref. 3) plus an extra 30 minutes (0.5 hours) for the information collection related to Section 3, Part B of the form. FDA estimates that it will take the persons in charge of healthcare facility types, schools, and retail food stores 150 minutes (2.5 hours), 120 minutes (2 hours), and 180 minutes (3 hours), respectively, to accompany the data collectors while they complete Sections 1 and 3 of the form. FDA estimates that it will take the program director (or designated individual) of the respective regulatory authority 30 minutes (0.5 hours) to answer the questions related to Section 2 of the form. The total burden estimate for a data collection, including both the program director's and the person in charge's responses, in healthcare facility types is 180 minutes (150+30)(3 hours), in schools is 150 minutes (120+30)(2.5 hours), and in retail food stores is 210 minutes (180+30)(3.5 hours).

Based on the number of entry refusals from the 2013–2014 Risk Factor Study in the restaurant facility types, we estimate a refusal rate of 2 percent in the institutional foodservice and retail food store facility types. The estimate of the time per non-respondent is 5 minutes (0.08 hours) for the person in charge to listen to the purpose of the visit and provide a verbal refusal of entry.

TABLE 1: ESTIMATED ANNUAL REPORTING BURDEN

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	No. of Non-Respondents	No. of Responses per Non-Respondent	Total Annual Non-Responses	Average Burden per Response (hours)	Total Hours
2015-2016 Data Collection (Healthcare Facilities) - Completion of Sections 1 and 3	400	1	400	-	-	-	2.5	1,000
2015-2016 Data Collection (Schools) - Completion of Sections 1 and 3	400	1	400	-	-	-	2	800
2015-2016 Data Collection (Retail Food Stores) - Completion of Sections 1 and 3	400	1	400	-	-	-	3	1,200
2015-2016 Data Collection-Completion of Section 2 – All Facility Types	1,200	1	1,200	-	-	-	0.5 (30 minutes)	600
2017-2018 Data Collection-Entry Refusals –	-	-	-	24	1	24	0.08 (5 minutes)	1.92

All Facility Types								
Total Hours	-	-	-	-	-	-	-	3,601.92

12b. Annualized Cost Burden Estimate

The cost associated with this collection is directly related to the speed at which a respondent can respond to the survey. A study by the U.S. Bureau of Labor Statistics in September 2014 found that managers in state/local government employees earn an average of $52.88 per hour and private industry employees earn an average of $30.32 per hour.[1] This includes the total wages and other compensation, as well as benefits like health insurance and retirement contributions.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Person in charge of the selected facility – fast food and full service restaurants	3,001.92	$30.32	$91,018.21
Program director of the respective regulatory authority	600	$52.88	$31,728.00
Total			$122,746.21

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

The estimated total cost to the Federal Government for completing the 2015-2016 data collection is $317,740. This value is derived as follows:

Description of Cost	Factor Used	Total Cost
Cost of FDA staff involved in study design, data collection and analysis, database maintenance, and report writing	6,000 work plan hours x $38.54 (2015 hourly rate of pay for GS-13, Step 4)	$231,240
Travel expenses of FDA staff	$37.50 (average) per inspection x	$45,000

[1]United States Bureau of Labor Statistics. (September 2014). Employer Costs for Employee Compensation. Retrieved from http://www.bls.gov/news.release/ecec.toc.htm.

(to perform data collection inspections)	1,200 inspections	
Travel expenses of FDA staff (two face-to-face meetings to analyze the data and write the reports)	$24,000 per year x 1 year	$24,000
Purchase of handheld tablet computers for pilot	5 x $2,500	$12,500
Miscellaneous (equipment, printing, etc.)	$2,500 per year x 2 years	$5,000
Total Cost		$317,740

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency anticipates disseminating the results of the data collection after the data is collected, analyzed, tabulated in written reports, and cleared. Activities associated with the outcomes of this research will primarily consist of written and oral presentations as well as a written final report. In addition, journal manuscripts and oral and/or poster presentations will be planned to disseminate the information to the public, including professionals, academics, and industry and consumer organizations. This dialogue will help improve the effectiveness of the agency's regulatory and education initiatives in promoting and protecting the public health. The planned schedule for project activities is shown in Table 3.

Project Schedule

Date	**Activity**	**Audience**
October 1, 2015	Data collection initiated	Not applicable
By December 30, 2016	Data collection completed	Not applicable
By June 30, 2017	Data analysis completed	FDA
By March 1, 2018	Final report summarizing the results issued	Public

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

We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.