Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

OMB Control Number 0910-0744

SUPPORTING STATEMENT

Terms of Clearance: Previous terms continue: OMB continues to encourage FDA to work with CDC to find opportunities to minimize burden and combine collections when possible.

Part 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

   Information will be gathered from state/local governments and businesses in the private sector 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. Data will be entered into a web-based data platform from secured computers. The interface will support the manual entering of data, as well as the ability to upload a fillable and fileable PDF, should the need arise. The PDF is not signable by the data collector. 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.

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.

For the 2015-2016 data collection, FDA piloted the use of hand-held technology for capturing the data on-site during the data collection visits. The tablets that were made available for the data collections were part of a broader agency initiative focused on internal uses of hand-held technology. The tablets provided for the data collection presented several technical and logistical challenges and increased the time burden associated with the data collection as compared to the manual entry of data collections. FDA continues to assess the feasibility for fully incorporating use of hand-held technology in subsequent data collections during the 10-year study period.

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.

To address the terms of clearance, 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 Environmental Assessment Reporting System (NEARS)] relative to the following (see Attachment E):

- 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 1,600 respondents in this survey, 800 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

A data collection was performed in 2013-2014 to establish a baseline measurement. A minimum of three data points are needed to determine statistically significant trends in improvement or regression over time; thus, FDA conducted follow-up data collection in 2017-2018 and plans a subsequent collection in 2021-2022 (the subject of this ICR extension). 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. Respondents will only respond once during each data collection period.

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 March 16, 2021 (86 FR 14433). FDA received two comments, only one comment we received was responsive to the four collection of information topics solicited.

(Comment 1) Academy of Nutrition and Dietetics commented that they support the proposed information collection for the survey on the occurrence of foodborne illness risk factors in various settings. The Academy provided comments pertaining to the following general areas of the study:

a. Question whether 90 minutes is adequate for surveying larger facilities.
b. Request the FDA evaluate the impact of conducting surveys during peak hours of operation.
c. Suggest that the use of gloves is not adequately addressed in the survey
d. Encourage continued efforts to simplify and standardize expiration dates

Related to foodservice operations at the retail level, the Academy provided the following comments:

e. FDA consider modifying the survey to account for new foods and new means of conveying food
f. FDA consider modifying the survey to include trends for hot holding and online delivery due to the COVID-19 pandemic
g. FDA make the dataset public for further analysis
h. FDA consider peer review of the report

(Response 1) FDA thanks the submitter for their comments and appreciates their support. Regarding general areas of the study, FDA provides the following responses:

a. The current 10-year study estimates 90 minutes as the average time needed to adequately collect necessary information, taking into account

both small and large facilities. This average time is consistent with the amount of time burden estimated for the previous data collection periods and provides a sufficient timeframe to observe food safety practices and procedures that are the focus of the study.

b. Based on the methodology of the study, the information collection is performed during hours of operation of the randomly selected facility. Data collections are scheduled at times which provide the best opportunity to observe food preparation activities, which often include peak operations.
c. Information collection related to handwashing and no bare hand contact with ready to eat foods, which may include use of gloves, is based on assessment of observations against the most current addition of the *FDA Model Food Code*. Provisions of the *FDA Food Code* identify when handwashing and no bare hand contact with ready to eat food are required during food preparation and service. The current *FDA Food Code* does not recognize the use of hand antiseptics in lieu of handwashing during food preparation and service.
d. The scope of this data collection focuses on foodborne illness risk factors and does not include assessment of expiration dates of manufactured foods as part of this research assessment.

Related to foodservice operations at the retail level, FDA provides the following responses:

e. The study design accounts for a variety of food conveyances in the retail food setting. The study includes four major segments of the retail and foodservice industries that account for over a million varied and diverse types of operations in the United States:
    - Restaurants
    - Healthcare Facilities
    - Schools (K-12)
    - Retail Food Stores
f. The study design is based on operations regardless of extenuating circumstances. While there is utility in investigating the trends in food service, this study must focus its efforts throughout the 10-year period to ensure data can be adequately trended. Two of the three data collections for this trending were already complete before the pandemic and a singular data point with these new metrics would not be of much utility. FDA fully supports the New Era of Smarter Food Safety blueprint and endeavors to collect data to support that effort.
g. FDA strives to ensure the data is available to parties upon request. Additionally a new Topline Summary is published to www.fda.gov/retailfoodriskfactorstudy along with the technical report, with much of the data commonly requested for independent analysis.
h. FDA acknowledges the benefit of peer review. For any manuscripts published resulting from the data set peer review is sought. For the technical

report of the data FDA will continue to utilize the format which is familiar and accepted by our stakeholders.

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. They also suggested that the wording of the data items be phrased as positive statements (i.e. the desired behavior) versus negative statements (i.e. undesired behavior or violations).

In addition, key industry committees are continually informed on the progress of the study and key results from each of the data collection periods. These groups include 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.

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-FNS and the CDC. Specifically:

- 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

We have consulted with the FDA Privacy Office and confirmed this ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports "Survey on the Occurrence of Foodborne Illness Risks in Selected Institutional Foodservice and Retail Stores Facility Types" and does not require the collection of PII.

FDA further determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA (including vendors or service providers acting on behalf of FDA) does not use name or any other personal identifier to retrieve records from the information collected.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

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

12 a. Annualized Hour Burden Estimate

The burden for the 2021-2022 data collection is as follows. For each data collection, the respondents will include: 1) the person in charge of the selected restaurant facility (whether it be a fast food or full service restaurant); 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 the same number of data collections will be required in each of the two restaurant facility types as was required in the 2013-2014 and 2017-2018 data collections (i.e. 400). Therefore, the total number of responses for restaurants will be 1,600 (400 data collections x 2 facility types x 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 person in charge to accompany the data collector as he or she completes Sections 1 and 3 of the form. 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 the same facility types during the 2017-2018 data collection. FDA estimates that it will take the persons in charge of full service restaurants and fast food restaurants 104 minutes (1.73 hours) and 82 minutes (1.36 hours), respectfully, 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. These burden estimates are unchanged from the last data collection. Hence, the total burden estimate for a data collection in a full service restaurant, including both the program director's and the person in charge's responses, is 134 minutes (104 + 30) (2.23 hours). The total burden estimate for a data collection in a fast food restaurant, including the both the program director's and the person in charge's responses, is 112 minutes (82 + 30)(1.86 hours).

Based on the number of entry refusals from the 2017-2018 data collection, we estimate a refusal rate of 2%. The estimate of the time per non-respondent is five 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	Total Hours
2021-2022-Data Collection (Fast Food Restaurants) - Completion of Sections 1 and 3	400	1	400	-	-	-	1.36	544
2021-2022 Data Collection (Full Service Restaurants) - Completion of Sections 1 and 3	400	1	400	-	-	-	1.73	692
2021-2022 Data Collection-Completion of Section 2 – All Facility Types	800	1	800	-	-	-	0.5 (30 min.)	400
2021-2022 Data Collection-Entry Refusals – All Facility Types	-	-	-	16	1	16	0.08 (5 min.)	1.28
Total Hours	-	-	-	-	-	-	-	1,637.28

[1]There are no capital costs of operating and maintenance costs associated with this collection of information.

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 December 2020 found that managers in state/local government employees earn an average of $64.02 per hour and private industry employees earn an average of $36.23 per hour.[1] This includes the total wages and other compensation, as well as benefits like

[1]United States Bureau of Labor Statistics. (December 2020). Employer Costs for Employee Compensation. Retrieved from http://www.bls.gov/news.release/ecec.toc.htm.

health insurance and retirement contributions. Estimates of annualized cost burden are tabulated below:

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	1237.28	$36.23	$44,826.65
Program director of the respective regulatory authority	400	$64.02	$25,608.00
Total			$70,434.65

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 2021-2022 data collection is $206,804.00. 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	3,600 work plan hours x $41.89 (2021 hourly rate of pay for GS-13, Step 4)	$150,804
Travel expenses of FDA staff (to perform data collection inspections)	$37.50 per inspection x 800 inspections	$30,000
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
Miscellaneous (equipment, printing, etc.)	$1,000 per year x 2 years	$2,000
Total Cost		$206,804.00

15. Explanation for Program Changes or Adjustments

Based on analysis of the burden from the 2017-2018 data collection there are no program anticipated changes or adjustments.

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 the table below:

Project Schedule

Date	**Activity**	**Audience**
October 1, 2021	Data collection initiated	Not applicable
By September 30, 2022	Data collection completed	Not applicable
By June 1, 2022	Data analysis completed	FDA
By June 1, 2023	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.