U.S. Food and Drug Administration
Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

OMB Control Number 0910-0744 - Revision

SUPPORTING STATEMENT

**Terms of Clearance:** 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

   This information collection supports Food and Drug Administration (FDA, us or we) food safety programs. The Public Health Service (PHS) Act [42 USC 243, Section 311(a)] 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.

   The FDA's National Retail Food Team conducted a study to measure trends in the occurrence of foodborne illness risk factors, preparation practices, and employee behaviors most commonly reported to the Centers for Disease Control and Prevention as contributing factors to foodborne illness outbreaks at the retail level. Specifically, data was collected in retail and foodservice establishments at 5-year intervals (1998, 2003, and 2008) in order to observe and document trends in the occurrence of the following foodborne illness risk factors:

   •Food from Unsafe Sources,
   •Poor Personal Hygiene,
   •Inadequate Cooking,
   •Improper Holding/Time and Temperature, and
   •Contaminated Equipment/Cross- Contamination.

FDA developed reports summarizing the findings for each of the three data collection periods, released in 2000, 2004, and 2009.[1,2,3] Data from all three data collection periods were analyzed to detect trends in improvement or regression over time and to determine whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in selected retail and foodservice facility types.[4]

Using this 10-year survey as a foundation, FDA initiated a new study in full-service and fast-food restaurants. This study will include data collections completed in 2013–2014 and 2017–2018. An additional collection planned for 2021– 2022 was halted due to the Covid-19 pandemic.

We therefore request OMB approval and conclusion of the food safety survey as discussed in this supporting statement.

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.

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[1] FDA, "Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000)." Available at https://wayback.archive-it.org/7993/20170406023019/https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf.

[2] FDA, "FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)." Available at https://wayback.archive-it.org/7993/20170406023011/https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf.

[3] FDA, "FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009)." Available at https://wayback.archive-it.org/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm224321.htm.

[4] FDA National Retail Food Team, "FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998-2008)." (2010). Available at https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm.

Table 1.--Description of the Facility Types Included in the Survey

| Facility Type | Description |
|---|---|
| Full-Service Restaurants | A restaurant where customers place their orders at their tables, are served their meals at the tables, receive the services of the wait staff, and pay at the end of the meals. |
| Fast-Food Restaurants | A restaurant that is not a full-service restaurant. This includes restaurants commonly referred to as quick-service restaurants and fast, casual restaurants. |
| Retail Food Stores | Supermarkets and grocery stores that have a deli department/operation as described as follows:<br>• Deli department/operation--Areas in a retail food store where foods, such as luncheon meats and cheeses, are sliced for the customers and where sandwiches and salads are prepared onsite or received from a commissary in bulk containers, portioned, and displayed. Parts of deli operations may include:<br>  • Salad bars, pizza stations, and other food bars managed by the deli department manager.<br>  • Areas where other foods are cooked or prepared and offered for sale as ready-to-eat and are managed by the deli department manager.<br>Data will also be collected in the following areas of a supermarket or grocery store, if present:<br>• Seafood department/operation--Areas in a retail food store where seafood is cut, prepared, stored, or displayed for sale to the consumer. In retail food stores where the seafood department is combined with another department (e.g., meat), the data collector will only assess the procedures and practices associated with the processing of seafood.<br>• Produce department/operation--Areas in a retail food store where produce is cut, prepared, stored, or displayed for sale to the consumer. A produce operation may include salad bars or juice stations that are managed by the produce manager. |

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 Risk Factor 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 800 respondents in this survey, 400 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
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. . 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* March 6, 2024 (89 FR 15996). One comment was received. It was in favor of the study, but it was not responsive to the four collection of information topics solicited.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

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 a data collector is assigned a specific firm, the data collector 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 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

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 2.--Estimated Annual Reporting Burden[1]

| Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| Fast-Food and Full-Service Restaurants--Form FDA 3966 | 400 | 1 | 400 | 2 | 800 |
| Retail Food Stores--Form FDA 3967 | 400 | 1 | 400 | 2 | 800 |
| Entry Refusals--All Facility Types | 24 | 1 | 24 | 0.08 (5 minutes) | 2 |
| Total | | | | | 1,602 |

[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 June 2023 found that managers in state/local government employees earn an average of

$67.70 per hour and private industry employees earn an average of $40.32 per hour.[5] This includes the total wages and other compensation, as well as benefits like 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 | 800 | $40.32 | $32,256 |
| Program director of the respective regulatory authority | | $67.70 | $54,160 |
| Person in charge of the selected facility –retail food store facility types | 800 | $40.32 | $32,256 |
| Program director of the respective regulatory authority | | $67.70 | $54,160 |
| Total | | | $172,832 |

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 data collection is $531,776. 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 | 9,600 work plan hours x $44.56 (2023 hourly rate of pay for GS-13, Step 4) | $427,776 |
| Travel expenses of FDA staff (to perform data collection inspections) | $37.50 per inspection x 2,000 inspections | $75,000 |

[5]United States Bureau of Labor Statistics. (June 2023). Employer Costs for Employee Compensation. Retrieved from http://www.bls.gov/news.release/ecec.toc.htm.

| | | |
|---|---|---|
| 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.) | $2,500 per year x 2 years | $5,000 |
| Total Cost | | $531,776 |

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to our burden estimate. On our own initiative, however, and for efficiency of Agency operations, we are revising the information collection to include and consolidate related information collection found in 0910-0799. Our estimated burden for the information collection reflects a decrease of 35 total burden hours and a corresponding decrease of 792 total annual responses.

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:

| **Date** | **Activity** | **Audience** |
|---|---|---|
| October 1, 2023 | Begin data collection in Fast Food and Full-service Restaurants | Not Applicable |
| September 30, 2025 | Complete data collection in Fast Food and Full-service Restaurants | Not Applicable |
| By October 1, 2026 | Data analysis completed for Fast Food and Full-service Restaurants | FDA |
| October 1, 2026 | Begin data collection in retail food store facility types | Not applicable |
| By July 1, 2027 | Final report summarizing the results issued for Fast Food and Full-service Restaurants | Public |
| By September 30, 2027 | Complete data collection in retail food store facility types | Not applicable |
| By October 1, 2028 | Data analysis completed for retail food store facility types | FDA |
| By July 1, 2029 | Final report summarizing the results | Public |

| | | |
|---|---|---|
| | issued for retail food store facility types | |

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.