



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0270]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0799. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional
Foodservice and Retail Food Stores Facility Types
OMB Control Number 0910-0799--Reinstatement

I. Background

From 1998 to 2008, 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 by FDA specialists in retail and foodservice establishments at 5-year intervals (1998, 2003, and 2008) 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 (1998, 2003, and 2008) (Refs. 1 to 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 (Ref. 4).

Using this 10-year survey as a foundation, in 2013 to 2014, FDA initiated a new study in full service and fast food restaurants. This study will span 10 years with additional data collections planned for 2017 to 2018 and 2021 to 2022.

FDA recently completed the baseline data collection in select healthcare, school, and retail food store facility types in 2015 to 2016. This proposed study will also span 10 years with additional data collections planned for 2019 to 2020 (the subject of this information collection request reinstatement) and 2023 to 2024 (which will be posted in the *Federal Register* at the next renewal).

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

Facility Type	Description
Healthcare Facilities	Hospitals and long-term care facilities foodservice operations that prepare meals for highly susceptible populations as defined as follows: - Hospitals--A foodservice operation that provides for the nutritional needs of inpatients by preparing meals and transporting them to the patient's room and/or serving meals in a cafeteria setting (meals in the cafeteria may also be served to hospital staff and visitors). - Long-term care facilities--A foodservice operation that prepares meals for the residents in a group care living setting such as nursing homes and assisted living facilities. Note: For the purposes of this study, healthcare facilities that do not prepare or serve food to a highly susceptible population, such as mental healthcare facilities, are not included in this facility type category.
Schools (K-12)	Foodservice operations that have the primary function of preparing and serving meals for students in one or more grade levels from kindergarten through grade 12. A school foodservice may be part of a public or private institution.
Retail Food Stores	Supermarkets and grocery stores that have a deli department/operation as described as follows: - 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: - Salad bars, pizza stations, and other food bars managed by the deli department manager. - Areas where other foods are cooked or prepared and offered for sale as ready-to-eat and are managed by the deli department manager. Data will also be collected in the following areas of a supermarket or grocery store, if present: - 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. - 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.

The purpose of the study is to:

- Assist FDA with developing retail food safety initiatives and policies focused on the control of foodborne illness risk factors;
- 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; and
- 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.

The statutory basis for FDA conducting this study is derived from the Public Health Service Act (PHS Act) (42 U.S.C. 243, section 311(a)). Responsibility for carrying out the provisions of the PHS 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 U.S.C. 301 *et seq.*) and the Economy Act (31 U.S.C. 1535) require FDA to provide assistance to other Federal, State, and local government bodies.

The objectives of the study are to:

- Identify the least and most often occurring foodborne illness risk factors and food safety behaviors/practices in healthcare, school, restaurant, and retail food store facility types during each data collection period;
- Track improvement and/or regression trends in the occurrence of foodborne illness risk factors during the 10-year study period;

- Examine potential correlations between operational characteristics of food establishments and the control of foodborne illness risk factors;
- Examine potential correlations between elements within regulatory retail food protection programs and the control of foodborne illness risk factors; and
- Determine the extent to which food safety management systems and the presence of a certified food protection manager impact the occurrence of foodborne illness risk factors.

The methodology to be used for this information collection is described as follows. To obtain a sufficient number of observations to conduct statistically significant analysis, FDA will conduct approximately 400 data collections in each facility type. This sample size has been calculated to provide for sufficient observations to be 95 percent confident that the compliance percentage is within 5 percent of the true compliance percentage.

A geographical information system database containing a listing of businesses throughout the United States provides the establishment inventory for the data collections. FDA samples establishments from the inventory based on the descriptions in table 1. FDA does not intend to sample operations that handle only prepackaged food items or conduct low-risk food preparation activities. The "FDA Food Code" contains a grouping of establishments by risk, based on the type of food preparation that is normally conducted within the operation (Ref. 5). The intent is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 25 Regional Retail Food Specialists (Specialists) who serve as the data collectors for the 10-year study. The Specialists are geographically dispersed throughout the United States and possess technical expertise in retail food safety and a solid understanding of the operations within each of the facility types to be surveyed. The Specialists

are also standardized by FDA's Center for Food Safety and Applied Nutrition personnel in the application and interpretation of the FDA Food Code (Ref. 5).

Sampling zones have been established that are equal to the 150-mile radius around a Specialist's home location. The sample is selected randomly from among all eligible establishments located within these sampling zones. The Specialists are generally located in major metropolitan areas (i.e., population centers) across the contiguous United States. Population centers usually contain a large concentration of the establishments FDA intends to sample. Sampling from the 150-mile radius sampling zones around the Specialists' home locations provides three advantages to the study:

1. It provides a cross-section of urban and rural areas from which to sample the eligible establishments.
2. It represents a mix of small, medium, and large regulatory entities having jurisdiction over the eligible establishments.
3. It reduces overnight travel and therefore reduces travel costs incurred by the Agency to collect data.

The sample for each data collection period is evenly distributed among Specialists. Given that participation in the study by industry is voluntary and the status of any given randomly selected establishment is subject to change, substitute establishments have been selected for each Specialist for cases where the institutional foodservice, school, or retail food store facility is misclassified, closed, or otherwise unavailable, unable, or unwilling to participate.

Prior to conducting the data collection, Specialists contact the State or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected

establishment. The Specialist verifies with the jurisdiction that the facility has been properly classified for the purposes of the study and is still in operation. The Specialist ascertains whether the selected facility is under legal notice from the State or local regulatory authority. If the selected facility is under legal notice, the Specialist will not conduct a data collection, and a substitute establishment will be used. An invitation is extended to the State or local regulatory authority to accompany the Specialist on the data collection visit.

A standard form is used by the Specialists during each data collection. The form is divided into three sections: Section 1--"Establishment Information"; Section 2--"Regulatory Authority Information"; and Section 3--"Foodborne Illness Risk Factor and Food Safety Management System Assessment". The information in Section 1--"Establishment Information" of the form is obtained during an interview with the establishment owner or person in charge by the Specialist and includes a standard set of questions.

The information in Section 2--"Regulatory Authority Information" is obtained during an interview with the program director of the State or local jurisdiction that has regulatory responsibility for conducting inspections for the selected establishment. Section 3 includes three parts: Part A for tabulating the Specialists' observations of the food employees' behaviors and practices in limiting contamination, proliferation, and survival of food safety hazards; Part B for assessing the food safety management system being implemented by the facility; and Part C for assessing the frequency and extent of food employee hand washing. The information in Part A is collected from the Specialists' direct observations of food employee behaviors and practices. Infrequent, nonstandard questions may be asked by the Specialists if clarification is needed on the food safety procedure or practice being observed. The information in Part B is collected by making direct observations and asking followup questions of facility management to obtain

information on the extent to which the food establishment has developed and implemented food safety management systems. The information in Part C is collected by making direct observations of food employee hand washing. No questions are asked in the completion of Section 3, Part C of the form.

FDA collects 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 data collections are not duplicative. Other information related to the nature of the operation, such as seating capacity and number of employees per shift, is also collected. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study.

FDA has collaborated with the Food Protection and Defense Institute¹ to develop a web-based platform in FoodSHIELD to collect, store, and analyze data for the Retail Risk Factor Study. This platform is accessible to State, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies. For the 2015 to 2016 data collection, FDA piloted the use of hand-held technology for capturing the data onsite 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.

When a data collector is assigned a specific establishment, he or she conducts the data collection and enters the information into the web-based data platform. The interface will

¹ <https://foodprotection.umn.edu/>

support the manual entering of data, as well as the ability to directly enter information in the database via a web browser.

In the *Federal Register* of February 7, 2018 (83 FR 5441), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments.

(Comment 1) National Association of County and City Health Officials (NACCHO) provided comments related to the following areas:

- a. Supports FDA's efforts to reduce the occurrence of foodborne illness through the proposed study and activities on retail food safety.
- b. Recommends that Assisted Living Facilities should be included in the facility types surveyed in the study.
- c. Recommends that FDA interview food handlers at retail food facilities.
- d. Strongly urges FDA to use weighted random sampling to select retail food facilities for the study and consider more factors for establishing sampling zones.
- e. Recommends that FDA work with State and local health departments to obtain data needed.

(Response 1) FDA provides the following responses to the comments provided by NACCHO:

- a. FDA thanks the submitter for supporting FDA's efforts to reduce the occurrence of foodborne illness through the proposed study and activities on retail food safety.
- b. The information collection identifies assisted living facilities within the Long-Term Care category. The study protocol defines Long-Term Care Facilities as foodservice

operations that prepare meals for residents in a group care living setting such as nursing homes and assisted living centers.

- c. The study data collection protocol combines direct observations of procedures and practices and interaction with both the Person In Charge and front line food employees.
- d. Sampling zones for this information collection contain approximately 59 percent of all healthcare establishments, 59 percent of all school establishments, and 61 percent of all retail food store establishments in the contiguous United States. The sample size of the information collections provides sufficient observations to be 95 percent confident that compliance percentages derived from the data collections are within 5 percent of their actual occurrence.
- e. This type of research requires a standardized design and methodology to ensure that the occurrences of the foodborne illness risk factors are uniformly assessed. Retail Food Specialists are standardized by the Center for Food Safety and Applied Nutrition and have a strong working knowledge of retail food industry. State and local regulators are encouraged to accompany the data collectors during the data collection.

(Comment 2) Academy of Nutrition and Dietetics commented that they support the proposed information collection for 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 FDA evaluate the impact of conducting surveys during non-peak hours of operation.
- c. Suggest that the use of gloves is not adequately addressed in the survey.

- d. Recommend adding a food allergy component.
- e. Encourage continued efforts to simplify and standardize expiration dates.

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

- a. Seeks clarification related to health systems as to whether FDA will focus on the central facilities in hospital food service due to their higher potential reach, impact, and risk.
- b. Seeks clarification whether the survey will be part of routine inspections or in addition to them and whether the information collections will be scheduled or unannounced.
- c. Seeks clarification on how FDA will analyze the information collected and which data points will be tied to which outcomes.

(Response 2) FDA thanks the submitter for their comment 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 that provide the best opportunity to observe food preparation activities.
- 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 edition of the FDA Model Food Code. Provisions of the Food Code

identify when handwashing and no bare hand contact with ready-to-eat food are required during food preparation and service. The current Food Code does not recognize the use of hand antiseptics in lieu of handwashing during food preparation and service.

- d. The study is collecting information regarding the knowledge of the person in charge related to food allergens and training of food service employees on allergy awareness as it relates to their assigned duties in their facility.
- e. 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 institutional operations at the retail level, FDA provides the following responses:

- a. The data collection protocol provides the definition of the hospital facility type that will be the focus of information collection. It is described as foodservice operations that provide for the nutritional needs of inpatients, by preparing meals and transporting them to the patient's room and/or serving meals in a cafeteria setting (meals in the cafeteria may also be served to hospital staff and visitors).
- b. The data collections are unannounced and separate from any regulatory routine inspections. Industry's participation in the study is voluntary. This methodology allows for assessment of direct observations related to the foodborne illness risk factors during food preparation and service.
- c. The study is designed to investigate data points focused on the relationship between food safety management systems, certified food protection managers, and the occurrence of

risk factors and food safety behaviors/practices commonly associated with foodborne illness in the randomly selected facility.

Data items 1 through 10 are considered primary data items. Each of the primary data items has been placed under the appropriate FDA foodborne illness risk factor category that will be used as the key indicator for FDA's statistical analysis for the study:

- Risk Factor--Poor Personal Hygiene
 - (1) Employees practice proper handwashing
 - (2) Food Employees do not contact ready-to-eat foods with bare hands
- Contaminated Equipment/Protection from Contamination
 - (3) Food is protected from cross-contamination during storage, preparation, and display
 - (4) Food contact surfaces are properly cleaned and sanitized
- Improper Holding/Time and Temperature
 - (5) Foods requiring refrigeration are held at the proper temperature
 - (6) Foods displayed or stored hot are held at the proper temperature
 - (7) Foods are cooled properly
 - (8) Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening
- Inadequate Cooking
 - (9) Raw animal foods are cooked to required temperatures
 - (10) Cooked foods are reheated to required temperatures

The burden for the 2019 to 2020 data collection is as follows. For each data collection, the respondents will include: (1) the person in charge of the selected facility (whether it be a healthcare facility, school, or supermarket/grocery store) and (2) the program director (or

designated individual) of the respective regulatory authority. 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 $\times$ 3 facility types $\times$ 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 during the site visit and answer the data collector's 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 uses the average data collection duration for similar facility types during the FDA's 2008 Risk Factor Study plus an additional 30 minutes (0.5 hour) for the information related to Section 2 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 hour) to answer the questions related to Section 2 of the form. This burden estimate is unchanged from the last data collection. Hence, the total burden estimate for a data collection in healthcare facility types is 180 minutes (150 + 30) (3 hours), in schools is 150 minutes (120 + 30) (2.5 hours), and retail food stores is 210 minutes (180 + 30) (3.5 hours).

Based on the number of entry refusals from the 2015 to 2016 baseline data collection, we estimate a refusal rate of 2 percent for the data collections within healthcare, school, and retail food store facility types. The estimate of the time per non-respondent is 5 minutes (0.08 hour) for the person in charge to listen to the purpose of the visit and provide a verbal refusal of entry.

FDA estimates the burden of this collection of information as follows:

Table 2.--Estimated Annual Reporting Burden¹

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
2019-2020 Data Collection (Healthcare Facilities)--Completion of Sections 1 and 3	400	1	400	-	-	-	2.5	1,000
2019-2020 Data Collection (Schools)--Completion of Sections 1 and 3	400	1	400	-	-	-	2	800
2019-2020 Data Collection (Retail Food Stores)--Completion of Sections 1 and 3	400	1	400	-	-	-	3	1,200
2019-2020 Data Collection-Completion of Section 2--All Facility Types	1,200	1	1,200	-	-	-	0.5 (30 minutes)	600
2019-2020 Data Collection-Entry Refusals--All Facility Types	-	-	-	24	1	24	0.08 (5 minutes)	1.92

Table 2.--Estimated Annual Reporting Burden¹

Total	3,601.92
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¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden for this information collection has not changed since the last OMB approval.

II. References

The following references are on display in the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. "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 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 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)." Available at: <https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm>.

5. "FDA Food Code." Available at: <https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm>.
Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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