

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS–10650]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 30, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

Type of Information Collection Request: Extension without change of a previously approved collection; *Title of Information Collection:* State Permissions for Enrollment in Qualified Health Plans in the Federally-Facilitated Exchange & Non-Exchange Entities; *Use:* On March 23, 2010, the Patient Protection and Affordable Care Act (PPACA; Pub. L. 111–148) was signed into law and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was signed into law. The two laws implement various health insurance policies. This Information Collection Request (ICR) serves as the renewal of the data collection clearance related to the ability of states to permit agents and brokers, as well as web-brokers, to assist qualified individuals, qualified employers, or qualified employees enrolling in Qualified Health Plans in the Federally Facilitated Exchange (45 CFR 155.220) and data collection requirements related to non-exchange entities. (45 CFR 155.260). *Form Number:* CMS–10650 (OMB control number: 0938–1349); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 93,684; *Number of Responses:* 93,684; *Total Annual Hours:* 473,440. (For questions

regarding this collection, contact Michele Oshman at (410–786–4396).

William N. Parham, III,
Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–19558 Filed 8–29–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA–2024–N–0021]

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 Restaurant and Retail Foodservice 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: Submit written comments (including recommendations) on the collection of information by September 30, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910–0744. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@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 Restaurant and Retail Foodservice Facility Types

OMB Control Number 0910-0744—
Revision

This information collection supports food safety projects administered by FDA. 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; however, an additional data collection is planned for 2023–2025 (the subject of this information collection request extension). Three data collections are necessary to trend the data.

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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 results of this study period will be used to:

- Develop retail food safety initiatives, policies, and targeted intervention strategies focused on controlling foodborne illness risk factors;
 - Provide technical assistance to State, local, tribal, and territorial regulatory professionals;
 - Identify FDA retail work plan priorities; and
 - Inform FDA resource allocation to enhance retail food safety nationwide.
- The objectives of this study are to:

- Identify the least and most often occurring foodborne illness risk factors and food safety behaviors/practices in restaurants within the United States;
- 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 and food safety behaviors/practices; and
- Determine whether the occurrence of foodborne illness risk factors food safety behaviors/practices in delis differs based on an establishment’s risk categorization and status as a single-unit or multiple-unit operation (e.g.,

restaurants that are part of an operation with two or more units).

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

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/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/](https://wayback.archive-it.org/7993/20170406023011/https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf)

[Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf](https://www.fda.gov/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](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>.

within the operation.⁵ The intent is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 25 Retail Food Specialists (Specialists) who serve as the data collectors for the study. 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 handwashing. 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 follow-up 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 handwashing. 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.

The burden associated with the completion of Sections 1 and 3 of Form FDA 3967 is specific to the persons in charge of the selected facilities. The burden 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. This burden includes the time it will take to answer the data collectors’ questions and is the same regardless of the facility type. 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 Institute 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. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study.

In the **Federal Register** of March 6, 2024 (89 FR 15996), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received. It was in favor of the study, but it was not responsive to the four collection of information topics solicited.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number 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.

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. Since the publication of the 60-day notice, we made adjustments to our burden estimate. Our estimated burden for the information collection reflects a

decrease of 35 total burden hours and a corresponding decrease of 792 total annual responses.

Dated: August 27, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
 [FR Doc. 2024–19574 Filed 8–29–24; 8:45 am]
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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0740]

Policy Letter for the Application of Fishing Vessel Construction Requirements

AGENCY: Coast Guard, DHS.
ACTION: Notice of availability.

⁵ FDA, “FDA Food Code.” Available at <https://www.fda.gov/FoodCode>.