

the prevention of food safety problems before they occur. With the enactment of FSMA in 2011, the collaboration with NCFST/IFSH has become increasingly important as FDA works to fulfill its mandate to develop a modern, prevention-based food safety system. FDA regards the development and strengthening of public-private partnerships for research and outreach on preventive controls to be a key element of its FSMA implementation strategy.

This cooperative agreement will provide continued support so that NCFST/IFSH can meet the objective to support the implementation of FSMA through research, education, and outreach, with particular emphasis on identifying the science to support implementation of preventive controls associated with manufacturing, processing, packing, and holding of human and animal food, and on training and technical assistance.

### C. Eligibility Information

Competition is limited to IIT as FDA believes IIT's continued support of the Food Safety Preventive Controls Alliance (FSPCA) already established at NCFST/IFSH uniquely qualifies IIT to fulfill the objectives of the proposed cooperative agreement. IIT's Moffett Center, where NCFST is located, is a unique facility that includes offices, classrooms, a distance-learning center, and support facilities, which permit appropriate research, development, and training activities. The physical layout of the facility provides maximum versatility in the use and capability to simultaneously operate several different activities related to research, development, and training to support FSMA rules. The distance learning facility located in room 216 in building 91 of the IIT Moffett Campus is equipped with state-of-the-art audio-visual equipment for conducting and broadcasting interactive training programs and workshops to the food industry, as well as for Webinar communications with IFSH stakeholders, including government, academia, and industry.

Since 1988, IIT has provided an environment in which scientists from diverse backgrounds such as academia, government, and industry have brought their unique perspectives to focus on contemporary issues of food safety. NCFST/IFSH functions as a neutral ground where scientific exchange about generic food safety issues occurs freely and is channeled into the design of cooperative food safety programs. Activities at NCFST are focused on multiple areas associated with food

safety and FSMA, including but not limited to, preventive controls for human and animal foods, supplier verification, and national training.

Since 2011, IIT has served as the coordinator of the FSPCA and, since 2012, the Sprout Safety Alliance (SSA), leveraging the expertise of academia, industry, and FDA for the purpose of developing and delivering standardized curricula related to food safety and FSMA requirements. In addition to alliance training, NCFST/IFSH plans to develop the National Training and Technical Assistance Network to provide outreach and technical assistance to industry in the future. The new distance-learning training center developed at the IIT's Moffett Center can be used to partially address training and outreach needs related to FSMA. Through this facility, training can be provided on curricula currently being developed by the FSPCA for human and animal food and by the SSA for sprouts, and for training activities related to other appropriate FSMA activities such as the Foreign Supplier Verification Program.

The proposed cooperative activities will fill existing gaps in knowledge, food safety training, and expertise for outreach associated with improving the safety of foods via FSMA implementation, and will provide fundamental food safety information in the public domain for use by all segments of the food science community for industry and regulatory training activities.

## II. Award Information/Funds Available

### A. Award Amount

The Center for Food Safety and Applied Nutrition (CFSAN) at FDA intends to commit up to \$5 million in FY 2015 (direct plus indirect costs) with the possibility of 2 additional years of up to \$7 million each year. Future year amounts will depend on annual appropriations and successful performance.

### B. Length of Support

The award will provide 1 year of support and include future recommended support for 2 additional years, contingent upon satisfactory performance in the achievement of project and program objectives during the preceding year and the availability of Federal fiscal year appropriations.

## III. Electronic Application, Registration, and Submission

Only one electronic application will be accepted. To submit an electronic application in response to this FOA, the

applicant should first review the full announcement located at <http://www.grants.gov/>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) For the electronically submitted application, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 6, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit the electronic application to: <http://www.grants.gov>.

Dated: July 15, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-2076]

### 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 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 August 20, 2015.

**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](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0744. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto: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 Facility Types (2013–2022)**

OMB Control Number 0910–0744

**I. Background**

In 2013–2014, the U.S. Food and Drug Administration (FDA) initiated a study in two foodservice facility types: Full service and fast food restaurants. The study will span 10 years in its entirety and aims to:

- Assist 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 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/cross-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; 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.

TABLE 1—DESCRIPTION OF THE FACILITY TYPES INCLUDED IN THE SURVEY

Facility type	Description
Full Service Restaurants .....	A restaurant where customers place their order at their table, are served their meal at the table, receive the service of the wait staff, and pay at the end of the meal.
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.

The statutory basis for FDA conducting this study is derived from the Public Health Service Act (42 U.S.C. 243, section 311(a)). 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 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 foodborne illness risk factors that are in most need of priority attention during each data collection period;
- Track trends in the occurrence of foodborne illness risk factors over time;
- 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
- Evaluate the impact of industry food safety management systems in controlling the occurrence of foodborne illness risk factors.

The data from the 2013–2014 information collection in restaurants is currently being analyzed by FDA. A

report summarizing the findings is expected to be released in 2015. In order to analyze trends, FDA is proposing to conduct two additional data collections in 2017–2018 and 2021–2022 using the same methodology employed in the 2013–2014 data collection. This methodology is described as follows.

In order to obtain a sufficient number of observations to conduct statistically significant analysis, FDA will conduct approximately 400 data collections in each restaurant facility type during each data collection period. 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 will be used as the establishment inventory for the data collections. FDA will sample 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. 1). The intent is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 25 Regional Retail Food Specialists (Specialists) who will 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. 1).

Sampling zones will be established which are equal to the 150 mile radius around a Specialist’s home location. The sample will be 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 will be 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 will be selected for each Specialist for cases where the restaurant facility is misclassified, closed, or otherwise unavailable, unable, or unwilling to participate.

Prior to conducting the data collection, Specialists will contact the state or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected establishment. The Specialist will verify with the jurisdiction that the facility has been properly classified for the purposes of the study and is still in operation. The Specialist will also ascertain 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 will be extended to the state or local regulatory authority to accompany the Specialist on the data collection visit.

A standard form will be 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" will be obtained during an interview with the establishment owner or person in charge by the Specialist and will include a standard set of questions.

The information in Section 2—"Regulatory Authority Information" will be 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 being implemented by the facility; and Part C for assessing the frequency and extent of food employee hand washing. The information in Part A will be 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 will be 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 will be collected by making direct observations of food employee hand washing. No questions will be asked in the completion of Section 3, Part C of the form.

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. 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, 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.

FDA is working with the National Center for Food Protection and Defense to develop a Web-based platform in FoodSHIELD to collect, store, and analyze data for the Retail Risk Factor Study. Once developed, this platform will be accessible to state, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies. FDA is currently transitioning from the manual entry of data to the use of hand-held technology. FDA will be pilot testing the use of hand-held technology during its 2015–2016 risk factor study data collection in institutional foodservice and retail food stores, with the goal to have it fully implemented for the 2017–2018 data collection in restaurants. When a data collector is assigned a specific establishment, he or she will conduct the data collection and enter the information into the Web-based data platform. The interface will support the manual entering of data, as well as the ability to upload a fillable PDF.

In the **Federal Register** of December 11, 2014 (79 FR 73596), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment; however, this comment did not address the information collection.

The burden for the 2017–2018 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 data collection (*i.e.* 400). Therefore, the total number of responses for restaurants will be 1,600 (400 data collections × 2 facility types × 2 respondents per data collection).

The burden associated with the completion of Sections 1 and 3 of the form is specific to the person 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 2013–2014 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), respectively, to accompany the data collectors while they complete Sections 1 and 3 of the form. In comparison, for the 2013–2014 data collection, the burden estimate was 106 minutes (1.76 hours) in full service restaurants and 73 minutes (1.21 hours) in fast food restaurants. 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. This burden estimate is 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 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 2013–2014 data collection, we estimate a refusal rate of 2 percent. 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 2—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Number of non-respondents	Number of responses per non-respondent	Total annual non-responses	Average burden per response	Total hours
2017–2018 Data Collection (Fast Food Restaurants)—Completion of Sections 1 and 3 .....	400	1	400	.....	.....	.....	1.36	544
2017–2018 Data Collection (Full Service Restaurants)—Completion of Sections 1 and 3 .....	400	1	400	.....	.....	.....	1.73	692
2017–2018 Data Collection—Completion of Section 2—All Facility Types .....	800	1	800	.....	.....	.....	0.5 (30 minutes)	400
2017–2018 Data Collection—Entry Refusals—All Facility Types .....	.....	.....	.....	16	1	16	0.08 (5 minutes)	1.28
<b>Total Hours</b> .....	.....	.....	.....	.....	.....	.....	.....	1,637.28

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**II. Reference**

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. *FDA Food Code* available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm>.

Dated: July 15, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

[Document Identifier: HHS–OS–0990–0424–30D]

**Agency Information Collection Activities; Proposed Collection; Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on the ICR must be received on or before August 20, 2015  
**ADDRESSES:** Submit your comments to [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or by calling (202) 690–6162.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or (202) 690–6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier HHS–OS–0990–0424–30D for reference.

*Information Collection Request Title:* Pregnancy Assistance Fund (PAF) Study Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting approval by OMB on a revised data collection. The Pregnancy Assistance Fund (PAF) Study will provide information about program design, implementation, and impacts through a rigorous assessment of program impacts and implementation of

two programs designed to support expectant and parenting teens. These programs are located in Houston, Texas and throughout the state of California. This revision to this information collection request includes the 12-month follow-up survey instrument related to the impact study. The data collected from this instrument in the two study sites will provide a detailed understanding of program impacts about one year after youth are enrolled in the study, at which time they first have access to the programming offered by each site. Clearance is requested for three years.

*Need and Proposed Use of the Information:* The data will serve two main purposes. First, the data will be used to determine program effectiveness by comparing outcomes on repeat pregnancies, sexual risk behaviors, health and well-being, and parenting behaviors between treatment (program) and control youth. Second, the data will be used to understand whether the programs are more effective for some youth than others. The findings from these analyses of program impacts will be of interest to the general public, to policymakers, and to organizations interested in supporting expectant and parenting teens.

*Likely Respondents:* 1,913 study participants