

Supporting Statement Part A

**Supporting Statement (Part A: Justification) of the
Request for OMB Review and Approval of
Environmental Health Specialists Network (EHS-Net) Program
Revision**

**OMB No. 0920-0792
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**Laura Brown, Ph.D.
EHS-Net
Centers for Disease Control and Prevention
National Center for Environmental Health
Emergency and Environmental Health Services
Environmental Health Services Branch
4770 Buford Highway
Atlanta, GA 30341-3724
lrg0@cdc.gov
770-488-4332**

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Goal of the study: The goal of this food safety research program (Environmental Health Specialists Network [EHS-Net]) is to collect data in retail food establishments that will identify and help to understand environmental factors (e.g. manager food safety certification, implementation of food safety practices, etc.) associated with retail-related foodborne illness and outbreaks.

Intended use of the resulting data: The information collected from establishments will be used by CDC to develop food safety prevention and intervention recommendations for environmental public health/food safety programs and the retail food establishment industry.

Methods to be used to collect data: Data will be collected through interviews or pen-and-paper assessments; and observations in random samples of food establishments in the EHS-Net-funded state and local food safety programs.

Subpopulation to be studied: The population to be studied will be randomly sampled voluntarily participating restaurants in the EHS-Net funded programs' jurisdictions (Minnesota; New York City; New York; Tennessee; Rhode Island; Franklin County, Ohio; Southern Nevada Health District; and Harris County, Texas).

How data will be analyzed: Initial analyses will typically involve descriptive analyses and tests for association. Additional logistic or multivariable regression will be performed where appropriate.

A. Justification

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), is requesting a three-year Paperwork Reduction Act (PRA) approval for the revision Generic Information Collection (Generic ICR) titled, Environmental Health Specialists (EHS-Net) Program (OMB Control No. 0920-0792; exp. date: 8/31/2021). The EHS-Net program, developed by CDC, conducts studies designed to identify and understand environmental factors associated with foodborne illness outbreaks and other food safety issues (e.g., ill workers). These data are essential to environmental public health regulators' efforts to respond more effectively to and prevent future outbreaks and food safety-associated events. This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Appendix A).

The current request for PRA clearance is a revision, which involves modest modifications to the Generic ICR.

EHS-Net is a collaborative project of the CDC, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and eight state and local public health departments (Minnesota; New York City; New York; Tennessee; Rhode Island; Franklin County, Ohio; Southern Nevada Health District; and Harris County, Texas); The EHS-Net sites are funded through CDC cooperative agreement EH20-001. EHS-Net's funding to these state and local health departments enables them to collaborate with CDC on study design, and data collection and analysis. The federal partners provide funding and input into study design, data analysis, and ensuring that research is not overlapping with their own studies.

Foodborne illness is a significant problem in the U.S.—an estimated 48 million cases of domestically acquired foodborne illness in the United States annually, resulting in over 127,000 hospitalizations and, over 3,000 deaths (Scallan, Griffin, Angulo, Tauxe, & Hoekstra, 2011; Scallan, Hoekstra, et al., 2011). Angulo (2006) reported that over 50% of the reported foodborne outbreaks are attributable to restaurants, making an understanding of the practices implemented in these establishments critical to preventing future cases of foodborne illness. Reducing foodborne illness requires identification and understanding of

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the environmental factors that allow these illnesses to occur – we need to know how and why the food becomes contaminated.

Environmental factors associated with foodborne illness include both food safety practices (e.g., inadequate cleaning practices) and the factors in the environment associated with those practices (e.g. worker and retail food establishment characteristics). To understand these factors, we need to collect data from those who prepare food (i.e., food workers) and on the environments in which the food is prepared (i.e. retail food establishment kitchens). Each EHS-Net data collection will be a onetime data collection with a well-defined scope and objectives. Data collection methods for this generic package include: manager and food worker interviews/assessments and observation of restaurants. Both methods allow data collection on complementary aspects of the food safety practices and environmental factors associated with those practices.

This data collection supports the U.S. Department of Health and Human Services' Healthy People 2020 Goal to "Improve food safety and reduce foodborne illnesses." Specifically, these studies can be used to understand the inter-relationship between existing intervention strategies (e.g. development of procedures and training) and food safety performance. It can also be used to understand current implementation practices of food safety provisions. This knowledge will allow for the development of future interventions that may have a higher efficacy in improving food safety practices.

Background

An estimated 47.8 million foodborne illnesses occur annually in the United States, resulting in 127,839 hospitalizations, and 3,037 deaths annually (Scallan, Hoekstra et al., 2011; Scallan, Griffin et al., 2011). These figures indicate that foodborne illness is a significant problem in the U.S.

Reducing foodborne illness requires identification and understanding of the environmental factors that cause these illnesses—we need to know how and why food becomes contaminated with foodborne illness pathogens. This information can then be used to determine effective food safety prevention methods. Ultimately, these actions can lead to increased regulatory program effectiveness and decreased foodborne illness. The purpose of this food safety research program is to identify and understand environmental factors associated with foodborne illness and outbreaks. This program is conducted by the Environmental Health Specialists Network (EHS-Net), a collaborative project of CDC, FDA, USDA, and local and state sites.

Environmental factors associated with foodborne illness include both food safety practices (e.g., inadequate cleaning practices) and the factors in the environment associated with those practices (e.g., worker and retail food establishment characteristics). To understand these factors, we need to collect data from those who prepare food (i.e., food workers) and on the environments in which the food is prepared (i.e., retail food establishment kitchens). Thus, data collection methods for this generic package include: 1) manager and worker interviews/information collection instruments, and 2) observation of kitchen environments. Both methods allow data collection on food safety practices and environmental factors associated with those practices.

On October 21, 2008, OMB gave generic clearance to CDC's EHS-Net program (no. 0920-0792). OMB gave generic clearance to a revision of the EHS-Net program on February 29, 2012, and then again on August 13, 2018. The current submission requests a revision of this OMB generic clearance. This revision will provide OMB clearance for EHS-Net data collections conducted in 2021 through 2024.

Experience to Date

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To date, EHS-Net has conducted five studies under this generic clearance. The first study collected data on improper cooling of hot foods, a food handling practice associated with foodborne illness and outbreaks. The second study collected data on the relationship between kitchen manager food safety certification and foodborne illness risk factors in restaurants. Public health agencies are increasingly encouraging or requiring certification as a foodborne illness prevention measure, yet little is known about its effectiveness. The third study collected data on the environmental factors associated with contamination of the retail deli environment with *Listeria*, a foodborne illness pathogen ranked 3rd in terms of the number of deaths it causes. This study was conducted at the request of and in collaboration with USDA, who will use the data to inform their ground-breaking *Listeria* risk assessment modeling. The fourth study collected data on restaurant managers' and workers' food allergen knowledge, attitudes, and practices. Food allergens are an important food safety issue for restaurants. Data indicate that severe allergic reactions caused by foods account for 50,000-125,00 emergency room visits per year in the U.S. and that food allergic reactions commonly occur in restaurants, with prevalence estimates ranging from 14% to 47%. The fifth study collected data on restaurant managers' and workers' food safety attitudes, beliefs, and practices to assess restaurants' food safety culture and its relationship to food safety practices. Recent research indicates that food safety culture may be an important component of restaurant food safety.

The data from these studies have been disseminated to environmental public health/food safety regulatory programs and the food industry in the form of presentations at conferences and meetings, scientific journal publications, and website postings. To date, we have presented data from these studies in nine articles in peer-reviewed scientific journals, in multiple presentations at national food safety conferences, and on CDC's website. We are still analyzing the data from three of these studies and expect that they will continue to provide valuable and useful data about environmental factors associated with foodborne illness outbreaks and food safety issues. We will continue to disseminate the data through presentations at conferences and meetings, publications, and website postings.

The current package differs from the previous package in three primary ways, described below.

- The sites in which data will be collected differ. CDC funded a renewal of the EHS-Net cooperative agreement in 2020; as a result, one site was dropped from the agreement (California), and one was added (Franklin County, Ohio). The other sites remained the same. These are: Harris County, Texas; Minnesota, New York; New York City, New York; Rhode Island; Southern Nevada Health District, Nevada; and Tennessee.
- Since the previous PRA clearance, the NCEH Human Subjects Contact has determined that EHS-Net information collections are not human subjects research, and thus, do not require IRB review or approval.
- The annual burden estimate has been revised downward by 933 hours from 1,777 hours in 2018 to 844 hours in 2021. We estimated interviewing 10 workers per restaurant in the last cycle; we have revised this down to 5 workers per restaurant.

A.1. Circumstances Making the Collection of Information Necessary

The purpose of the information collection is to identify and understand environmental factors associated with foodborne illness outbreaks.

This research program is conducted by the Environmental Health Specialists Network (EHS-Net), a collaborative project of the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and state and local sites. It is funded by the CDC's National Center for Environmental Health, Water, Food, and Environmental Health Services Branch. The federal partners provide funding and input into study design and data analysis. The

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site partners, funded by CDC, work with CDC to design studies, and collect and analyze data from these studies. These state and local sites were Franklin County, Ohio; Harris County, Texas; Minnesota, New York; New York City, New York; Rhode Island; Southern Nevada Health District, Nevada; and Tennessee.

Research indicates that retail food establishments are an important source of foodborne illnesses and outbreaks. Case-control studies have revealed significant associations between eating at retail food establishments and sporadic foodborne illness infections (Friedman et al., 2004; Kassenborg et al., 2004). Additionally, results of outbreak investigations indicate that restaurants are the most common location of outbreaks (CDC, 2017, CDC, 2019). Thus, our data collection efforts have focused on retail food establishments.

Environmental factors associated with foodborne illness include both food handling and food safety practices and behaviors (e.g., inadequate cooking and cleaning practices) and the factors in the environment associated with those practices (e.g., worker characteristics, such as lack of worker food safety knowledge; and establishment characteristics, such as lack of food safety policies and lack of adequate equipment). To understand these environmental factors, we need to collect data from those who store, prepare and cook food (i.e., food workers) and on the environments in which the food is stored, prepared, and cooked (i.e., retail food establishment kitchens). Thus, data collection methods for this generic package include: 1) manager and worker interviews/pen-and-paper assessments, and 2) observation of kitchen environments. Both methods allow data collection on food handling and food safety practices and behaviors and environmental factors associated with those practices, such as worker and establishment characteristics.

EHS-Net data collections are often conducted in response to foodborne illness outbreaks. Timely data on factors related to outbreaks are essential to environmental public health regulators' efforts to respond to outbreaks and prevent future, similar outbreaks. Due to its composition of state and federal environmental public health regulators, which leads to unique expertise and ability at collecting data on environmental factors in retail food establishments, EHS-Net is the best mechanism for responding to the need for these data. EHS-Net data collections are designed to provide data on environmental factors associated with foodborne illness outbreaks and answer specific questions related to the causes of outbreaks. This information is then used to assist environmental public health regulatory programs in responding more effectively to outbreaks and in developing effective prevention recommendations and actions to prevent future outbreaks.

EHS-Net's tomato handling practices data collection provides an example of a situation in which EHS-Net was able to quickly collect data essential to environmental public health regulatory programs. In response to several outbreaks associated with tomatoes in restaurants, EHS-Net collected data on restaurants' tomato handling policies and practices (Kirkland, et al., 2009). These data were used by CDC and FDA to determine policies and practices that could be changed to reduce the occurrence of future, similar outbreaks.

EHS-Net is the only research program of which we are aware that has the collective expertise and ability to collect high quality data on environmental factors of foodborne illness in retail food establishments. As knowledge about environmental factors is critical to the development of effective foodborne illness prevention and intervention methods, it is important that EHS-Net continue to collect these valuable data.

The data collections conducted by the EHS-Net research program support CDC's research agenda goal of "Decreasing health risks from environmental exposures," as foodborne illness is an environmental exposure health risk. The data collections also support CDC's winnable battle of reducing foodborne

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diseases (<http://www.cdc.gov/winnablebattles/foodsafety/index.html>). Data collection authority is found in Section 301 of the Public Health Service Act (42 USC 241) (Appendix A).

A.2. Purpose and Use of the Information Collection

The purpose of the information collection is to gather data that will help us identify and understand environmental factors associated with foodborne illness.

Specifically, the information will be used to:

- 1) Describe retail food establishment food handling and food safety practices and manager/worker and establishment characteristics.
- 2) Determine how retail food establishment and worker characteristics are related to food handling and food safety practices.

The data will be used to enable CDC to develop food safety prevention and intervention recommendations for environmental public health/food safety programs and the retail food establishment industry. For example, if an EHS-Net research project identifies an unsafe food handling practice or an environmental factor associated with an unsafe food handling practice, CDC can develop food safety recommendations addressing it. In turn, environmental public health regulatory programs and the food industry can take action to address the recommendation. This process will lead to increased food safety regulatory program effectiveness, increased industry effectiveness, increased food safety, and decreased foodborne illness.

To date, EHS-Net has summarized its research efforts in 30 publications and has presented its research findings at numerous conferences. Also, CDC and FDA used EHS-Net research to support a change to the 2017 FDA Food Code that requires restaurants to have a Certified Food Protection Manager present during all hours of operation. State and local food codes are based on the FDA Food Code; thus, this change is significant and influential.

Applicability of Results

Data will be collected in a random sample (obtained through the use of a statistical software package) of the retail food establishments in the jurisdictions of the eight EHS-Net sites funded through the EHS-Net cooperative agreement. These sites are demographically diverse and provide good geographical coverage of the U.S. Random sampling will allow the results of collections covered by this generic OMB package to be used to generalize to the population of retail food establishments in the given EHS-Net sites.

Furthermore, the geographic and demographic variability across the sites may make it possible for CDC to use data collected from these studies to draw conclusions about relationships that are likely relevant to establishments in other parts of the U.S.

A.3. Use of Improved Information Technology and Burden Reduction

Most EHS-Net data collections will involve face-to-face or telephone interviews with respondents. Thus, respondents will provide their responses verbally to interviewers. Verbal responses, compared to typed or hand-written responses, are easier for the majority of respondents to provide. In some cases, data collections may also involve a short pen-and-paper assessment. An example would be a food safety knowledge assessment. In these cases, we would ensure that the required written response is easy and simple- circling an answer choice, for example.

Participation in all EHS-Net data collections is voluntary, and every effort will be made to reduce the overall burden on respondents and still meet the needs of the data collections.

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A.4. Efforts to Identify Duplication and Use of Similar Information

EHS-Net strives to ensure that the data collections proposed are not a duplication of effort. We search relevant scientific bibliographical databases (e.g., PubMed, Ovid, Agricola), attend national meetings (e.g., National Environmental Health Association, International Association of Food Protection), and consult with other organizations (e.g., FDA, USDA-FSIS) concerning research on the proposed topics. We have determined that there is little high quality data available on retail food worker and establishment characteristics combined with food handling and food safety practices. However, prior to designing each data collection, we will conduct a comprehensive review of the scientific literature to determine if data already exist on the specific topic of interest.

A.5. Impact on Small Businesses or Other Small Entities

We expect that about half of the restaurants contacted for participation in this study will be small businesses. Given that small businesses are likely to have different experiences and practices than larger businesses, it is important that small businesses be included in the data collections. Short forms for small businesses will not be developed. Both large and small businesses will be presented with the same questions, and the results will be assessed for differences by various restaurant characteristics (e.g. seating capacity, number of food service workers, level of food handling, etc.). We will, however, strive to hold the number of questions to the minimum needed for the intended use of the data.

A.6. Consequences of Collecting the Information Less Frequently

Respondents will be asked to respond to each data collection only one time. If this data collection is not conducted, it will be more difficult for CDC, other federal, state and local food safety programs, and the food service industry to address the environmental factors that are associated with foodborne illness. In turn, it will be more difficult to decrease the number of incidents of foodborne illness caused by these factors and for CDC to fully address the U.S. Department of Health and Human Services' Healthy People 2020 Goal to "Improve food safety and reduce foodborne illnesses." There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with information collection package. This request fully complies with 5 CFR 1320.5 and will be voluntary.

A.8. Comments in Response to the *Federal Register* Notice and Efforts to Consult Outside the Agency

- A. The 60-day *Federal Register* notice was published April 5, 2021 in volume 86, number 63 (p. 17603) (Appendix B). No comments were received in response to the 60-day Federal Register Notice.
- B. Consultation with staff from EHS-Net participant sites, CDC centers, and federal agencies will occur in preparation for and in conjunction with the fielding of data collections under this request. Table 8.1 lists the current individuals that will be consulted. The officials identified under EHS-Net sites is comprised of epidemiology and environmental health professionals from each of the participating sites. These individuals have been actively involved in the identification, prioritization, development, and implementation of data collection activities in the past and we anticipate their ongoing support to play a similar role in the future. This list may change in the future as individuals take on new roles or change positions.

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Table A.8.2 lists the officials from each of the EHS-Net sites. These officials represent epidemiology and environmental health programs in the sites. They will be actively involved in the identification, prioritization, development and implementation of data collection activities in 2021-2024.

Table A.8.1 Federal Consultants

FDA/USDA	
<p>Laurie Williams Consumer Food Safety Officer Food and Drug Administration Center for Food Safety and Applied Nutrition 5100 Paint Branch Parkway College Park, MD 20740 Laurie.Williams@fda.hhs.gov</p>	<p>Stephanie Mickelson Epidemiologist USDA stephanie.mickelson@fns.usda.gov 703-305-2894</p>
<p>Glenda Lewis Team Leader, Retail Food Protection Team Food and Drug Administration Center for Food Safety and Applied Nutrition 5100 Paint Branch Parkway College Park, MD 20740 240-402-2150 Glenda.Lewis@fda.hhs.gov</p>	

Table A.8.3 State Consultants

2020-2025 EHS-Net Sites	
<p>Nicole Hedeem Epidemiologist MN. Dept. of Health Nicole.hedeem@state.mn.us 651-201-4075</p>	<p>Danny Ripley Food Inspector II TN Dept. of Health Danny.ripley@nashville.gov 615-340-5620</p>
<p>JoAnn Monroy Food Safety Program Manager Harris County Health Department joann.monroy@hcphe.org 713-274-6319</p>	<p>Lauren DiPrete Senior Coordinator Southern Nevada Health District DiPrete@snhdmail.org 702-759-1504</p>
<p>David Nicholas NY State Dept of Health Bureau of Community Sanitation & Food Protection Troy, NY 12180 (518) 402-7600 dcn01@health.state.ny.us</p>	<p>Brendalee Viveiros Environmental Health Program Rhode Island Department of Health Office of Food Protection Providence, RI 02908 (401) 222-2749 Brendalee.Viveiros@health.ri.gov</p>
<p>Nichole Lemin Assistant Health Commissioner Franklin County Public Health nikilemin@franklincountyohio.gov 614-525-6130</p>	<p>Wendy McKelvey Deputy Commissioner New York City Department of Health and Mental Hygiene wmckelvey@health.nyc.gov 212-788-9641</p>

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A.9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCEH Information Systems Security Officer (ISSO) has determined that the Privacy Act does not apply to these information collections. Information in identifiable form (IIF) will not be collected at the research sites. These information collections will collect anonymous data only. Therefore, a system of records notice (SORN) is not applicable.

EHS-Net data collectors will report data to CDC through a web-based information system, the REDCAP data management system. All electronic data will be stored on secure CDC networks. Access to the data will be limited to those with a bona fide need-to-know to perform job duties related to the project. User accounts will be issued to the specialists who will serve as the administrator of the system for his or her own site. Through these password-protected accounts, users will be granted privileges including entering and accessing data, and correction and deletion of records capabilities. All data records are owned by the site entering the data. Each site possesses ownership of its records and must grant permission to other sites or agencies who would like to use the data. Each site's data will be stored for twelve years.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

EHS-Net information collections have been classified as research not involving identifiable human subjects (Appendix D). CDC institutional review board (IRB) approval is not required. These collections center around restaurant food safety policies and practices, are not about human subjects, and do not ask sensitive questions.

Verbal consent will be obtained from respondents. Typical informed consent scripts can be found in Attachments 1 and 2. Participation in this data collection is voluntary, and respondents are informed of the voluntary nature of the data collection during recruiting (Attachments 2 and 3) and in informed consent scripts (Attachments 1 and 2).

A.11.1. Overview of the Data Collection System. Data for these studies will be collected by CDC-funded environmental health specialists employed by the EHS-Net sites (the state and local health departments participating in the EHS-Net cooperative agreement). These environmental health specialists are skilled and experienced in food safety and in retail food environments. Retail food establishment managers and/or workers will be the respondents for these studies. Data collection methods include: 1) manager/worker interviews/ pen-and-paper assessments (see examples in Attachments 4 and 5), and 2) observation of kitchen environments (see example in Attachment 6). These data collection methods will allow the collection of needed information about environmental factors associated with foodborne illness. Both methods allow data collection on food handling and food safety practices and environmental factors (e.g., manager/worker and establishment characteristics).

A.11.2. Items of Information to be Collected. No individually identifiable information will be collected.

A.11.3. How the Information will be Shared and for What Purpose. Data analysis results will be shared informally with the EHS-Net sites through presentations at EHS-Net meetings. Results will be shared with other stakeholders and the food safety and environmental public health community through presentations at meetings and conferences, peer-reviewed publications in scientific journals, and 'plain language' summaries on the CDC website. Results will be presented in aggregate form.

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The results will be used to develop recommendations for food safety and environmental public health programs and the retail food industry. For example, if a data collection identifies specific ways in which retail food establishments are handling tomatoes unsafely, CDC can develop recommendations that address these unsafe practices and disseminate the information to environmental public health programs and the retail food industry.

A.11.4. Whether Individuals are Informed that Providing Information is Voluntary or Mandatory.

Retail establishment managers will be informed that the provision of information, through interviews and site observations, is voluntary. They will be informed during the recruiting process (See example in Attachments 2 and 3), and at the beginning of the actual data collection process (See example in Attachment 6). Workers will be informed that the provision of information is voluntary at the beginning of the recruiting/data collection process (See example in Attachments 4 and 5). Both managers and workers will be told that their participation or lack thereof will not impact their food safety inspection outcomes. Workers will also be told that their manager will not be told whether or not they participate.

Note that the recruiting/informed consent process differs for managers and workers, because managers are contacted for recruiting purposes before the data collection visit to their establishment, we have two scripts for them: one for the initial recruiting call and the second for informed consent at the establishment. Workers are not contacted before the data collection visit to their establishment; thus, recruiting and informed consent happens in the same conversation; thus, there is only one recruiting/informed consent script for them.

A.11.5. Opportunities to Consent. Both managers and workers will be given the opportunity to verbally consent to participation (Attachments 1 and 2). Prior to beginning the data collection, the data collector will read to them a short introduction describing the purpose of the study and how the data will be used. The data collector will then ask them if they agree to participate in the study. Because the study is not considered human subjects research, documentation of consent is not required.

A.11.6. How information will be Secured. Hard copy data forms will be secured under lock and key at the EHS-Net sites. User accounts will be issued to authorized EHS-Net site personnel; these personnel will enter the data from these forms into a CDC electronic information system. The EHS-Net sites own all the data from their site. Only authorized CDC and EHS-Net site personnel can access this system. Additionally, this information system meets all CDC information technology security requirements; data stored in this system are secure.

A.12. Estimates of Annualized Burden hours and costs

For each project under this collection, we anticipate collecting data in approximately 50 restaurants per site. Thus, there will be approximately 400 restaurants per site (8 EHS-Net sites*50 restaurants). We anticipate a manager/restaurant recruitment rate of approximately 45%; thus, we will need to contact 889 restaurant managers to meet our goal of 400 respondents (Attachment 3 contains a sample telephone manager recruiting script). Each respondent to the script will respond only once, and the average burden per response will be approximately 3 minutes (44 annual burden hours.)

In restaurants that voluntarily agree to participate in this study, we will obtain verbal informed consent (Attachment 1) and interview the manager about the restaurant's characteristics and existing food safety procedures and practices (Attachment 4). It is estimated that manager interviews will take 30 minutes (200 annual burden hours). Following this, food worker(s) will be recruited from the restaurant for participation in either a semi-structured interview or structured written/electronic survey (Attachment 5). We anticipate recruiting a maximum of 5 food workers per restaurant with an estimated burden time of 2

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minutes per respondent for recruiting and informed consent (67 annual burden hours), and 10 minutes per respondent for data collection (333 annual burden hours).

The EHS-Net data collectors will complete the restaurant observation form (Attachment 6) documenting practices and infrastructure in the restaurant related to food safety. These observations will require interactions between the data collectors and managers and is estimated to take approximately 30 minutes (200 annual burden hours). As the HD staff are compensated for their time through a cooperative agreement (EH20-001), the HD staff burden hours will not be reflected in the annualized burden; this is reflected in the annualized costs to the federal government (awards to sites) in Table 14.1. The table includes the observation burden for managers (200 annual burden hours).

For the specific study designs, we will assess the number of respondents and time necessary and strive to minimize the burden, when possible. We have provided conservative estimates in Tables 12.1 and 12.2, as a data collection study would not occur on an annual basis; we expect to conduct two (three maximum) data collections during a three-year PRA cycle.

A.12-1- Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Retail managers	Manager Telephone Recruiting Script	889	1	3/60	44
	Manager Interview/Assessment	400	1	30/60	200
	Observation	400	1	30/60	200
Retail food workers	Worker Recruiting/Informed Consent Script	2,000	1	2/60	67
	Worker Interview/Assessment	2,000	1	10/60	333
Total					844

A.12-2- Annualized Cost to Respondents

The maximum total annualized cost of this data collection to respondents is estimated in Table 12-2. This figure is based on an estimated mean hourly wage of \$18.21 for managers (occupational code 35-1012) and \$13.38 for workers (occupational code 35-2000). These estimated hourly wages were obtained from the U.S. Department of Labor Bureau of Labor Statistics 2020 National Occupational Employment and Wage Estimates (https://stats.bls.gov/oes/current/oes_nat.htm).

12.2- Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Managers	444	\$18.21	\$8,085.24
Workers	400	\$13.38	\$5,352.00
Total			\$13,437.24

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A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There will be no direct costs to the respondents other than their time to participate in each information collection.

A.14. Annualized Cost to the Federal Government

The annualized cost to the federal government is \$818,333. Costs to the government include a portion of the total EHS-Net funding provided to 8 EHS-Net sites, salaries of CDC employees and contractors supporting the program, and travel (Table A.14.1).

14.1-Estimated Annualized Cost to the Federal Government

Expenditure	Cost
Awards to sites (\$64,167 * 8 sites)	\$513,333
CDC Salary (50% of 2 staff members)	\$150,000
FOA administration	\$150,000
Travel for site visits	\$5,000
Total	\$818,333

A.15. Explanation for Program Changes or Adjustments

This is a revision ICR for a generic clearance that expires on 8/31/2021. The current package differs from the previous package in three primary ways, described below.

- The sites in which data will be collected differ. CDC funded a renewal of the EHS-Net cooperative agreement in 2020; as a result, one site was dropped from the agreement (California), and one was added (Franklin County, Ohio). The other sites remained the same. These are: Harris County, Texas; Minnesota, New York; New York City, New York; Rhode Island; Southern Nevada Health District, Nevada; and Tennessee.
- Since the previous PRA clearance, the NCEH Human Subjects Contact has determined that EHS-Net information collections are not human subjects research, and thus, do not require IRB review or approval.
- The annual burden estimate has been revised downward by 933 hours from 1,777 hours in 2018 to 844 hours in 2021. We estimated interviewing 10 workers per restaurant in the last cycle; we have revised this down to 5 workers per restaurant.

After 2018, the time burden table and attachment numbers have been restructured in 2021 as follows:

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Type of Respondents	Form Name	Form Number		Description of Changes
		2018	2021	
Retail managers	Manager Telephone Recruiting Script	Att 5	Att 3	No change in burden estimate.
	Manager Interview/Assessment	Att 7	Att 4	Remove “Informed Consent” from and add “Assessment” to the Form Name; Burden estimate remains the same.
	Observation	Att 9	Att 6	Moved row up in table to group like respondent types together. Burden remains the same.
Retail food workers	Worker Recruiting/Informed	Att 8	Att 2	Add “Assessment” to the Form Name; Split out the worker interview template from the recruiting/informed consent row in the burden table;
	Worker Interview/Assessment		Att 5	Change annual number of respondents from 4,000 to 2,000. Total burden for workers is reduced from 1,333 hours in 2018 to 400 in 2021.
The change above accounts for the reduction in annual time burden requested by 933 hours in 2021. In addition, the restructuring of the burden table results in 5,689 annual responses in 2021, which does not change compared to 2018.				

A.16. Plans for Tabulation and Publication and Project Time Schedule

We expect to conduct one data collection every other year. Table A.16.1 provides a timeline of expected data collections annually. Table A.16.2 provides specific data collection activities expected to take place for each data collection.

A.16.1 – Project Time Schedule Annually

Activity- Year 1
Retail food worker data collection #1
Activity- Year 3
Retail food worker data collection #2
Activity- Year 5
Retail food worker data collection #3

A.16.2– Example Data Collection Activity Schedule

Activity	Time Frame
Protocol development	5 months
OMB determination	3 months

Supporting Statement Part A

Data collection	4 months
Data analysis	4 months
Manuscript development	4 months

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not requesting an exemption to the display of the expiration date.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There will be no exceptions to certification for Paperwork Reduction Act.

References

Centers for Disease Control and Prevention (CDC). Surveillance for Foodborne Disease Outbreaks, United States, 2017, Annual Report. Atlanta, Georgia: U.S. Department of Health and Human Services, CDC, 2019.

Dewey-Mattia D, Manikonda K, Hall AJ, Wise ME, Crowe SJ. Surveillance for Foodborne Disease Outbreaks — United States, 2009–2015. *MMWR Surveill Summ* 2018;67(No. SS-10):1–11. DOI: <http://dx.doi.org/10.15585/mmwr.ss6710a1external icon>