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
Expiration Date: 01/31/2025

November 4, 2024

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Supporting Statement Part A

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List of Attachments and Appendices

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 used to collect data: Data will be collected through interviews or surveys; 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.
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.

List of Substantive Changes

Section	Description of change
A.	Updated "Experience to Date" section
A.	Identified two ways current package differs from previous package
A.8	Responses to three comments received to the 60-day FRN
A.8	Edited for brevity and clarity
Table A.8.1	Updated federal consultants and contact information
Table A.8.2	Updated state and local consultants and contact information
A.9	Explanation for incentives for participating managers and workers
A.12.2	Updated estimated annualized burden costs to reflect increased mean hourly wage for managers and workers
A.14	Explanation of the annualized cost to the federal government for translating interview forms into Spanish
Table A.14.1	Added the estimated annual cost to the federal government for translating interview forms into Spanish
A.15	Explanation for program changes, including potential for incentives for participants and translation of interview forms into Spanish
References	Completed the list of references

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 a revision of this Generic Information Collection (Generic ICR) titled, Environmental Health Specialists Network (EHS-Net) Program (OMB Control No. 0920-0792; exp. date: 01/31/2025). 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 state and local public health departments. State and local EHS-Net sites are funded through a CDC cooperative agreement. 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, et al 2011; Scallan, Hoekstra, et al 2011). Jones and 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 (Jones and Angulo, 2006). Reducing foodborne illness requires identification and understanding of the environmental factors that allow these illnesses to occur – we need to know how and why 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). Data collection methods for this generic package include: manager and food worker interviews or 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 2030 Goals to "Improve food handling practices and reduce foodborne illnesses." Specifically, these studies can be used to understand the relationship between existing intervention strategies (e.g., 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 revisions of the EHS-Net program on February 29, 2012, August 13, 2018, and January 26, 2022. The current submission requests a revision of this OMB generic clearance. This revision will provide OMB clearance for EHS-Net data collections conducted in 2025 through 2028.

Experience to Date

To date, EHS-Net has conducted five studies under this generic clearance.

1. The first study collected data on improper cooling of hot foods, a food handling practice associated with foodborne illness and outbreaks.

2. 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 was known about its effectiveness.

3. 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 used the data to inform their ground-breaking *Listeria* risk assessment modeling.

4. 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%.

5. 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.

Finally, EHS-Net recently received OMB clearance for a sixth study to assess restaurants' policies and practices regarding outbreak prevention and response.

The data from these studies have been disseminated to environmental public health/food safety regulatory programs and the food industry in peer-reviewed scientific journals, multiple presentations at national food safety conferences, and on CDC's website. We are still analyzing the data from one 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 two primary ways, described below.

- Potential for inclusion of incentives for participation in EHS-Net studies. This will not result in an increased cost to the federal government because the cost of incentives is included in the existing EHS-Net cooperative agreement.
- The annual cost to the federal government has increased by a maximum of $614 per year to cover the cost of Spanish translation of the manager and worker interview forms by the CDC Multilingual Services Team.

A.1. Circumstances Making the Collection of Information Necessary

The purpose of the information collection is to identify and understand the prevalence of 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 health departments. 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 state and local partners, funded by CDC, work with CDC to design studies, and collect and analyze data from these studies.

Research indicates that retail food establishments are an important source of foodborne illnesses and outbreaks. Surveillance for foodborne outbreaks has identified restaurants as the primary setting for single-setting foodborne outbreaks (White et al., 2022; Jones and Angulo, 2006). Thus, our data collection efforts have focused on retail food establishments.

Environmental factors associated with foodborne illness include both food handling, 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 personnel often collect timely data on factors that lead to foodborne illness outbreaks. Such data are essential to environmental public health regulators' efforts to understand and respond to outbreaks and prevent future, similar outbreaks. EHS-Net is the best mechanism to respond to this need, due to its composition of state and federal environmental public health regulators, which leads to unique expertise and ability to collect data on environmental factors in retail food establishments. 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's findings were also used to assess the impact of deli practices on risk of infection with *Listeria* species (Brown et al., 2016). This assessment was included in USDA's guidelines on best practices for controlling these harmful bacteria in delis (U.S. Department of Agriculture, 2015).

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 the U.S. Department of Health and Human Services' Healthy People 2030 Goals to "Improve food handling practices." Moreover, they support CDC's research agenda goal of "decreasing health risks from environmental exposures," as foodborne illness is an environmental exposure health risk, and CDC's winnable battle of reducing foodborne 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) (Attachment 1).

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 manager 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 over 40 CDC- and partner-authored publications (Appendix 1) 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 most 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 while still meeting the needs of the data collections.

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) 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. 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 EHS-Net studies 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 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 2030 Goals to "Improve food handling practices 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

The 60-day *Federal Register* notice was published August 9, 2024, in volume 89, number 154 (p. 65356) (Attachment 2). Three comments were received in response to the 60-day Federal Register Notice.

- Comment 1 and 2 (attachments 2a and 2b) were considered non-substantive in nature.
- Comment 3 (attachment 2c) was considered substantive in nature and discussed during the 2024 EHS-Net Grantee Vision Meeting on September 19, 2024. It was proposed as a potential project for the 2025–2030 EHS-Net cooperative agreement cycle. A written response to the submitter was provided via e-mail on October 4, 2024 (attachment 2d).

Consultation with staff from CDC centers, federal agencies, and EHS-Net participant sites will occur in preparation for and in conjunction with the fielding of data collections under this request. Tables A.8.1 and A.8.2 list the individuals that will be consulted. The officials identified in EHS-Net sites are epidemiology and environmental health professionals from sites participating in the current cooperative agreement. These individuals have been actively involved in the identification, prioritization, development, and implementation of data collection activities. This list may change in the future as individuals take on new roles, change positions, or if sites change during the next cooperative agreement cycle.

Table A.8.1 Federal Consultants

FDA/USDA	
Laurie Williams Consumer Food Safety Officer Food and Drug Administration Center for Food Safety and Applied Nutrition	**Lauren McClean** Food Safety Specialist US Department of Agriculture Food Safety and Nutrition Division Food and Nutrition Service
Glenda Lewis Director, Retail Food Protection Food and Drug Administration Center for Food Safety and Applied Nutrition	

Table A.8.2 State and Local Consultants

2020-2025 EHS-Net Sites	
Kirk Smith Deputy State Epidemiologist Minnesota Dept. of Health	**Danny Ripley** Environmental Health Specialist Tennessee Dept. of Health
JoAnn Monroy Principal Investigator Harris County Health Department	**Lauren DiPrete** Environmental Health Supervisor Southern Nevada Health District
David Nicholas Chief Epidemiologist New York State Dept. of Health	**Brendalee Viveiros** Chief, Center for Food Protection Rhode Island Dept. of Health
Sarah Jensen Director of Environmental Health Franklin County Public Health	**Wendy McKelvey** Executive Director, Env. Surveillance & Policy New York City Department of Health and Mental Hygiene

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

If warranted and justified, managers and workers may receive compensation for participating in an in-person data collection activity (e.g., face-to-face interview or completing a knowledge assessment). Compensation may be in the form of a cash equivalent gift card, food-safety related gift (e.g., a food thermometer), or other compensation. Because this document is a Generic Information Collection Request, the type of compensation (e.g., monetary vs. gift) and incentive amounts will be dependent on the nature of data collection activities at the time of specific protocol development and approval.

Some EHS-Net sites report increasing difficulty recruiting retail food establishments to participate in data collection activities, leading to a higher recruitment burden on our state and local partners. Offering an

incentive is a way to not only demonstrate gratitude for the time managers and workers take to participate, but also improve participation rates.

Incentives have been used in previous restaurant studies.
Published studies have used incentives during data collection activities in restaurants and from food workers. Financial incentives have varied between $5 and $20 for food workers and, in one study, $300 for restaurant owners who agreed that their restaurant could serve as a study site (Rosemberg et al., 2023; Courtney et al., 2010; Averbach et al., 2002; Ayala et al., 2017). A prior single-site EHS-Net study offered waterproof thermometers (an approximately $50 value) as an incentive for participation (Hedeen and Smith, 2020).

Incentives can improve participation rates.
Although, to our knowledge, no research has been published on improving participation specifically of restaurant workers, published literature has often found that incentives can improve participation rates in surveys and interviews, including among other occupational groups. Early studies of NHANES participation found that offering a monetary incentive (Bryant et al., 1975) and offering a higher monetary incentive ($20 vs. $10) (Findlay and Schaible, 1980) both succeeded in improving overall participation rates. A recent meta-analysis of 168 observational studies found that for interviews among non-patient study populations (similar to what is done for EHS-Net data collection activities), response rates were increased by monetary incentives by an estimated 39% (van Gelder et al., 2018). In a meta-analysis of surveys in healthcare providers, providers receiving monetary incentives were more likely to respond than those who did not receive an incentive (Cho et al., 2013).

Incentives can improve cost-efficiency.
By improving response rates, offering incentives can save the government money by reducing efforts needed to complete recruitment. The National Adult Literacy Survey demonstrated that a $20 incentive resulted in not only higher response rates, but also lower costs per completed survey than the comparison group (Berlin et al., 1992). Moreover, the incentives yielded higher response rates in people reporting non-white race and less education, characteristics that are also prevalent in restaurant workers. A more recent online survey experiment likewise found that incentives resulted in quicker data collection, less money spent on recruitment, and higher response rates (Sobolewski et al., 2024).

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

There have been no changes to the privacy aspects of this project since the last submission. The NCEH Information Systems Security Officer (ISSO) has determined that the Privacy Act does not apply to these information collections (Attachment 3). 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. All data collected will be kept private to the extent allowed by law.

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 on a need-to-know basis to those who 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.

Information in identifying form will not be collected or transmitted to CDC. Data collectors will use a code to identify restaurants, but that code will not be linked to any identifying information.

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 (Attachment 4). 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 appendices 2 and 3. Participation in this data collection is voluntary, and respondents are informed of the voluntary nature of the data collection during recruiting (appendices 3 and 4) and in informed consent scripts (appendices 2 and 3).

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 and worker interviews/ pen-and-paper assessments (see examples in appendices 5 and 6), and 2) observation of kitchen environments (see example in appendix 7). 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.

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 at the time of recruitment and when they are interviewed (see example in appendices 2 and 4). Workers will be informed that the provision of information is voluntary at the beginning of the recruiting/data collection process (see example in appendix 3). 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 if they participate.

Note that the recruiting and 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 managers: 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 — 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 or decline participation (appendices 2 and 3). Prior to beginning 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. 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 (appendix 4 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 a study, we will obtain verbal informed consent (appendix 2) and interview the manager about the restaurant's characteristics and existing food safety procedures and practices (appendix 5). 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 (appendix 6). We anticipate recruiting a maximum of 5 food workers per restaurant with an estimated burden time of 2 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 (appendix 7) 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). Table A.12.1 includes the observation burden for retail managers (200 annual burden hours). Since data collectors are health department staff who are paid through a cooperative agreement, the data collectors' 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.

For the specific study designs, we will assess the number of respondents and time necessary and strive to minimize the burden. We have provided conservative estimates in Tables A.12.1 and A.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 $20.82 for managers (occupational code 35-1012) and $16.35 for workers (occupational code 35-2000). These estimated hourly wages were obtained from the U.S. Department of Labor Bureau of Labor Statistics 2023 National Occupational Employment and Wage Estimates (https://stats.bls.gov/oes/current/oes_nat.htm).

A.12.2. Estimated Annualized Burden Costs

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Managers	444	$20.82	$9,244.08
Workers	400	$16.35	$6,540.00
Total			$15,784.08

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 $818,947. 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, travel, and Spanish translation of interview forms (Table A.14.1).

The manager interview (appendix 5) and worker interview (appendix 6) forms will be available in both English and Spanish. We expect to carry out a maximum of three data collections during the three years

this OMB approval covers. One set of appendices has already been translated, leaving two additional sets left. The CDC Multilingual Services Team translates the English forms into Spanish at a one-time fee of $919.79. Spread over the course of three years, this averages out to about $307 per year.

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
Spanish translation of interview forms ($919.79/3 years)	$614
Total	$818,947

A.15. Explanation for Program Changes or Adjustments

This is a revision ICR for a generic clearance that expires on 01/31/2025. The current package differs from the previous package in two primary ways, described below.

- Potential for inclusion of incentives for participation in EHS-Net studies. This will not result in an increased cost to the federal government because the cost of incentives is included in the existing EHS-Net cooperative agreement.
- The annual cost to the federal government has increased by a maximum of $614 per year to cover the cost of Spanish translation of the manager and worker interview forms by the CDC Multilingual Services Team.

After 2021, the appendices have been restructured in 2024 as follows:

Type of Respondents	Form Name	Form Number		Description of Changes
		2021	2024	
Retail managers	Manager Informed Consent	Apx 1	Apx 2	Document number changed Added wording for incentives EHS-Net staff can use if applicable No change in burden estimate
	Manager Telephone Recruiting Script	Apx 3	Apx 4	Document number changed Added wording for incentives EHS-Net staff can use if applicable No change in burden estimate
	Manager Interview	Apx 4	Apx 5	Document number changed No change in burden estimate
	Observation	Apx 6	Apx 7	Document number changed No change in burden estimate
Retail food workers	Worker Recruiting/Informed Consent	Apx 2	Apx 3	Document number changed Added wording for incentives EHS-Net staff can use if applicable No change in burden estimate
	Worker Interview	Apx 5	Apx 6	Document number changed No change in burden estimate

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 over the course of the EHS-Net cooperative agreement cycle. 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
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

We are not requesting exceptions to certification for Paperwork Reduction Act.

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