

**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 Generic Package**

**Reinstatement (with change)**

**OMB No. 0920-0792  
Expiration Date: 2/28/2015**

**January 25, 2021**

**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, NE F – 58  
Atlanta, GA 30341-3724  
lrg0@cdc.gov  
770-488-4332**

**Supporting Statement Part A**

**Table of Contents**

A. Justification..... 3

    1. Circumstances Making the Collection of Information Necessary..... 5

    2. Purpose and Use of Information Collection..... 6

    3. Use of Improved Information Technology and Burden Reduction..... 7

    4. Efforts to Identify Duplication and Use of Similar Information..... 7

    5. Impact on Small Businesses or Other Small Entities..... 7

    6. Consequences of Collecting the Information Less Frequently..... 7

    7. Special Circumstances Related to the Guidelines of 5 CFR 1320.5..... 8

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

    9. Explanation of Any Payment or Gift to Respondents..... 10

    10. Assurance of Confidentiality Provided to Respondents..... 10

    11. Justification for Sensitive Questions..... 11

    12. Estimates of Annualized Burden Hours and Costs..... 11

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

    14. Annualized Cost to the Federal Government..... 13

    15. Explanation for Program Changes or Adjustments..... 13

    16. Plans for Tabulation and Publication and Project Time Schedule..... 14

    17. Reason(s) Display of OMB Expiration Date is Inappropriate..... 14

    18. Exceptions of Certification for Paperwork Reduction Act Submissions..... 14

**List of Attachments**

- Attachment 1- Regulation Authorizing Data Collection
- Attachment 2- 60 Day Federal Register Notice
- Attachment 2a- Public Comment
- Attachment 3- Research Determination
- Attachment 4- Example of EHS-Net Manager Interview
- Attachment 5- Example of EHS-Net Observation
- Attachment 6- Example of EHS-Net Manager Recruiting Script
- Attachment 7- Example of EHS-Net Data Collection Manager Informed Consent
- Attachment 8- Example of EHS-Net Data Collection Worker Recruiting/Informed Consent Script
- Attachment 9- Example of EHS-Net Worker Interview

## Supporting Statement Part A

- Goal: The goal of this food safety research program (called EHS-Net) is to collect data in retail food establishments (about 376 per data collection) that will identify and understand environmental factors (e.g., manager food safety certification, equipment condition, 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 (about 376 per data collection), and observations (about 376 per data collection) in random samples of establishments in the 8 EHS-Net-funded state and local food safety programs.
- The subpopulation to be studied: Data will be collected in establishments (about 376 per data collection) in the 8 EHS-Net-funded state and local food safety programs, and from the managers and workers in those establishments.
- How data will be analyzed: Descriptive analyses (frequencies, means, etc.), tests for association, and logistic regression models.

### A. Justification

#### **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 first 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, EPA, 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). On February 29, 2012, OMB gave generic clearance to a revision of the EHS-Net program. Because of uncertainty about whether the EHS-Net program would receive continued funding, a discontinuation request for this generic clearance was sent on 1/23/2015. The current submission requests a reinstatement

## Supporting Statement Part A

of this OMB generic clearance. This reinstatement will provide OMB clearance for EHS-Net data collections conducted in 2015 through 2018.

### **Experience to Date**

To date, EHS-Net has conducted four 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 3<sup>rd</sup> 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 50,000-125,000 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 data from the first two 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 three articles in peer-reviewed scientific journals, in five presentations at national food safety conferences, and on CDC's website. We are still analyzing the data from all four 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. As indicated earlier, the EHS-Net cooperative agreement that funds the EHS-Net program ends in 2015. The sites included in the EHS-Net program from 2010-2015 were California; San Mateo, California; Minnesota, New York; New York City; Rhode Island; and Tennessee. The EHS-Net cooperative agreement that funds these sites was re-announced in 2015 and will fund EHS-Net for another five years (2016-2020). The 2016-2020 sites are California; Harris County, Texas; Minnesota; New York City; New York State; Rhode Island; Southern Nevada Health District; and Tennessee.
- The study sample size and burden estimates have been revised downward, due to two factors. First, we reduced the number of retail food establishments in which EHS-Net sites will collect data. We had originally required EHS-Net sites to collect data in more establishments than were required to meet our sample size calculations. Because it was statistically unnecessary and created an undue burden on the sites, we have eliminated this requirement. Second, in the previous package, we overestimated the number of studies we could feasibly conduct in a year, and consequently overestimated the burden. In this reinstatement, the burden estimate is based on a more accurate study schedule of one study a year.
- In the previous package, we had proposed weighting the data collected from the sample establishments on several establishment characteristics to allow better generalization to the retail

## Supporting Statement Part A

establishment population. However, the poor quality of the population characteristic data precludes such analyses.

### 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, Environmental Health Services Branch. The federal partners provide funding and input into study design and data analysis. The site partners, funded by CDC, work with CDC to design studies, and collect and analyze data from these studies. From 2012 through 2015, these state and local sites were California; New York City, New York; New York; Minnesota, Rhode Island, and Tennessee. The EHS-Net cooperative agreement that funds these sites was re-announced in 2015 and will fund EHS-Net for another five years (2016-2020). The 2016-2020 sites are California; Harris County, Texas; Minnesota; New York City; New York State; Rhode Island; Southern Nevada Health District; and Tennessee.

Recent studies have indicated that retail food establishments are an important source of foodborne illnesses. 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 a substantial proportion of reported foodborne illness outbreaks are associated with retail food establishments (Jones et al., 2004; Olsen et al., 2000). 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.

## Supporting Statement Part A

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 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 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.

### **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. These sites are demographically diverse and provide good geographical coverage of the United States. 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.

## **Supporting Statement Part A**

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

All EHS-Net data collections will involve face-to-face 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.

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

Through searches of relevant databases (e.g., PubMed, Ovid, Agricola), attendance at national meetings (e.g., National Environmental Health Association, International Association of Food Protection), and consultations with other organizations (e.g., FDA, USDA) we have determined that there are little high-quality data available on retail food worker and establishment characteristics and food handling and food safety practices. For example, in developing our Food Cooling Practices Study, we found no existing data on restaurant food cooling methods, and in developing our Kitchen Manager Certification Study, the only studies we found were conducted in local areas and were limited in scope. Thus, the EHS-Net data collections will not be duplications of effort. However, before we begin design of each data collection, we will conduct extensive review of scientific literature to determine if data already exist on the specific topic of interest.

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

Managers and workers in retail food service establishments will be respondents to these studies, and some proportion (an estimated 30%) of these establishments will be small businesses. Given that small businesses are likely to have different experiences, practices, and barriers than larger businesses, it is important that small businesses be included in our data collections. This will help ensure that their concerns and needs can be adequately understood and addressed.

Short forms for small businesses will not be developed. 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. Without this information collection, CDC will be unable to fully address CDC's research agenda goal of decreasing health risks from environmental exposures, CDC's winnable battle of reducing foodborne diseases, and the U.S. Department of Health 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.

**Supporting Statement Part A**

**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 1/12/2015 in Vol. 80, No. 7, pages 1505-1506 (Attachment 2). We received one substantive comment (Attachment 2a). CDC’s standard response was sent.

B. Below is a list of individuals from other CDC Centers and federal agencies (Table A.8.1) who are consulted to obtain their views on the EHS-Net research program. These individuals are consulted about the availability of existing data, the clarity of instructions, recordkeeping, disclosure, reporting format, and on the data elements to be recorded and reported for each specific data collection.

Table A.8.2 lists those individuals representing the industry groups impacted by EHS-Net data collections. These individuals are consulted to obtain their input regarding the EHS-Net research program and individual data collection activities. They are consulted about the need for various data collection activities, availability of existing data, the clarity of instructions, appropriateness of questions, and data elements to be recorded and reported for each specific data collection.

Table A.8.3 lists the officials from each of the 2010-2015 EHS-Net sites. These officials represent epidemiology and environmental health programs in the sites. They were consulted with and were actively involved in the identification, prioritization, development and implementation of data collection activities in 2010-2015. Officials from the 2016-2020 sites, once identified, will play similar roles in future EHS-Net activities.

**Table A.8.1 Federal Consultants**

<b>FDA/USDA/CDC</b>	<b>CDC</b>
<p><b>Laurie Williams</b>                      Consumer Food Safety Officer                      Food and Drug Administration                      Center for Food Safety and Applied Nutrition                      5100 Paint Branch Parkway                      College Park, MD 20740  <a href="mailto:Laurie.Williams@fda.hhs.gov">Laurie.Williams@fda.hhs.gov</a></p>	<p><b>Art Liang, MD, MPH</b>                      Director, Food Safety Office                      National Center for Zoonotic, Vector-Borne, &amp;                      Enteric Diseases                      1600 Clifton Rd. MS C09                      Atlanta, GA 30333                      404-371-5410  <a href="mailto:aliang@cdc.gov">aliang@cdc.gov</a></p>
<p><b>Glenda Lewis</b>                      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  <a href="mailto:Glenda.Lewis@fda.hhs.gov">Glenda.Lewis@fda.hhs.gov</a></p>	<p><b>Kristen Holt, DVM</b>                      Epidemiologist                      U.S. Department of Agriculture                      Food Safety and Inspection Service                      1924 Building, Suite 3R90A                      100 Alabama Street, SW                      Atlanta, Georgia 30303                      404-562-5936  <a href="mailto:kristen.holt@fsis.usda.gov">kristen.holt@fsis.usda.gov</a></p>

**Table A.8.2 Industry Consultants**

<b>Industry/Trade Associations</b>	<b>Industry/Trade Associations</b>
<p><b>Michael Roberson</b>                      Director, Corporate Quality Assurance</p>	<p>Larry Kohl                      Director, Food Safety and Quality Assurance</p>



### Supporting Statement Part A

Publix Super Markets, Inc. 863.688.1188 x32422 <a href="mailto:michael.roberson@publix.com">michael.roberson@publix.com</a>	Delhaize America 2110 Executive Drive , P.O. Box 1330 Salisbury, NC 28145 704-633-8250 <a href="mailto:lrkohl@foodlion.com">lrkohl@foodlion.com</a>
Becky Stevens-Grobbelaar Director, Food Safety & Regulatory Affairs Yum! Brands, Inc. 140 Lake Park South Drive Griffin, GA 30224 Office (770)228-8319 <a href="mailto:Becky.stevens-grobbelaar@yum.com">Becky.stevens-grobbelaar@yum.com</a>	Hilary S. Thesmar, PhD, RD Vice President, Food Safety Programs Food Marketing Institute 2345 Crystal Drive, Suite 800 Arlington, VA 22202-4801 Office (202) 220-0658 <a href="mailto:hthesmar@fmi.org">hthesmar@fmi.org</a>

Table A.8.3 State Consultants

2012-2015 EHS-Net Sites	2012-2015 EHS-Net Sites
<b>Kirk Smith</b> State Epidemiologist Minnesota Department of Health 625 Robert St N Minneapolis, MN 55164 612-676-5414 <a href="mailto:Kirk.smith@state.mn.us">Kirk.smith@state.mn.us</a>	<b>Danny Ripley</b> Food Safety Investigator Food Division Metro Public Health Department 311 23rd Ave. North Nashville, TN 37203 615-340-2701 <a href="mailto:danny.ripley@nashville.gov">danny.ripley@nashville.gov</a>
<b>Dave Reimann</b> Public Health Sanitarian III MN Dept of Health 410 Jackson St. Suite 500 Mankato, MN 56001 507-389-2203 <a href="mailto:david.reimann@health.state.mn.us">david.reimann@health.state.mn.us</a>	<b>Ernest Julian</b> Director, Environmental Health Program Rhode Island Department of Health Office of Food Protection 3 Capitol Hill Providence, RI 02908 (401) 222-2749 <a href="mailto:ERNIEJ@DOH.STATE.RI.US">ERNIEJ@DOH.STATE.RI.US</a>
<b>Dave Nicholas</b> NY State Dept of Health Bureau of Community Sanitation and Food Protection 547 River St. Troy, NY 12180 (518) 402-7600 <a href="mailto:dcn01@health.state.ny.us">dcn01@health.state.ny.us</a>	<b>Henry Blade</b> Rhode Island Department of Health Office of Food Protection 3 Capitol Hill Providence, RI 02908 (401) 222-7735 <a href="mailto:Henry.Blade@health.ri.gov">Henry.Blade@health.ri.gov</a>
<b>Brenda Faw</b> California Public Health Center for Environmental Health 1500 Capitol Avenue PO Box 997435 Sacramento, CA 95899 (916) 445-9548 <a href="mailto:Brenda.Faw@cdph.ca.gov">Brenda.Faw@cdph.ca.gov</a>	<b>Melissa Wong</b> Bureau of Environmental Surveillance and Policy New York City Department of Health and Mental Hygiene 22 Cortlandt Street, 12th floor, CN-34E New York, NY 10007 Phone: 212-676-2731 <a href="mailto:Mwong2@health.ny.gov">Mwong2@health.ny.gov</a>

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

CDC will not provide payments or gifts to respondents.

## Supporting Statement Part A

### A.10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply. No assurances of confidentiality will be provided to respondents. While face-to-face interviews will sometimes be conducted, respondents will not be asked, nor will they provide individually identifiable information. CDC will not be directly engaged in human subjects data collection, will not interact with any respondents, and will not receive identifying information on any of the participating establishments or staff from the EHS-Net sites. CDC-funded state and local environmental health specialists employed by the eight EHS-Net sites (state and local health departments participating in the EHS-Net cooperative agreement) will be responsible for collecting data from respondents.

Information collections conducted under this generic OMB package will be classified as “human subjects research, but CDC is not engaged.” Attachment 3 is an example of such a research determination from a previous EHS-Net information collection. For each data collection request submitted under this generic OMB package, a research determination will be submitted and the EHS-Net site personnel will acquire IRB approval from their respective IRBs, as appropriate.

#### A.10.1 Privacy Impact Assessment Information

**Overview of the Data Collection System.** As indicated, data for these studies will be collected by environmental health specialists employed by the eight EHS-Net sites. 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 (about 376 per data collection, and 2) observation of kitchen environments (about 376 per data collection). 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). Attachment 4 contains an example interview; Attachment 5 contains an example observation.

Hard copy data forms will be maintained for three years; electronic data will be maintained for ten years.

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

**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 (Food and Drug Administration, U.S. Department of Agriculture, restaurant industry representatives, food safety and environmental organizations such as National Environmental Health Association and Conference for Food Protection) 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.

**Impact the Proposed Collections will have on the Respondent’s Privacy.** Respondents’ privacy will not be impacted by the information collection. Anonymous data will be collected; thus, no individually identifiable information will be collected.

## Supporting Statement Part A

**Whether Individuals are Informed that Providing Information is Voluntary or Mandatory.** Retail establishment managers are informed at two times that the provision of information, through interviews and site observations, is voluntary. They are informed during the recruiting process (See example in Attachment 6), and at the beginning of the actual data collection process (See example in Attachment 7). Workers are informed that the provision of information is voluntary at the beginning of the recruiting/data collection process (See example in Attachment 8). Both managers and workers are told that their participation or lack thereof will not impact their food safety inspection outcomes. Workers are also 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 by telephone 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.

**Opportunities to Consent.** Both managers and workers will be given the opportunity to verbally consent to participation (Attachments 6, 7, and 8). 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.

A waiver of documentation of informed consent will be requested in accordance with 45 CFR 46.117(c) (2). The studies meet the first criterion for the waiver, as the probability and magnitude of harm or discomfort in participation are not greater in and of themselves than those ordinarily encountered in daily life. Additionally, as the studies involve no procedures for which written consent is normally required outside the research context, the studies also meet the second criterion for waiver.

**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 state and local environmental health specialists employed by the EHS-Net sites; 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.

**System of Records.** As no individually identifiable data will be collected, a system of records is not being created.

### A.11. Justification for Sensitive Questions

No information will be collected that are of personal or sensitive nature.

### A.12. Estimates of Annualized Burden hours and costs

For each data collection, we will collect data in approximately 47 retail food establishments per site. Thus, there will be approximately 376 establishments per data collection (an estimated 8 sites\*47 establishments). We expect a manager/establishment response rate of approximately 60 percent; thus, we will need to attempt to recruit 627 managers/establishments via telephone in order to meet our goal of 376 establishments. Each manager will respond to the recruiting script only once for approximately 3 minutes. Thus, the maximum burden for the manager recruiting attempts will be 31 hours (627 managers\*3 minutes). We will collect interview/assessment data from a manager in each establishment. Each manager

### Supporting Statement Part A

will respond only once for approximately 30 minutes. Thus, the maximum burden for the manager interview/assessment will be 188 hours (376 managers \*30 minutes). In total, the average burden for managers will be 219 hours (31 hours for recruiting+188 hours for the interview/assessment).

For each data collection, we will recruit a worker from each participating establishment to provide interview/assessment data (See example in Attachment 9). Each worker will respond to the recruiting script only once for approximately 3 minutes. Thus, the maximum burden for the worker recruiting attempts will be 19 hours (376 workers\*3 minutes). We expect a worker response rate of 90 percent (339 workers). Each worker will respond only once for approximately 10 minutes. Thus, the maximum burden for the worker interview/assessment will be 57 hours (339 workers\*10 minutes). In total, the average burden per worker response will be 75 hours (19 hours for recruiting+57 hours for the interview/assessment).

The total estimated annual burden for each data collection will be 295 hours.

#### A.12-1- Estimated Annualized Burden Hours

<b>Respondents</b>	<b>Form Name</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden (in hours)</b>
Retail managers	Manager Telephone Recruiting Script	627	1	3/60	31
Retail managers	Manager Interview/ Assessment	376	1	30/60	188
Retail food workers	Worker Recruiting Script	376	1	3/60	19
Retail food workers	Worker Interview/ Assessment	339	1	10/60	57
Total					295

For each data collection, one observation will be conducted in each establishment and it will take approximately 30 minutes, the EHS-Net specialists will observe the kitchen environment and observe food handling practices (Attachment 5). However, managers and workers will not be burdened by these observations, as they will simply be engaging in their regular work activities during them. Data collectors will have minimal interaction with the workers during these observations. Thus, we did not include the observation time in the burden estimation.

#### A.12-2- Annualized Cost to Respondents

The maximum total annualized cost of this data collection to respondents is estimated to be \$4,119.8 (See Table 12-2). This figure is based on an estimated mean hourly wage of \$15.30 for managers and \$10.05 for workers. These estimated hourly wages were obtained from the U.S. Department of Labor Bureau of Labor Statistics 2012 national occupational employment and wage estimates report (<http://stats.bls.gov/oes/current/oes351012.htm>; <http://stats.bls.gov/oes/current/oes352021.htm>).

**Supporting Statement Part A**

**12.2- Estimated Annualized Burden Costs**

<b>Type of Respondent</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Respondent Costs</b>
Managers	219	\$15.30	\$3,350.70
Workers	76	\$10.05	\$763.80
Total			\$4,119.80

**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 \$2,223,500. Costs to the government include funding provided to 7 EHS-Net sites, salaries of CDC employees and contractors supporting the program, travel and office supplies (Table A.14.1).

**Table A.14.1**

<b>Expenditure</b>	<b>Cost</b>
Salaries (Object Class 11 & 12)	\$475,000
Grants to States	\$1,400,000
Travel	\$14,000
Office Supplies	\$9,500
Contract Costs	\$325,000
<b>Total</b>	<b>\$2,223,500</b>

**A.15. Explanation for Program Changes or Adjustments**

This is a reinstatement with change of a generic clearance for an existing research program that expired on 2/28/2015. The current package differs from the previous package in three primary ways, described below.

- The sites in which data will be collected differ. The sites included in the EHS-Net program from 2010-2015 were California; San Mateo, California; Minnesota, New York; New York City; Rhode Island; and Tennessee. 2016-2020 sites include California; Harris County, Texas; Minnesota; New York City; New York State; Rhode Island; Southern Nevada Health District; and Tennessee.
- The study sample size and burden estimates have been revised downward, due to two factors. First, we reduced the number of retail food establishments in which EHS-Net sites will collect data. We had originally required EHS-Net sites to collect data in more establishments than were required to meet our sample size calculations. Because it was statistically unnecessary and created an undue burden on the sites, we have eliminated this requirement. Second, in the previous package, we overestimated the number of studies we could feasibly conduct in a year, and consequently overestimated the burden. In this reinstatement, the burden estimate is based on a more accurate study schedule of one study a year.
- In the previous package, we had proposed weighting the data collected from the sample establishments on several establishment characteristics to allow better generalization to the retail

## Supporting Statement Part A

establishment population. However, the poor quality of the population characteristic data precludes such analyses.

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

We expect to conduct one data collection a 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

<b>Activity- Year 1</b>
Retail food worker data collection #1
<b>Activity- Year 2</b>
Retail food worker data collection #2
<b>Activity- Year 3</b>
Retail food worker data collection #3

#### A.16.2– Example Data Collection Activity Schedule

<b>Activity</b>	<b>Time Frame</b>
Protocol development	5 months
IRB determination	1 month
Data collection	4 months
Data analysis	4 months
Manuscript development	3 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.