

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

REVISION

January, 2012

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Executive Summary

An estimated 47.8 million foodborne illnesses occur annually in the U.S., resulting in 127,839 hospitalizations, and 3,037 deaths. 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. To meet these purposes, this program will involve up to 3 data collections a year. This program is conducted by the Environmental Health Specialists Network (EHS-Net), a collaborative project of CDC, FDA, USDA, EPA, and six state/local sites (CA, NYC, NY, MN, RI, and TN).

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) worker interviews/surveys, 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 (no. 0920-0792) to CDC for the EHS-Net program. This submission requests a revision of this OMB generic clearance. This revision will provide OMB clearance for EHS-Net data collections conducted in 2012 through 2014.

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Environmental Health Specialists Network (EHS-Net) Program

CDC requested a generic OMB clearance for the EHS-Net program approach and methodology in 2008. On October 21, 2008, OMB gave generic clearance (no. 0920-0792) to CDC for the EHS-Net program. The current submission requests a revision of this OMB generic clearance. This revision will provide OMB clearance for EHS-Net data collections conducted in 2012 through 2014 (a maximum of 3 annually). Once approval of this revision is obtained, each individual EHS-Net data collection that falls within the scope of the generic clearance will undergo expedited review.

We made several changes to the original OMB package, and these changes have resulted in a more focused package with a more accurate (and smaller) assessment of the burden to the public. The following list summarizes the differences between the original OMB submission and this current, revision.

- The original package covered data collection from three respondent groups. We have not collected data from two of those groups and have no immediate plans to do so. Thus, we deleted these two respondent groups from the package and the burden estimate.
- In the original package, we overestimated the number of studies we could conduct in a year, and consequently overestimated the burden. In this revision, the burden estimate is based on a more accurate study schedule.
- The studies we will conduct under the revised package will use enhanced methods in comparison to previous studies. Primarily, we plan to collect generalizable data, which we did not do in the past. The current revised package reflects and describes this change.
- This research program involves two primary data collection activities: interviews/surveys and observations. The revised package separates these activities into two types of data collection activities, while in the original package, they were include as one type.
- The revised package provides burden estimates for recruiting calls; the original package did not.

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

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 and how and why these pathogens are not eliminated from food before ingestion. This information can then be used to determine effective food safety prevention

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and intervention methods. The purpose of this research program is to identify and understand environmental factors associated with foodborne illness outbreaks. To meet this purpose, this research program will involve a maximum of 3 data collections per year.

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 six state/local sites (California; New York City, New York; New York; Minnesota, Rhode Island, and Tennessee). The site partners work with CDC to design studies, and collect and analyze data from these studies. The federal partners provide funding and input into study design and data analysis.

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) worker interviews/surveys, 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. There is a need for generic OMB clearance for the EHS-Net program because it is important that EHS-Net be able to conduct its data collections rapidly, so that necessary changes for both environmental public health regulators responsible for food safety and the industry involved can be implemented as quickly as possible.

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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.

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. Data collection authority is found in Section 301 of the Public Health Service Act (42 USC 241) (Attachment 1).

Privacy Impact Assessment

Overview of the Data Collection System. Data for these studies will be collected by environmental health specialists in the participating EHS-Net sites. Retail food establishment workers (managers and/or workers) will be the respondents for these studies. Data collection methods include: 1) worker interviews/surveys, and 2) observation of kitchen environments. 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., worker and establishment characteristics). Attachment 3 contains an example interview/survey.

All data will be reported to CDC by the EHS-Net data collectors through a web-based information system. These data will be stored for seven years.

Items of Information to be Collected. Below is a description of the types of information to be collected with each method used.

- Worker interviews/surveys
 - Self-reported food handling and food safety practices (e.g., how often workers wash their hands)
 - Worker characteristics (e.g., food safety knowledge and beliefs, training and certification)
 - Establishment characteristics (e.g., establishment size, food safety policies)
- Observation of kitchen environments and worker food handling and food safety practices
 - Food handling and food safety practices (e.g., worker use of gloves, thermometers, etc.)
 - Establishment characteristics (e.g., cooking and refrigeration units, type of food served)

No individually identifiable information will be collected.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age. Information will be reported through a web-based system. This system is password protected- only people given access to the system by CDC can access it. The system does not contain any content directed at children under 13 years of age.

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A.2. Purpose and Use of the Information Collection

The purpose of these data collections will be to collect 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 worker and establishment characteristics.
- 2) Determine how retail food establishment and worker characteristics are related to food handling and food safety practices.

The data collected in these studies will be used by CDC to develop food safety prevention and intervention recommendations for environmental public health 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.

This research program is funded by the CDC's National Center for Environmental Health, Environmental Health Services Branch, FDA, and the USDA.

Applicability of Results

EHS-Net is comprised of retail food establishments in selected geographical areas in California, Minnesota, New York City, New York State, Rhode Island and Tennessee. While the number of areas included in EHS-Net is small, they are demographically diverse and provide good geographical coverage of the U.S. (northeast, mid-west, south, and west). When the statistical methods outlined here for ensuring a representative sample in one or more EHS-Net data collections are used, the results of collections covered by this generic OMB package can be used to generalize to the population of retail food establishments in given the EHS-Net site(s). Furthermore, the geographic and demographic variability across these sites suggests that CDC may be able 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.

Experience to Date

To date, EHS-Net has conducted two studies using the methods described in this package. 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. We are still analyzing the data from these studies, and expect that they will provide valuable and useful data about environmental factors associated with foodborne illness outbreaks. They will lead to the

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publication of peer-reviewed journal articles. More importantly, the results and recommendations from these studies will be disseminated to environmental public health regulatory programs and the food industry, in the form of presentations at conferences, annual meetings, and other forums.

A third EHS-Net study is currently under OMB review, and is focused on understanding 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 (Scallan, Hoekstra et al., 2011). This study is being conducted at the request of and in collaboration with USDA, who will use the data to inform their ground-breaking *Listeria* risk assessment modeling.

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.

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Why is the information being collected. The information collected in these studies will be used to 1) describe retail food establishment food handling and food safety practices and worker and establishment characteristics, and 2) determine how retail food worker and establishment characteristics are related to food handling and food safety practices.

Intended use of the information being collected. The information will be used to develop recommendations for 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.

No individually identifiable information will be collected.

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

Most EHS-Net data collections will involve interviews with respondents. Thus, respondents will provide their responses verbally to interviewers. Compared to typed or hand-written responses, verbal responses are easier for the majority of respondents to provide. In some cases, data collections may be better suited for the collection of written, rather than verbal, responses. A short, simple data collection administered to a group of respondents and requiring little assistance or explanation to respondents is an example of such a case.

Participation in all EHS-Net data collections is voluntary, and every effort will be made to keep the data collections as short as possible 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. 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

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 or Not at All

Respondents will be asked to respond to each data collection only one time. If the EHS-Net data collections are not conducted, it will be difficult for CDC to fully address CDC's research agenda goal of decreasing health risks from environmental exposures. 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 for EHS-Net data collections. EHS-Net data collections will fully comply with 5 CFR 1320.5.

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 June 23, 2011 in Volume 76, Number 121, Pages 36924-36925 (Attachment 2). We did not receive any comments.
- 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.

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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 participating sites involved in the EHS-Net research program. These officials represent epidemiology and environmental health programs in each of the sites. They are consulted with and are actively involved in the identification, prioritization, development and implementation of data collection activities.

Table A.8.1 Federal Consultants

FDA/USDA	CDC
<p>Jack Guzewich, RS, MPH Director-Emergency Coordination & Response U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition MS HFS-600 Bld. CPK1 College Park, MD 20740 301-436-1608 john.guzewich@cfsan.fda.gov</p>	<p>Patricia Griffin, MD Chief, Foodborne Disease Epidemiology Section Epidemiologist National Center for Zoonotic, Vector-Borne, & Enteric Diseases 1600 Clifton Rd. MS A38 Atlanta, GA 30333 404-639-3384 pmg1@cdc.gov</p>
<p>Patrick McCarthy, PhD, MPH Statistician U.S. Food and Drug Administration 5100 Paint Branch Parkway MS HFS-728 Bldg. CPK1 Rm2C097 College Park, MD 20740 301-436-1822 Patrick.mccarthy@cfsan.fda.gov</p>	<p>Fred Angulo, DVM, PhD, MPH Epidemiologist National Center for Zoonotic, Vector-Borne, & Enteric Diseases 1600 Clifton Rd. MS D63 Atlanta, GA 30333 404-371-5410 Fja0@cdc.gov</p>
<p>Morris Potter, DVM U.S. Food and Drug Administration 60 Eighth Street, NE Atlanta, GA 30309 404-253-1225 mpotter@cfsan.fda.gov</p>	<p>Michael Lynch, MD Epidemiologist National Center for Zoonotic, Vector-Borne, & Enteric Diseases 1600 Clifton Rd. MS A38 Atlanta, GA 30333 404-371-5410 Mlynch1@cdc.gov</p>

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<p>Kristen Holt, DVM 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 kristen.holt@fsis.usda.gov</p>	<p>Art Liang, MD, MPH Director, Food Safety Office National Center for Zoonotic, Vector-Borne, & Enteric Diseases 1600 Clifton Rd. MS C09 Atlanta, GA 30333 404-371-5410 aliang@cdc.gov</p>
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Table A.8.2 Industry Consultants

Industry	Trade Associations
<p>Robert Scott Director, Total Quality Darden Restaurants 5900 Lake Ellenor Drive Orlando FL 32809 407-245-6764 BScott@darden.com</p>	<p>Donna Garren Vice President, Health and Safety Regulatory Affairs National Restaurant Association 1200 17th Street, NW Washington, DC 20036 202-331-5986 dgarren@dineout.org</p>
<p>Michael Roberson Director, Corporate Quality Assurance Publix Super Markets, Inc. 863.688.1188 x32422 michael.roberson@publix.com</p>	<p>Jill Hollingsworth Group Vice President, Food Safety Programs Food Marketing Institute 655 15th Street, N.W. Washington, DC 20005 202-220-0658 jhollingsworth@fmi.org</p>
<p>Gale Prince Director of Regulatory Affairs The Kroger Co. 1014 Vine Street Cincinnati, OH 45202 513-762-4209 gale.prince@kroger.com</p>	
<p>Dale Yamnik Manager, Food Safety & Regulatory Affairs Yum! Brands, Inc. 542 Castle Rock, CO 80104 303-708-1536 Dale.Yamnik@Yum.com</p>	

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Table A.8.3 State Consultants

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

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

There will be no payments or gifts to respondents.

A.10. Assurance of Confidentiality Provided to Respondents

The proposed program has been reviewed and it has been determined that the Privacy Act does not apply. No assurances of confidentiality will be provided to respondents. While face to face interviews will sometimes be conducted, no identifying information on retail food establishments or workers will be collected. 45 CFR 46 (Regulations for Protection of Human Subjects) applies

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to this research program. The data collection protocols will receive exempt or expedited review and approval by CDC IRB (see Attachment 4 for a previous approval letter). EHS-Net sites will obtain approval from their IRBs as appropriate.

Privacy Impact Assessment Information

- A. This submission has been reviewed by CDC's Privacy Officer, who determined that the Privacy Act does not apply. Respondents will not be providing individually identifiable information.
- B. CDC will collect no paper files. All electronic data will be stored on secure CDC networks. Access to the data will be limited to those with a bonafide need-to-know in order to perform job duties related to the project.
- C. Verbal consent will be obtained from respondents. An example consent script can be found in Attachment 5.
- D. Participation in this data collection is voluntary, and respondents are informed of this during the recruiting call and at the beginning of the data collection process.

No IIF is being collected.

A.11. Justification for Sensitive Questions

The use of sensitive questions is not anticipated at this time.

A.12. Estimates of Annualized Burden hours and costs

For each data collection, we will collect data in approximately 80 retail food establishments per site. Thus, there will be approximately 480 establishments per data collection (6 sites*80 establishments). For each data collection, we will collect interview/survey data from 1 to 3 workers (one of whom will be a manager) per establishment. Each respondent will respond only once. Thus, there will be a maximum of 1,440 worker respondents participating in each data collection annually (480 establishments per data collection*3 workers). Each worker interview/survey will take approximately 30 minutes. Thus, the maximum burden for the interview/surveys per data collection will be 720 hours (1,440 workers *30 minutes). As we expect to conduct up to 3 data collections annually, the maximum annual worker interview/survey burden will be 2,160 hours (720 hours*3 data collections) See Attachment 3 for an example of a worker interview/survey.

We expect a worker response rate of approximately 70 percent for each data collection. We will need to conduct a recruiting screener (see Attachment 6) with approximately 2,057 worker respondents to obtain the needed number of respondents. Each screener will take approximately 3 minutes. Thus, the maximum annual burden for the recruiting screeners per data collection will be 103 hours (2,057 workers*3 minutes), and the maximum annual burden for up to 3 data collections will be 309 hours (103 hours*3 data collections).

Thus, the maximum annual burden will be 2,469 hours (2,160 hours for worker interview/surveys+309 hours for worker recruiting screener) (see Table A.12-1).

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A.12-1- Estimated Annualized Burden Hours

Respondents	Data Collection Activity/ Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Retail food workers	Interview/survey	4,320	1	30/60	2,160
Retail food workers	Recruiting screener	6,171	1	3/60	309
Total					2,469

For each data collection, one observation will be conducted in each establishment and it will take approximately 60 minutes. However, 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 research program to respondents is estimated to be \$24,789 (See Table A.12-2). This figure is based on an estimated mean hourly wage of \$10.04 for retail food workers. These estimated hourly wages were obtained from the U.S. Department of Labor's 2009 national occupational employment and wage estimates report (food preparation and serving related occupations: http://stats.bls.gov/oes/current/oes_nat.htm#35-0000).

A.12.2- Estimated Annualized Burden Costs

Type of respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Retail food workers	2,469	10.04	\$24,789
Total			\$24,789

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents or record keepers.

A.14. Annualized Cost to the Federal Government

The annualized cost to the federal government is \$1,873,500. This figure is based on the actual costs during the 2010 fiscal year, annualized over 3 years. Costs to the government include funding provided to the 6 EHS-Net sites, salaries of CDC employees and contractors supporting the program, travel and office supplies (A.14.1). The U.S. Food and Drug Administration (\$200,000) provided funding support for this program in 2010, continued support will be contingent upon availability of funds.

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Table A.14.1

Expenditure	Cost
Salaries (Object Class 11 & 12)	\$475,000
Grants to States	\$1,050,000
Travel	\$14,000
Office Supplies	\$9,500
Contract Costs (3 ORISE fellows)	\$325,000
Total	\$1,873,500

A.15. Explanation for Program Changes or Adjustments

This is a revision of a generic clearance for an existing research program.

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

We expect to conduct up to 3 data collections 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

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

A.16.2– Example Data Collection Activity Schedule

Activity	Time Frame
Protocol development	5 months
IRB determination	1 month
Data collection	4 months
Data analysis	4 months
Manuscript development	3 months

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Analysis Plan

For each data collection, the following analyses will be conducted:

- 2) Descriptive analyses (frequencies, means, etc.) to describe food handling and food safety practices and worker and establishment characteristics and
- 3) Predictive analyses (multivariable regression) to examine relationships between worker and establishment characteristics and food handling and food safety practices.

Below is an example table shell illustrating the results of a multivariable regression analysis examining worker and establishment characteristics associated with the lack of use of shallow pans for cooling hot food (an unsafe food cooling practice).

Table A.16.3- Example Table Shell: Establishment and worker characteristics associated with the lack of use of shallow pans for cooling hot food

	OR (95% CI)	P
Kitchen manager certification		
Yes	x.xx (ref)	.xxx
No	x.xx (ref)	
Worker food safety knowledge		
Good/Safe	x.xx (ref)	.xxx
Bad/Unsafe	x.xx (ref)	
Establishment policies		
Good/Safe	x.xx (ref)	.xxx
Bad/Unsafe	x.xx (ref)	
Quality of equipment		
Good/Safe	x.xx (ref)	.xxx
Bad/Unsafe	x.xx (ref)	

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.

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References

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Supporting Statement Part A

Attachments

1. Regulation Authorizing Data Collection
2. 60 Day Federal Register Notice
3. Example of EHS-Net Data Collection Instrument- Interview
4. Example of EHS-Net Data Collection CDC IRB Determination
5. Example of EHS-Net Data Collection Informed Consent
6. Example of EHS-Net Data Collection Instrument- Recruiting Screener