

**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**

**NEW**

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## **Supporting Statement Part A**

### **Executive Summary**

The Environmental Health Specialists Network (EHS-Net) program, developed by the Centers for Disease Control and Prevention (CDC), conducts research designed to 1) identify and understand environmental factors associated with food- and water-borne illness and outbreaks, and 2) identify and understand the strengths and weaknesses of environmental public health regulatory programs responsible for food and water safety. EHS-Net data collections are typically conducted in response to food- and water-borne illness outbreaks, and provide timely data on the causes of outbreaks, including environmental factors associated with outbreaks. These data are essential to environmental public health regulators' efforts to respond more effectively to outbreaks and prevent future, similar outbreaks.

To meet its purposes, EHS-Net conducts up to 35 data collections per year. These data collections can involve collecting data from retail food service workers, water system operators, and environmental public health program regulators. Given the need for EHS-Net to be able to conduct these data collections rapidly, this submission requests a generic OMB clearance for all EHS-Net data collections conducted in 2008 through 2011.

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## Environmental Health Specialists Network (EHS-Net) Program

### A. Justification

#### A.1. Circumstances Making the Collection of Information Necessary

An estimated 76 million foodborne illnesses occur annually in the United States, resulting in 325,000 hospitalizations and 5,000 deaths annually (Mead et al., 1999). These figures indicate that foodborne illness is a significant problem in the U.S.

A recent study indicates that, on average, 8.5% of acute gastrointestinal illness cases in the U.S. are associated with community drinking water supplies (Messner et al., 2006). Another recent study estimated that a median of 12% of acute gastrointestinal illness cases are associated with community drinking water supplies (Colford et al., 2006). These percentages suggest that between 4 and 33 million people per year in the U.S. may develop acute gastrointestinal illness from public drinking water supplies, and indicate that waterborne illness, like foodborne illness, is a significant problem in the U.S.

Reducing food- and water-borne illnesses first requires identification and understanding of the environmental factors that cause these illnesses—we need to know how and why food and water become contaminated with food- and water-borne illness pathogens and how and why these pathogens are not eliminated from food and water before ingestion. This information can then be used to determine effective food and water safety prevention and intervention methods.

Additionally, we need to understand the role that environmental public health regulatory programs play in food and water safety—we need to know what regulatory programs are doing in regards to food and water safety, and what they could be doing to more effectively reduce food- and water-borne illness. This information can then be used to improve food and water safety regulatory programs' policies and practices to prevent future food-and water-borne illness.

The purposes of this research program are to: 1) identify and understand environmental factors associated with food- and water-borne illness, and 2) identify and understand the strengths and weaknesses of environmental public health regulatory programs. This information can then be used to reduce the incidence of food- and water-borne illness. To meet these purposes, this research program will involve a maximum of 35 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), the U.S. Environmental Protection Agency (EPA), and nine states (California, Connecticut, Georgia, Iowa, New York, Minnesota, Oregon, Rhode Island, and Tennessee). The state 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. The EHS-Net research program has two components—one focused on food safety

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and one focused on water safety. All nine states participate in the food safety component; only five states participate in the water safety component (California, Georgia, Minnesota, New York, and Tennessee). In some cases, data for a study are collected in all nine states; in other cases, data for a study are collected in only one state. As described below, EHS-Net data collections can involve collecting data from retail food service establishment workers, water system operators, and environmental public health program regulators. However, participation in all EHS-Net data collections is voluntary.

To identify and understand the environmental factors associated with foodborne illness, we need to collect data on food handling practices, policies, and environments from those responsible for preparing and cooking food. Recent studies have indicated that retail food service establishments are an important source of food- and water-borne illnesses. Case-control studies have revealed significant associations between eating at food service 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 food service establishments (Jones et al., 2004; Olsen et al., 2000). Thus, our data collection efforts have focused on retail food service establishments. Many of our data collections involve interviewing and/or observing food service establishment managers and workers to learn about their food preparation practices and policies and environmental factors related to those practices and policies, and conducting food and environmental sampling to learn about levels, types, and locations of pathogen contamination in the establishments. Attachment 3 contains an example of an EHS-Net retail food service worker data collection instrument.

Similarly, to identify and understand the environmental factors associated with waterborne illness, we need to collect data on water handling practices, policies, and environments from those who operate public and non-public water systems, as they are responsible for providing safe water to the public. Thus, some of our data collections involve interviewing and/or observing water system operators to learn about their practices and policies and environmental factors associated with these practices and policies, and conducting water and environmental sampling to learn about levels, types, and locations of pathogen contamination in water systems. Attachment 4 contains an example of an EHS-Net water system operator data collection instrument.

To identify and understand the strengths and weaknesses of environmental public health regulatory programs and the role they play in food and water safety, we need to collect data on regulatory practices and policies from food and safety regulatory program personnel. These personnel are responsible for ensuring food and water safety, and attempt to do so through activities such as restaurant food safety inspections, water system inspections, and food- and water-borne illness outbreak investigations. Thus, some of our data collections involve interviewing and/or observing these regulatory personnel to learn about their practices and policies. Attachment 5 contains an example of an EHS-Net environmental public health regulator data collection instrument.

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EHS-Net data collections are typically conducted in response to food- and water-borne 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 unique composition of state and federal environmental public health regulators, 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 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 and water safety and the industry involved can be implemented as quickly as possible.

EHS-Net's tomato data collection provide 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 (See Attachment 3 for this data collection instrument). These data are currently being reviewed by CDC and FDA to determine how policies and practices can be changed to lessen the occurrence of future, similar outbreaks. These data can also be used in the development of effective outbreak prevention messages.

In order to accomplish the necessary public health functions of identifying and understanding environmental factors associated with food- and water-borne illness and outbreaks, and identifying and understanding the strengths and weaknesses of environmental public health regulatory programs, CDC is requesting a three-year generic approval of the EHS-Net program approach and methodology. Once this approval is obtained, each individual EHS-Net data collection that falls within the scope of the generic clearance (a maximum of 35 annually) would undergo expedited review.

Since the inception of EHS-Net, CDC has believed that EHS-Net data collections were exempt from the OMB clearance process. However, a recent organizational change at CDC led to a review of EHS-Net activities in regards to OMB clearance, and it was determined that past interpretation of OMB guidelines was incorrect and that EHS-Net does in fact need OMB clearance. Without the required approval, this necessary public health activity must cease.

The data collections conducted by the EHS-Net research program support CDC's research agenda goal of "Decreasing health risks from environmental exposures," as food- and water-borne illness are environmental exposure health risks. Data collection authority is found in Section 301 of the Public Health Service Act (42 USC 241) (Attachment 1).

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### A.2. Purpose and Use of the Information Collection

The information collected through the EHS-Net research program will be used to: 1) identify and understand environmental factors associated with food- and water-borne illness, and 2) evaluate and improve state and local food and water safety regulatory programs. CDC can then use this information to develop food and water safety recommendations and technical assistance activities for environmental public health regulatory programs. Additionally, CDC will disseminate the information learned from the data collections through scientific publications frequently subscribed to by environmental public health regulators and food and water industry representatives, such as the *Journal of Food Protection*, *Food Protection Trends*, and *Journal of Environmental Health*. Additionally, the information will be disseminated through presentations at conferences attended by environmental public health regulators and food and water industry representatives, such as the *National Environmental Health Association*, the *International Association of Food Protection*, and the *Conference for Food Protection*. Finally, findings from EHS-Net research projects will be posted on the CDC EHS-Net website.

These disseminations will allow environmental public health regulatory programs and food and water industries to access and use the information gained from the EHS-Net research program to improve their food and water safety programs. For example, if an EHS-Net research project identifies an environmental factor associated with foodborne illness caused by restaurant-prepared food, environmental public health regulatory programs can develop and disseminate interventions designed to reduce or eliminate the environmental factor in restaurants. The food industry can do likewise. Ultimately, these actions will lead to increased food and water safety regulatory program effectiveness, increased industry effectiveness, increased food and water safety, and decreased food- and water-borne illness.

This research program is funded by the Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health, Environmental Health Services Branch, the U.S. Food and Drug Administration, and the U.S. Environmental Protection Agency.

### 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. In these cases, participants will be able to submit their responses electronically through a web-based system. This use of improved information technology will reduce the burden for respondents. However, because all participants may not have access to the web or may not wish to use the web for this purpose, they will also have the option of responding to the

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data collections on paper. We expect approximately 15% of EHS-Net data collections will be electronic.

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 data available on environmental factors related to food- and water-borne illness or on evaluations of the specific topics of interest concerning food and water safety regulatory programs. 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**

For some EHS-Net data collections, retail food service establishments and water systems will be respondents, and some proportion of these establishments and water systems 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**

In general, 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.



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### 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 July 25, 2007 in Volume 72, Number 142, Pages 40884-40885 (Attachment 2). Two comments were received on this notice. The first commenter requested a copy of the data collection instruments referenced in the FRN. We responded by providing the commenter the data collection instruments used as examples in the OMB supporting statement and we explained that the FRN referred to a variety of studies conducted via the EHS-Net program.

The second commenter asked four questions. Below we have provided those questions and the answers we provided.

**1) How was the number of respondents to each research project determined?**

The EHS-Net conducts both multi-state projects and the participating EHS-Net states conduct individual state projects. The number of respondents and the burden estimates were based on our experience conducting these types of multi-state projects and the experience of individual states who have conducted individual state projects. The estimates are based on the maximum number of respondents we felt possible (based on our experience) for any one study. Our web site is a good source of information regarding our multi-state studies and give insights on the number of respondents that have been involved in some of our projects. Please see: <http://www.cdc.gov/nceh/ehs/EHSNet/highlights.htm>

**2) How was the burden to respondents determined?**

There is no cost to the respondents other than their time so the burden estimates are based on the amount of time required of the respondent. The maximum amount of time involved for a respondent in any of our past projects has been approximately 90 minutes.

**3) What information will be collected?**

Examples of the type of information to be collected can be found in the attached documents. Please realize that the attachments are only examples of the different types of data collections that this announcement references.

**4) How will the collected and reviewed information be used?**

Below is an excerpt from a draft document explaining how the collected information will be used. A very specific example of how the information has been used in the past can be found at <http://www.cdc.gov/nceh/ehs/EHSNet/certification.htm> .

- B. Below is a list of individuals from other CDC Centers and federal agencies (Table B.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. The federal and state consultants have been

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consulted by CDC on an intermittent basis since 2000; the industry consultants have been consulted by CDC since 2006.

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

Dr. Craig Hedberg is the primary consultant representing academia.

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**Table A.8.1 Federal Consultants**

<b>FDA / USD / EPA</b>	<b>CDC</b>
<p><b>Jack Guzewich, RS, MPH</b>                      Director-Emergency Coordination &amp; 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  <a href="mailto:john.guzewich@cfsan.fda.gov">john.guzewich@cfsan.fda.gov</a></p> <p><b>Patrick McCarthy, PhD, MPH</b>                      Statistician                      U.S. Food and Drug Administration                      5100 Paint Branch Parkway</p>	<p><b>Patricia Griffin, MD</b>                      Chief, Foodborne Disease Epidemiology Section                      Epidemiologist                      National Center for Zoonotic, Vector-Borne, &amp; Enteric Diseases                      1600 Clifton Rd.                      MS A38                      Atlanta, GA 30333                      404-639-3384  <a href="mailto:pmg1@cdc.gov">pmg1@cdc.gov</a></p> <p><b>Fred Angulo, DVM, PhD, MPH</b>                      Epidemiologist                      National Center for Zoonotic, Vector-</p>

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**Table A.8.2** Industry Consultants

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

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**Table A.8.3 State Consultants**

State Consultants	State Consultants
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**A.9. Explanation of Any Payment or Gift to Respondents**

There will be no payments or gifts to respondents.

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

This submission has been reviewed by ICRO, who has determined that the Privacy Act does apply to portions of this ICR. The applicable Systems of Records Notice is 09-20-0136, 'Epidemiologic Studies and Surveillance of Disease Problems.' This determination is explained further in the paragraph below.

No assurances of confidentiality will be provided to respondents for any EHS-Net data collections. Many data collection will be anonymous. Others will involve the use of identification codes, but these codes will allow us to keep respondents' identities separate from their data. In these cases, respondents will be assigned an identity code and we will maintain a list of respondent names and identification codes. The lists will be stored on secure computers, only study personnel will have access to the lists, and after we have completed the data collections, the lists will be destroyed. For these types of data collections, the Privacy Act will apply. Records will be covered under system notice 09-20-0136, 'Epidemiologic Studies and Surveillance of Disease Problems.' Identification codes may be used in situations in which we would need to follow up with participants at a later date, or check on the accuracy of information obtained from respondents.

45 CFR 46 (Regulations for Protection of Human Subjects) apply to this research program. All data collection protocols will be reviewed by the CDC Institutional Review Board (IRB). We expect most EHS-Net data collections to be exempt from IRB clearance, because they will involve survey/interview procedures, and the data collected will be anonymous (45 CFR 46.101 (b)). However, those data collections that do not meet these criteria will receive IRB clearance from the CDC's IRB. Additionally, we will obtain informed consent, even for data collections that are exempt from IRB clearance.

### **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**

We expect to conduct up to 10 multi-state data collections and 25 single state data collections annually. Some projects will be focused on food safety and some projects will be focused on water safety. All 9 states will participate in the food data collections; only the 5 states receiving water safety funding will participate in water data collections.

We expect to conduct up to 12 retail food service worker data collections annually (3 multi-state and 9 single state). There will be a maximum of 3,600 retail food service worker respondents to these data collections annually (100 respondents per state per study: multi-state studies- 3 studies\*9 states\*100 respondents=2,700; single state studies- 9 studies\*1 state\*100 respondents=900; 2,700+900=3,600). Additionally, a maximum of 300 retail food service workers will participate in pretesting of these data collections (25 respondents per study: 12 studies\*25 respondents=300). Each respondent will respond only once and the average burden per response will be approximately 90 minutes. The estimated



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maximum total annual burden for retail food service workers is 5,850 hours (450 for pre-testing, 5,400 for data collections). As described earlier, the retail food service worker data collections have not yet been developed; thus, the figures in the Part II worksheet for retail food service worker data collections are based on these estimates. However, we have provided an example retail food service worker data collection and pretest in Attachments 3 and 6.

We expect to conduct up to 8 water system operator data collections annually (3 multi-state and 5 single state). There will be a maximum of 2,000 water system operator respondents to these data collections annually (100 respondents per state per study: multi-state studies- 3 studies\*5 states\*100 respondents=1,500; single state studies- 5 studies\*1 state\*100 respondents=500; 1,500+500=2,000). Additionally, a maximum of 200 water system operators will participate in pretesting of these data collections (25 respondents per study: 8 studies\*25 respondents=200). Each respondent will respond only once and the average burden per response will be approximately 90 minutes. The estimated maximum total annual burden for water system operators is 2,200 hours (200 for pre-testing, 2,000 for data collections). As the water system operator data collections have not yet been developed, we have provided an example water system operator data collection and pretest in Attachments 4 and 7.

We expect to conduct up to 15 environmental public health (food and water) program regulator data collections annually (4 multi-state and 11 single state). Two of the multi-state studies will focus on food safety (9 states) and two will focus on water safety (5 states). Seven of the single state studies will focus on food safety (9 states) and four will focus on water safety (5 states). There will be a maximum of 2,800 regulator respondents to the multi-state data collections annually (100 respondents per state per study: food safety- 2 studies\*9 states\*100 respondents=1,800; water safety- 2 studies\*5 states\*100 respondents=1,000; 1,800+1,000=2,800). There will be a maximum of 1,100 regulator respondents to the single state data collections annually (100 respondents per state per study: food safety- 7 studies\*1 state\*100 respondents=700; water safety- 4 studies\*1 state\*100 respondents=400; 700+400=1,100). Thus, the maximum number of environmental public health regulator respondents will be 3,900 annually (2,800 for multi-state; 1,100 for single state). Additionally, a maximum of 375 environmental public health program regulators will participate in pretesting of these data collections (25 respondents per study: 15 studies\*25 respondents=375). Each respondent will respond only once and the average burden per response will be approximately 90 minutes. The estimated maximum total annual burden for environmental public health program regulators is 6,413 hours (563 for pre-testing, 5,850 for data collections). As the environmental public health regulator data collections have not yet been developed, we have provided an example regulator data collection and pretest in Attachments 5 and 8.

The maximum total annual burden for all EHS-Net data collections is approximately 15,563 hours (see Table A.12-1).

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**A.12-1- Estimates of Annualized Burden Hours**

<b>Respondents</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden (in hours)</b>
Retail food service workers- pretest for data collection	300	1	1.5	450
Retail food service workers- data collection	3,600	1	1.5	5,400
Water system operators- pretest for data collection	200	1	1.5	300
Water system operators- data collection	2,000	1	1.5	3,000
Environmental public health program (food and water) regulators- pretest for data collection	375	1	1.5	563
Environmental public health program (food and water) regulators- data collection	3,900	1	1.5	5,850
<b>Total</b>				<b>15,563</b>

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

The maximum total annualized cost of this research program to respondents is estimated to be \$292,835 (See Table A.12-2). This figure is based on an estimated mean hourly wage of \$7.72 for retail food service workers, \$17.88 for water system operators, and \$29.38 for environmental public health regulatory program (food and water) workers. These estimated hourly wages were obtained from the U.S. Department of Labor’s 2006 national occupational employment and wage estimates report (retail food service workers: <http://stats.bls.gov/oes/current/oes352021.htm>; water system operators: <http://stats.bls.gov/oes/current/oes518031.htm>; regulatory program workers: <http://stats.bls.gov/oes/current/oes192041.htm>).

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**A.12.2- Annualized Cost to Respondents**

<b>Type of respondent</b>	<b>No. of Respondents</b>	<b>Response Burden per Respondent</b>	<b>Hourly Wage Rate</b>	<b>Respondent Cost</b>
Retail food service workers- pretest for data collection	300	90/60	\$7.72	\$3,474
Retail food service workers- data collection	3,600	90/60	\$7.72	\$41,688
Water system operators- pretest for data collection	200	90/60	\$17.88	\$5,634
Water system operators- data collection	2,000	90/60	\$17.88	\$53,640
Environmental public health program (food and water) regulators- pretest for data collection	375	90/60	\$29.38	\$16,526
Environmental public health program (food and water) regulators- data collection	3,900	90/60	\$29.38	\$171,873
<b>Total</b>				<b>\$292,835</b>

**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 based on the actual costs during the 2007 fiscal year, annualized over 3 years. These costs include funding provided to the 9 EHS-Net states participating in this research program. The U.S. Food and Drug Administration (\$400,000) and the U.S. Environmental Protection Agency (\$250,000) have provided funding support for this program in 2007, continued support will be contingent upon availability of funds.

The annualized costs of the research program are described in the following table (A.14.1).

**Table A.14.1**

<b>Expenditure</b>	<b>Cost</b>
Salaries (Object Class 11 & 12)	\$475,000
Grants to States	\$1,900,000
Travel	\$14,000
Office Supplies	\$3,800
Contract Costs	\$280,000
<b>Total</b>	<b>\$2,672,800</b>

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

This is a new research program.

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

We expect to conduct up to 10 multi-state data collections and 25 individual state data collections annually. 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 – Data Collection Schedule**

	<b>Activity</b>
1	Multi-state retail food service worker data collection #1
2	Multi-state retail food service worker data collection #2
3	Multi-state retail food service worker data collection #3
4	Multi-state water operator data collection #1
5	Multi-state water operator data collection #2
6	Multi-state water operator data collection #3
7	Multi-state environmental public health regulator data collection #1
8	Multi-state environmental public health regulator data collection #2
9	Multi-state environmental public health regulator data collection #3
10	Multi-state environmental public health regulator data collection #4
11	Single state retail food service worker data collection #1
12	Single state retail food service worker data collection #2
13	Single state retail food service worker data collection #3
14	Single state retail food service worker data collection #4
15	Single state retail food service worker data collection #5
16	Single state retail food service worker data collection #6
17	Single state retail food service worker data collection #7
18	Single state retail food service worker data collection #8
19	Single state retail food service worker data collection #9
20	Single state water operator data collection #1
21	Single state water operator data collection #2
22	Single state water operator data collection #3
23	Single state water operator data collection #4
24	Single state water operator data collection #5
25	Single state environmental public health program regulator data collection #1
26	Single state environmental public health program regulator data collection #2
27	Single state environmental public health program regulator data collection #3
28	Single state environmental public health program regulator data collection #4
29	Single state environmental public health program regulator data collection #5
30	Single state environmental public health program regulator data collection #6
31	Single state environmental public health program regulator data collection #7
32	Single state environmental public health program regulator data collection #8

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33	Single state environmental public health program regulator data collection #9
34	Single state environmental public health program regulator data collection #10
35	Single state environmental public health program regulator data collection #11

**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.

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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 retail food service worker data collection
4. Example of water system operator data collection
5. Example of environmental public health regulator data collection
6. Example of retail food service worker pretest for data collection
7. Example of water system operator pretest for data collection
8. Example of environmental public health regulator pretest for data collection