

Supporting Statement Part A

Supporting Statement (Part A) for
EHS-Net Food Service Establishment Cooling Practices Study

Change Request #1-09
Submitted under Generic Clearance #0920-0792

Environmental Health Specialists Network (EHS-Net) Program

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Environmental Health Specialists Network (EHS-Net) Program

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

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.

Given the need to conduct its data collections rapidly, EHS-Net requested a generic OMB clearance for all EHS-Net data collections conducted through 2011. On October 21, 2008, OMB gave generic clearance (no. 0920-0792) to CDC for the Environmental Health Specialists Network (EHS-Net) Program. CDC is now requesting OMB approval of a new retail food service worker food handling practices study under this program. Under the EHS-Net Program generic clearance, OMB has agreed to expedite review of EHS-Net Program data collections. Thus, no additional Federal Register notices are necessary, and the expected turn-around time for requested packages submitted under this clearance is six weeks or less. The data collection proposed in this package is the first to be submitted since its approval.

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-borne illnesses (Friedman et al., 2004; Kassenborg et al., 2004; Jones et al., 2004; Olsen et al., 2000). Thus, some of our data collection efforts will focus on retail food service establishments. These data collections will 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. The data collection for which we are seeking approval is one of these efforts. Specifically, this data collection focuses on food cooling practices in food service establishments. Improper cooling of food contributed to 44% of 1,918 foodborne illness outbreaks occurring in the U.S. over a 20-year period (Bryan, 1988). From 2001 to 2005, improper cooling was identified as a contributing factor in over 500 confirmed foodborne outbreaks (internal CDC data). Indeed, improper cooling is considered to be the most frequent contributing factor to foodborne illness outbreaks. These data clearly indicate that improper cooling is a significant source of foodborne illness and needs to be the focus of prevention and intervention efforts. However, little data exists on current food service establishment cooling practices, policies and environments. As this information is essential to the development of effective prevention and intervention efforts, this study will focus on collecting these data (See Attachments 1 and 2 for the data collection instrument and recruiting screener).

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This data collection supports 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).

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. CDC can then use this information to develop food safety recommendations for the food service industry and environmental public health regulators responsible for assisting the food service industry in improving its cooling practices. 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 industries to access and use the information gained from the EHS-Net research program to improve their food safety programs. For example, the proposed data collection will identify food service establishments' most frequent improper food cooling practices; environmental public health regulatory programs can develop and disseminate interventions designed to reduce or eliminate these practices in food service establishments. The food industry can do likewise. Ultimately, these actions will lead to increased food safety regulatory program effectiveness, increased industry effectiveness, increased food safety, and decreased food-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

This data collection will involve face-to-face semi-structured interviews with respondents (retail food service managers). 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.

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.

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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 food service establishment food cooling practices. Thus, this EHS-Net data collection will not be a duplication of effort.

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

Some proportion (an estimated 30%) of the food service establishments contacted for participation in this study 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 this data collection. 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 this data collection only one time. If this data collection is not conducted, it will be difficult for CDC, state and local environmental public health regulators, and the food service industry to develop programs that will effectively improve food cooling practices in food service establishments. Additionally, it will be difficult for environmental public health regulators to respond effectively to foodborne illness outbreaks related to cooling. Thus, it would also 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 July 25, 2007 in Volume 72, Pages 40884-40885. The 30 day Federal Register notice was published March 17, 2008 in Volume 73, Pages 14256-14257. The original EHS-Net package contains all relevant information on the comments received on this notice and our responses to those comments.

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B. Federal and state consultants are listed in Table A.8.1.

Table A.8.1

Federal Consultants		
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Table A.8.1 Continued

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Table A.8.1 Continued

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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 project 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 be conducted, names will not be recorded. This data collection has been determined to be exempt from CDC IRB oversight (45 CFR 46.101 (b)). However, EHS-Net sites may need to obtain approval from their IRBs. No identifying information on food service establishments or workers will be collected. Although specialists will keep a list of establishments in which they have collected data, no data will be stored with this list, and there

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will be no way to link establishment names with the data collected from those establishments. Additionally, a list of names will not be maintained, and any information used to schedule visits, such as call logs, will be destroyed once data collection is complete.

Although this study is exempt from IRB review because CDC is not engaged in human subjects research (as determined by the Human Subjects Contact for NCEH/ATSDR), we will obtain verbal informed consent. The informed consent script can be found in Attachment 3.

A.11. Justification for Sensitive Questions

There are no sensitive questions in this data collection.

A.12. Estimates of Annualized Burden hours and costs

All 9 EHS-Net states will collect data for this study; each state will collect data in 50 food service establishments. Thus there will be approximately 450 retail food service manager respondents (see attachment 1 for the data collection instrument). Each respondent will respond only once and the average burden per response will be approximately 90 minutes. Thus, the estimated burden for respondents to the data collection instrument is 675 hours. We expect a response rate of approximately 70 percent; thus, we will need to conduct the telephone recruiting screener with approximately 643 respondents in order to meet our goal of 450 respondents (see attachment 2 for this screener). Each respondent to the screener will respond only once and the average burden per response will be approximately 3 minutes. Thus the estimated burden for respondents to the recruiting screener is 32.2 hours. The total annualized response burden for is estimated at 707.2 hours (675+32.2). (See Table A.12-1)

A.12-1- Estimates of Annualized Burden Hours

Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Retail food service managers	Recruiting screener	643	1	.05	32.2
Retail food service managers	Data collection instrument	450	1	1.5	675.0
Total					707.2

A.12-2- Annualized Cost to Respondents

The maximum total annualized cost of this data collection to respondents is estimated to be \$9,713 (See Table A.12-2). This figure is based on an estimated mean hourly wage of \$14.39 for retail food service managers. These estimated hourly wages were obtained from the U.S. Department of Labor's 2007 national occupational employment and wage estimates report (<http://stats.bls.gov/oes/2007/may/oes351012.htm>).

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A.12.2- Annualized Cost to Respondents

Type of respondent	Form Name	No. of Respondents	Response Burden per Respondent	Hourly Wage Rate	Respondent Cost
Retail food service managers	Recruiting screener	643	3/60	\$14.39	\$463
Retail food service managers	Data collection instrument	450	90/60	\$14.39	\$9,713
Total					\$10,176

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

Costs to the government include a portion of the annual grant to the states that will collect the data and the costs of CDC personnel and CDC contractors working on the data collection (A.14.1).

Table A.14.1

Expenditure	Cost
Grants to States	\$95,000
Salaries	\$23,750
Contract Costs	\$14,000
Total	\$132,750

A.15. Explanation for Program Changes or Adjustments

This is new data collection associated with an existing generic clearance.

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

Table A-16.1 provides the data collection activity schedule.

A.16.1 – Data Collection Schedule

Activity	Time Frame
Data collection	1 month after obtaining OMB clearance
Data analysis	6 months after obtaining OMB clearance
Manuscript development	12 months after obtaining OMB clearance

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

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

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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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- Olsen, S., L. MacKinon, J. Goulding, N. Bean, and L. Slutsker. 2000. Surveillance for foodborne disease outbreaks—United States, 1993-1997. *MMWR.* 49:1–51.

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Attachments

1. Attachment 1- EHS-Net Cooling Practices Study Data Collection Instrument
2. Attachment 2- EHS-Net Cooling Practices Study Telephone Recruiting Screener and Nonrespondent Questions
3. Attachment 3- EHS-Net Cooling Practices Study Informed Consent