Supporting Statement (Part A) for

EHS-Net Kitchen Manager Certification Study

Change Request #2-09
Submitted under Generic Clearance #0920-0792

Environmental Health Specialists Network (EHS-Net) Program

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Table of Contents

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.

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 six state and local public health departments (California, New York, New York City, Minnesota, Rhode Island, and Tennessee). The state and local 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.

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 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.

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 foodborne 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 determining how kitchen manager food safety certification is related to foodborne illness risk factors.

Foodborne illness risk factors are food preparation practices and behaviors associated with foodborne illness outbreaks. CDC has identified the most frequent risk factors to foodborne illness outbreaks associated with foodservice establishments. These risk factors include: food from unsafe sources, inadequate cooking, improper holding time and temperature, contaminated equipment/cross contamination, and poor personal hygiene.

Under the assumption that kitchen managers (KM) with certified (by an exam) food safety knowledge are better able to control these risk factors, public health agencies are increasingly encouraging or requiring KM certification, in which KMs receive training on food safety and prevention of risk factors and demonstrate knowledge of these topics by passing a food safety certifying exam. Kitchen manager certification is also one way to show compliance with one of the FDA Food Code's interventions to protect consumer health—kitchen manager 'demonstration of knowledge.'

Recent data has suggested that the presence of a certified KM in restaurants is related to fewer foodborne illness risk factors and reduced risk of a foodborne illness outbreak (Cates et al.; FDA, 2004; Hedberg et al, 2007). However, some studies have not found a relationship between KM certification and food safety (Green et al. 2007; Sumner et al., in press). Additionally, little is known about the specific mechanisms through which KM certification might work to improve food safety. One likely possibility is that certified KMs are better able to control environmental antecedents -- factors in the environment that lead to risk factors. Examples of environmental antecedents include lack of food safety knowledge, lack of policies designed to prevent risk factors, and lack of adequate equipment.

Given the widespread recommendation or requirement of KM certification, it is important to determine how KM certification is related to environmental antecedents and foodborne illness risk factors. Thus, the purpose of this study is to collect and analyze data that will help us better understand the relationship between KM certification and environmental antecedents and risk factors in restaurants. Environmental antecedents examined in this study include: manager and worker food safety knowledge and beliefs, restaurant food handling policies, and kitchen equipment and facilities. Risk factors examined in this study include food handling practices related to inadequate cooking, improper holding time and temperature, contaminated equipment/cross contamination, and poor personal hygiene.

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) (Attachment 1).

Privacy Impact Assessment

Overview of the Data Collection System. Data will be collected by environmental health specialists in the participating EHS-Net sites. Food service establishment managers and food workers are the respondents in this study. Data collection methods include: 1) manager interview, 2) manager survey (completed by manager with pen and paper), 3) worker interview, and 4) observation of kitchen environment and food handling practices.

These multiple data collection methods are necessary to accurately assess all components of this study. The manager interview is necessary for collecting information about manager training and certification and also about environmental antecedents to foodborne illness risk factors, the manager survey is necessary to collect information about manager food safety knowledge, the observation is necessary to collect data about foodborne illness risk factors, and the worker interview is necessary to collect data about an important environmental antecedent- worker food safety knowledge. Attachments 3-5 contain the manager interview, survey, and observation and Attachment 6 contains the worker interview. Attachment 7 describes the items from the data collection instrument that measure specific environmental antecedents and foodborne illness risk factors.

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.

- Manager interview
  - manager and worker training and certification information
  - restaurant and manager demographics
  - manager food safety beliefs (environmental antecedents)
  - restaurant food handling policies (environmental antecedents)
- Manager survey
  - manager food safety knowledge (environmental antecedents)
- Worker interview
  - worker food safety knowledge and beliefs (environmental antecedents)
  - worker demographics
- Observation of kitchen and food handling practices
  - foodborne illness risk factors
  - equipment and facilities (environmental antecedents)
  - restaurant demographics

The majority of the information collected in the study is collected on the food service establishment, not individuals. However, we will collect basic demographic data on the managers and workers and will also collect data about their food safety knowledge and beliefs.

No individually identifiable information is being 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.

A.2. Purpose and Use of the Information Collection

The purpose of this data collection is to collect data that will contribute to our understanding of the relationships between KM training and certification, environmental antecedents and foodborne illness risk factors in restaurants.

Specifically, the information will be used to answer the following questions:

1) How is KM certification related to environmental antecedents?
2) How is KM certification related to foodborne illness risk factors?
3) What contribution does KM training and certification and environmental antecedents make, individually and together, toward explaining variation in the occurrence of foodborne illness risk factors?
4) Does the relationship between KM certification and foodborne illness risk factors vary by the type of certification? In other words, are some types of certification more likely to be related to fewer foodborne illness risk factors than others?

The data collected in this study can be used by CDC to develop food safety prevention and intervention recommendations for food safety programs and the restaurant industry.

Generalizability of Results

The information collected will be generalizable to the restaurant population in the EHS-Net catchment area, which includes Rhode Island, New York City, and selected counties in California, New York, Minnesota, and Tennessee. Financially and logistically it is not feasible to collect data from all states. While the number of states included is small, the states are demographically diverse and provide good geographical coverage of the U.S. (northeast, mid-west, south, and west). And within each state, the restaurants are randomly selected. These factors make the restaurants selected in this study representative of other restaurants in the U.S.

Privacy Impact Assessment

Why is the information being collected. The information collected in this study is being collected to answer specific questions about the relationships between KM training and certification, environmental antecedents, and foodborne illness risk factors in restaurants.

Intended use of the information being collected. The information will be used to develop recommendations for food safety programs and the restaurant industry. For example, if data analysis reveals that certification is related to some environmental antecedents and foodborne illness risk factors but not others, CDC can disseminate this information and encourage food safety programs and the restaurant industry to address the lacking environmental antecedents and foodborne illness risk factors by improving their certification programs or by implementing other interventions.

No individually identifiable information will be collected.

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 and workers). 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. Manager respondents will also complete a short written survey that will require circling responses options- no written responses will be required.

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

We have searched relevant databases (e.g., PubMed, Ovid, Agricola), attended national meetings (e.g., National Environmental Health Association, International Association of Food Protection), and consulted with other organizations (e.g., FDA, USDA) concerning research on this topic. FDA is conducting a study that will contain some data on the relationship between KM certification and foodborne illness risk factors. However, that is not the primary purpose of their study. Thus, more data, and more detailed data, are needed on this topic. 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 and practices than larger businesses, it is important that small businesses be included in this data collection. 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 adequately assess the relationship between KM certification, environmental antecedents, and foodborne illness risk factors. 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 this data collection. It 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 (Attachment 2). 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.

B. Personnel from our EHS-Net states worked with CDC to develop this data collection in 2009. Additionally, FDA, an EHS-Net partner, also consulted on the data collection. Names and contact information are provided below.

States	
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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, no identifying information on food service establishments or workers will be collected. This data collection protocol received expedited review and approval by CDC IRB (Attachment 8). EHS-Net sites will obtain approval from their IRBs as appropriate. The informed consent scripts can be found in Attachments 9 and 10. The informed consent for the manager (Attachment 9) will be incorporated into the beginning of the manager interview and the manager interview burden estimate includes the burden estimate for this informed consent (thus, the manager informed consent does not contain the OMB headings that are on the other data collection instruments).

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. The consent scripts can be found in Attachments 9 and 10.
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

There are no sensitive questions in this data collection.

A.12. Estimates of Annualized Burden hours and costs

Six EHS-Net sites will collect data for this study; each site will collect data in 80 food service establishments. Thus, there will be 480 retail food service manager respondents. Each respondent will respond only once. Each manager respondent will be interviewed; the interview will last approximately twenty minutes (the time to conduct the manager informed consent is included in this estimate). Each manager respondent will also complete a short survey; the survey will take approximately ten minutes. The data collectors will then conduct an observation of the kitchen which will take approximately 50 minutes. The observation does not directly involve the managers and they need not be available during the observation. However, to be conservative, we have chosen to include them in the manager burden estimation, as the data collectors will be

in the restaurant during that time. Thus, the average manager burden per response will be approximately 80 minutes (640 burden hours). We expect a manager response rate of approximately 70 percent; thus, we will need to conduct the telephone recruiting screener with approximately 686 manager respondents in order to meet our goal of 480 respondents (Attachment 11 contains the manager recruiting script). Each respondent to the screener will respond only once and the average burden per response will be approximately 3 minutes (34 burden hours).

We will also attempt to obtain a worker respondent in each establishment. Each worker respondent will respond only once. Each worker respondent will be interviewed; the interview will last approximately 10 minutes. To obtain the worker respondent, we will conduct a recruiting screener with a worker in each establishment (Attachment 10 contains the worker recruiting script). Each respondent to this screener will respond only once and the average burden per response will be approximately 3 minutes (24 burden hours). We expect 90 percent of these worker respondents to agree to participate (432 workers; 72 burden hours). The total annualized response burden is estimated at 770 hours (See Table A.12-1).

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 service managers	Recruiting screener	686	1	3/60	34
Retail food service managers	Manager interview	480	1	20/60	160
Retail food service managers	Manager survey	480	1	10/60	80
Retail food service managers	Kitchen observation	480	1	50/60	400
Retail food service workers	Recruiting screener	480	1	3/60	24
Retail food service workers	Worker interview	432	1	10/60	72
Total					770

A.12-2- Annualized Cost to Respondents

The maximum total annualized cost of this data collection to respondents is estimated to be $10,732 (See Table A.12-2). This figure is based on an estimated mean hourly wage of $14.72 for retail food service managers and $8.45 for retail food service workers. These estimated hourly wages were obtained from the U.S. Department of Labor’s 2009 national occupational employment and wage estimates report (http://www.bls.gov/iag/tgs/iag722.htm#earnings).

A.12.2- Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Retail food service managers	674	$14.72	$9,921
Retail food service workers	96	$8.45	$811
Total			$10,732

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 cooperative agreement to the states that will collect the data and the costs of CDC personnel working on the data collection (A.14.1). We estimate that the states will use approximately 20% of their cooperative agreement funds to conduct this data collection, and that two CDC staff will spend approximately 20% of their time on this data collection.

Table A.14.1

Expenditure	Cost
Grants to States	$203,500
Salaries	$38,000
Total	**$241,500**

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 – Project Time Schedule

Activity	Time Frame
Data collection	1 month after obtaining OMB clearance
Data analysis	8 months after obtaining OMB clearance
Manuscript development	14 months after obtaining OMB clearance

Analysis Plan

Descriptive analyses (frequencies, means, etc.) will be conducted to describe the sample. Predictive analyses (multivariable regression) will be conducted to examine relationships between KM certification and environmental antecedents and foodborne illness risk factors. Planned analyses are presented below by research question.

1) How is KM certification related to environmental antecedents?
   Predictive analyses will be conducted to determine whether KM training and certification is a significant predictor in explaining the variation in observed occurrences of environmental antecedents.

2) How is KM certification related to foodborne illness risk factors?
   Predictive analyses will be conducted to determine whether KM training and certification is a significant predictor in explaining the variation in observed occurrences of foodborne illness risk factors.

3) What contribution does KM training and certification and environmental antecedents make, individually and together, toward explaining variation in the occurrence of foodborne illness risk factors?
   Predictive analyses will be conducted to assess the relative contribution of KM certification and environmental antecedents in predicting foodborne illness risk factors.

4) Does the relationship between KM certification and environmental antecedents and foodborne illness risk factors vary by the type of certification? In other words, are some types of certification more likely to be related to fewer environmental antecedents and foodborne illness risk factors than others?
   Predictive analyses will be conducted to determine whether type of certification is a significant predictor in explaining the variation in observed occurrences of environmental antecedents and foodborne illness risk factors.

Below is an illustrative table shell of the results from an analysis conducted to assess the contribution KM certification and environmental antecedents make in predicting a foodborne illness risk factor.

Table A.16.2- Table Shell: KM certification and environmental antecedents associated with the observed occurrence of a foodborne illness risk factor

	OR (95% CI)	P
KM certification		
Yes	x.xx (ref)	.xxx
No	x.xx (ref)	
Manager food safety knowledge		
Good/Safe	x.xx (ref)	.xxx
Bad/Unsafe	x.xx (ref)	
Worker food safety knowledge		
Good/Safe	x.xx (ref)	.xxx
Bad/Unsafe	x.xx (ref)	
Manager beliefs		
Good/Safe	x.xx (ref)	.xxx
Bad/Unsafe	x.xx (ref)	
Worker beliefs		
Good/Safe	x.xx (ref)	.xxx
Bad/Unsafe	x.xx (ref)	
Restaurant policies		
Good/Safe	x.xx (ref)	.xxx
Bad/Unsafe	x.xx (ref)	
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.

References

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Attachments

Attachment 1- Authorizing Legislation
Attachment 2- 60-day Federal Register Notice
Attachment 3- EHS-Net KMC Study Data Collection Instrument: Manager Interview
Attachment 4- EHS-Net KMC Study Data Collection Instrument: Manager Survey
Attachment 5- EHS-Net KMC Study Data Collection Instrument: Kitchen Observation
Attachment 6- EHS-Net KMC Study Data Collection Instrument: Worker Interview
Attachment 7- EHS-Net KMC Study Analysis Variables
Attachment 8- EHS-Net KMC Study CDC IRB Determination
Attachment 9- EHS-Net KMC Study Manager Informed Consent
Attachment 10- EHS-Net KMC Study Worker Recruiting Screener and Informed Consent
Attachment 11- EHS-Net KMC Study Manager Telephone Recruiting Screener