

EHS-Net Food Safety Practices & Beliefs Study

EHS-NET Generic Information Collection Request

OMB No. 0920-0792

OMB Exp. Date: 9/30/2018

Supporting Statement - A

Submitted: August 2017

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Goal of the study: The goal of this study is to identify and understand the environmental factors associated with food handling and food safety practices in retail food establishments that cause foodborne illnesses and outbreaks.

Intended use of the resulting data: The data collected will be used by CDC to further develop food safety prevention and intervention recommendations for environmental public health/food safety programs and the retail food establishment industry.

Methods to be used to collect data: The study will use a cross-sectional design. It will involve an interview with a restaurant manager, survey of food workers, and observation of the restaurant.

The subpopulation to be studied: The population to be studied will be randomly sampled from voluntarily participating restaurants in the Environmental Health Specialists Network sites.

How data will be analyzed: Initial analyses will involve factor analysis to understand the belief domains. Additional descriptive analyses and multivariable regression will be performed where appropriate.

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), is requesting Paperwork Reduction Act (PRA) clearance for a data collection entitled "EHS-Net Food Safety Practices and Beliefs Study." This new data collection is being conducted using the generic information collection mechanism of the Environmental Health Specialists Network (EHS-Net; OMB No. 0920-0792, expiration 9/30/2018). EHS-Net is funded through CDC cooperative agreement EH15-001.

The respondent universe for this data collection aligns with that specified for the EHS-Net generic, that is, retail food workers. EHS-Net studies are designed to collect data in retail food establishments; to identify and understand environmental factors e.g., food safety practices, manager food safety certification, equipment condition, etc. associated with retail-related foodborne illnesses. This data collection focuses on retail food establishment staff knowledge, beliefs, and practices concerning food safety procedures. These data are essential to increase program effectiveness and support environmental public health regulators' efforts to successfully respond to, and prevent food safety-associated events. The results of this data collection are not generalizable beyond the population of retail food establishments in the given EHS-Net site(s).

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1). The data collection also supports the U.S. Department of Health and Human Services' Healthy People 2020 Goal to "Improve food safety and reduce foodborne illnesses."

The EHS-Net program, developed by CDC, conducts studies designed to identify and understand environmental factors associated with foodborne illness outbreaks and other food safety issues (e.g., ill workers). These data are essential to environmental public health regulators' efforts to respond more effectively to and prevent future outbreaks and food safety-associated events.

EHS-Net is a collaborative project of the CDC, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and eight state and local public health departments (California, Minnesota, New York, New York City, Rhode Island, Tennessee, Southern Nevada Health District, and Harris County Texas). EHS-Net's funding to these state and local health departments enables them to collaborate with CDC on identifying a topic; selecting a study design; collecting and co-analyzing data and prevents duplication of efforts. EHS-Net also has industry partners (Attachment 2) that support its goals and research by reviewing and providing feedback on study design and data analysis. To date, EHS-Net has summarized its research efforts in 30 publications (Attachment 3).

Approaches to managing food safety in retail food establishments (hereafter referred to as restaurants) continues to evolve. Initial studies under EHS-Net assessed risk factors in outbreaks vs non-outbreak restaurants and typically involved restaurants with an outbreak. The other studies have focused on food safety practices and beliefs to understand the scope of what is occurring and how/why something is being done in a restaurant. Examples of previously

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approved EHS-Net projects include: 1) study on improper cooling of hot foods, a food handling practice associated with foodborne illness; 2) study on relationship between kitchen manager food safety certification and foodborne illness risk factors in restaurants; 3) study on the environmental factors associated with contamination of the retail deli environment with *Listeria* (a foodborne illness pathogen); and 4) study on restaurant managers' and workers' food allergen knowledge, attitudes, and practices.

Foodborne illness attributable to restaurants continues to remain a major issue even with the evolution of intervention practices. According to 2015 data, restaurants were associated with 60% of the reported foodborne outbreaks (Centers for Disease Control and Prevention, 2017). Preliminary research has occurred to examine food safety culture, with surveys being done with various segments of the food industry (Abidin, Fatimah, Arendt, & Strohbehn, 2014; De Boeck, Jacxsens, Bollaerts, & Vlerick, 2015; Neal, Binkley, & Henroid, 2012), however the reporting has primarily focused on the psychometric properties of their instruments. Only DeBoeck (2015) has linked their results with outcomes, finding that meat processors with an improved employee and organizational food safety culture had lower bacterial contamination on their meat products.

The current study focusses on food safety practices and employee beliefs, which is the next step in preventing foodborne illness, and gaining an understanding of the food safety culture in restaurants. This includes the beliefs of the food workers, whose job it is to handle food safely and understand if their beliefs influence whether they implement safe food handling practices. While this specific GenIC is not associated with investigating a restaurant with an outbreak, the information gained can be used to prevent foodborne illness outbreaks and enhance foodborne illness investigations in the future. Additionally, this study may yield a tool that can be incorporated into a foodborne illness investigation to help explain why an illness outbreak occurred.

Along with assessing food safety beliefs and knowledge, we will also be examining two specific food safety practices: date-marking practices of ready-to-eat potentially hazardous foods; and the implementation of the consumer advisory provision of the Food Code for eating raw or undercooked food items. FDA has requested that we assess these practices because issues have been identified with the implementation of these provisions of the Food Code, and it is suspected that the failures are based on employees understanding of the requirements. The date-marking provision is intended to control the growth of *L. monocytogenes* and it has been anecdotally reported that individuals are incorrectly implementing the provision and using a discard date that is beyond what is proscribed. The consumer advisory provision is intended to provide the customer with information on whether a menu item contains undercooked or raw ingredients, and eating that item will increase their risk for a foodborne illness. Collecting information from food workers will inform how the requirement is being implemented and food workers' beliefs towards the provisions.

The knowledge of the inter-relationships between existing procedures and worker beliefs will allow for enhanced development of future interventions that address why there is a lapse in food safety practices.

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2. Purpose and Use of the Information Collection

The purpose of this study is understanding the environmental factors within a restaurant that may be an underlying cause of foodborne illness. Specifically we will request information on and analyze responses to this information collection on:

- a) Food workers' *knowledge* and *beliefs* towards food safety.
- b) Existing food safety *practices* in the restaurants (e.g. the current date-marking practices of ready to eat foods, are refrigeration temperatures at the appropriate level, are food workers washing their hands as needed, etc.)
- c) The existence of *procedures* within restaurants affecting food safety (e.g. do they have procedures addressing what temperature to cook food, when a food worker should wash their hands, when and how to clean the restaurant, etc.)

Data will be collected by environmental health specialists in participating EHS-Net sites. Restaurant managers and food workers are the respondents in this study. Data will be collected using: 1) a manager recruitment script and interview (Attachments 4 and 5); 2) a food worker survey (Attachments 8 and 9); and 3) a structured restaurant environment observation (Attachment 10).

Managers and food workers have important roles to play in the prevention of foodborne illness, thus we need to collect information from both of these groups. The manager interview (Attachment 5) is necessary to gather information on the restaurant characteristics and existing procedures. The food worker surveys (Attachments 8 and 9) are necessary to gather information on worker beliefs, knowledge, and practices around the existing procedures in their restaurants towards food safety. The structured restaurant environment observation filled out by health department staff (Attachment 10) is necessary for collecting data on the restaurant characteristics and assessing the implementation of the practices.

The data collected for this study can be used to understand the interconnected effects of food safety procedures and beliefs on food safety practices. This study can inform whether knowledge or beliefs has the greatest effect on implementing food safety practices and thus allow regulatory agencies to target their efforts to improve overall food safety. The goal of this information collection is to assist CDC and other federal, state, and local food safety programs to develop food safety prevention and intervention recommendations, and tools for food safety programs and the restaurant industry. For example, if the number of written food safety procedures is associated with a corresponding level of food workers' food safety beliefs, CDC can disseminate the information and encourage food safety programs and the restaurant industry to implement intervention strategies. Ultimately, these types of actions can contribute to a decrease in the number of incidents of foodborne illness caused by poor food handling practices of food workers.

This study does have limitations on the generalizability of the results. First, the study is being conducted in restaurants within the EHS-Net catchment area. Therefore, the results of this study are generalizable to restaurants in those sites and would not be generalizable to other restaurants in the United States. Secondly, the data collection materials are in English, which limits the

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results to the English speaking population of restaurant workers. This is due to our limited resources to translate materials into the potential universe of languages used by restaurant workers. Third, since we are asking for voluntary participation there may be a selection bias, however based upon previous studies we have seen restaurants with both positive and negative practices volunteer to participate. Lastly, there could be a potential social desirability bias, in which respondents may be more likely to provide what they perceive as the answer that the interviewer is looking for. Again, based on previous studies this has not seemed to generate a problem. Regardless, all of these potential limitations will be notated in any presentations or journal articles.

3. Use of Improved Information Technology and Burden Reduction

The primary burden to respondents of participation in this study involves their participation in interviews and surveys (Attachments 5, 8, and 9). It is less burdensome for respondents to provide open-ended interview responses verbally than to have to type their responses into an electronic reporting system. Thus, we have chosen not to collect interview data electronically, but rather, collect the data through face-to-face verbal interviews with respondents. Data collectors will record the managers' responses on paper-and-pencil forms (Attachment 5). For structured surveys, in which the respondent only needs to pick a response, a written or electronic survey would be the least burdensome. Structured food worker surveys will be provided on a paper and pencil form (Attachment 8) at the time of the site visit and a link will be provided for an online survey (Attachment 9) of the same questions for other workers that are not present at the time and to allow food workers to reply at their convenience. We anticipate approximately 75% of food worker surveys will be filled out online. The information for the surveys is standardized and it is expected that either method will take a similar amount of time.

Participation in this data collection is **voluntary**, and every effort has been made to keep the data collection as short as possible and still meet the needs of the data collection.

4. Efforts to Identify Duplication and Use of Similar Information

This EHS-Net data collection will not be a duplication of effort. We have searched relevant scientific bibliographical 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-FSIS) concerning research on this topic. Few studies exist on this topic; the research that exists has focused primarily on the psychometric properties of the various tools and has been tested with limited populations (we could not identify any studies that targeted restaurant food workers.) One study has been performed linking food safety culture in meat processing plants with microbiological properties of meat. Consequently, data are needed from a random sample of a geographically and demographically diverse population of restaurants. This study will do this. We have consulted with both FDA and USDA and neither agency is conducting similar research, but they are interested in the results.

5. Impact on Small Businesses or Other Small Entities

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We expect that about half of the restaurants 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. Both large and small businesses will be presented with the same questions, and the results will be assessed for differences by various restaurant characteristics (e.g. seating capacity, number of food service workers, level of foodhandling, etc.) We will, however, strive to hold the number of questions to the minimum needed for the intended use of the data.

6. Consequences of Collecting the Information Less Frequently

All participating restaurant workers will be interviewed or surveyed once (Attachments 5, 8 and 9). If this data collection is not conducted, it will be more difficult for CDC, other federal, state and local food safety programs, and the food service industry to address the barriers in developing food safety intervention strategies. In turn, it will be more difficult to decrease the number of incidents of foodborne illness caused by food workers not following acceptable food safety practices and for CDC to fully address the U.S. Department of Health and Human Services' Healthy People 2020 Goal to "Improve food safety and reduce foodborne illnesses." There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this data collection. This request fully complies with 5 CFR 1320.5.

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

- A. The notice for the renewal for the generic information collection request did not receive any comments. The 60-Day *Federal Register* notice was published January 12, 2015 in Vol. 80, No. 7, pages 1505-1506. The 30 day Federal Register notice was published April 28, 2015 in Vol. 80, No. 81, page 23554.
- B. Personnel from the EHS-Net sites worked with CDC to develop this data collection in 2017. Additionally, FDA and USDA, EHS-Net partners, also consulted on the data collection. Names and contact information is provided below.

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EHS-Net Sites	
Brenda Faw Senior Environmental Health Specialist CA Dept. of Health brenda.faw@cdph.ca.gov 916-445-9548	David Nicholas Research Scientist NY Dept. of Health dcn01@health.state.ny.us 518-402-7600
Daniel O’Halloran Research Assistant NYC Dept. of Health dohalloran@health.nyc.gov 646-632-6523	Nicole Hedeem Epidemiologist MN. Dept. of Health Nicole.hedeem@state.mn.us 651-201-4075
Brendalee Viveiros RI EHS-Net Coordinator RI Dept. of Health Brendaleee.Viveiros@health.ri.gov 401-222-4774	Lauren DiPrete Senior Coordinator Southern Nevada Health District DiPrete@snhdmail.org 702-759-1504
Deanna Copeland Environmental Health Specialist Harris County Health Department dcopeland@hcuphes.org 713-274-6443	Danny Ripley Food Inspector II TN Dept. of Health Danny.ripley@nashville.gov 615-340-5620
Federal Partners	
Laurie Williams Consumer Safety Office Office of Food Safety FDA/CFSAN Laurie.Williams@fda.hhs.gov 240-402-2938	Stephanie Mickelson Epidemiologist USDA stephanie.mickelson@fns.usda.gov 703-305-2894

9. Explanation of Any Payment or Gift to Respondents

There will be no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The proposed project has been reviewed by the NCEH Information Systems Security Officer (ISSO) who has determined that the Privacy Act does not apply to this collection. Therefore a system of records notice (SORN) will not be created. No assurances of confidentiality will be provided to respondents. While face-to-face interviews will be conducted, CDC will not be directly engaged in data collection, will not interact with any respondents, nor will we receive identifying information on any of the participating restaurants or staff from the EHS-Net sites.

The NCEH human subjects contact has reviewed this project and has determined that it is research but CDC is not engaged (Attachment 11) and further review beyond the center is not required. Therefore, CDC’s Institutional Review Board (IRB) approval is not required. However, EHS-Net sites will obtain approval from their respective IRBs as appropriate.

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Information in identifying form (IIF) will not be transmitted to CDC. IIF will only be collected for the restaurant to allow for the site visit. After that visit the IIF will be destroyed. The individual EHS-Net sites will assign a code number to the restaurant and only that code number will be reported to Environmental Health Specialists Network Information System (EHSNIS). Subsequent to the site visit, the restaurant name and address will no longer be needed and will be destroyed by the sites.

No paper files will be delivered to CDC. Instead, data collectors will enter all paper-and-pencil responses into the EHSNIS. Data will be reported to CDC through a web-based information system, the EHSNIS. All electronic data will be stored on secure CDC networks. Access to the data will be limited to those with a bona fide need-to-know in order to perform job duties related to the project. User accounts will be issued to the specialists who will serve as the administrator of the system for his or her own site. Through these password protected accounts, users will be granted privileges including entering and accessing data, and correction and deletion of records capabilities. As previously stated, all data records are owned by the site entering the data. Each site possesses ownership of its records and must grant permission to other sites or agencies who would like to use the data.

Verbal consent will be obtained from respondents. For the online surveys (Attachment 9), the food worker will have to give consent prior to being able to reach the survey. As a part of the informed consent, respondents will be made aware of their ability to retrieve a summary of the study's findings by contacting their health department 12 months following data collection. The manager's informed consent script can be found at the beginning of the manager interview (Attachment 5); the food workers informed consent script is combined with the recruiting script and can be found at the beginning of the survey form (Attachments 8 and 9).

Participation in this data collection is voluntary, and respondents are informed of the voluntary nature of the data collection during recruiting and in the informed consent script.

All data records are owned by the site entering the data. Each site has authority over its records and must grant permission to other sites or agencies who would like to use the data. Each site's data will be stored for twelve years.

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

- Manager interview
 - Restaurant characteristics and existing restaurant procedures and practices
- Food worker survey
 - Worker characteristics and food safety knowledge, beliefs, and practices
- Structured Restaurant Environment observation by health department staff
 - Restaurant characteristics and food safety practices.

Information on restaurant name and address will be maintained by each site to facilitate the site visit. Once, the site visit has been recorded the information will be destroyed by each site by deleting any electronic keys or shredding paper keys. This information will not be recorded in the EHSNIS system and CDC will not have access to it.

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11. Justification for Sensitive Questions

There are no sensitive questions in this data collection.

12. Estimates of Annualized Burden Hours and Costs

Eight EHS-Net sites will collect data for this study; each site will collect data in 47 restaurants. Thus, there will be approximately 376 establishments in this data collection (an estimated eight sites*47 establishments). The total number of burden hours approved for the EHS-Net generic are 885 and 5,154 responses. The estimated burden hours for the genIC are 856 burden hours and 4,596 responses. We are not anticipating any additional studies under the current generic for the duration of the current PRA clearance (expiration 9/30/2018).

In restaurants that voluntarily agree to participate in this study, we will interview the manager about the restaurant’s characteristics and existing food safety procedures and practices (Attachment 5). It is estimated that this will take approximately 20 minutes (125 annual burden hours). Following this, a written survey will be provided to food workers that are present, have the time, and are voluntarily willing to complete the survey (Attachment 8). A flyer (Attachment 7) will also be left with the restaurant for other food workers to voluntarily complete an online version of the survey (Attachment 9) at their convenience. We anticipate up to 8 responses per restaurant and each food worker survey takes approximately 10 minutes to complete (501 annual burden hours). While the food workers are completing the survey, the health department workers will complete the restaurant observation form (Attachment 10) documenting practices in the restaurant related to food safety. These observations will not require interactions between the data collectors and restaurant staff and is estimated to take approximately 30 minutes (188 annual burden hours.)

Table 12.1- Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Managers	Telephone Manager Recruiting Script	836	1	3/60	42
Managers	Manager Informed Consent and Interview	376	1	20/60	125
Food Workers	Food Worker Informed Consent and Written Survey	752	1	10/60	125
Food Workers	Food Worker Informed Consent	2,256	1	10/60	376

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	and Electronic Survey- Screenshots				
Health Department Workers	Restaurant Environment Observation Form	376	1	30/60	188
TOTAL		4,596			856

The maximum total annualized cost of this data collection to respondents is estimated to be \$15,117.82 (See Table 12-2). This figure is based on an estimated mean hourly wage of \$16.68 for managers and \$11.02 for food workers and \$36.23 for health department workers. These estimated hourly wages were obtained from the U.S. Department of Labor Bureau of Labor Statistics 2016 national occupational employment and wage estimates report (<http://stats.bls.gov/oes/current/oes351012.htm>; <http://stats.bls.gov/oes/current/oes352021.htm>; <https://www.bls.gov/oes/current/oes192041.htm>).

12.2- Estimated Annualized Burden Costs

Type of Respondents	Form Name(s)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Managers	Telephone Manager Recruiting Script Manager Informed Consent and Interview	167	\$16.68	\$2,785.56
Food Workers	Food Worker Informed Consent and Written Survey Food Worker Informed Consent and Electronic Survey- Screenshots	501	\$11.02	\$5,521.02
HD Workers	Restaurant Environment Observation Form	188	\$36.23	\$6,811.24
Total				\$15,117.82

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

There are no other costs to respondents or record keepers.

14. Annualized Cost to the Federal Government

Costs to the government include a portion of the annual cooperative agreement to the EHS-Net sites that will collect the data and the costs of CDC personnel working on the data collection (A.14.1). The EHS-Net sites participating in this study receive equal funding, and we estimate

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that the sites will use approximately 20% of their cooperative agreement funds to conduct this data collection. We also estimate that one CDC staff member will spend approximately 50% of their time on this data collection.

Table 14.1-Estimated Annualized Cost to the Federal Government

Expenditure	Cost
Awards to sites	\$308,000
CDC Salary (1 staff member)	\$50,000
Total	\$358,000

15. Explanation for Program Changes or Adjustments

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

16. Plans for Tabulation and Publication and Project Time Schedule

Table 16.1 provides the data collection activity schedule.

16.1 – Project Time Schedule

Activity	Time Frame
Train EHS-Net sites on data collection	Within 1 month of OMB approval
Recruitment of restaurants	Within 2 months of OMB approval
Data collection	Within 10 months of OMB approval
Data entry and quality assurance	Within 12 months of OMB approval
Data cleaning	Within 18 months of OMB approval
Data analysis	Within 22 months of OMB approval
Manuscript development	Within 24 months of OMB approval

A detailed analysis plan can be found in Supporting Statement B (B.4).

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification for Paperwork Reduction Act.

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References for Part A

- Abidin, U. Z., Fatimah, U., Arendt, S. W., & Strohbehn, C. H. (2014). Food safety culture in onsite foodservices: development and validation of a measurement scale. *Journal of Foodservice Management & Education*, 8(1), 1-10.
- Centers for Disease Control and Prevention. (2017). Surveillance for Foodborne Disease Outbreaks, United States, 2015, Annual Report. *Atlanta, Georgia: US Department of Health and Human Services*.
- De Boeck, E., Jacxsens, L., Bollaerts, M., & Vlerick, P. (2015). Food safety climate in food processing organizations: Development and validation of a self-assessment tool. *Trends in Food Science & Technology*, 46(2, Part A), 242-251. doi: <http://doi.org/10.1016/j.tifs.2015.09.006>
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