EHS-Net Food Allergen Study

EHS-NET Generic Information Collection Request
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Supporting Statement - A

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A. Justification

1. Circumstances Making the Collection of Information Necessary

This new data collection is being conducted using the generic clearance mechanism of the Environmental Health Specialists Network (EHS-Net; OMB No. 0920-0792, expiration date February 28, 2015).

The EHS-Net Food Allergen Study is the second generic information collection (GenIC) request submitted under the generic clearance umbrella. The respondent universe for this data collection aligns with that specified for the EHS-Net generic clearance, that is, retail food workers. This data collection focuses on retail food establishment staff knowledge, attitudes, and practices concerning food allergens. Data will be collected by personnel in six state and local health departments (California, Minnesota, New York, New York City, Rhode Island, and Tennessee). Data will be collected in restaurants in the six health department jurisdictions.

Background. The EHS-Net Program, developed by the Centers for Disease Control and Prevention (CDC), conducts research designed to identify and understand environmental factors associated with foodborne illness outbreaks and other food safety issues (e.g., food allergies). 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 six state and local public health departments (California, Minnesota, New York, New York City, Rhode Island, and Tennessee). In total, EHS-Net provides funding for six full-time and three part-time personnel in these state and local health departments, and they are responsible for collaborating with CDC on study design, collecting study data, and co-analyzing study data with CDC. The federal partners provide funding and input into study design and data analysis. EHS-Net also has industry partners that support its goals and research by collaborating on study design and data analysis; Attachment 1 contains a list of industry partners. To date, EHS-Net has summarized its research efforts in 19 publications; Attachment 2 contains a bibliography of EHS-Net publications.

Food Allergen Data Collection Under EHS-Net Generic IC. Food allergy, a potentially serious immune response to eating specific foods or food additives, is a growing public health and food safety issue in the United States. An estimated 12 million Americans have food allergies, and severe allergic reactions caused by foods account for 50,000 – 125,000 emergency room visits and 150 – 200 deaths per year in the U.S (Decker et al., 2008). It is generally believed that food allergies are increasing, especially among children (Branum & Lukacs, 2008).

Research suggests that retail food establishment food is a significant cause of allergic reactions. Of the 5,149 registrants in the U.S. Peanut and Tree Nut Allergy Registry, 14% reported allergic reactions associated with retail food establishments (Furlong, DeSimone, & Sicherer, 2001). Additionally, 46% of 63 fatal food allergy reactions occurring in the U.S. over a 13-year period were caused by food from a retail food establishment (Weiss & Munoz-Furlong, 2008). Other research conducted with food allergic respondents has consistently found that food allergic

reactions commonly occur in restaurants, with prevalence estimates ranging from 14% to 47% (Eigenmann & Zamora, 2002; Uguz, et al., 2005; Weiss & Munoz-Furlong, 2008).

A recent research study analyzed data on food-allergic fatalities associated with food eaten in restaurants (Weiss & Munoz-Furlong, 2008). The results indicate that the fatal reactions were sometimes the result of action or inaction on the part of the food-allergic individual, sometimes the result of action/inaction on the part of restaurant personnel, and sometimes the result of action/inaction by both parties.

Despite the increasing evidence of the role of retail food establishments in food allergic reactions, few studies have examined these establishments' practices concerning food allergies, or the knowledge and attitudes held by these establishments' staff concerning food allergies. This type of information is essential to the identification of gaps in retail food establishments' knowledge, attitudes, and practices, and consequently, to the development of successful prevention programs. Thus, the primary purpose of this study is to gain a better understanding of these issues. Additionally, the study will attempt to estimate the frequency of food allergic customers and food allergic reactions associated with retail food establishments.

This data collection supports the U.S. Department of Health and Human Services' Healthy People 2020 Goal to "Improve food safety and reduce foodborne illnesses." Specifically, these data can be used to develop educational materials, trainings, and tools that are targeted towards improving retail food establishment food allergen knowledge, attitudes, and practices. This improvement can contribute to a decrease in the number of food allergic reactions caused by retail food establishment food.

1.1 Privacy Impact Assessment

Overview of the Data Collection System. Data will be collected by environmental health specialists in the participating EHS-Net sites. Retail food establishment (hereafter referred to as restaurants) managers, food workers, and servers are the respondents in this study. Data will be collected using: 1) a manager interview, 2) a food worker interview, 3) a server interview, and 4) a structured observation of the restaurant environment.

These multiple data collection instruments are needed to achieve the study's objectives. Managers, food workers, and servers all have important roles to play in the prevention of food allergic reactions in restaurants. Thus, we need to collect information from each of these three groups. All three interviews are necessary for collecting data on restaurant characteristics and food allergen practices, and food allergen frequency. The manager interview is necessary for collecting data on manager food allergen knowledge, attitudes, and practices. The food worker and server interviews are necessary for collecting data on worker and server food allergen knowledge, attitudes, and practices. The structured observation is necessary for collecting data on restaurant characteristics and food allergen practices. Attachments 3, 4, 5, and 6 contain the manager interview, food worker interview, server interview, and structured observation instruments, respectively.

Data will be reported to CDC by EHS-Net data collectors through a 10-year old web-based information system, the Environmental Health Specialists Network Information System (EHSNIS). User accounts will be issued to the EHS-Net specialist in each state. Account privileges identify the data each specific user is authorized to access and the functions he or she is authorized to perform. Each EHS-Net specialist is responsible for the administration of the system for his or her own site, and includes user administration, correction and record deletion capabilities. 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 seven years.

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

- Manager interview
  - Restaurant characteristics and food allergen practices, and food allergen frequency
  - Manager characteristics and food allergen knowledge, attitudes, and practices
- Food worker interview
  - Restaurant food allergen practices and food allergen frequency
  - Worker characteristics and food allergen knowledge, attitudes, and practices
- Server interview
  - Restaurant food allergen practices and food allergen frequency
  - Server characteristics and food allergen knowledge, attitudes and practices
- Structured observation
  - Restaurant characteristics and food allergen practices

No individually identifiable information is being collected.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age. Study information will be reported through a web-based system. This system is password protected; only people given permission by the CDC can access it. There is no public web site, nor is there any content directed at children less than 13 years of age.

2. Purpose and Use of the Information Collection

Study Purpose and Use of Data. The primary purpose of this study is to collect descriptive data on restaurant staff knowledge, attitudes, and practices concerning food allergens. We will also collect data on food allergen frequency. These descriptive data will be used to identify gaps in restaurant staff knowledge, attitudes, and practices. They can also be used to assess how prepared restaurants are to manage customer food allergy concerns. Specifically, the data will be used to identify knowledge, attitudes, and practices (or lack thereof) that could lead to food allergic customers having food allergic reactions to restaurant food.

The secondary purpose of this study is to assess relationships among 1) restaurant and restaurant staff characteristics and 2) restaurant staff food allergen knowledge, attitudes, and practices. The relationship data will be used to identify restaurant and staff characteristics that may contribute to good (or poor) food allergen knowledge, attitudes, and practices. This information can be used by 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.

The identification of knowledge, attitudes, and practices to assess in this study was informed by The Food Allergy and Anaphylaxis Network's (FAAN) document entitled: *Welcoming Guests with Food Allergies: A Comprehensive Program for Training Staff to Safely Prepare and Serve Food to Guests Who Have Allergies* (FAAN, 2010). FAAN is a nonprofit organization established to raise public awareness, to provide advocacy and education, and to advance research on behalf of all those affected by food allergies and anaphylaxis.

Generalizability of Results. EHS-Net personnel will collect data in retail food establishments in selected geographical areas in California, Minnesota, New York City, New York State, Rhode Island, and Tennessee. These geographical areas are demographically diverse and provide good geographical coverage of the U.S. (northeast, mid-west, south, and west). When the statistical methods outlined here for ensuring a representative sample in the current study are used, the results of the collection covered by this OMB package can be used to generalize to the population of retail food establishments in the given EHS-Net site(s). Furthermore, the geographic and demographic variability across these sites suggests that CDC may be able to use data collected from these studies to draw conclusions about relationships that are likely relevant to establishments in other parts of the U.S.

2.1 Privacy Impact Assessment

Why is the information being collected. The information collected in this study is being collected to describe restaurant staff food allergen knowledge, attitudes, and practices, to estimate food allergen frequency, and to identify restaurant and staff characteristics that are associated with good/poor food allergen knowledge, attitudes, and practices.

Intended use of the information being collected. These data will be useful for CDC and other federal, state, and local food safety programs. The data can be used to develop prevention and intervention recommendations and tools for food safety programs and the restaurant industry. For example, if data analysis reveals that restaurant servers do not know the food allergens in the food they serve, CDC can disseminate this information and encourage food safety programs and the restaurant industry to address this lack of knowledge by improving their educational programs or by implementing other interventions. Ultimately, these types of actions can contribute to a decrease in the number of food allergic reactions caused by restaurant food.

No IIF is being collected.

3. Use of Improved Information Technology and Burden Reduction

The primary burden to respondents involves their participation in interviews. It is less burdensome for respondents to provide 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, to collect the data through face-to-face verbal interviews with respondents. Data collectors will record responses on paper-and-pencil forms. This data

collection method has been used in previous, successful EHS-Net studies (Bogard, et al., under review; Brown, et al., under review; Brown, et al., 2012; Coleman, et al., under review; Green et al., 2006; Kirkland et al., 2009; Lee et al., 2004; Sumner et al., 2011).

Participation in this data collection is **voluntary**, and every effort is 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

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 been conducted in small geographical regions or with convenience samples. Consequently, data are needed from a random sample of a geographically and demographically diverse population of restaurants. This EHS-Net data collection will do this and will not be a duplication of effort.

5. Impact on Small Businesses or Other Small Entities

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. 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

Respondents will be asked to respond to this data collection **only one time**. 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 gaps in restaurant manager, worker, and server food allergen knowledge, attitudes, and practices. In turn, it will be more difficult to decrease the number of food allergic reactions caused by restaurant food 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 of the generic clearance did not receive any comments. The 60-Day *Federal Register* notice was published June 23, 2011 in Volume 76, Pages 36924-36925. The 30 day Federal Register notice was published September 21, 2011 in Volume 76, Page 58517.

B. Personnel from the EHS-Net sites worked with CDC to develop this data collection in 2011-12. Additionally, FDA and USDA, EHS-Net partners, also consulted on the data collection. Names and contact information are provided below.

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
Jessica Egan Research Scientist NY Dept. of Health jse01@health.state.ny.us 518-402-7600	Nicole Koktavy Epidemiologist MN. Dept. of Health Nicole.koktavy@state.mn.us 651-201-4075
Henry Blade RI EHS-Net Coordinator RI Dept. of Health Henry.Blade@health.ri.gov 401-222-7735	David Reimann Sanitarian MN. Dept. of Health david.reimann@state.mn.us 507-389-2203
Ernestine Davis Environmental Health Specialist TN Dept. of Health Ernestine.d.davis@tn.gov 615-741-8537	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 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, 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.

It has been determined that this study is classified as human subjects research but CDC's involvement does not constitute engagement (Attachment 7); therefore, CDC Institutional Review Board (IRB) approval is not required. However, EHS-Net sites will obtain approval from their respective IRBs as appropriate.

10.1 Privacy Impact Assessment Information

A. This submission has been reviewed by CDC's Information Collection Request Office, which determined that the Privacy Act does not apply.
B. No paper files will be delivered to CDC. Instead, EHS-Net site data collectors will enter all paper-and-pencil responses into 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 EHS-Net specialist who will serve as the administrator of the system for his or her own site. Through these password protected accounts, EHS-Net specialists 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.
C. The manager's informed consent script can be found at the beginning of the manager interview in Attachment 3; the worker's and server's informed consent scripts are combined with the recruiting scripts and can be found in Attachments 4 and 5, respectively. Verbal consent will be obtained from respondents. 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.
D. 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.

No IIF is being collected.

11. Justification for Sensitive Questions

There are no sensitive questions in this data collection.

12. Estimates of Annualized Burden Hours and Costs

Six EHS-Net sites will collect data for this study; each site will collect data in 50 restaurants. Thus, there will be 300 restaurant manager respondents. Each manager respondent will be interviewed only once; the interview will last approximately 20 minutes (100 total burden hours) (Attachment 3). We expect a manager response rate of approximately 70 percent; thus, we will need to contact 429 managers via telephone in order to meet our goal of 300 respondents

(Attachment 8 contains the manager recruiting script). Each respondent to the script will respond only once, and the average burden per response will be approximately 3 minutes (22 total burden hours).

In each restaurant, we will ask the manager to help recruit a worker respondent who speaks English to be interviewed (see worker recruiting script in Attachment 4). Each worker respondent will respond only once. Each worker respondent will be interviewed; the interview (along with informed consent) will take approximately 12 minutes. In total, the average burden per response for worker respondents will be 60 hours (12 minutes * 300 workers).

In each restaurant, we will also ask the manager to help recruit a server respondent who speaks English to be interviewed (see server recruiting script in Attachment 5). Each server respondent will respond only once. Each server respondent will be interviewed; the interview (along with informed consent) will last approximately 12 minutes. In total, the average burden per response for server respondents will be 60 hours (12 minutes * 300 servers).

The data collectors will also conduct an observation of the restaurant environment which will take approximately 20 minutes (Attachment 6). These observations will not require interactions between the data collectors and restaurant staff. Because there is no burden to the staff, the observation hours are not included in the total annualized response burden estimate of 242 hours (See Table A.12-1).

Table 12.1- Estimated Annualized Burden Hours

Respondents	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden (in hours)**
Managers	Manager Recruiting Script	429	1	3/60	22
	Manager Informed Consent and Interview	300	1	20/60	100
Workers	Worker Recruiting Script, Informed Consent, and Interview	300	1	12/60	60
Servers	Server Recruiting Script, Informed Consent, and Interview	300	1	12/60	60
Total					242

The maximum total annualized cost of this data collection to respondents is estimated to be $3,010 (See Table 12-2). This figure is based on an estimated mean hourly wage of $15.30 for managers, $10.05 for workers, and $9.00 for servers. These estimated hourly wages were obtained from the U.S. Department of Labor Bureau of Labor Statistics 2012 national occupational employment and wage estimates report

(http://stats.bls.gov/oes/current/oes351012.htm; http://stats.bls.gov/oes/current/oes352021.htm; http://stats.bls.gov/oes/current/oes353021.htm).

12.2- Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Managers	122	$15.30	$1,867
Workers	60	$10.05	$603
Servers	60	$ 9.00	$540
Total			$3,010

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 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 her time on this data collection.

Table 14.1-Estimated Annualized Cost to the Federal Government

Expenditure	Cost
Awards to sites	$203,500
CDC Salary (1 staff member)	$50,000
Total	**$253,500**

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
Data collection	Within 1.5 months of OMB approval
Data entry and quality assurance	Within 1.5-2 months of OMB approval
Data cleaning	Within 7 months of OMB approval
Data analysis	Within 8 months of OMB approval
Manuscript development	Within 10 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.

References for Part A

Ahuja, R. & S. Sicherer. 2007. Food-allergy management from the perspective of restaurant and food establishment personnel. *Ann Allergy Asthma Immunol*. 98:344–348.

Bogard, A., C. Fuller, V. Radke, C. Selman, and K.Smith. Under review. Ground beef handling and cooking practices in restaurants in eight states. *J. Food Protect*.

Brown, L., S. Khargonekar, L. Bushnell, and the EHS-Net Working Group. Under review. Restaurant chicken preparation and cooking practices. *J. Food Protect*.

Brown, L., D. Ripley, H. Blade, D. Reimann, K. Everstine, D. Nicholas, J. Egan, N. Koktavy, D. Quilliam, and the EHS-Net Working Group. 2012. Restaurant food cooling practices. *J. Food Protect*. 75:2172-2178.

Branum, A., S. Lukacs. 2008. *Food allergy among U.S. children: Trends in prevalence and hospitalizations. NCHS Data Brief*, Number 10.

Coleman, E., K. Delea, K., and K. Everstine. Under review. Restaurant leafy green handling practices. *J. Food Protect*.

Eigenmann, P. & S. Zamora. 2002. An internet-based survey on the circumstances of food-induced reactions following the diagnosis of IgE-mediated food allergy. *Allergy*. 57: 449–453

Welcoming Guests with Food Allergies: A Comprehensive Program for Training Staff to Safely Prepare and Serve Food to Guests Who Have Allergies. 2010. Food Allergy and Anaphylaxis Network.Website: http://www.foodallergy.org/document.doc?id=143.

Furlong, T., J. DeSimone, & S. Sicherer. 2001. Peanut and tree nut allergic reactions in restaurants and other food establishments. *J. Allergy Clin. Immunol*. 867-070.

Green, L., C. Selman, V. Radke, D. Ripley, J. Mack, D. Reimann, T. Stigger, M. Motsinger, and L. Bushnell. 2006. Food worker hand washing practices: An observation study. *J. Food Protect*. 69:2417-2423.

Kirkland, E., L. Green, C. Stone, D. Reimann, D. Nicholas, R. Mason, R. Frick, S. Coleman, L. Bushnell, H. Blade, V. Radke, C. Selman, and the EHS-Net Working Group. 2009. Tomato handling practices in restaurants. *J. Food Protect*. 72:1692–1698.

Lee, R., M. Beatty, A. Bogard, M. Esko, R. Anglulo, C. Selman, and the EHS-Net Working Group. 2004. Prevalence of high-risk egg-preparation practices in restaurants that prepare breakfast egg entre: An EHS-Net study. *J Food Protect*. 67:1444-1450.

Sumner, S., L. Brown, R. Frick, C. Stone, L. Carpenter, L. Bushnell, D. Nicholas, J. Mack, H. Blade, M. Tobin-D'Angelo, K. Everstine, and EHS-Net. 2011. Factors associated with food workers working while experiencing vomiting or diarrhea. *J. Food Protect*. 74:215–220.

Weiss, C. & Munoz-Furlong, A. 2008. Fatal food allergy reactions in restaurants and food-service establishments: Strategies for prevention. *Food Protect. Trends*. 28:657-661.