Supporting Statement (Part A) for

OMB Review and Approval of Centers for Disease Control and Prevention

Survey of Food Safety Programs
OMB No. 0920-NEW

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This is a new Centers for Disease Control and Prevention (CDC) request for a two-year Office of Management and Budget (OMB) approval for the National Center for Environmental Health (NCEH) "Survey of Food Safety Programs." New data will be collected from local and state health departments implementing food safety programs (FSPs) in the United States (U.S.)

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment 1**). The 60-day Federal Register Notice was published on September 5th, 2013 (see **Attachment** 2).

Background

Foodborne illness is a significant problem in the U.S. An estimated 47.8 million foodborne illnesses occur annually in the U.S., resulting in 127,839 hospitalizations, and 3,037 deaths annually (Scallan, Hoekstra et al., 2011; Scallan, Griffin et al., 2011). Many of these illnesses result from foodborne illness outbreaks. An average of 1,329 foodborne illness outbreaks occurs in the U.S. every year (Lynch, Painter, Woodruff and Braden, 2006). The most recent data indicates that from 2009 to 2010, a total of 1,527 foodborne illness outbreaks were reported, resulting in 29,444 cases of illness, 1,184 hospitalizations, and 23 deaths (Gould, Mungai et al., 2013).

Local and state food safety programs (FSPs) in the U.S. are responsible for a number of activities designed to improve food safety and reduce foodborne illness and outbreaks. These activities include: 1) licensing and food safety inspections of commercial food operations such as restaurants, cafeterias, grocery stores, delis, concession stands, mobile food units, pushcarts, and food manufacturers; 2) investigating reports of food-borne illness and general public health complaints associated with food service operations; and 3) investigating foodborne illness outbreaks to identify their cause and reduce illness associated with them. Through these services, FSPs can reduce the factors that cause foodborne illness and outbreaks, help ensure that food sold and served to the public is wholesome, free of contamination and spoilage, and encourage compliance with local and state food safety laws and regulations through education and enforcement.

FSPs are typically located in local and state public health programs. Data indicate that these public health programs have been negatively impacted by the recession of 2008. Between 2007 and 2012, local and state health departments in the U.S. experienced decreased federal, state, and local funding (NACCHO, 2009). In 2008, 27 percent of local health departments operated with budgets that were less than that of the previous years. Local health departments serving larger jurisdictions were disproportionately impacted. These experienced a mean budget reduction of about $2.6 million (NACCHO, 2009). In 2009, 55 percent of local health departments cut important public health programs, including those related to food safety. Between July 2010 and

June 2011, 55 percent of all local health departments cut at least one public health program, affecting over two-thirds of the U.S. population (68 percent) (NACCHO, 2011).

Through the Environmental Health Specialists Network (EHS-Net), CDC currently funds and works with local and state health departments in five states (California, New York, Minnesota, Rhode Island, and Tennessee) to: 1) identify environmental antecedents (underlying factors) to illness and disease outbreaks; 2) translate findings into improved prevention efforts using a systems-based approach; 3) offer training opportunities to current and future environmental health specialists; and 4) strengthen collaboration among epidemiology, laboratory, and environmental health programs. EHS-Net participants, along with other groups representing over 3,000 health departments in the nation, are often challenged with fluctuations in funding that impacts their ability to provide food safety services to their communities. With the dramatic national economic situation during the 2007-2012 timeframe all public health programs were faced with what has been accepted as a significant deviation from the perceived funding challenges normally faced. While federal funding such as that provided to the EHS-Net participants may have helped mitigate the possible impacts of budget reductions during the 2007-2012 timeframe, how funding fluctuations impact the ability of public health programs to prevent disease and outbreaks is not understood.

To this end, CDC has designed a survey to measures changes in FSP activities retrospectively from 2007 through 2012. Since this is the period over which funding cuts to public health programs occurred, we hope to provide insight into survey the extent to which availability of funding has affected the status and ability of local and state FSPs in the U.S. Specifically, we plan to collect retrospective data on the food safety activities, workforce capacity and competency, workforce staffing, financial resources, community health, and demographics of FSPs for each year between 2007 and 2012. The data collection will involve asking respondents to complete a FSP survey. Data collected will be used to 1) describe the current status and activities of local and state FSPs; 2) describe changes in status and activities that occurred within FSPs from 2007-2012; and 3) determine if there is an association between different levels of FSP funding and FSP status and activities. It is understood that the associations documented must be interpreted with caution, as survey responses will likely be influenced by local variability in the baseline of services offered and differences in background among respondents.

1.1 Privacy Impact Assessment

Overview of the Data Collection System

Data will be collected by assigned CDC staff. Local and state health departments implementing FSPs in the U.S. will be the respondents of this data collection. Data will be collected through a self-administered paper or electronic FSP survey. **Attachment 3** contains the paper Food Safety Program Survey and **Attachment 4** contains screenshots of the electronic Food Safety Program Survey

Assigned CDC staff will contact local and state health departments implementing FSPs in the U.S. about the FSP survey and solicit their participation via email (**Attachment 6**).

The email will describe the survey and its importance, and will also provide informed consent information. It will also contain a link to the electronic version of the survey along with a password to access it. Finally, the email will tell respondents to respond to the email if they prefer to complete a paper version of the survey. CDC staff will mail a paper survey (**Attachment 3**), the FSP survey fact sheet (**Attachment 7),** and a self-addressed stamped envelope to those who request a paper version of the survey.

Data collected will be stored in a database designed specifically for the survey. These data will be stored in accordance with CDC's record control schedule.

Items of Information to be collected

Below is a description of the type of information to be collected through the FSP survey

- Food safety activities (e.g., foodborne outbreaks and illness response activities, licensing/permitting activities, and inspection activities)
- Workforce capacity and competency (e.g., staff quality)
- Financial resources (e.g., funding sources, means of finance, and budget)
- Community health (e.g., foodborne illnesses and outbreaks reported)
- Demographics (e.g., population served and staffing profile)

The respondents for this information collection will be local and state health departments implementing FSPs in the U.S., and not individuals.

No sensitive information will be collected about the individuals who are taking the survey in their official capacity. Health department responses will be identified by the health department name and location (e.g., state, and city/county).

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age.

The FSP survey will not involve maintenance of any websites and website content directed at children less than 13 years of age.

2. Purpose and Use of the Information Collection

This survey has three main objectives. The first is to collect descriptive data on the current status and activities of local and state FSPs in the U.S. To obtain this information, data will be collected on the food safety activities, workforce capacity and competency, financial resources, workforce staffing, community health, and demographics of FSPs. Specifically, current data will be collected on:

- FSP actions related to foodborne illness and food safety complaint calls in their areas of jurisdiction
- FSP licensing/permitting, inspecting and investigating of foodborne outbreaks in food establishments
- FSP provision of public health essential services
- FSP funding source(s)
- FSP staff competency and demographics

Data collected will be used to update existing information on the current status and activities of FSPs across the aforementioned themes. It will also be used to highlight FSP existing situation and provide opportunities for improvement. The data can be used by local and state health departments to improve FSP effectiveness.

The second objective of this survey is to collect data to describe changes in status and activities that occurred within FSPs from 2007 to 2012. Just like the first objective, data will be collected across the themes of food safety activities, workforce staffing, financial resources, community health, and demographics. Specifically, data will be collected on the following:

- The number of annual foodborne illnesses and outbreaks reported to FSPs over the period of interest
- The number of complaint calls acted on
- FSP hiring practices, staff size and quality
- FSP annual budgets and expenditures

The third objective of the survey is to determine if there is a relationship between available funding and FSP status and activities. Through data analysis, we will examine what effects funding changes have had specifically on FSP licensing/permitting, inspection and investigation activities. For example, we would like to find out if funding affects the number of investigations or inspections conducted by FSPs.

We will sample all 49 state health departments (Delaware does not have a state health department). In addition, we will sample from a frame that comprises 3,502 local health departments in the U.S. The study design (multi-stage cluster), sampling strategy (random sampling within clusters), and recruitment procedures, as described in Supporting Statement B, are designed to minimize selection bias, provide study units within each cluster an equal probability of being selected for the survey, and to ensure that an appropriate number of study units with certain characteristics (size, type, and governance structure) are represented. Thus, the resulting sample is designed to be nationally representative of both local and state health departments in the U.S. Assuming a high response rate, the findings from this data collection effort will be generalizable to all health departments in the U.S.

Thus, information collected will be valuable to improve upon FSP effectiveness.

2.1 Privacy Impact Assessment

Data collected will be shared with state, local health departments and the environmental health community. This endeavor will add to their knowledge base on FSPs, identify the service gaps created, and enable informed decision-making about the next steps to take to bridge the gaps created. The proposed data collection will have minimal to no impact on the respondents' privacy. Individuals will respond in their official capacity on behalf of their local or state health department. For this study, no individually identifiable or sensitive information will be collected about respondents. Responses of health departments will be identified by their health department names and locations (e.g., state, and city/county). All completed paper surveys will be stored in a secure locked cabinet that will be locked at all times in accordance with CDC records control

schedule. All electronic data will be stored on secure CDC networks. Access to the data will be limited to CDC employees with a bonafide need-to-know to perform job duties related to the project. No files will have associated information that might directly identify respondents.

3. Use of Improved Information Technology and Burden Reduction

The primary burden to local and state health departments for participating in this survey is their completion of either a paper (see **Attachment 3**) or electronic FSP survey (see **Attachment 4**), both estimated to take approximately 2 hours to complete. We estimate that 80% of the surveys will be conducted by electronic means and 20% by manual means for both local and state health departments. This estimate is based on feedback received during the pilot testing of the survey instrument by eight key specialists implementing FSPs. The advantage of electronic data collection lies in the fact that data will be more accurate, as respondents will enter their responses directly into the system. This will reduce manual data entry error and ensure data quality.

4. Efforts to Identify Duplication and Use of Similar Information

We have searched relevant databases [e.g., National Association of County and City Health Officials (NACCHO) and consulted with agencies and organizations (e.g., USDA, FDA, and NACCHO) concerning research on this topic. In the process, we found that FDA has conducted a study on food safety and defense. While the FDA study was on food safety, its focus is food defense and its target population is local and state health and agricultural agencies. The focus of our survey on the other hand, is food safety and the effect of funding changes and our target population is local and state health departments implementing FSPs. Given these differences, we will collect data that are specifically related to our survey. Thus, this data collection will not be a duplication of effort.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently or Not at All

Individuals responding for local and state health departments will be asked to respond to this data collection only once. Without this data collection, it will be difficult for CDC and local and state health departments to adequately describe the current status of FSPs, to describe within agency changes over time (i.e., 2007-2012), and to determine if there is a relationship between funding of FSPs and the services they provide.

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. It will fully comply with 5 CFR 1320.5.

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 in the *Federal Registrar* on September 5th, 2013, Volume 78, No. 172, pp. 54652- 53 (see **Attachment 2**). During the public comment period, one minor non-substantive public comment was received and the Agency sent a standard response.

B. CDC worked with local and state health departments to develop this survey in 2012. Names and contact information are provided below.

States	
Brenda VanSchaik Faw, Sr. REHS California Department of Public Health Brenda.Faw@cdph.ca.gov (916) 445-9548	Manuel M. Ramirez Environmental Health Manager City of Berkeley Environmental Health mramirez@ci.berkeley.ca.us (510) 981-5261
Ernie Julian Chief, Office of Food Protection Rhode Island Department of Health Ernest.Julian@health.ri.gov 401-222-4774	Henry Blade Rhode Island Department of Health Henry.Blade@health.ri.gov 401-222-7735
Ron Lee Chief Environmental Health Food Specialist Rhode Island Department of Health ron.lee@health.ri.gov 401-222-7712	David Nicholas Research Scientist NY Dept. of Health dcn01@health.state.ny.us 518-402-7600
John Luker Assistant Director New York State Department of Agriculture & Markets Food Safety & Inspection Division john.luker@agriculture.ny.gov (518) 457-538	Erin Sawyer New York State Department of Agriculture & Markets Food Safety & Inspection Division Erin.Sawyer@agriculture.ny.gov (518) 457-5380

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

No assurances of confidentiality will be provided to respondents.

10.1 Privacy Impact Assessment Information

A. The proposed survey has been reviewed and it has been determined that the Privacy Act does not apply. Individuals will respond in their official capacity on behalf of their local or state health department. No individually identifiable or sensitive information will be collected about the individuals. Responses of health departments will be identified by their health department names and locations (e.g., state, and city/county).
B. All completed paper surveys will be stored in a secure cabinet that will be locked at all times in accordance with the CDC records control schedule. All electronic data will be stored on secure CDC networks. Access to the data will be limited to CDC employees with a bonafide need-to-know to perform job duties related to the project.
C. Informed consent (A**ttachment 6**) will be obtained from respondents via return email.
D. Participation in this data collection is voluntary. Individuals responding for the local and state health departments will be informed of this during the recruiting call and at the beginning of the data collection process.

No information in identifiable form (IIF) is being collected.

IRB Approval

This data collection protocol has been reviewed by the NCEH/ATSDR Human Subjects Contact and has determined that the proposed collection is not human subjects research and does not require CDC human research review (see **Attachment 5**).

11. Justification for Sensitive Questions

There are no sensitive questions in this data collection.

12. Estimates of Annualized Burden Hours and Costs

Assigned CDC staff will collect data for the FSP survey. Five hundred and two (502) local and 49 state health departments implementing FSPs in the U.S. will be contacted via email/phone about participating in the one-time FSP survey (total n=551). The average respondent burden per recruitment response will be approximately 3 minutes (20 burden hours).

We expect a total of 380 respondents (i.e., 346 local and 34 state health departments) to complete the survey over the two years. Each respondent will respond only once. The average respondent burden per response will be approximately 2 hours for both the 20 percent of paper-based and for the 80 percent of electronic forms. We expect a response rate of approximately 69 percent based on the most recent NACCHO study of local health departments (NACCHO, 2012); thus, we will need to contact a total of 551 respondents by phone in order to meet our goal of 380 respondents.

The information collection forms are the same for both local and state health departments implementing FSPs. The total estimated annualized response burden of the FSPs survey is 380 hours.

Table A.12-A- Estimate of Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Local health departments	FSPs Survey (electronic)	138	1	2	276
	FSPs Survey (paper-based)	35	1	2	70
State health departments	FSPs Survey (electronic)	14	1	2	28
	FSPs Survey (paper-based)	3	1	2	6
				Total	**380**

A.12-B Estimated Annualized Cost to Respondents

The maximum total annualized cost of this data collection to respondents is estimated to be $ 12,570.40. **(**See Table A.12-B). This figure is based on an estimated mean hourly wage of $33.08 for environmental specialists assumed to be the same for all food safety programs in local and state health departments. This estimated hourly wage was obtained from the U.S. Department of Labor's 2011 national occupational employment and wage estimates (http://www.bls.gov/oes/current/oes192041.htm).

A.12- B- Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Local health departments	346	$33.08	$ 11445.68
State health departments	34	$33.08	$ 1124.72
		Total	**$ 12,570.40**

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 Government

Costs to the government include costs of CDC personnel working on the data collection. We estimate that one CDC staff and two fellows will spend approximately 20% and 100% of their time respectively on this data collection.

Table A.14.A

Expenditure	**Cost**
CDC Staff	$15,000
ORISE Fellow 1	S50,000
ORISE Fellow 2	$25,000
Total	**$90,000**

15. Explanation for Program Changes or Adjustments

This is new data collection.

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**
Recruit Respondents	Within 12 months of OMB approval
Data collection	Within 15 months of OMB approval
Data entry and quality assurance	Within 18 months of OMB approval
Data cleaning	Within 19 months of OMB approval
Data analysis	Within 21 months of OMB approval
Manuscript development	Within 24 months of OMB approval

Analysis Plan

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 will be no exceptions to certification for Paperwork Reduction Act.

References

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