

Supporting Statement A

**National Environmental Assessment Reporting System (NEARS)**

**(formerly National Voluntary Environmental Assessment Information System [NVEAIS])**

**OMB Control No. 0920-0980 (Expiration Date: 08/31/2016)**

**REVISION**

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## A. Justification

- **Goal:** The goal of NEARS is to improve public health practice by providing a standardized, detailed reporting system for food safety programs, to collect foodborne outbreak environmental assessment data, and to establish a sound epidemiological basis for disease prevention activities.

To assist in accomplishing this goal within this revision we are proposing to rename this surveillance system the National Environmental Assessment Reporting System (NEARS), requesting an increase in burden hours based on the addition of new e-learning materials for respondents, making a minor change to a data collection form, and revising the project timeline.

- **Intended use of the resulting data:** The foodborne outbreak environmental assessment data reported to NEARS will be used to characterize data on food vehicles and monitor trends; identify contributing factors and their environmental antecedents; generate hypotheses, guide planning, and implementation; evaluate food safety programs, and ultimately assist to prevent future outbreaks.
- **Methods to be used to collect data:** Foodborne outbreak environmental assessment data will be collected through retail food service establishment observations by the state and local food safety programs currently registered to report data to NEARS, and through manager interviews or pen-and-paper assessments in retail food service establishments.
- **The subpopulation to be studied:** Foodborne outbreak environmental assessment data collected in retail food service establishments from state and local food safety programs, and from the kitchen managers and food workers in those establishments.
- **How data will be analyzed:** Descriptive analyses (frequencies, means, etc.), tests for association, and logistic regression models.

### A.1. Circumstances Making the Collection of Information Necessary

Foodborne illness is a significant problem in the U.S.—an estimated 47.8 million foodborne illnesses occur annually in the United States, 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 occur in the United States every year (Lynch, Painter, Woodruff and Braden, 2006).

Reducing the number of outbreaks requires identification and understanding of the etiology of outbreaks. We need to know the pathogen, food, and the pattern of illness associated with each outbreak. We also need to identify the environmental factors associated with each outbreak; in other words, we need to know how and why the food became contaminated with pathogens and how and why these pathogens were not eliminated before ingestion.

Environmental health specialists in environmental health or food safety programs (hereafter referred to as food safety programs) also typically conduct foodborne illness outbreak investigations, and they focus on identifying the environmental factors associated with the outbreak. When this information is reported to CDC it provides an opportunity to systematically monitor and evaluate environmental factors of foodborne illness which then can be used to develop effective foodborne illness outbreak response and preventative controls.

On August 23, 2013, the Office of Management and Budget (OMB) gave Paperwork Reduction Act (PRA) clearance to CDC's National Voluntary Environmental Assessment Information System (NVEAIS; OMB Control No. 0920-0980; expiration date 08/31/2016). Since 2014, environmental assessment factor data associated with foodborne outbreaks were reported to NVEAIS.

In 2015, it was recommended that NVEAIS be renamed as the National Environmental Assessment Reporting System (NEARS). This name change is an enhancement of the current system and was recommended by CDC leadership, and other food safety partners who desired to simplify and improve the name. In addition to the system name change, approval for the following changes are requested (further discussed in the indicated sections) in the PRA clearance for the next three years:

- The annualized burden hours are estimated to decrease from 3,267 hours to 2,125 hours a decrease of 1,142 hours. These burden hours are based on current data and attainable increase in participation to NEARS for the next cycle of PRA clearance (2016–2019).
- A minor change to a data collection form (Attachment 6, Section A.2); and
- A revised project timeline (Section A.16).

NEARS will continue to identify and understand environmental factors associated with foodborne illness outbreaks, through improved surveillance, a task essential to decreasing outbreaks.

Many surveillance systems are used in the United States to provide information about the occurrence of foodborne disease. Most of CDC's surveillance systems rely on data from state and local food safety programs. Some focus on specific pathogens likely to be transmitted through food and have been used extensively for decades. For example, Foodborne Diseases Active Surveillance Network, referred to as FoodNet, is the principal foodborne disease component of CDC's Emerging Infections Program. It is a sentinel<sup>1</sup> surveillance system that collects information from sites in 10 states—covering 15% of the US population, or 46 million Americans—about diseases that are caused by any of seven bacteria and two parasites<sup>2</sup> commonly transmitted through food. The system has been in operation since 1995. Investigators actively seek out laboratory confirmed cases of illness in an attempt to detect every person in the 10 sites who went to a doctor's office, had a sample tested, and was diagnosed with one of these infections. More recently, new surveillance methods have emerged which improve the quality, quantity, and timeliness of data (e.g., sentinel surveillance systems and national laboratory networks). Additionally, the CDC sponsors the National Outbreak Reporting System (NORS). NORS is maintained by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) under the National Disease Surveillance Program II - Disease Summaries (OMB

Control Number: 0920-0004, expiration date October 31, 2017). NORS is a mature passive surveillance system into which food safety programs (i.e. each state epidemiologist) voluntarily report epidemiological and clinical information about foodborne outbreaks. There is no mandatory requirement for food safety programs to report data to CDC through NORS. Currently all fifty states report outbreak data to NORS. Based on existing NORS data, it is estimated that a minimum of 800 foodborne illness outbreaks will occur in the United States annually (see Table A.1.1)

<b>Table A.1.1. Outbreaks Reported to NORS</b>				
<b>Year</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
Total number of outbreaks	801	831	818	864

The Foodborne Outbreak Online Database has been designed to allow the public direct access to information on foodborne outbreaks reported to the Centers for Disease Control and Prevention (CDC). Most outbreaks are reported to the NORS by the state, local, territorial, or tribal health department that conducted the outbreak investigation. Outbreak reporting is voluntary. Multi-state outbreaks are generally reported to NORS by CDC. Data available via the Foodborne Outbreak Online Database originate from a dynamic outbreak surveillance database. Reporting agencies (state, local, territorial, and tribal health departments, and CDC) can modify their NORS reports at any time, even months or years after an outbreak. Therefore, results from Foodborne Outbreak Database Search Tool are subject to change.

Although CDC’s long-term goal is to have one foodborne illness outbreak surveillance system that will collect these two sets of data, it is currently not feasible. The consolidation to one foodborne illness surveillance system will be a long-term process, and environmental factor data are a priority now. The collection of environmental factor data and efforts to improve coordination and communication across communicable disease control programs that report to NORS and food safety control programs that report to NEARS will continue to occur simultaneously. When linked, both NORS and NEARS data are critical to food safety efforts. The anticipated timeline for the merger of NORS and NEARS systems is tentatively expected to occur by December, 2018. This timeline will include extensive project planning amongst NORS and NEARS teams and also information technology (IT) developers. This will be followed by design, development and review of the integrated system which will be led by IT developers. Lastly, CDC and its partners will thoroughly conduct testing of the system to ensure user acceptance prior to release.

**Foodborne Illness Outbreak Environmental Factors.** As indicated, environmental health specialists in food safety programs focus on collecting detailed environmental factor data during foodborne illness outbreak investigations in NEARS. These data identify how and why the food became contaminated with pathogens, and how and why these pathogens were not eliminated before ingestion. To identify these environmental factors, environmental health specialists

conduct environmental assessments, which involve a thorough assessment of the environment in which the outbreak occurred.

**Foodborne Illness Outbreak Surveillance.** Data obtained through foodborne illness outbreak investigations, such as the number of ill people associated with individual outbreaks and the pathogen involved, are collected and reported by communicable disease control programs to NORS. Data are typically reported into this system through state epidemiology programs. Environmental factor data are not frequently reported to this system. The names of contributing factors identified in outbreak investigations are reported, but no details on these contributing factors are reported (e.g., when the factor occurred, how it was identified, etc.), nor is any other information obtained from environmental assessments (e.g., environmental antecedents) reported.

### **National Food Safety Context**

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). The data collection is also authorized by Section 205 of FSMA (21 USC 2201) (Attachment 1).

The President's Food Safety Working Group was created in 2009 to advise the President on how to improve the U.S. food safety system. The Working Group recommended a new, public health-focused approach to food safety based on several core principles, one of which is strengthening surveillance and enforcement. *This working group recommended the development of a national surveillance system to collect environmental data related to foodborne illness outbreaks.* Additionally, the Food Safety Modernization Act (FSMA), which became a law in 2011, recognizes that robust foodborne illness surveillance data are needed to inform targeted prevention interventions. FSMA directed CDC, with its expertise in surveillance, to *expand national food safety surveillance systems and increase state and local participation in these systems.*

NEARS addresses the above-stated goals of the President's Working Group and FSMA. NEARS collects environmental data on foodborne illness outbreaks on a national level, as recommended by the President's Working Group. NEARS expands the current national food safety surveillance from collection of epidemiological and clinical data through NORS to collection of environmental data. NEARS will also increase state and local participation in food safety surveillance, as this system is designed for use by local, state, federal, territorial, and tribal food safety programs.

Additionally, NEARS continues to support the U.S. Department of Health and Human Services' Healthy People 2020 Goal to, "Improve food safety and reduce foodborne illnesses." NEARS will also support one of CDC's *Winnable Battles*, "Reducing foodborne diseases."

### **A.2. Purpose and Use of the Information Collection**

The information reported to NEARS is primarily used by the CDC to identify and understand environmental factors (contributing factors and environmental antecedents) associated with

foodborne illness outbreaks. The instruments for data collection can be found in Attachments 6 and 8.

To summarize, data collected through NEARS will be used to:

- *Describe outbreaks and outbreak responses.* NEARS collects detailed descriptive data on outbreaks and outbreak responses (e.g., number of locations associated with the outbreak, number of establishments involved, number of environmental assessments conducted, etc.).
- *Describe environmental factors associated with outbreaks.* NEARS collects detailed information on environmental antecedents (economics, equipment, food, people, processes) and contributing factors (contamination, proliferation, survival) associated with outbreaks.
- *Describe the associations between environmental antecedents and specific contributing factors.* NEARS collects data that will allow us to understand the associations between environmental antecedents and specific contributing factors associated with outbreaks. For example, an analysis may reveal that the environmental antecedent of lack of paid sick leave was associated with the contributing factor of an ill worker contaminating food.
- *Describe outbreaks reported to NORS and describe characteristics of outbreaks not reported to NORS.* NEARS collects data that will allow us to understand the characteristics of outbreaks reported to NEARS but, not reported to NORS. For example, an analysis may reveal that outbreaks reported to NEARS but, not reported to NORS are more likely to be single location outbreaks. Outbreaks reported to NORS typically involve multi-locations (i.e. multi-states). This analysis may also reveal information on the number of outbreaks that NORS reporting misses.

As part of this revision ICR, the following modifications to Attachments 6 and 7 are planned:

Question Number	Previously Approved Question	Modified Question
I	Attachment 4 (NVEAIS – Data Reporting Instrument), question 7a. “What was the identified agent?”	Attachment 6. (NEARS – Data Reporting Instrument) was modified to collect suspected vs. confirmed data for agents identified in Part I (General Outbreak Characterization). In Attachment 6, question 7a was modified to “Was the agent identified suspected or confirmed?”  This additional information helps further categorize the degree of certainty for the identified agent.

**Experience to Date**

- Currently, there are 21 local and state food safety programs registered to begin reporting outbreaks to NEARS. **Table A.2.1.** provides a snapshot of data on outbreaks reported to NEARS 2014 – 2016. Reporting data to NEARS is not mandatory for local and state food safety programs.

<b>Table A.2.1. Outbreaks Reported to NEARS</b>			
	<b>2014</b>	<b>2015</b>	<b>2016 (Jan–July)</b>
California	12	7	2
Connecticut	28	20	5
Davis County (Utah)	0	1	0
Fairfax County (Virginia)	0	1	0
Harris County (Texas)	0	2	0
Minnesota	11	27	0
New York City	8	21	29
New York State	15	5	3
Rhode Island	18	4	0
South Carolina	0	0	9
Southern Nevada Health District	0	0	6
Tennessee	10	9	3
Wisconsin	9	15	3
<b>Total</b>	<b>111</b>	<b>112</b>	<b>60</b>

- NORS collects de-identified outbreak data on the epidemiologic and clinical laboratory data from outbreaks. NORS and NEARS data are linked using outbreak ID numbers (unique system-generated numbers given to each outbreak in each system upon data entry). When data for the same outbreak are reported to both NORS and NEARS, these data can be linked. When NORS and NEARS data are linked, it provides opportunities to strengthen the robustness of outbreak data reported to CDC. Collectively, these data play a vital role in improving the food safety system.
- In May 2015, CDC formed a NORS-NEARS workgroup to improve reporting and analysis of foodborne illness outbreak. This work group was established to:
  - Aid foodborne illness outbreak response and prevention by collecting and analyzing high quality epidemiological, laboratory, and environmental outbreak data.
  - Improve reporting of foodborne illness outbreak data from state and local health departments to CDC (NEARS and NORS).



- Reduce the burden of reporting overlapping/complimentary foodborne illness outbreak data to CDC (NEARS and NORS).

This workgroup (~14 members) also conducts monthly meetings to discuss:

- Comparing NORS and NEARS data collection instruments
  - Reconciling outbreaks
  - Improving NORS guidance on NEARS reporting
  - Identifying NORS and NEARS users
- Lastly, 58% of outbreaks reported to NEARS identified contributing factors in the outbreaks. Contributing factors are determinants that directly or indirectly cause an outbreak. They describe how the outbreak occurred. When data are available to understand how outbreaks occur, they can be used to assist in the development of outbreak prevention efforts. Identifying contributing factors is a key component of understanding the causes of outbreaks and preventing future ones. It is a significant accomplishment that the majority of NEARS outbreaks had an identified contributing factor, since, historically this data was not available at a national level. NEARS is also relatively a new system, data submission commenced in 2014. Therefore, in order to increase enrollment, it is critical for food safety programs to work to identify contributing factors for all outbreaks. Our research findings also identified some key program activities, such as conducting timely, comprehensive and frequent environmental assessments may assist in this goal. Additionally, the CDC provides free, high-quality training on conducting environmental assessments during outbreak investigations that can improve investigators' ability to identify contributing factors. ([http://www.cdc.gov/nceh/ehs/eLearn/EA\\_FIO/index.htm](http://www.cdc.gov/nceh/ehs/eLearn/EA_FIO/index.htm)).

Participation of food safety programs in NEARS is voluntary and a convenience sample; therefore, the information collected is not designed to contribute to generalizable knowledge applicable to all foodborne illness outbreaks. Data collected in NEARS will be invaluable in determining and understanding the ultimate causes of outbreaks, and are critically important to outbreak response and prevention efforts, because they answer how and why questions about the causes of outbreaks. Over time CDC will use data from NEARS to develop recommendations specific to individual food safety programs and those that are broadly applicable to other NEARS participants engaged in foodborne illness outbreak response and prevention. For example, if data analysis reveals that the lack of policies requiring workers to tell managers when they are ill is associated with the contributing factor of workers working while ill, CDC can develop interventions designed to increase the food safety programs' implementation of such policies. Other public health agencies (FDA, USDA, state and local food safety programs, industry) may use the data in this way. CDC will also use these data to improve the data collection instrument. However, no substantial changes have been made to the instrument.

Without these data, it will be difficult for CDC to identify the environmental factors associated with contributing factors and foodborne illness outbreaks, and without this information, it will be difficult to reduce outbreaks and consequently reduce illness associated with them.

In the future, should a nationally representative program evolve, we may be able to generalize our data. We expect that program participation will increase over time. However, until all eligible programs are participating, a limitation of our data will be that it applies to only those jurisdictions participating in NEARS.

### **A.3. Use of Improved Information Technology and Burden Reduction**

Participating food safety programs will record all their information on pen and paper (Attachments 6 and 8) and then enter all their data into a secured web-based system (Attachment 7) designed to make data entry easy for respondents. This eliminates the need to copy data collection forms or to mail or fax forms to CDC.

In the future, CDC plans to develop a mobile web application (contingent on receiving additional funding) that will extend the functionality of the current system. When available, CDC will seek PRA clearance for the approved use of this application. This mobile web application will support the storing and reporting of environmental assessment data. By enhancing the current system to allow mobile data importing into NEARS, this will allow greater productivity in the field as data collectors are no longer confined to an office infrastructure to electronically capture and enter data.

### **A.4. Efforts to Identify Duplication and Use of Similar Information**

Through examination of the activities of other organizations, such as FDA, and organizations within CDC, such as NCEZID, we have confirmed that no local, state, federal, territorial, or tribal surveillance system for reporting of information about environmental factors associated with foodborne illness outbreaks presently exists. However, epidemiological and clinical information on foodborne illness outbreaks is currently reported in other national surveillance systems, such as NORS. So that data from other systems and NEARS can be linked when appropriate, NEARS collects information related to whether epidemiological or laboratory information has been reported to other surveillance systems and the reporting numbers associated with those systems for each outbreak.

Additionally, both NORS and NEARS collect the names of identified contributing factors; however, NEARS also collects several important additional details about the contributing factors, such as when the contributing factors occurred and how they were identified. Once NEARS is an established reporting system for food safety programs, the contributing factor data points will be dropped from NORS, eliminating this overlap.

As noted earlier, the implementation of NEARS resulted in two foodborne illness outbreak surveillance systems at CDC—NORS and NEARS. NORS and NEARS will collect different and complementary sets of data on foodborne illness outbreaks; both data sets are critical to food safety efforts. Although CDC's long-term goal is to have one foodborne illness outbreak surveillance system that will collect these two data sets, it is currently not feasible, given coordination and communication issues at the local, state, federal, territorial, or tribal level. CDC will be working to improve coordination and communication between these two types of

programs so that we can eventually meet the goal of one foodborne illness outbreak surveillance system.

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

Local, state, federal, territorial, and tribal food safety program officials are the primary respondents for this data collection. As indicated earlier, the foodborne illness outbreak investigation data reported into NEARS by these officials is reported to CDC as a part of routine public health practice (Attachment 6). Food safety programs do vary in size; some of them are small, with few staff (estimate: 30%). Reporting to NEARS may be difficult for some of these small programs. However, reporting into NEARS is voluntary; and small entities will be encouraged to delay their participation until they can do so relatively easily.

Retail food managers of establishments in which outbreak investigations occur are respondents to the manager interview (Attachment 8). Some of these establishments will be small (estimate: 30%). However, it is important to note that this interview will only be conducted in establishments in which a routine public health activity- an outbreak investigation- is already occurring, and this manager interview is a part of that investigation.

#### **A.6. Consequences of Collecting the Information Less Frequently**

Each respondent is asked to provide information once per outbreak. Programs that voluntarily participate in NEARS are expected to report data on all outbreaks occurring in their jurisdictions. All food safety programs in the United States are invited to participate.

If this data collection is not conducted, this major gap in overall foodborne illness surveillance will remain, hampering efforts to develop these effective prevention measures. 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 fully complies with 5 CFR 1320.5.

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

A 60-day Federal Register Notice (FRN) was published in the Federal Register on February 5, 2016 vol. 81, No. 24, pp. 6272-6274 (see Attachment 2). No public comments were received in response to the 60-day FRN.

The data collection instrument was developed by the Environmental Health Specialists Network (EHS-Net), a collaborative network of federal, state, and local epidemiologists and environmental health specialists. This network developed the instrument in 2004 and 2005 and

revised and tested it extensively from 2006 through 2009. Federal and state consultants are listed in Table A.8.1.

**Table A.8.1**

<b>Federal Consultants</b>		
<p><b>Jack Guzewich, RS, MPH (Retired)</b>            Director-Emergency Coordination &amp; Response            U.S. Food and Drug Administration            Center for Food Safety and Applied Nutrition            MS HFS-600 Bld. CPK1            College Park, MD 20740            301-436-1608            john.guzewich@cfsan.fda.gov</p>	<p><b>Morris Potter, DVM</b>            U.S. Food and Drug Administration            60 Eighth Street, NE            Atlanta, GA 30309            404-253-1225            mpotter@cfsan.fda.gov</p>	<p><b>Shirley Bohm</b>            Consumer Safety Officer            U.S. Food and Drug Administration            Center for Food Safety and Applied Nutrition            5100 Paint Branch Parkway,            MS HFS-627            College Park, MD 20740            301-436-2096            shirley.bohm@cfsan.fda.gov</p>
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<b>State Consultants</b>		
<p><b>Susan Strong</b>            Retail Food Program Specialist            California Department of Health Services, Food and Drug Branch            Sacramento, CA 95899            (916) 650-6617            sstrong1@dhs.ca.gov</p>	<p><b>Roberta Frick</b>            Environmental Health Specialist            Department of Health Services            Food and Drug Branch            850 Marina Bay Parkway,            Building P, 1st Floor            Richmond, CA 94804            (510) 620-3482            rfrick@dhs.ca.gov</p>	<p><b>Dawn Norton</b>            Senior Epidemiologist,            FoodNet            Connecticut FoodNet            1611 Telegraph Avenue, Suite            1200            Oakland, CA 94612            (510) 625-7974            dnorton@ceip.us</p>
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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. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

Data are being collected on outbreaks, not respondents. The information reported into NEARS will be obtained through environmental assessments (Attachment 6) routinely conducted by local, state, federal, territorial, or tribal environmental health specialists working in food safety programs during foodborne illness outbreak investigations. Food safety program personnel participating in NEARS will report the data collected through their environmental assessments into web based NEARS system (Attachment 7). No information in identifiable form (IIF) is being collected.

#### **Privacy Impact Assessment Information**

- A. The NCEH PRA Contact has determined that Privacy Act does not apply. Respondents will not be providing identifiable information. As no IIF will be collected, a system of records is not being created.
- B. No paper files will be collected at CDC. The paper-based interview data will be entered into a web-based information system (Attachment 7). 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. The NCEH Information Systems Security Officer (ISSO) has reviewed and completed the Privacy Impact Assessment (PIA) on the NEARS electronic system; based on the changes to the system a revised PIA will be completed before data collection begins.

There are two data collection activities for NEARS. For the first activity, participating food safety programs will record all their environmental assessment data by pen-and-paper form (Attachment 6) and then enter all their data into the secure NEARS web-based system (Attachment 7), which is designed to make data entry easy for respondents. The respondents for this activity are the food safety program personnel participating in NEARS. This will be done once for each outbreak.

The second activity is the manager interview that will be conducted at each establishment associated with an outbreak (Attachment 8). The respondents for this activity are the retail food managers of the outbreak establishments. Manager interviews are a routine part of outbreak investigations; however, food safety program personnel participating in NEARS conducts a structured interview and enters data into web based system (Attachment 7), and will thus conduct their interviews slightly differently than they would if they were not participating in NEARS. Approximately four manager interviews can be completed for outbreak.

Data analysis results will be shared informally with participating sites through annual data summary reports and presentations during NEARS quarterly webinars. Results will also be shared with other stakeholders (e.g. NORS Team) and the food safety and environmental public health community through presentations at meetings and conferences, peer-reviewed publications in scientific journals, and possibly ‘plain language’ summaries on the CDC website. Results will be presented in aggregate form.

The results will be used to develop recommendations for food safety and environmental public health programs and the retail food industry. For example, if data collection identifies specific environmental antecedents are associated with certain foodborne outbreaks, CDC can develop recommendations that address these unsafe polices and/or practices and disseminate the information to environmental public health programs and the retail food industry.

#### **A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions.**

Per the CDC Human Subjects Protection Office policies and procedures, this data collection system is currently classified as non-research, and does not require CDC Institutional Review Board (IRB) review (Attachment 9). The participating food safety programs are a voluntary convenience sample; therefore, the information collected cannot be generalized to all foodborne illness outbreaks. In the future, should a nationally representative program evolve, we may be able to generalize our data. There are no sensitive questions in this data collection.

#### **A.12. Estimates of Annualized Burden Hours and Costs**

Local, state, federal, territorial, and tribal food safety programs are the primary respondents for this data collection. One official from each participating program will report environmental assessment data on outbreaks. These programs are typically located in public health or agriculture agencies. There are approximately 3,000 such agencies in the United States. Currently, 13 state and local health departments are reporting data on outbreaks to NEARS, we expect participation to go up to 25 entities in the next round of PRA clearance.

Since NEARS is *voluntary*, it is not possible to determine how many programs will choose to participate. It is also not possible to determine exactly how many outbreaks will occur in the future, nor where they will occur. An overview of data reported to NEARS 2014–2016 is provided in Table A.2.1. Based on these reporting trends (2014–2016) and ongoing efforts to increase participation, it is likely that up to 250 foodborne illness outbreaks may be reported annually to NEARS from up to 25 entities for the duration of the next PRA clearance. Only programs in the jurisdictions in which these outbreaks occur would report to NEARS. Thus, not every program of the approximate 3,000 programs will respond every year. Assuming each outbreak occurs in a different jurisdiction, there will be one respondent per outbreak. If the Program receives an increase in participation that surpasses the current estimated number; then a revision request will be submitted for PRA clearance.

Efforts are also in progress to increase enrollment for NEARS which involve integrating NEARS and NORS surveillance systems. The Program is also working with National Environmental Health Association (NEHA) to develop media kits, organize webinars, conduct in-person trainings and increase awareness and market NEARS and promote data reporting.

The activities associated with NEARS that require a burden estimate consist of training, observing, data recording, and data reporting events. The first activity is the training for the food safety program personnel participating in NEARS. These staff will be encouraged to attend a Lync Meeting (i.e., webinar) training session conducted by CDC staff (Attachment 4). This training is voluntary and will cover identifying environmental factors, logging in and entering data into the web-based NEARS data entry system, and troubleshooting problems. There will be no website, form, or presentation document associated with this training. Instead, CDC personnel will be guiding participants through the NEARS data entry system. Attachment 4 contains a brief description of the training. Training burden is based on the maximum expected participation from the reporting entities which could be up to 25 local and state health departments. We estimate the burden of this training to be a maximum of 2 hours. Respondents will only have to take this training one time. Assuming a maximum participation of up to 25 entities and about 5 staff being trained at each participating program of the estimated burden for this training is  $(5 * 25 * 2)$  250 burden hours

Although not a requirement, food safety program personnel participating in NEARS will also be encouraged to complete CDC's e-Learning on Environmental Assessment of Foodborne Illness Outbreaks (Attachment 5). This e-Learning course provides training to staff on how to use a systems approach in foodborne illness outbreak environmental assessments. Participants acquire in-depth skills and knowledge to investigate foodborne illness outbreaks as a member of a larger outbreak response team, identify an outbreak's environmental causes, and recommend appropriate control measures. The course is presented in the context of a simulated virtual environment where participants can interact and practice the skills being learned. Attachment 5 contains a brief description of the training. We estimate the burden of this training to a maximum of 10 hours. Respondents will only have to take this training one time. Assuming a maximum participation of up to 25 entities and approximately 5 staff being trained at each program, the estimated burden for this training is  $1,250$  hours  $(10 \text{ hours} * 25 * 5)$ .



Data reporting activities for NEARS will be done once for each establishment involved in the outbreak. Information collection activities for NEARS consist of the following: NEARS data reporting (Attachment 6) and NEARS manger’s interview (Attachment 8). For each outbreak, the respondent, one official from each participating program, will spend around 30 minutes to record environmental assessment data (Attachment 6) on pen and paper. Assuming a maximum number of 250 outbreaks, the estimated annual burden is 125 hours (30 minutes \* 250/60 outbreaks hours) for recording observations.

The manager interview (Attachment 8) will be conducted at each establishment associated with an outbreak and data is initially recorded on to pen and paper. The respondents for this activity are the retail food managers of the outbreak establishments. Manager interviews are a routine part of outbreak investigations; however, food safety program personnel participating in NEARS conduct a structured interview and will thus conduct their interviews slightly differently than they would if they were not participating in NEARS. For this reason, we have presented the burden for this interview separately. Most outbreaks are associated with only one establishment; however, some are associated with multiple establishments. We estimate that a maximum of 4 manager interviews will be conducted per outbreak. Each interview and data reporting will take about 20 minutes. Again assuming a maximum number of 250 outbreaks, the estimated annual burden is 333 hours (20 minutes \* 4 interviews per outbreak \* 250/60 outbreaks).

Web based data entry (Attachment 7) for both activities (Attachment 6 and 8) will be combined. Data entry into NEARS system is expected to take approximately 40 minutes for the combined activities and total of 167 burden hours (40 minutes \* 250/60 outbreaks).

The total estimated annual burden is **2,125 hours** (see Table A.12-1).

**A.12-1- Estimate of Annualized Burden Hours**

<b>Type of Respondents</b>	<b>Form Name</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>
Food safety program personnel	NEARS Food Safety Program Training	125	1	2	250
	NEARS e-Learning (screen shots)	125	1	10	1,250
	NEARS Data Recording (paper form)	250	1	30/60	125

	NEARS Data reporting and manager's interview (web entry)	250	1	40/60	167
Retail food personnel	NEARS Manager Interview	1000	1	20/60	333
<b>Total</b>					2,125

The maximum total annualized cost of this data collection to respondents is estimated to be \$ 36,550.00 (See Table A.12-2). This figure is based on an estimated mean hourly wage of \$34.64 for food safety program personnel and \$10.57 for retail food workers. This estimate was obtained from the U.S. Department of Labor's May 2014 national occupational employment and wage estimates report (Environmental Scientists and Specialists, Including Health <http://www.bls.gov/oes/current/oes192041.htm> and Food Preparation and Serving Related Occupations <http://www.bls.gov/oes/current/oes350000.htm>).

#### A.12.2- Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Food safety program personnel	NEARS Food safety program training	125	\$34.64	\$4,330.00
	NEARS e-Learning (screenshots)	125	\$34.64	\$4,330.00
	NEARS Data Recording (paper form)	250	\$34.64	\$8,660.00
	NEARS Data reporting and manager's interview (web entry)	250	\$34.64	\$10,570.00
Retail food personnel	NEARS Manager Interview	1000	\$10.57	\$10,570.00
<b>Total</b>				\$36,550.00

### 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

NEARS is funded through Environmental Health Specialists Network (EHS-Net) - Practice based research to improve food safety (OMB Control No. 0920-0792; expiration 9/30/2018). In FY 2015, EHS-Net committed to fund up to eight applications. The annualized cost to the federal government of the total cooperative agreement is \$1,425,000 through CDC-RFA-EH15-001, an additional \$14,375 available to each applicant totaling \$115,000 (14,375\* 8 sites) annually specifically to address NEARS related activities (e.g. personnel to serve as NEARS liaisons with local food safety programs, personnel to enter NEARS data, etc.), and costs of CDC personnel and contractors who maintain the system and assist respondents in data entry as summarized in Table A.14.1.

EHS-Net food safety activities include conducting applied behavioral and environmental epidemiologic research to identify environmental factors that contribute to disease transmission.

The focus of this research is to:

- Identify and understand environmental factors associated with retail food safety, including food related illness and outbreaks (e.g. the reporting of foodborne outbreak environmental assessment data to NEARS).
- Evaluate food safety service programs, providers and their activities;
- Develop and disseminate the findings from EHS-Net projects to the environmental public health and food safety communities.

The project period will run from 09/30/2015 to 09/29/2020.

**Table A.14.1**

Category	Number of staff	% effort	Average Yearly Salary	Total Costs
Environmental Health Specialists Network (EHS-Net)-Practice based research to improve food safety RFA-EH-15-001	N/A	N/A	N/A	1,425,000
NEARS related activities funding	N/A	N/A	N/A	115,000
CDC fellow	1	100%	\$50,000	\$50,000
IT Contractor	1	50%	\$50,000	\$50,000

(maintains the system)				
CDC FTE	1	50%	\$65,000	\$65,000
<b>Total</b>				<b>\$1,705,000</b>

### A.15. Explanation for Program Changes or Adjustments

Estimates of annualized burden hours have been decreased from 3,267 hours to 2,125 hours, a decrease of 1,142 hours. These burden hours are based on current data and attainable increase in participation and reporting to NEARS for the next cycle of PRA clearance.

Additionally, CDC is introducing the e-Learning on Environmental Assessment of Foodborne Illness Outbreaks (Attachment 5). This e-Learning course will provide training on how to use a systems approach in foodborne illness outbreak environmental assessments. Upon PRA clearance, participants may begin acquiring in-depth skills and knowledge to investigate foodborne illness outbreaks as a member of a larger outbreak response team, identify an outbreak’s environmental causes, and recommend appropriate control measures. The course is presented in the context of a simulated virtual environment where participants can interact and practice the skills being learned. Although this course is not a requirement of NEARS participation, CDC will recommend food safety programs complete this before participating in NEARS. In total, CDC recommends 10 hours of training per respondent prior to collecting and reporting data into NEARS.

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

#### A. Time schedule for the project

A three-year clearance revision is requested to continue annual data collection. Although respondents will be asked to report data on an annual basis, they will be able to enter data year round. CDC verification and program correction of reported data will occur in the three months following the annual reporting deadline. Data analysis will occur in the three months following that.

#### A.16.1 – Project Time Schedule

<b>Activity</b>	<b>Time Frame</b>
2 <sup>nd</sup> year (2015) data collection	2015
2 <sup>nd</sup> year (2015) data verification and correction	completed May 2016
1 <sup>st</sup> and 2 <sup>nd</sup> year (2014 and 2015) data analysis	completed January 2017
1 <sup>st</sup> and 2 <sup>nd</sup> year (2014 and 2015) report publication	completed June 2017
3 <sup>rd</sup> year (2016) data collection	2016
3 <sup>rd</sup> year (2016) verification and correction	completed May 2017
4 <sup>th</sup> year (2017) year data collection	2017
4 <sup>th</sup> year (2017) data verification and correction	completed May 2018
3 <sup>rd</sup> and 4 <sup>th</sup> (2016 and 2017) data analysis	completed January 2019

3 <sup>rd</sup> and 4 <sup>th</sup> (2016 and 2017) report publication	completed June 2019
5 <sup>th</sup> year (2018) data collection	2018
5 <sup>th</sup> year (2018) verification and correction	completed May 2019
6 <sup>th</sup> year (2019) year data collection	2019
6 <sup>th</sup> year (2019) data verification and correction	completed May 2020
5 <sup>th</sup> and 6 <sup>th</sup> year (2018 and 2019) data analysis	completed January 2021
5 <sup>th</sup> and 6 <sup>th</sup> year (2018 and 2019) report publication	completed June 2021

**B. Publication plan**

Although PRA clearance for NEARS was obtained in 2013, data submission commenced in 2014. Therefore, at this time there have been no publications using NEARS data; however, CDC plans to periodically publish these data through relevant sources. These disseminations will also allow food safety programs, food industries, and academia to access and use the information gained from NEARS to improve their foodborne illness outbreak response and prevention. Ultimately, these actions will lead to increased food safety program effectiveness, increased food safety, and decreased foodborne illness.

Each year, CDC will prepare and distribute a report to participating programs following analysis. This report will also be available on CDC’s public website. A publication based on the first three years of data will be developed in 2017 (tentatively). Additionally, a publication based on the first six years of data will then be developed in 2019 (tentatively).

**C. Analysis plan**

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

**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

- Lynch M, Painter J, Woodruff R, Braden C. Surveillance for foodborne-disease outbreaks—United States, 1998–2002. *Morb. Mortal. Wkly. Rep.* 2006; 55:1–34.
- Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis.* 2011;17:7–15.
- Scallan E, Griffin PM, Angulo FJ, Tauxe RV, Hoekstra RM. Foodborne illness acquired in the United States—unspecified agents. *Emerg Infect Dis.* 2011;17:16–22.