

# National Environmental Assessment Reporting System (NEARS)

OMB Control No. 0920-0980 (Expiration Date: 08/31/2019)

Revision

Supporting Statement Part A –

Justification

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# Table of Contents

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A.1. Circumstances Making the Collection of Information Necessary.....	3
A.2. Purpose and Use of the Information Collection.....	6
A.3. Use of Improved Information Technology and Burden Reduction.....	9
A.4. Efforts to Identify Duplication and Use of Similar Information.....	9
A.5. Impact on Small Businesses or Other Small Entities.....	10
A.6. Consequences of Collecting the Information Less Frequently.....	10
A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	10
A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	11
A.9. Explanation of Any Payment or Gift to Respondents.....	13
A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	14
A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	15
A.12. Estimates of Annualized Burden Hours and Costs.....	15
A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers.....	18
A.14. Annualized Cost to the Federal Government.....	18
A.15. Explanation for Program Changes or Adjustments.....	20
A.16. Plans for Tabulation and Publication and Project Time Schedule.....	20
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	21
A.18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	21
References.....	21
List of Attachments.....	22

## Part A. Justification

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**Goal of the study:** The goal of this information collection request is to continue 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.

**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:** 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.

**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

The Centers for Disease Control and Prevention (CDC) requests a three-year Paperwork Reduction Act (PRA) clearance for the National Environmental Assessment Reporting System (NEARS), OMB Control No. 0920-0980, Expiration Date: 08/31/2019. This is a revision of a previously approved information collection request (ICR). Requested revisions include the following:

- Reducing the total burden from 2,125 hours to 1,350 hours, due to a reduction in the estimated number of respondents that need to take the training.
- Changes to data collection forms. These changes were based on feedback from NEARS users and analysis of data, and include the following:
  - 22 questions were removed.
  - 21 questions were added.

- o 10 questions were revised.
- o 10 questions were moved to a different section of the data collection instrument to streamline and improve the data collection process.
- o 7 questions that were asked for every environmental sample taken are now only asked for positive samples.

Foodborne illness is a significant problem in the United States (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 823 foodborne illness outbreaks occur in the U.S. every year (Dewey-Mattia, Manikonda, Hall, Wise, Crowe (2018)).

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.

**Foodborne Illness Outbreak Environmental Factors.** Environmental health specialists in environmental health or food safety programs (hereafter referred to as food safety programs) focus on collecting detailed environmental factor data during foodborne illness outbreak investigations. 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. When this information is reported to CDC, it provides an opportunity for CDC to systematically monitor and evaluate environmental factors of foodborne illness, which can then be used to develop effective foodborne illness outbreak response and preventative controls.

**Foodborne Illness Outbreak Surveillance.** Many surveillance systems are used in the U.S. 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 (EIP). It is a sentinel surveillance system that collects information from one site in each of 10 states—covering 15% of the U.S. population, or 48 million Americans—about diseases that are caused by any of seven bacteria and two parasites 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 EIP sites who went to a doctor's office, had a sample tested, and was diagnosed with one of these infections (<https://www.cdc.gov/ncezid/dpei/eip/>).

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). The CDC sponsors the National Outbreak Reporting System (NORS), which 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, 2020). 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 50 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 U.S. annually (see Table A.1.1).

**Table A.1.1. Outbreaks Reported to NORS**

<b>Year</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>
Total number of outbreaks	834	829	877	924	849	839

The NORS Dashboard allows the general public direct access to information on foodborne outbreaks reported to CDC (<https://wwwn.cdc.gov/norsdashboard/>). Most outbreaks are reported to NORS by the state, local, territorial, or tribal health department that conducted the outbreak investigation. Multi-state outbreaks are generally reported to NORS by CDC. Data available via the NORS Dashboard 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 the NORS Dashboard Search Tool are subject to change.

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. 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.

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 original anticipated timeline for the merger of NORS and NEARS systems was December 2018. This timeline has been revised to December 2019, and will include extensive project planning amongst NORS and NEARS teams and 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.

### **National Food Safety Context**

President Obama established the Federal Food Safety Working Group (FSWG) in 2009 to strengthen federal efforts and establish short-term and long-term strategies to improve food safety. FSWG recommended a new, public health-focused approach to food safety based on several core principles, one of which is strengthening surveillance and enforcement. FSWG also 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 was signed into law on January 4, 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 FSWG and FSMA. NEARS collects environmental data on foodborne illness outbreaks on a national level, and expands the current national food safety surveillance from collection of epidemiological and clinical data through NORS to collection of environmental data. NEARS also increases 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. 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."

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. § 241) (Attachment 1A) and Section 205 of the Food Safety Modernization Act (FSMA) (21 U.S.C § 2201) (Attachment 1B).

The 60-day Federal Register Notice was published on 03/06/2019 (Attachment 2) and is further discussed in Section A.8.

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

The information collected through NEARS is primarily used by the CDC to identify and understand environmental factors (contributing factors and environmental antecedents) associated with foodborne illness outbreaks.

Data collected through NEARS will also 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 (Attachment 3).
- *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.

**Experience to Date**

- Currently, there are 31 local and state food safety programs registered to report outbreaks to NEARS. **Table A.2.1.** provides a snapshot of data on outbreaks reported to NEARS between 2014 and 2017. Reporting data to NEARS is not mandatory for local and state food safety programs; however, **Table A.2.1.** shows that the number of outbreaks reported to NEARS is increasing each year.

<b>Table A.2.1. Outbreaks Reported to NEARS</b>				
	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>
<b>Total</b>	<b>111</b>	<b>112</b>	<b>168</b>	<b>217</b>

- In 2017, CDC held a NEARS User Meeting; a representative from each participating NEARS site attended. At this meeting, users discussed their experiences with NEARS and

provided CDC with feedback on how to improve NEARS. We have revised the NEARS instrument based on this feedback, and on analysis of NEARS data. Specifically, we:

- o Removed 22 questions that users said did not work in the field or were unnecessary.
  - o Added 21 questions that users felt were important to understanding foodborne outbreaks. Most of these were focused on food safety issues related to norovirus prevention, given that the majority of outbreaks reported to NEARS were caused by norovirus.
  - o Revised 10 questions to improve their clarity.
  - o Moved 10 questions to a different section of the data collection instrument to streamline the data collection process.
  - o Changed the data collection protocol so that seven questions that were asked for every environmental sample taken are now only asked for positive samples.
- 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 2018, CDC merged NEARS and NORS data for 2014-2016. We were able to match records across the two databases for 85% of outbreaks reported to NEARS. CDC is currently working with sites to understand why the remaining 15% of NEARS outbreaks failed to match.
  - Over half (58%) of outbreaks reported to NEARS had identified contributing factors. Contributing factors are determinants that directly or indirectly cause an outbreak, and 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 these data were not available at a national level.
  - Analysis of NEARS data identified some key investigation activities related to identifying outbreak contributing factors. These include conducting timely and comprehensive environmental assessments (Brown, Hoover, Selman, Coleman, Schurz Rogers, 2017). These analyses provide valuable information about how to improve outbreak investigations.
  - 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 also use the data in this way.

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. The proposed 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 U.S. are invited to participate.

If this information is not collected, a major gap in overall foodborne illness surveillance will remain, hampering efforts to develop 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

This request fully complies with the regulation 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 was published in the *Federal Register* on March 6, 2019, Vol. 84 No. 44, pp. 8101-8103 (**Attachment 2**). CDC did not receive public comments related to this notice.

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. We also revised the instrument in 2018; these revisions were based on feedback from NEARS users. Federal and state consultants are listed in Table A.8.1.

**Table A.8.1.** 2016 ATSDR External Consultations

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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 collected on outbreaks, not respondents. The information reported into NEARS are 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 using pen and paper form (Attachment 6) and then enter all their data into the secure NEARS web-based system (Attachment 7). 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 conduct a structured interview and enter data into the NEARS 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 associated with certain foodborne outbreaks, CDC can develop recommendations that address these unsafe policies 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

The NCEH/ATSDR Human Subjects Contact has reviewed this data collection system and determined that it is not 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. In the U.S., there are approximately 3,000 such agencies. Currently, 31 state and local health departments are registered to report data on outbreaks to NEARS. Based on our experience over the past five years, we expect participation to reach a maximum of 41 programs in the next three years.

It is 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 between 2014 and 2017 is provided in Table A.2.1. Based on these reporting trends, it is likely that up to 300 foodborne illness outbreaks may be reported annually to NEARS from up to 41 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.

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 Skype Meeting (i.e., webinar) training session conducted by CDC staff. 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. Attachment 4 contains a template of this training. Training burden is based on the maximum expected participation from the reporting entities which could be up to 10 additional local and state health departments (most current participants have already taken the training). We estimate the burden of this training to be a maximum of 2 hours. Respondents will only be required to take this training one time. Assuming a maximum participation of up to 10 new programs and about five staff being trained at each participating program, the total estimated burden associated with this training is 100 hours (2 hours x 10 entities x 5 staff per entity).

Although not a requirement, food safety program personnel participating in NEARS will also be encouraged to complete CDC's Environmental Assessment Training Series (EATS). 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 screenshots from the training. We estimate the burden of this training to be a maximum of 10 hours. Respondents



will only have to take this training one time. Assuming a maximum participation of up to 10 new programs and approximately five staff being trained at each program, the estimated burden associated with this training is 500 hours (10 hours x 10 entities x 5 staff per entity).

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 manager interview (Attachment 8). For each outbreak, the respondent (one official from each participating program) will spend around 30 minutes recording environmental assessment data (Attachment 6) on pen and paper. Assuming a maximum number of 300 outbreaks, the estimated annual burden is 150 hours (30 minutes per outbreak x 300 outbreaks) for recording observations.

The manager interview (Attachment 8) will be conducted at each establishment associated with an outbreak and data is initially recorded using 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 four manager interviews will be conducted per outbreak. Each interview and data reporting will take about 20 minutes. Again assuming a maximum number of 300 outbreaks, the estimated annual burden is 400 hours (20 minutes x 4 interviews per outbreak x 300 outbreaks).

Web-based data entry for both activities (Attachment 7) will be combined. Data entry into the NEARS system is expected to take approximately 40 minutes for the combined activities, for a total of 200 burden hours (40 minutes x 300 outbreaks).

The total estimated annual burden for this information collection is 1,350 hours (see Table A.12.1).

**Table A.12.1: Estimated Annualized Burden Hours**

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Food safety program personnel	NEARS Food Safety Program Training	50	1	2	100
	NEARS e-Learning (screenshots)	50	1	10	500
	NEARS Data Recording (paper form)	300	1	30/60	150
	NEARS Data reporting and manager's interview (web entry)	300	1	40/60	200
Retail food personnel	NEARS Manager Interview	1200	1	20/60	400
<b>Total</b>					<b>1,350</b>

The maximum total annualized cost of this data collection to respondents is estimated to be \$39,560.00 (See Table A.12.2). This figure is based on an estimated mean hourly wage of \$36.64 for food safety program personnel and \$11.88 for retail food workers. This estimate was obtained from the U.S. Department of Labor's May 2017 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>).

**Table A.12.2: Estimated Annualized Burden Costs**

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Food safety program personnel	NEARS Food safety program training	100	\$36.64	\$3,664.00
	NEARS e-Learning	500	\$36.64	\$18,320.00

	(screenshots)			
	NEARS Data Reporting (paper form)	150	\$36.64	\$5,496.00
	NEARS Data reporting and manager's interview (web entry)	200	\$36.64	\$7,328.00
Retail food personnel	NEARS Manager Interview	400	\$11.88	\$4,752.00
Total				\$39,560.00

### A.13. 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 08/31/2021). 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 is available to each applicant totaling \$115,000 (14,375 x 8 sites) annually; this additional funding is 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 09/30/2019 to 09/29/2025.

**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 (maintains the system)	1	50%	\$50,000	\$50,000
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 2,125 hours to 1,350 hours, resulting in a decrease of 775 hours. This decrease primarily results from a reduction in the estimated number of program staff who will take the NEARS food safety training. Our records indicate that most current NEARS participants have already taken the training; only new participants or the few current participants who have not yet taken the training will take the training.

As detailed earlier in this document, we also revised the NEARS instrument based on feedback from NEARS users, and from data analysis. Specifically, we

- o Removed 22 questions that users said did not work in the field or were unnecessary.

- o Added 21 questions that users felt were important to understanding foodborne outbreaks. Most of these were focused on food safety issues related to norovirus prevention, given that the majority of outbreaks reported to NEARS were caused by norovirus.
- o Revised 10 questions to improve their clarity.
- o Moved 10 questions to a different section of the data collection instrument to streamline data collection process.
- o Changed the data collection protocol so that 7 questions that were asked for every environmental sample taken are now only asked for positive samples.

Pilot testing with data collectors and enterers indicated that the burden of collecting and entering data associated with the revised NEARS instrument did not differ significantly from the burden associated with the original instrument.

## 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.

**Table A.16.1: Project Time Schedule**

<b>Activity- Data collection and cleaning</b>	<b>Time Frame</b>
6 <sup>th</sup> year (2019) data collection	2019
6 <sup>th</sup> year (2019) data verification and correction	Completed May 2020
7 <sup>th</sup> year (2020) data collection	2020
7 <sup>th</sup> year (2020) data verification and correction	completed May 2021
8 <sup>th</sup> year (2021) data collection	2021
8 <sup>th</sup> year (2021) verification and correction	completed May 2022
9 <sup>th</sup> year (2022) data collection	2022
9 <sup>th</sup> year (2022) data verification and correction	completed May 2023
<b>Activity- Data analysis and publication</b>	
4 <sup>th</sup> year (2017) data analysis and annual report	completed Dec. 2019
5 <sup>th</sup> year (2018) data analysis and annual report	completed Dec.2020
6 <sup>th</sup> year (2019) data analysis and annual report	completed Dec.2021
4 <sup>th</sup> -6 <sup>th</sup> year (2017-2019) aggregate data analysis and report publication	completed Dec.2022
7 <sup>th</sup> year (2020) data analysis and annual report	completed Dec.2022

8 <sup>th</sup> year (2021) data analysis and annual report	completed Dec.2023
9 <sup>th</sup> year (2022) data analysis and annual report	completed Dec.2024
7 <sup>th</sup> -9 <sup>th</sup> year (2020-2022) aggregate data analysis and report publication	completed Dec.2025

## B. Publication plan

To date, CDC has released two annual NEARS reports (for years 2014-2015) on the CDC website (<https://www.cdc.gov/nceh/ehs/nears/publications.htm>). Additionally, CDC has published three articles in peer-reviewed scientific publications based on NEARS data. These are:

- Outbreak characteristics associated with identification of contributing factors to foodborne illness outbreaks (2017) *Epidemiology and Infection* (<https://www.cdc.gov/nceh/ehs/docs/contributing-factors.pdf>)
- Foodborne outbreak establishment characteristics and policies--National Environmental Assessment Reporting System (NEARS), 2014-2016 (2019) *MMWR*
- Facilitators and barriers to conducting Environmental Assessments for food establishment outbreaks - National Environmental Assessment Reporting System, 2014-2016 (2019) *MMWR*

CDC plans to continue to periodically publish NEARS data through relevant sources. These disseminations will 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.

## 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

The display of the OMB expiration date is appropriate.

### A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

## References

Brown, L, Hoover, E, Selman, C, Coleman, E, Schurz Rogers, H. Outbreak characteristics associated with identification of contributing factors to foodborne illness outbreaks. *Epi Infect.* 2017;1:1-9.

Dewey-Mattia D, Manikonda K, Hall AJ, Wise ME, Crowe SJ. Surveillance for Foodborne Disease Outbreaks — United States, 2009–2015. *MMWR Surveill Summ* 2018;67(No. SS-10):1–11.

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.

## List of Attachments

Attachment 1A. Authorizing Legislation 42 U.S.C. § 241

Attachment 1B. Authorizing Legislation 21 U.S.C § 2201

Attachment 2. 60-day Federal Register Notice

Attachment 3. Definition of Contributing Factors to Foodborne Illness Outbreaks

Attachment 4. NEARS Food Safety Program Training Webinar

Attachment 5. NEARS Environmental Assessment Training on Foodborne Illness Outbreaks (screenshots)

Attachment 6. NEARS Data Reporting Instrument

Attachment 7. NEARS Data Recording and Manager Interview Web Entry (screenshots)

Attachment 8. NEARS Manager Interview

Attachment 9. Research Determination Form