National Environmental Assessment Reporting System (NEARS)

OMB Control No. 0920-0980 (Expiration Date: 02/28/2026)

Revision

Supporting Statement Part A –

Justification

Program Official: Laura G. Brown, Ph.D.
Title: Lead Behavioral Scientist
Phone: (770) 488-4332
Email: lrg0@cdc.gov
Fax: (770) 488-7310

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Table of Contents

Part A. Justification

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.

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: 02/28/2026).

Foodborne Illness in the United States. Foodborne illness is a significant problem in the United States (U.S.)—the major pathogens cause an estimated 9.4 million domestically acquired foodborne illnesses in the U.S. annually. Additionally, an average of 823 foodborne illness outbreaks occur annually. (Scallan, et al., 2025; Dewey-Mattia, Manikonda, Hall, Wise, Crowe, 2018).

Reducing the number of foodborne illness outbreaks requires identification and understanding of the etiology of outbreaks. We need to know the pathogen, food, and pattern of illness associated with each outbreak, as well as 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 Surveillance. The Food Safety Modernization Act (FSMA) recognizes that robust foodborne illness surveillance data are needed to inform targeted prevention interventions. FSMA directed CDC to expand national food safety surveillance systems and increase state and local participation in these systems. Most infectious disease surveillance systems, such as FoodNet and the National Outbreak Reporting System (NORS) (OMB Control No. 0920-1304, expiration date 09/30/2025), either actively seek out cases of illness or collect epidemiological and clinical information about cases identified during foodborne outbreaks. Although these systems capture the pathogen, food, and patterns of illness associated with outbreaks, they do not capture detailed environmental data.

Foodborne Illness Outbreak Environmental Factors. During foodborne illness outbreak investigations, environmental health specialists collect detailed environmental data by conducting environmental assessments. These data identify how and why the food became contaminated with pathogens, and how and why these pathogens were not eliminated before ingestion. When reported to CDC via NEARS, this information provides an opportunity to systematically monitor and evaluate environmental factors, which can then be used to develop effective foodborne illness outbreak response and preventative controls.

Justification for NEARS. NEARS addresses the goals of FSMA by collecting environmental data on foodborne illness outbreaks on a national level and expanding national food safety surveillance beyond collection of epidemiological and clinical data to include collection of environmental data. In addition, NEARS continues to support the U.S. Department of Health

and Human Services' Healthy People 2030 Goal to "improve food safety and reduce foodborne illnesses."

Revision Information Collection Request. A summary of the requested changes is below, and details of the changes are discussed in **Section A.15**.

- We adjusted downward the anticipated number of new programs reporting to NEARS over the next 3-year PRA period from 10 to 6, leading to an anticipated 6 new programs, for a total of 46 reporting programs.
- We more accurately estimated the maximum burden for environmental assessments.
- We deleted one question that measured the social vulnerability of the census tract where the food establishment is located. This deletion will not appreciably change the response time burden.
- These changes led to an increase in time burden of 153 hours over the previously approved 1,371 hours.

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 USC 2201) (**Attachment 1B**).

The 60-day Federal Register Notice was published on October 2nd (**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.
- *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.

Experience to Date

- Currently, 75 state, local, and U.S. Territorial health departments are registered to report data on outbreaks to NEARS. **Table A.2.1.** provides data on outbreaks reported to NEARS between 2016 and 2024. Note that food establishment closures and redirection of food safety program staff and resources due to the COVID-19 pandemic likely contributed to the lower reporting numbers in 2020 and 2021.

Table A.2.1. Outbreaks Reported to NEARS

Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total	Average per year
Number of outbreaks	168	217	307	278	95	196	252	252	298	2,063	229

- We have conducted 8 major sets of analyses of NEARS data that have led to significant findings and recommendations. Analysis of NEARS data:
    - Identified the most common antecedents of outbreaks, including lack of oversight of employees/enforcement of policies, lack of training of employees, and lack of a food safety culture. These findings highlight the critical role that employees play in restaurant food safety and that restaurant management can play in managing these antecedents.
    - Identified multiple antecedents to *C. perfringens* outbreaks, including factors related to 1) people (e.g., a lack of adherence to food safety procedures), 2) processes (e.g., a process change during food preparation), and 3) equipment (e.g., not enough equipment). Recommendations were that food establishments support food safety training and certification programs, adhere to a food safety management plan to reduce errors, and conduct routine maintenance on equipment and use only properly working equipment.
    - Found that food contamination by an ill worker was a contributing factor to the majority of outbreaks and that many outbreak restaurants lacked written policies for ill worker management, glove use, and paid sick leave. These findings highlight the importance of proper hand hygiene and preventing workers who are ill from working.
    - Found that only 16% of outbreak establishments had all recommended components of a strong ill worker policy. The implementation of strong policies that prevent contamination of food by workers is important to foodborne outbreak prevention.
    - Found that investigations more often identified factors contributing to outbreaks when an outbreak etiologic agent had been identified and when the environmental component of the investigation was timely and comprehensive. Identification of contributing factors is key to outbreak prevention. These findings highlight the need for

strong environmental health programs and cooperation between epidemiology and environmental health programs during investigations.

- Identified investigation practices that increase the probability of a successful outbreak investigation: a rigorous epidemiology investigation method; a thorough environmental assessment; and the collection of clinical samples. This research highlights the importance of a comprehensive outbreak investigation, which includes epidemiology, environmental health, and laboratory staff working together to solve the outbreak.
- Identified barriers to investigators conducting environmental assessments during outbreak investigations, including limited resources, insufficient training, and uncooperative establishment personnel. Identifying and addressing barriers to conducting environmental assessments can improve health departments' ability to conduct them.
- Found that norovirus outbreaks were smaller in restaurants in which managers received food safety certification, managers and workers received food safety training, food workers wore gloves, and restaurants had cleaning policies. These findings highlight the importance of strong food safety training, policies, and practices to norovirus outbreak mitigation.

Participation of food safety programs in NEARS is voluntary and is 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; 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 their information with pen and paper (**Attachments 6 and 7**) and then enter their data into a secured web-based system (**Attachment 8**) 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. Enhancing the current system to allow mobile data to be imported into NEARS will allow greater productivity in the field as data collectors are no longer confined to an office to electronically 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 the National Center for Emerging and Zoonotic Infectious Diseases (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 another national surveillance system--NORS. So that data from NORS and NEARS can be linked, NEARS collects data on whether epidemiological or laboratory information has been reported to other surveillance systems, the outbreak identification numbers associated with those systems for each outbreak, and the outbreak pathogen. Note that NEARS data are reported by environmental health staff, while NORS data are reported by epidemiological staff.

NORS and NEARS collect different and complementary sets of data on foodborne illness outbreaks; both data sets are critical to food safety efforts. Since the last NEARS PRA package was approved, NEARS and NORS were moved to the same information technology (IT) platform, the One CDC Data Platform (1CDP), to align with CDC's data modernization initiative. This move to the same platform is a key integration step that significantly reduced CDC staff time dedicated to supporting two IT systems. NEARS is now part of 1CDP's System for Enteric Disease Response, Investigation, and Coordination (SEDRIC) community, along with NORS, Calicinet, PulseNet, and OHAABS.

Below is an estimated timeline for fully integrating the two systems. The activities and timeline are dependent on continuation of funding.

Table A.4.1 Estimated Timeline for Merging NEARS and NORS

Activity	Timeline
Add functionality such that there is only one data set of remaining duplicated data points (whether outbreaks have been reported to other surveillance systems, outbreak identification numbers associated with those systems, and outbreak pathogen) that can be accessed and edited by environmental health (NEARS) or epidemiological (NORS) staff; this will reduce duplication	End of 2026
Conduct a thorough review of both systems to identify any additional revisions needed to reduce duplication and ensure an integrated system	Mid 2026

The goal of these activities is to ensure that environmental health staff are reporting only the environmental health investigation data they collected to CDC and that epidemiological staff are reporting only the epidemiological investigation data they collected to CDC. The functionality of these activities will also encourage collaboration between environmental health and epidemiological staff. Thus, the experts who collected that data are also reporting the data, ensuring its quality. We estimate that the implementation of these steps will result in a reduction of 20 minutes of data entry per outbreak for state/local staff.

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. The foodborne illness outbreak investigation data reported into NEARS by these officials is reported to CDC as a part of routine public health practice. Food safety programs 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 7**). 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

Programs that voluntarily participate in NEARS are expected to report data on all outbreaks occurring in their jurisdictions. We estimate that registered food safety programs will respond to and report up to seven outbreaks per year. They are asked to provide information once per outbreak. 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 its research agenda goal of decreasing health risks from environmental exposures.

There are no technical or legal obstacles to reduce the burden.

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

Registered food safety programs may voluntarily report information to the CDC more often than quarterly. Ideally, they will report the data to NEARS after each outbreak investigation is complete; this may result in more frequent reporting than quarterly. Based on our experience to date (see **Section A.2**), we estimate that up to 46 registered programs will collect and report NEARS data on up to six outbreaks in their jurisdiction each year. This will result in a total of up to 276 outbreaks reported to NEARS per year.

In all other aspects, this request fully complies with regulation 5 CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on October 2nd (Vol. 90, No. 189, p. 47762) (**Attachment 2**). CDC/ATSDR received one non-substantive anonymous comment (Attachment 2A).

B. The data collection instruments (**Attachments 6 and 7**) were 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. External Consultations

Jack Guzewich, RS, MPH (Retired) Director-Emergency Coordination & Response	**David Nicholas** NY State Dept. of Health	**Danny Ripley** Food Safety Investigator
Brendalee Viveiros, PhD Principal Public Health Promotion Specialist	**Lauren DiPrete, MPH, REHS** Sr. Environmental Health Specialist	**Nicole Hedeen, MPH** Senior Epidemiologist
Wendy McKelvey, PhD, MS Executive Director	**Jo Ann Monroy, MPH** Environmental Health Specialist	--

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 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 the web-based NEARS system (**Attachment 8**).

Privacy Impact Assessment Information

A. As part of the close collaboration between CDC's NCEH and NCEZID foodborne and waterborne disease programs, the NEARS data is collected, transferred, and stored in the NCEZID Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) Outbreak Event Surveillance (OES) System. The DFWED OES contains three modules: National Outbreak Reporting System (NORS) (OMB Control No. 0920-1304, expiration date 09/30/2025), One Health Harmful Algal Bloom System (OHHABS) (OMB Control No. 0920-1105, expiration date 08/31/2028), and NEARS.
B. On 04/21/2023, the CDC Chief Privacy Officer has determined that the Privacy Act does not apply to the DFWED OES. Although PII are collected, they are not used to retrieve records.
    a. **Attachment 10** is the Privacy Impact Assessment (PIA) Form for the NCEZID DFWED OES System.
    b. **Attachment 10A** documents NEARS as part of the DFWED OES System in the CDC Enterprise System Catalog.

C. No paper files will be collected at CDC. The paper-based assessment and interview data (**Attachments 6 and 7**) will be entered into a web-based information system (**Attachment 8**). All electronic data will be stored on secure CDC networks. Access to the data will be limited to those who need it to perform job duties related to the project.

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 a non-research public health surveillance activity and does not require CDC Institutional Review Board (IRB) review under §46.102(l)(2) (**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. Not every one of these agencies will register in NEARS or respond every year.

It is not possible to determine exactly how many outbreaks will occur in the future, nor where they will occur. Forty programs reported outbreaks to NEARS from 2021-2024. Based on our experience over those years, we expect a maximum of 6 additional sites (2 per year) to register with and report data to NEARS over the next PRA cycle, for a total of 46 reporting programs. We also expect each program to report an average of 6 outbreaks annually, for a total of 276 outbreaks annually.

The activities associated with NEARS that require a burden estimate consist of registration, training, observing and reporting the data, and interviewing managers and reporting the data. Food safety programs interested in participating in NEARS must first register to use the system, which takes about 10 minutes (**Attachment 3**). We anticipate 6 new programs to join in the next three years, resulting in 2 new programs per year. Therefore, the total estimated annual burden associated with registration is 1 hour (10 minutes x 2 programs = .3 hours rounded to 1 hour).

The second activity is the training for the new food safety program personnel participating in NEARS. These staff will be encouraged to attend a Microsoft Teams (i.e., webinar) training

session on using the NEARS data entry system, conducted by CDC staff. 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 2 new programs annually and about five staff being trained at each participating program, the total estimated annual burden associated with this training is 20 hours (2 programs x 5 staff x 2 hours). **(Attachment 4)**

New 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. We estimate the burden of this training to be a maximum of 10 hours. Respondents will only take this training one time. Assuming a maximum participation of up to 2 new programs annually and approximately five staff being trained at each program, the estimated annual burden associated with this training is 100 hours (2 programs x 5 staff x 10 hours). **(Attachment 5)**

Program respondents (one official from each participating program) will record environmental assessment data on pen and paper for each establishment associated with an outbreak. Most outbreaks are associated with only one establishment; however, some are associated with multiple establishments. We estimate a maximum of four establishments will be associated with any given outbreak. Recording for each assessment will take about 25 minutes. The annual burden for this activity is 460 hours (276 outbreaks x 4 establishments x 25 minutes). **(Attachment 6)**

Program respondents will conduct a manager interview with each establishment associated with an outbreak and initially record the data with pen and paper. Each interview will take about 20 minutes. The annual burden for this activity is 368 hours (276 outbreaks x 4 establishments x 20 minutes). **(Attachment 7)**

Respondents will also report this environmental assessment and manager interview data into the NEARS web-based system. This data entry is expected to take approximately 25 minutes for the environmental assessment data and 20 minutes for each manager interview (assuming a maximum of four). The annual burden for this activity is 207 hours (276 outbreaks x 45 minutes). **(Attachment 8)**

The retail food managers interviewed are another group of respondents. Again, assuming a maximum number of 276 outbreaks, the estimated annual burden is 368 hours (276 outbreaks x 4 establishments x 20 minutes each). **(Attachment 7)**

The total estimated annual burden for this information collection is 1,524 hours. There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Food safety program personnel	NEARS registration	2	1	10/60	1
	NEARS introduction training	10	1	2	20
	NEARS e-learning (screenshots)	10	1	10	100
	NEARS environmental assessment (recording form)	46	24	25/60	460
	NEARS manager interview form	46	24	20/60	368
	NEARS web entry (screenshots)	46	6	45/60	207
Retail food personnel	NEARS manager interview form	1,104	1	20/60	368
Total					1,524

Amounts under an hour were rounded to an hour.

The total annualized cost burden of this data collection is provided in Table A.12.2. This figure is based on an estimated mean hourly wage of $42.62 for food safety program personnel and $21.59 for first line supervisors of retail food workers. This estimate was obtained from the U.S. Department of Labor's May 2024 National Occupational Employment and Wage Estimates report (Environmental Scientists and Specialists, Including Health and Food Preparation and Serving Related Occupations - Occupational Employment and Wage Statistics Profiles).

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 registration	1	$42.62	$42.62
	NEARS introduction training	20	$42.62	$852.40
	NEARS e-learning (screenshots)	100	$42.62	$4,262.00
	NEARS environmental assessment (recording form)	460	$42.62	$19,605.20
	NEARS manager interview form	368	$42.62	$15,684.16
	NEARS web entry (screen shots)	207	$42.62	$8,822.34
Retail food personnel	NEARS manager interview form	368	$21.59	$7,945.12
Total				**$57,213.84**

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 primarily funded through a cooperative agreement titled “Environmental Health Specialists Network (EHS-Net) - Practice Based Research to Improve Food Safety” (CDC-FRA-EH20-001). In FY 2026, we hope to fund up to eight EHS-Net applications. The annualized cost to the federal government of the total cooperative agreement is $1,540,700 through CDC-RFA-EH20-001, annually; we estimate that one third of this funding ($513,567) is used for NEARS-related activities (e.g., personnel to serve as NEARS liaisons with local food safety programs, personnel to enter NEARS data, etc.). Additional costs to the federal government include the costs of CDC personnel and contractors who maintain the system and assist respondents in

data entry. The total estimated cost to the Federal Government is $713,567, 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.

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-20-001	N/A	N/A	N/A	$513,567
CDC FTEs	2	75%	$100,000	$150,000
IT Contractor (maintains the system)	1	50%	$100,000	$50,000
Total				**$713,567**

A.15. Explanation for Program Changes or Adjustments

A summary of the requested changes is below.

- We did not gain as many new NEARS programs as we had anticipated over the last three years. Thus, we adjusted downward the anticipated number of new programs reporting to NEARS over the next 3-year PRA period from 10 to 6, leading to an anticipated 6 new programs for a total of 46 reporting programs, with each reporting an average of 6 outbreaks annually.
- We more accurately estimated the maximum burden for environmental assessments.
- We deleted one question that measured the social vulnerability of the census tract where the food establishment is located. This deletion will not appreciably change the response time burden.
- The total estimated annual burden for this information collection is 1,524 hours. This reflects an increase in time burden of 153 hours over the previously approved 1,371 hours.

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

A. Time schedule for the project

A three-year clearance 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

Activity- Data collection and cleaning	**Time Frame**
9th year (2026) data collection	2026
9th year (20267 data verification and correction	completed May 2027
10th year (2027) data collection	2027
10th year (2027) data verification and correction	completed May 2028
11th year (2028) data collection	2028
11th year (2028) verification and correction	completed May 2029
12th year (2029) data collection	2029
12th year (2029) data verification and correction	completed May 2030
Activity- Data analysis and publication	
7th-9th year (2020-2022) aggregate data analysis and report publication	completed Jan 2026
10th year (2023) data analysis and annual report	completed Dec. 2026
11th year (2024) data analysis and annual report	completed Dec. 2027
12th year (2025) data analysis and annual report	completed Dec. 2028
10th-12th year (2023-2025) aggregate data analysis and report publication	completed Dec. 2029

B. Publication plan

To date, CDC has published eight articles in peer-reviewed scientific publications based on NEARS data. Published manuscripts include:

- Characteristics associated with successful foodborne outbreak investigations involving United States retail food establishments (2014–2016) (2024) *Journal of Food Protection* (Holst et al., 2023)
- Environmental antecedents of foodborne illness outbreaks, United States, 2017–2019 (2023) *Epidemiology and Infection* (Holst et al., 2024)

- Foodborne illness outbreaks at retail food establishments — National Environmental Assessment Reporting System, 25 state and local health departments, 2017–2019 (2023) *Morbidity and Mortality Weekly Report* (Moritz et al., 2019)
- Operational antecedents associated with *Clostridium perfringens* outbreaks in retail food establishments, United States, 2015-2018 (2022) *Foodborne Pathogens and Disease* (Wittry et al., 2022)
- Retail establishment policies and practices related to norovirus outbreak size and duration (2020) *Journal of Food Protection* (Hoover et al., 2020)
- Foodborne outbreak establishment characteristics and policies--National Environmental Assessment Reporting System (NEARS), 2014-2016 (2019) *Morbidity and Mortality Weekly Report* (Lipcsei et al., 2019)
- Facilitators and barriers to conducting Environmental Assessments for food establishment outbreaks – National Environmental Assessment Reporting System, 2014-2016 (2019) *Morbidity and Mortality Weekly Report* (Freeland et al., 2019)
- Outbreak characteristics associated with identification of contributing factors to foodborne illness outbreaks (2017) *Epidemiology and Infection* (Brown et al., 2017)

CDC plans to continue to periodically publish NEARS data through relevant sources, including an updated surveillance summary to be published in the *MMWR*. 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

Data analysis results will be shared 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 'plain language' summaries on the CDC website. Results will be presented in aggregate form. 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

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Attachments

Attachment 1A: Authoring Legislation USC241

Attachment 1B: Authorizing Legislation USC2201

Attachment 2: 60-day FRN

Attachment 2A: Comment on 60-day FRN

Attachment 3: NEARS Registration Form

Attachment 4: NEARS Intro Training

Attachment 5: E-Learning training on Outbreak Environmental Assessments

Attachment 6: NEARS Environmental Assessment Recording Form

Attachment 7: NEARS Manager Interview Recording Form

Attachment 8: NEARS Web Entry

Attachment 9: STARS Determination Form

Attachment 10: PIA DFWED OES System

Attachment 10A: NEARS in DFWED OES System