

# National Environmental Assessment Reporting System (NEARS)

OMB Control No. 0920-0980 (Expiration Date: 08/31/2022)

Revision

Supporting Statement Part A –

Justification

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## 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: 08/31/2022).

**Foodborne Illness in the United States.** Foodborne illness is a significant problem in the United States (U.S.)—an estimated 47.8 million foodborne illness cases and an average of 823 foodborne illness outbreaks occur annually in the U.S. (Scallan, Hoekstra et al., 2011; 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.

Previously existing surveillance systems, such as FoodNet and the National Outbreak Reporting System (NORS) (OMB Control No. 0920-1304, expiration date 09/30/2023), 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**.

- The guidance and definitions for contributing factors (**Attachment 3**) have been updated based on recommendations of a national workgroup (three factors were deleted, one was added).
- Due to the anticipated increase of 10 reporting sites from 34 to 44 registered food safety programs, with each reporting up to seven outbreaks each year, we are adding one hour in time burden for new food safety programs to register to participate in NEARS (**Attachment 4**).
- The requested changes to the NEARS Data Reporting (**Attachments 7 and 8**) include:
  - a change to update the answer choices for contributing factors. This revision poses no additional time burden.
  - an addition of one question to measure the social vulnerability of the census tract where the food establishment is located (**Attachment 7**). This question was added to address the federal government's focus on health equity. This new question will not appreciably change the response time burden. This question will be added to the web-based data entry system (**Attachment 8**) in the next fiscal year.
- The total estimated annual burden for this information collection is 1,371 hours. This reflects an increase in time burden of 21 hours over the previously approved 1,350 hours. The total number of respondents is 1,951 per year. This reflects an increase of 51 respondents over the previously approved 1,900 respondents.

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 additional question collecting the Social Vulnerability Index (SVI) of the food establishment's census tract is designed to address Executive Order 13985 (Advancing Racial Equity and Support for Underserved Communities Through the Federal Government) (**Attachment 1C**).

The 60-day Federal Register Notice was published on 04/08/2022 (**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, 34 local and state food safety programs have reported outbreaks to NEARS. **Table A.2.1.** provides a snapshot of data on outbreaks reported to NEARS between 2016 and 2021. 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.

| <b>Table A.2.1. Outbreaks Reported to NEARS</b> |             |             |             |             |             |             |                          |                                     |
|---|-------------|-------------|-------------|-------------|-------------|-------------|--------------------------|-------------------------------------|
| <b>By Year</b>                                  | <b>2016</b> | <b>2017</b> | <b>2018</b> | <b>2019</b> | <b>2020</b> | <b>2021</b> | <b>Total No. Reports</b> | <b>Average No. Reports per Year</b> |
| <b>No. Reports</b>                              | 168         | 217         | 307         | 278         | 95          | 196         | <b>1,261</b>             | <b>210</b>                          |

- Over half (58%) of the 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 an important 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.
- Analysis of NEARS and NORS outbreak data identified that components of food safety management systems, such as cleaning policies and certified kitchen managers, impact outbreak size and duration (Hoover, 2020). This informs food safety practices and policies.
- In 2018, CDC merged NEARS and NORS data for 2014-2016 and was able to match records across the two databases for 85% of outbreaks reported to NEARS by linking outbreak ID numbers. NORS collects outbreak data on the epidemiologic and clinical laboratory data from outbreaks. When NORS and NEARS data are linked, it provides opportunities to strengthen the robustness of outbreak data because the dataset now includes environmental, epidemiologic, and clinical laboratory information. Collectively, these data play a vital role in improving the food safety system. CDC is currently working with NEARS reporting sites to understand why the remaining 15% of NEARS outbreaks failed to match with NORS outbreaks.

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 7 and 9**) 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. 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 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 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 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.

The implementation of NEARS resulted in two foodborne illness outbreak surveillance systems at CDC—NORS and NEARS. NORS and NEARS collect different and complementary sets of data on foodborne illness outbreaks; both data sets are critical to food safety efforts. Both systems 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.

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 continues to improve coordination and communication between these two programs so that we can eventually meet the goal of one foodborne illness outbreak surveillance system. Since the last ICR was approved, NEARS and NORS have been moved to the same information technology platform and the integration of the only redundant section (contributing factors) is in progress. NORS will ultimately be using the revised contributing factors presented in A.15.

## 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 (**Attachment 8**). 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 9**). 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 will voluntarily report information to the CDC more often than quarterly. Based on our experience to date (see **Section A.2**), we estimate that up to 44 registered programs will collect and report NEARS data on up to seven outbreaks in their jurisdiction each year. This will result in a total of up to 308 outbreaks reported to NEARS per year.

In all other aspects, 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. A 60-day Federal Register Notice was published in the *Federal Register* on April 8, 2022, Vol. 87, No. 68, pp. 20867-69 (**Attachment 2**). CDC/ATSDR received one non-substantive comment (see **Attachment 2a**).
- B. The data collection instruments (**Attachments 7, 8, and 9**) 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.** 2016 External Consultations

|   |   |   |
|---|---|---|
| <p><b>Jack Guzewich, RS, MPH (Retired)</b><br/>         Director-Emergency Coordination &amp; Response<br/>         U.S. Food and Drug Administration<br/>         Center for Food Safety and Applied Nutrition<br/>         MS HFS-600 Bld. CPK1<br/>         College Park, MD 20740<br/>         301-436-1608<br/> <a href="mailto:john.guzewich@cfsan.fda.gov">john.guzewich@cfsan.fda.gov</a></p> | <p><b>David Nicholas</b><br/>         NY State Dept. of Health<br/>         Bureau of Community Sanitation and Food Protection<br/>         547 River St.<br/>         Troy, NY 12180<br/>         (518) 402-7600<br/> <a href="mailto:dcn01@health.state.ny.us">dcn01@health.state.ny.us</a></p> | <p><b>Danny Ripley</b><br/>         Food Safety Investigator<br/>         Food Division<br/>         Metro Public Health Department<br/>         311 23rd Ave. North<br/>         Nashville, TN 37203<br/>         615-340-2701<br/> <a href="mailto:danny.ripley@nashville.gov">danny.ripley@nashville.gov</a></p> |
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| <p><b>Brendalee Viveiros, PhD</b><br/>Principal Public Health Promotion Specialist<br/>Center for Food Protection, Division of Environmental Health<br/>Rhode Island Department of Health<br/>Phone: 401-222-2851<br/>Email:<br/><a href="mailto:Brendalee.viveiros@health.ri.gov">Brendalee.viveiros@health.ri.gov</a></p>          | <p><b>Lauren DiPrete, MPH, REHS</b><br/>Sr. Environmental Health Specialist<br/>Foodborne Illness &amp; EHS-Net Research<br/>Southern Nevada Health District<br/>Environmental Health, Food Ops<br/>Mailing Address: P.O. Box 3902, Las Vegas, NV 89127<br/><a href="mailto:diprete@snhd.org">diprete@snhd.org</a><br/>Office Phone: 702-759-1504</p> | <p><b>Nicole Hedeem, MPH</b><br/>Senior Epidemiologist<br/>Partnership &amp; Workforce Development Unit<br/><b>Minnesota Department of Health</b><br/>Phone: 651-201-4075<br/>Email: <a href="mailto:nicole.hedeem@state.mn.us">nicole.hedeem@state.mn.us</a></p> |
| <p><b>Wendy McKelvey, PhD, MS   Executive Director</b><br/>Bureau of Environmental Surveillance and Policy<br/>NYC Department of Health &amp; Mental Hygiene, 125 Worth St, 3<sup>rd</sup> flr – CN-34E<br/>New York, NY 10013<br/>Desk: 646-632-6523<br/><a href="mailto:wmckelvey@health.nyc.gov">wmckelvey@health.nyc.gov</a></p> | <p><b>Niki Lemin, MS, RS/REHS, MEP</b><br/>Assistant Health Commissioner<br/>Director of Environmental Health<br/>Franklin County Public Health<br/>280 East Broad Street<br/>Columbus, Ohio 43215-4562<br/><a href="mailto:ndlemin@franklincountyohio.gov">ndlemin@franklincountyohio.gov</a><br/>(614) 525-3852 Office<br/>(614) 928-8182 Cell</p>  | <p><b>Jo Ann Monroy, MPH</b><br/>Harris County Public Health (TX)<br/>2223 West Loop S, Houston, TX 77027<br/>Cell: (713) 516-5068  <br/>Phone: (713) 274-6319<br/>Email: <a href="mailto:JoAnn.Monroy@phs.hctx.net">JoAnn.Monroy@phs.hctx.net</a></p>            |

## 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 7**) 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**). Information in identifiable form (IIF) is collected during NEARS registration as the name of the NEARS Administrator of the participating program (**Attachment 4**).

### 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 09/30/2023), One Health Harmful Algal Bloom System (OHHABS) (OMB Control No. 0920-1105, expiration date 07/31/2022), and NEARS.

- B. On 12/16/2019, 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 11** is the Privacy Impact Assessment (PIA) Form for the NCEZID DFWED OES System.
  - b. **Attachment 11A** 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 7 and 9**) 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 10**). 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 and voluntarily respond every year.

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 2016 and 2021 is provided in Table A.2.1. Over the past six years, we received 1,261 reports to NEARS, with the highest number of 307 reports in 2018, and a yearly average of 210 reports. Currently, 34 sites have entered outbreak data into NEARS. We expect a maximum of 10 additional sites to register in the next three years, to reach a maximum of 44 reporting sites. Based on these reporting trends, we estimate that up to 308 foodborne illness outbreaks may be reported annually to

NEARS from up to 44 sites that will report up to seven local outbreaks per year for the duration of the next PRA clearance.

The activities associated with NEARS that require a burden estimate consist of registration, training, observing, data recording, and data reporting events. Food safety programs interested in participating in NEARS must first register to use the system (**Attachment 4**). The anticipated 10 new programs over the next three years is rounded to three new programs per year. Therefore, the total estimated annual burden associated with registration is one hour (10 minutes per hour x 3 registrations = 0.5 hours rounded to 1 hour).

The next activity is the training for the food safety program personnel participating in NEARS. These staff will be encouraged to attend a Microsoft Teams/Zoom 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 5** 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 6** contains screenshots from the training. 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 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 7**) and NEARS manager interview (**Attachment 9**). For each outbreak, the respondent (one official from each participating program) will spend around 30 minutes recording environmental assessment data (**Attachment 8**) on pen and paper. Assuming a maximum number of 308 outbreaks, the estimated annual burden is 154 hours (30 minutes per outbreak x 308 outbreaks) for recording observations.

The manager interview (**Attachment 9**) 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 308 outbreaks, the estimated annual burden is 411 hours (20 minutes x 4 interviews per outbreak x 308 outbreaks).

Web-based data entry for both assessment and manager interview activities (**Attachment 8**) are combined. Data entry into the NEARS system is expected to take approximately 40 minutes for the combined activities, for a total of 205 burden hours (40 minutes x 308 outbreaks).

The total estimated annual burden for this information collection is 1,371 hours (see Table A.12.1).

**Table A.12.1: 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 Food Safety Program Registration | 3                     | 1                                  | 10/60                                  | 1                       |
|                               | NEARS Food Safety Program Training     | 50                    | 1                                  | 2                                      | 100                     |
|                               | NEARS e-Learning (screenshots)         | 50                    | 1                                  | 10                                     | 500                     |
|                               | NEARS Data Recording (paper form)      | 44                    | 7                                  | 30/60                                  | 154                     |
|                               | NEARS Data Reporting and               | 44                    | 7                                  | 40/60                                  | 205                     |

|                       |                                 |       |   |       |              |
|-----------------------|---------------------------------|-------|---|-------|--------------|
|                       | Manager's Interview (web entry) |       |   |       |              |
| Retail food personnel | NEARS Manager Interview         | 1,232 | 1 | 20/60 | 411          |
| <b>Total</b>          |                                 |       |   |       | <b>1,371</b> |

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 \$39.06 for food safety program personnel and \$14.16 for retail food workers. This estimate was obtained from the U.S. Department of Labor's May 2021 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 Registration                   | 1                  | \$39.06          | \$39.06                |
|                               | NEARS Food Safety Program Training                       | 100                | \$39.06          | \$3,906.00             |
|                               | Environmental Assessment Training Series (screenshots)   | 500                | \$39.06          | \$19,530.00            |
|                               | NEARS Data Reporting (paper form)                        | 154                | \$39.06          | \$6,015.24             |
|                               | NEARS Data Reporting and Manager's Interview (web entry) | 205                | \$39.06          | \$8,007.30             |
| Retail food personnel         | NEARS Manager Interview                                  | 411                | \$14.16          | \$5,819.76             |
| <b>Total</b>                  |  |                    |                  | <b>\$43,317.36</b>     |

## 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 2020, EHS-Net committed to fund up to eight 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 \$678,567, 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 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>\$678,567</b> |

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

One question was added to **Attachment 7** to collect the community's Social Vulnerability Index ([CDC/ATSDR Social Vulnerability Index \(SVI\)](#)) based on the census tract where the food establishment is located. See the table below for this question which was added to address the federal government's focus on health equity. Users will begin collecting this information during their investigations January 1, 2023. This question will be added to the web-based data entry system (**Attachment 8**) as a change request just prior to that time to accommodate programmer budgets and scheduling.

The contributing factor definitions and guidance were revised by a national workgroup. The workgroup made multiple revisions to improve clarity and readability of the guidance. The final revised contributing factors can be seen in **Attachment 3**. The specific revisions can be seen in the following table. The answer choices were also revised; the revisions to the answer choices can also be seen in the following table (the final contributing factors content can be found in **Attachment 7** (Question VII.1) and **Attachment 8**).

| Revised contributing factors |   | Old contributing factors |  |
|------------------------------|---|--------------------------|--|
| <b>Contamination Factors</b> |   |                          |  |
| C1                           | <p><b>Toxin or chemical agent naturally part of tissue in food</b></p> <p><b>Description</b><br/>A natural toxin found in a plant, fungus, or animal;<br/>-OR-<br/>A chemical agent of biologic origin that occurs naturally in the plant, fungus, or animal or bioaccumulates in the plant, fungus, or animal before or soon after harvest or slaughter.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• Ciguatera fish poisoning due to consumption of tropical marine finfish which have bioaccumulated naturally-occurring ciguatera toxins through their diet</li> <li>• Scombroid fish poisoning due to consumption of fish containing elevated levels of histamine. (However, if there is environmental or traceback evidence of temperature abuse, then please also identify P4 or P5, as appropriate, in addition to C1.)</li> <li>• Mushroom poisoning due to consumption of toxic mushrooms</li> </ul> | C1                       | <p><b>Toxic substance part of the tissue (e.g., ciguatera):</b> A natural toxin found in a plant or animal, or in some parts of a plant, animal, or fungus; OR a chemical agent of biologic origin that occurs naturally in the vehicle or bioaccumulates in the vehicle prior to or soon after harvest.</p> <p>Common examples of this type of contributing factor include ciguatera fish poisoning due to consumption of marine finfish or mushroom poisoning due to consumption of toxic mushrooms.</p> |
| C2                           | <p><b>Poisonous substance or infectious agent intentionally added to food to cause illness (does not include injury)</b></p> <p><b>Description</b><br/>A poisonous substance, chemical agent, or infectious agent was intentionally/deliberately added to the</p>   | C2                       | <p><b>Poisonous substance intentionally/deliberately added (e.g., cyanide or phenolphthalein added to cause illness):</b> A poisonous substance intentionally or deliberately added to a food in quantities sufficient to cause serious illness. Poisons</p>   |



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|    | <p>food in quantities sufficient to cause illness. Poisons added because of sabotage, mischievous acts, and attempts to cause panic or for blackmail fall into this category. This CF does not apply to physical objects (such as a sharp object) intentionally added to food to cause injury.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• Cyanide or phenolphthalein deliberately added to food to cause illness</li> <li>• Methomyl pesticide intentionally added to food to cause illness</li> <li>• <i>Salmonella</i> intentionally added to food to cause illness</li> </ul>  |    | <p>added because of sabotage, mischievous acts, and attempts to cause panic or to blackmail a company fall into this category.</p> <p>This contributing factor only applies to poisonous substances, not to physical substances added to food.</p>   |
| C3 | <p><b>Poisonous substance accidentally/inadvertently added to food</b></p> <p><b>Description</b></p> <p>A poisonous substance or chemical agent was accidentally or inadvertently added to the food. This addition typically occurs at the time of preparation or packaging of the food. Misreading labels, resulting in either mistaking poisonous substances for foods or incorporating them into food mixtures, would also fall into this category.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• Sanitizer or cleaning compound accidentally added to food</li> <li>• Metallic ingredient accidentally added to food (e.g., copper in cake icing)</li> </ul> | C3 | <p><b>Poisonous substance accidentally/inadvertently added (e.g., sanitizer or cleaning compound):</b> A poisonous substance or chemical agent accidentally/inadvertently added to the vehicle. This addition typically occurs at the time of preparation or packaging of the vehicle.</p> <p>Examples of this type of contributing factor include sanitizer or cleaning compound added to food or chemicals that reach foods from spillage or indiscriminate spraying. Misreading labels, resulting in either mistaking poisonous substances for foods or incorporating them into food mixtures, also falls into this category.</p> |
| C4 | <p><b>Ingredients toxic in large amounts accidentally added to food</b></p> <p><b>Description</b></p> <p>An approved ingredient was accidentally added in excessive quantities to the food so as to make the food unacceptable for consumption.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• Excessive amount of niacin in bread</li> <li>• Excessive amount of nitrites in cured meat</li> <li>• Excessive amount of ginger powder in gingersnaps</li> </ul>   | C4 | <p><b>Addition of excessive quantities of ingredients that are toxic in large amounts (e.g., niacin poisoning in bread):</b> An approved ingredient in a food but accidentally added in excessive quantities so as to make the food unacceptable for consumption.</p> <p>Examples of this type of contributing factor include excessive amounts of nitrites in cured meat or excessive amounts of ginger powder in gingersnaps.</p>  |
| C5 | <p><b>Container or equipment used to hold or convey food was made with toxic substances</b></p> <p><b>Description</b></p> <p>The container that held or conveyed the implicated food is made of toxic substances. The toxic substance either migrates into the food or leaches into the food through contact with highly acidic foods.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• Galvanized container used to store acidic food/beverage</li> <li>• Flour stored in a container that previously held toxic materials</li> <li>• Pre-made ice stored in a toxic container</li> </ul>  | C5 | <p><b>Toxic container (e.g., galvanized containers with acid foods):</b> Container or pipe holding or conveying the implicated food is made of toxic substances. The toxic substance either migrates into the food or leaches into solution by contact with highly acid foods.</p> <p>One example of this type of contributing factor is a toxic metal (e.g., zinc coated) container used to store highly acidic foods.</p> <p>For this contributing factor, there may be confusion between foodborne outbreaks and</p>  |

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|    | <p><b>Notable Exceptions</b></p> <p>This factor should not be confused with contamination resulting in a waterborne outbreak, rather than foodborne. Waterborne outbreaks generally include contamination occurring in the source water or in the treatment or distribution of water to the end consumer. For example, in drink mix/soda machines, if the water enters a contaminated machine or if there is a problem with the internal plumbing of the machine resulting in contamination (e.g., cross-connections, backflow of carbonated water resulting in copper leaching), this is a waterborne outbreak. For ice, if ice is made with contaminated water, it is also a waterborne outbreak. However, if ice is already made and then it becomes contaminated because it was previously stored in a container made with toxic substances, it is a foodborne outbreak and it would be appropriate to list C5 as a CF. For more examples and details differentiating between foodborne and waterborne outbreaks, please see NORS <a href="#">Appendix A</a>.</p> | <p>waterborne outbreaks. If the outbreak is waterborne, the contributing factors should be listed in the waterborne section, not in this foodborne section. In general, waterborne disease includes contamination occurring in the source water or in the treatment or distribution of water to the end consumer. For example,</p> <ul style="list-style-type: none"> <li>• If water enters a contaminated drink mix/soda machine or if there is a problem with the internal plumbing of the machine resulting in contamination (e.g., cross-connections, backflow of carbonated water resulting in copper leaching)—it's waterborne and should not be entered in the foodborne section.</li> <li>• If ice is made with contaminated water—it's waterborne and should not be entered in the foodborne section.</li> <li>• If ice is already made and then it becomes contaminated because it was stored in a toxic container—it is a foodborne outbreak and it would be appropriate to list C5 as a contributing factor.</li> </ul>  |
| C6 | <p><b>Food contaminated by animal or environmental source at point of final preparation/sale</b></p> <p><b>Description</b></p> <p>The food was contaminated at <u>point of final preparation/sale</u> (e.g., restaurant, private home, etc.) by animal or environmental source(s), such as from dripping, flooding, airborne contamination, access of insects or rodents, and other situations conducive to contamination.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• Mouse feces in pantry contaminates food</li> <li>• A leaky roof permits water to seep into a walk-in refrigerator and contaminates stored food</li> </ul>  | <p><b>C6 Contaminated raw product—food was intended to be consumed after a kill step:</b> The vehicle or a component of the vehicle contained the agent when it arrived at the point of final preparation or service. This contributing factor applies to foods intended to be consumed after undergoing a kill step (such as cooking to the required temperature), but the food processing step was insufficient to lower the levels of the pathogen below an infectious dose.</p> <p>Examples of this type of contributing factor include a hamburger that was ordered well-done or medium-well but subsequently undercooked when it arrived at final preparation or raw chicken that was contaminated with Salmonella, which was then unintentionally undercooked.</p> <p>Note: Lab confirmation or a formal trace back can support or confirm the identification of this contributing factor (i.e., a trace back identifies a flock, herd, or farm as the source of the pathogen). If lab results are available or if a trace back was conducted, please complete the lab confirmation and/or the trace back sections (as appropriate) in the NORS report for this outbreak.</p> |

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| C7 | <p><b>Food contaminated by animal or environmental source <u>before arriving at point of final preparation</u> (pre or post-harvest)</b></p> <p><b>Description</b><br/>The food was contaminated before arriving at the point of final preparation by animal or environmental sources, either <u>pre-harvest</u> (e.g., growing field, harvest area, irrigation water, etc.) or <u>post-harvest</u> (e.g., processing or distribution facility, in warehouse storage, during transit, etc.).</p> <p>Note: Traceback may implicate the identification of where the food was contaminated (pre-harvest versus post-harvest). If identified, please indicate this in the Point of Contamination question in the NORS interface; otherwise, please select “before point of final/preparation/sale: unknown”.</p> <p><b>Examples</b></p> <p><b>Pre-Harvest:</b></p> <ul style="list-style-type: none"> <li>• Shellfish from sewage polluted waters or closed beds</li> <li>• Crops watered by contaminated irrigation water</li> <li>• Produce grown in soil contaminated by geese</li> <li>• Live poultry contaminated with <i>Campylobacter</i> then slaughtered and poultry distributed to retailers</li> <li>• Eggs contaminated with <i>Salmonella</i></li> </ul> <p><b>Post-Harvest:</b></p> <ul style="list-style-type: none"> <li>• Peanut butter contaminated by bird droppings in a processing plant</li> <li>• Cheese contaminated with <i>Listeria</i> in a cheese manufacturer plant</li> </ul> | C7 | <p><b>Contaminated raw product—food was intended to be consumed raw or undercooked/ underprocessed (e.g., raw shellfish, produce, eggs):</b> Contaminated products are ingested raw without being first subjected to a cooking step or another form of a kill step sufficient to kill any pathogens present. This contributing factor applies to foods intended to be consumed raw, as well as foods intended to be consumed after mild heating or another process that does not ensure pathogen destruction. Mild heating means heated to time-temperature exposures insufficient to kill vegetative forms of pathogenic bacteria or denature proteins.</p> <p>Examples of this type of contributing factor include mildly heated hollandaise sauce containing raw egg yolk, a hamburger or steak ordered to be prepared rare, raw milk, raw oysters or other shellfish, raw produce, or unpasteurized cider or juices.</p> |
| C8 | <p><b>Cross-contamination of foods, excluding infectious food workers/handlers</b></p> <p><b>Description</b><br/>The pathogen was transferred to the food source from contaminated surfaces, foods, and/or fomites to include, but not limited to, food worker’s hands, cutting boards, preparation tables, utensils, processing lines, etc.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• A ready-to-eat (RTE) food was prepared on the same cutting board as contaminated raw poultry</li> <li>• A food worker handled contaminated raw foods without subsequently washing their hands, and afterward handled an RTE food</li> <li>• Materials used to clean equipment (e.g., cloths, sponges, etc.) that processed contaminated raw foods were subsequently used on surfaces that came in contact with RTE foods without first being disinfected</li> </ul>  | C9 | <p><b>Cross-contamination of ingredients (does not include ill food workers):</b> Pathogen transferred to the vehicle by contact with contaminated worker hands, equipment, or utensils or by drippage or spillage. If worker hands were the mode of contamination, the worker was not infected with or a carrier of the pathogen.</p> <p>Examples of this type of contributing factor include</p> <ul style="list-style-type: none"> <li>• Contaminated raw poultry was prepared on a cutting board; later, a ready-to-eat food was cross-contaminated because it was prepared on this same cutting board without intervening cleaning.</li> <li>• A worker’s hands became contaminated by raw foods; subsequently, a ready-to-eat food was cross-contaminated because the worker’s hands touched this ready-to-eat</li> </ul>  |

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|     | <ul style="list-style-type: none"> <li>Contaminated raw foods touched or dripped onto foods that were not subsequently cooked</li> <li>Contaminated raw foods were processed on shared lines with non-contaminated food items</li> </ul> <p><b>Notable Exceptions</b><br/>This CF only applies to foods that are cross-contaminated by other food or fomites, and <u>not</u> by an infectious food worker/handler (please indicate C9 instead).</p>  | <p>food without intervening handwashing.</p> <ul style="list-style-type: none"> <li>Cloths, sponges, and other cleaning aids were used to clean equipment that processed contaminated raw foods. Before their next use, these cleaning items were not disinfected; instead, these cleaning items are used to wipe surfaces that come in contact with foods that are not subsequently heated.</li> <li>Contaminated raw foods touch or fluids from them drip onto foods that are not subsequently cooked.</li> </ul> <p>This contributing factor only applies to foods that are cross-contaminated by other ingredients. If food contamination was the direct result of the storage environment, it should be cited in C14.</p> |   |
| C9  | <p><b>Contamination from infectious food worker/handler through <u>bare hand</u> contact with food</b></p> <p><b>Description</b><br/>A food worker/handler, who is suspected or confirmed to be infectious, used their <u>bare hands</u> to touch/prepare foods that are not subsequently cooked. If it is unknown whether the food worker was wearing gloves or not, then cite C11. If there is evidence for both bare hand contact and glove-hand contact with the food, both C9 and C10 should be cited.</p> <p>This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.</p> <p>Potential reasons to suspect or confirm that a food worker is “infectious” — an all-inclusive term used to describe all persons who are colonized by, infected with, a carrier of, or ill due to a pathogen:</p> <ol style="list-style-type: none"> <li>They recently displayed or admitted to common enteric disease symptoms (e.g., diarrhea, vomiting, nausea, fever) that may be similar to symptoms identified in those who are ill in the outbreak investigation</li> <li>Their household member exhibited similar symptoms directly preceding the outbreak</li> <li>They tested positive for an enteric pathogen</li> <li>Other epidemiologic or environmental evidence.</li> </ol> <p><b>Example</b></p> <ul style="list-style-type: none"> <li>An infectious food worker/handler preparing deli meat without wearing gloves contaminated the food served to restaurant patrons</li> </ul> | C10  | <p><b>Bare-hand contact by a food handler/worker/preparer who is suspected to be infectious (e.g., with ready-to-eat-food):</b> A food worker suspected to be infectious uses his or her bare hands to touch or prepare foods that are not subsequently cooked. The term “infectious” is an all-inclusive term used to describe all persons who are colonized by, infected with, a carrier of, or ill due to a pathogen. This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.</p> <ul style="list-style-type: none"> <li>Only cite C10 if there is evidence of bare-hand contact of an implicated food item. If there is no evidence of bare-hand contact or it is unknown whether the food worker was wearing gloves or not, cite C12 instead.</li> </ul> |
| C10 | <p><b>Contamination from infectious food worker/handler through <u>glove-hand</u> contact with food</b></p> <p><b>Description</b><br/>A food worker/handler, who is suspected or</p>   | C11  | <p><b>Glove-hand contact by a food handler/worker/preparer who is suspected to be infectious (e.g., with ready-to-eat-food):</b> A food worker suspected to be infectious uses his</p>  |

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|     | <p>confirmed to be infectious, used their <u>glove-hands</u> to touch/prepare foods that were not subsequently cooked. If it is unknown whether the food worker was wearing gloves or not, then cite C11. If there is evidence for both bare hand contact and glove-hand contact with the food, both C9 and C10 should be cited.</p> <p>This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.</p> <p>See C9 for a further description of reasons to suspect or confirm an infectious food worker/handler.</p> <p><b>Example</b></p> <ul style="list-style-type: none"> <li>An infectious food worker/handler prepared deli meat while wearing gloves that were not changed after coughing into their hand, which contaminated the food served to restaurant patrons</li> </ul>   |     | <p>or her gloved hands to touch or prepare foods that are not subsequently cooked. The term “infectious” is an all-inclusive term used to describe all persons who are colonized by, infected with, a carrier of, or ill due to a pathogen. This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.</p> <p>Only cite C11 if there is evidence of glove-hand contact of an implicated food item. If there is no evidence of glove-hand contact or it is unknown whether the food worker was wearing gloves or not, cite C12 instead.</p>  |
| C11 | <p><b>Contamination from infectious food worker/handler through unknown type of hand contact with food or indirect contact with food</b></p> <p><b>Description</b></p> <p>A food worker/handler, who is suspected or confirmed to be infectious, used their hands to touch/prepare foods that were not subsequently cooked, but the epidemiologic/environmental investigation was unable to determine whether or not the food worker was wearing gloves during food preparation.</p> <p>-OR-</p> <p>A food worker/handler, who is suspected or confirmed to be infectious, contaminated the food indirectly (no direct bare-hand or glove-hand contact with the food).</p> <p>This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.</p> <p>See C9 for a further description of reasons to suspect an infectious food worker/handler.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>An infectious food worker/handler prepared deli meat, though it was unknown if gloves were worn, contaminated the food served to restaurant patrons</li> <li>An infectious food worker/handler contaminated utensils that subsequently contaminated food served to restaurant patrons.</li> </ul> | C12 | <p><b>Other mode of contamination (excluding cross-contamination) by a food handler/worker/preparer who is suspected to be infectious:</b> A food worker suspected to be infectious contaminates the food by another mode of contamination other than bare-hand contact or glove-hand contact, or an epidemiological/environmental investigation determines that an infectious food worker contaminates food with his or her hands but the investigation is unable to determine whether or not the food worker was wearing gloves during food preparation. This contaminated food is subsequently not cooked.</p> <ul style="list-style-type: none"> <li>Epidemiological or environmental investigation determines that an infectious food worker contaminates food with his/her hands but is unable to determine whether or not actual bare-hand contact or glove-hand contact contaminated the food. In norovirus outbreaks, an ill food worker’s aerosolized vomitus contaminates ready-to-eat food.</li> </ul> |
| C12 | <p><b>Contamination from infectious non-food worker/handler through direct or indirect contact with food</b></p> <p><b>Description</b></p>   | C13 | <p><b>Foods contaminated by non-food handler/worker/preparer who is suspected to be infectious:</b> A person other than a food handler/worker/preparer suspected to be</p>   |

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|     | <p>A person other than a food handler/worker who is suspected or confirmed to be infectious, contaminated ready-to-eat foods that were later consumed by other persons, resulting in spread of the illness. A “non-food handler/worker” is considered to be any person who is not directly involved in the handling or preparation of the food before service.</p> <p>Potential reasons to suspect or confirm that a non-food worker is “infectious” — an all-inclusive term used to describe all persons who are colonized by, infected with, a carrier of, or ill due to a pathogen:</p> <ol style="list-style-type: none"> <li>They recently displayed or admitted to common enteric disease symptoms (e.g., diarrhea, vomiting, nausea, fever, etc.) that may be similar to symptoms identified in those who are ill in the outbreak investigation</li> <li>Their household member exhibited similar symptoms directly preceding the outbreak</li> <li>They tested positive for an enteric pathogen</li> <li>Other epidemiologic or environmental evidence.</li> </ol> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>An ill person attended an event and contaminated ready-to eat-foods in a buffet line by handling food before someone else consumed it.</li> <li>Pizza was prepared by a healthy food worker and arrived pathogen-free. An ill non-food worker, such as a mother, rearranged pizza slices onto plates before serving the slices to a group of children at a birthday party, and these children subsequently developed foodborne illness.</li> <li>An infectious non-food worker/handler contaminated utensils that subsequently contaminated food at a potluck.</li> </ul> <p><b>Notable Exceptions</b></p> <p>This factor should not be confused with contamination from person-to-person, rather than foodborne. For person-to-person outbreaks, there would be no association with any particular food(s).</p> | <p>infectious contaminates ready-to-eat foods that are later consumed by other persons, resulting in spread of the illness. A non-food handler/worker/preparer is any person not directly involved in the handling or preparation of food before service. This is a typical situation when an ill person attends an event and contaminates ready-to eat-foods in a buffet line by handling food before someone else consumes it. The original ill person is identified as a source of the pathogen.</p> <p>One example of this type of contributing factor is a when healthy food worker prepares pizza, which arrives pathogen-free. A mother (a non-food worker) rearranges pizza slices onto plates before serving the slices to a group of children at a birthday party (regardless of setting—it could be at a home or a restaurant). These children subsequently develop foodborne illness and the mother is identified as a source of the pathogen.</p> |
| C13 | <p><b>Other source of contamination (specify)</b></p> <p><b>Description</b></p> <p>A form of contamination that does not fit into the above categories.</p>   | <p>C15 <b>Other source of contamination (please describe):</b> A form of contamination that does not fit into the above categories; specify the factor in the Remarks section of the report and/or in related text. Physical substances added intentionally or deliberately also fall into this category. Objects can get into food either from lack of removal of seeds or other hard particles or from objects in the soil.</p> <p>Examples of this contributing factor include glass shards intentionally or deliberately added to food, food in an uncovered bowl</p>  |

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|  |   |     | contaminated by flies, or food being washed or soaked in a food preparation sink that gets contaminated by sewage backflow from the sink's pipes.  |
| --   | --  | C14 | <p><b>Storage in contaminated environment (e.g., storeroom, refrigerator):</b> Storage in a contaminated environment (such as a storeroom or refrigerator) leads to contamination of the food vehicle or an ingredient in the vehicle. This contributing factor only applies to stored foods that were contaminated directly by environmental sources, not contamination by other foods. This usually involves storage of dry foods in an environment where contamination is likely from overhead drippage, flooding, airborne contamination, access of insects or rodents, and other situations conducive to contamination.</p> <p>This contributing factor only applies to food contaminated during storage, not foods contaminated during preparation or service.</p> |
| <b>Proliferation/Amplification Factors</b> |   |     |  |
| P1   | <p><b>Allowing foods to remain out of temperature control for a prolonged period <u>during preparation</u></b><br/> <b>Description</b><br/> During <u>food preparation</u>, food was kept out of temperature control for a prolonged period that allowed pathogenic bacteria and/or fungi to multiply to an amount sufficient to cause illness or to produce toxins if toxigenic.<br/> <b>Examples</b></p> <ul style="list-style-type: none"> <li>Improper thawing (such as allowing frozen food to thaw at room temperature or leaving frozen foods in standing water for prolonged periods) allowed pathogens to multiply</li> <li>Prolonged preparation time (such as prolonging preparation time by preparing too many foods at the same time) allowed pathogens to multiply</li> </ul> | P1  | <p><b>Food preparation practices that support proliferation of pathogens (during food preparation):</b> During food preparation, one or more improper procedures occurred (such as improper or inadequate thawing) that allowed pathogenic bacteria and/or molds to multiply and generate to populations sufficient to cause illness or to elaborate toxins if toxigenic.<br/> Improper thawing (such as allowing frozen food to thaw at room temperature or leaving frozen foods in standing water for prolonged periods) allows pathogens on the surface of the food to multiply and generate. Prolonged preparation time (such as prolonging preparation time by preparing too many foods at the same time) allows pathogens to multiply and generate.</p>            |
| P2   | <p><b>Allowing foods to remain out of temperature control for a prolonged period <u>during food service or display</u></b><br/> <b>Description</b><br/> During <u>food service or display</u>, food was kept out of temperature control for a prolonged period that allowed pathogenic bacteria and/or fungi to multiply to an amount sufficient to cause illness or to produce toxins if toxigenic.<br/> <b>Examples</b></p> <ul style="list-style-type: none"> <li>Left foods out at ambient temperature for a</li> </ul>   | P2  | <p><b>No attempt was made to control the temperature of implicated food or the length of time food was out of temperature control (during food service or display of food):</b> During food service or display of food, no attempt was made to control the temperature of the implicated food or no attempt was made to regulate the length of time food was out of temperature control.</p> <p>Examples of this type of contributing factor</p>   |

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|    | <p>prolonged time at a church supper</p> <ul style="list-style-type: none"> <li>No time or temperature control measures on a buffet line</li> </ul>  |    | <p>include leaving foods out at ambient temperature for a prolonged time at a church supper or no time and temperature control on a buffet line.</p>  |
| -- | --   | P3 | <p><b>Improper adherence of approved plan to use time as a public health control:</b> Food out of temperature control for more than the time allowed under an agreed-upon and preapproved plan by a regulatory agency to use time as a public health control.</p> <p>Examples of this type of contributing factor include</p> <ul style="list-style-type: none"> <li>Foods are placed on a buffet table that is not capable of maintaining proper hot or cold temperatures. The establishment has a plan approved by a regulatory agency to use time as a public health control. The plan allows foods to be displayed for service on the buffet line at ambient temperature, then discarded after 4 hours. However, the food is held on the buffet table for longer than 4 hours (either inadvertently or intentionally).</li> <li>A facility negotiates a plan with a regulatory agency to use time as a public health control. The facility improperly adheres to the plan because some of the dishes that the facility serves are traditionally held and served at room temperature longer than the time allowed in the approved plan.</li> </ul> |
| P3 | <p><b>Inadequate cold holding temperature due to malfunctioning refrigeration equipment</b></p> <p><b>Description</b><br/>Malfunctioning refrigeration equipment caused foods to be held at an inadequate cold holding temperature.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>Walk-in cooler malfunctioned causing inadequate cold holding temperature of food</li> <li>A broken or torn door gasket caused air leakage in a reach-in refrigerator resulting in inadequate cold holding temperature of food</li> </ul> | P4 | <p><b>Improper cold holding due to malfunctioning refrigeration equipment:</b> Malfunctioning refrigeration equipment (such as improperly maintained or adjusted refrigerators) causes foods to be held at an improper cold holding temperature or walk-in cooler malfunction causes elevated temperatures of food.</p> <p>Examples of this type of contributing factor include</p> <ul style="list-style-type: none"> <li>The reach-in (or walk-in) refrigerator unit temperature is not monitored and stays consistently higher than 41°F, causing elevated temperatures of food.</li> <li>A broken or torn door gasket causes air leakage in a reach-in refrigerator and subsequently food remains above 41°F.</li> </ul>  |
| P4 | <p><b>Inadequate cold holding temperature due to an improper practice</b></p> <p><b>Description</b><br/>Inadequate cold holding temperature occurred due to an improper practice.</p>  | P5 | <p><b>Improper cold holding due to an improper procedure or protocol:</b> Improper cold holding temperature because of an improper procedure or protocol (such as an overloaded refrigerator or inadequately iced salad bar).</p>   |



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|    | <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>Overloaded refrigerator resulting in poor air circulation</li> <li>Inadequately iced salad bar</li> <li>Time/Temperature Control for Safety (TCS) foods, such as tuna or egg salad, were stacked above the fill line of the cold holding wells in a deli cold holding unit</li> </ul>  |    | <p>Examples of this type of contributing factor include potentially hazardous foods such as tuna salad or egg salad stacked above the top levels of the cold holding wells in a deli sandwich cold holding unit.</p>   |
| P5 | <p><b>Inadequate hot holding temperature due to malfunctioning equipment</b></p> <p><b>Description</b><br/>Malfunctioning hot-holding equipment caused foods to be held at an inadequate hot holding temperature.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>A steam table or crockpot broke and caused food to be held at inadequate hot holding temperatures</li> </ul>   | P6 | <p><b>Improper hot holding due to malfunctioning equipment:</b> Equipment meant to be used for hot-holding malfunctions and causes foods to be held at an improper hot holding temperature.</p> <p>Examples of this type of contributing factor include a steam table that is improperly maintained or adjusted and causes food to be held at improper hot holding temperatures.</p>   |
| P6 | <p><b>Inadequate hot holding temperature due to an improper practice</b></p> <p><b>Description</b><br/>Inadequate hot holding temperature occurred due to an improper practice.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>A steam table or crockpot was not turned on or properly maintained and caused food to be held at inadequate hot holding temperatures</li> <li>A crockpot being used to heat or reheat food was overloaded and caused food to be held at inadequate hot holding temperatures</li> </ul>   | P7 | <p><b>Improper hot holding due to improper procedure or protocol:</b> Improper hot holding temperature because of an improper procedure or protocol.</p> <p>Examples of this type of contributing factor include</p> <ul style="list-style-type: none"> <li>An inadequate number of Sterno cans are used for holding foods hot in chafing dishes.</li> <li>Exhausted Sterno cans are not replaced under chafing dishes that hold hot foods.</li> <li>Steam table was not turned on.</li> </ul>   |
| P7 | <p><b>Improper cooling of food</b></p> <p><b>Description</b><br/>Foods were refrigerated in large quantities or stored in devices where the temperature was poorly controlled and allowed pathogens to multiply.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>Foods were refrigerated in large masses or as large volumes of foods in containers, which did not allow proper cooling</li> <li>Foods were stored in containers with tight-fitting lids, pans were stacked on top of others, or crowded storage in a refrigerator, all of which led to inadequate air circulation during cooling process</li> </ul> | P8 | <p><b>Improper/slow cooling:</b> Foods refrigerated in large quantities or stored in devices where temperature is poorly controlled allows pathogens to multiply. Improperly cooling foods are those outside of these parameters: Cooling foods from 135°F to 70°F within 2 hours and cooling that food from 70°F to 41°F within the next 4 hours.</p> <p>Examples of this type of contributing factor include</p> <ul style="list-style-type: none"> <li>Foods are refrigerated in large quantities (i.e., in large masses or as large volumes of foods in containers) that do not allow proper cooling.</li> <li>Foods are stored in containers with tight-fitting lids, leading to inadequate air circulation and thus improper cooling.</li> </ul> |
| P8 | <p><b>Extended refrigeration of food for an unsafe amount of time, relative to the food product and pathogen</b></p> <p><b>Description</b></p>   | P9 | <p><b>Prolonged cold storage:</b> This situation is a concern for psychrotrophic pathogenic bacteria (e.g., <i>Listeria monocytogenes</i>, <i>Clostridium botulinum</i> type E, <i>Yersinia enterocolitica</i>,</p>  |

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|     | <p>This situation is a concern for psychrotrophic pathogenic bacteria (e.g., <i>Listeria monocytogenes</i>, <i>Clostridium botulinum</i> type E, <i>Yersinia enterocolitica</i>, <i>Aeromonas hydrophila</i>) that can multiply over sufficient time at ordinary refrigerator temperatures and grow to an amount sufficient to cause illness or produce toxins if toxigenic (e.g., <i>C. botulinum</i>).</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• <i>Listeria</i> growth after refrigeration of deli meat for more than 7 days</li> <li>• Kept containers of commercially prepared foods for several weeks after they were opened</li> </ul>  |     | <p><i>Aeromonas hydrophila</i>) that multiply over sufficient time at ordinary refrigerator temperatures and generate to populations sufficient to cause illness or elaborate toxins if toxigenic (e.g., <i>C. botulinum</i>).</p> <p>Examples of this type of contributing factor include</p> <ul style="list-style-type: none"> <li>• Holding foods prepared in a food-service establishment in cold storage for more than 7 days.</li> <li>• Holding open containers of commercially prepared foods for several weeks.</li> </ul>  |
| P9  | <p><b>Inadequate Reduced Oxygen Packaging (ROP) of food</b></p> <p><b>Description</b></p> <p>Food was sealed using inadequate Reduced Oxygen Packaging (ROP) methods, which provided conditions conducive to growth of anaerobic or facultative bacteria in foods. ROP includes processing and packaging techniques that prevent the entry of oxygen into the container, such as vacuum packaging, modified or controlled atmosphere packaging, cook chill packaging, sous vide packaging, hermetically sealed containers (double seams/glass jar with lid), deep containers from which air is expressed, and products packed in oil.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• Inadequate process applied to vacuum-packed fish</li> <li>• Insufficient process applied to salad in gas-flushed bag</li> <li>• Ineffective hermetically seal on can</li> <li>• Garlic packaged in oil with unsatisfactory process</li> <li>• Lack of controlled atmosphere packaging of beef jerky</li> </ul> | P10 | <p><b>Inadequate modified atmosphere packaging (e.g., vacuum-packed fish, salad in gas-flushed bag):</b> Food stored in a container that provided an anaerobic environment. These factors create conditions conducive to growth of anaerobic or facultative bacteria in foods held in hermetically sealed cans or in packages in which vacuums have been pulled or gases added.</p> <p>All anaerobic bacteria must have a low oxygen reduction potential to initiate growth, but this factor is restricted only to foods that are put into the sealed package or container.</p>   |
| P10 | <p><b>Inadequate non-temperature dependent processes (e.g., acidification, water activity, fermentation) applied to a food to prevent pathogens from multiplying</b></p> <p><b>Description</b></p> <p>Non-temperature-dependent processes (e.g., acidification, water activity, fermentation) failed and allowed pathogens to multiply to an amount sufficient to cause illness. This situation is a concern for growth of preformed heat-stable toxins or bacterial spores (e.g., <i>Clostridium perfringens</i>, <i>Clostridium botulinum</i>, <i>Bacillus cereus</i>, <i>Staphylococcus aureus</i>).</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• Insufficient acidification (low concentration of</li> </ul>  | P11 | <p><b>Inadequate processing (e.g., acidification, water activity, fermentation):</b> Inadequate non-temperature-dependent processes (such as acidification, water activity, fermentation) that do not prevent proliferation of pathogens, which multiply and generate populations sufficient to cause illness.</p> <p>Examples of this type of contributing factor include</p> <ul style="list-style-type: none"> <li>• Insufficient acidification (low concentration of acidic ingredients) in home-canned foods.</li> <li>• Insufficiently low water activity (low concentration of salt) in smoked/salted fish.</li> <li>• Inadequate fermentation (starter culture</li> </ul> |

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|                         | <p>acidic ingredients) in home canned foods</p> <ul style="list-style-type: none"> <li>• Insufficiently low water activity (low concentration of salt) in smoked/salted fish</li> <li>• Inadequate fermentation (starter culture failure or improper fermentation conditions) in processed meat or processed cheese</li> </ul> <p><b>Notable Exceptions</b><br/>Outbreaks caused by pathogenic bacteria, including <i>E. coli</i>, <i>Listeria monocytogenes</i>, and <i>Salmonella</i> species do not usually grow in high-acid food, but may be able to survive for extended periods of time. In these cases, please cite S4.</p>  |     | <p>failure or improper fermentation conditions) in processed meat or processed cheese.</p>  |
| P11                     | <p><b>Other situations that promoted or allowed microbial growth or toxic production (specify)</b><br/><b>Description</b><br/>A factor that promoted growth, proliferation, amplification, or concentration of bacterial agents but that did not fit into any of the other defined categories.</p>   | P12 | <p><b>Other situations that promote or allow microbial growth or toxic production (please describe):</b> A factor that promotes growth, proliferation, amplification, or concentration of etiologic agents but does not fit into any of the other defined categories; the factor should be specified.</p> <p>One examples of this type of contributing factor is a box of tomatoes that was unknowingly contaminated by Salmonella before its arrival at a restaurant. Soon after the delivery, some of the tomatoes were served to customers but these customers did not become ill. Some of the other tomatoes from the box were not served soon after delivery—instead, these tomatoes were allowed to ripen at room temperature for several days, which allowed the Salmonella to amplify. Customers who ate the room-ripened tomatoes became ill. Although allowing intact tomatoes to ripen at room temperature is not a food code violation, this process likely led to bacterial proliferation.</p> |
| <b>Survival Factors</b> |  |     |   |
| S1                      | <p><b>Inadequate time and temperature control during initial cooking/thermal processing of food</b><br/><b>Description</b><br/>The time and temperature during <u>initial cooking/thermal processing</u> (e.g., pasteurizing, blanching, drying, dry roasting, frying, infrared, microwave, oil roasting, steaming) was inadequate to kill or reduce the pathogen population to below an infectious dose. In reference to cooking, but not retorting, it refers to the destruction of vegetative forms of bacteria, viruses, and parasites, but not bacterial spores. If the food under investigation was retorted, then spore-forming bacteria would be included.<br/><b>Examples</b></p> | S1  | <p><b>Insufficient time and/or temperature during cooking/heat processing (e.g., roasted meats/poultry, canned foods, pasteurization):</b><br/>Time/temperature exposure during initial heat processing or cooking inadequate to kill the pathogen under investigation. In reference to cooking, it refers to the destruction of vegetative forms of bacteria, viruses, and parasites, but not bacterial spores. If the food under investigation was retorted, then spore-forming bacteria would be included.</p> <p>S1 does not include inactivation of preformed heat-stable toxins or destruction of bacterial spores during cooking.</p>  |

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|    | <ul style="list-style-type: none"> <li>Inadequate cooking of meats/poultry before service</li> <li>Inadequate pasteurization of milk</li> </ul> <p><b>Notable Exceptions</b></p> <ul style="list-style-type: none"> <li>Citation of S1 does not include inactivation of preformed heat-stable toxins or destruction of bacterial spores, such as <i>Clostridium botulinum</i>, unless the food underwent a retort process. If this retort process was determined to be inadequate to kill the pathogen, please cite S1. Otherwise, please cite the appropriate proliferation factor.</li> </ul> <p>Norovirus in food cannot be inactivated by moderate heat treatments, such as pasteurization. However, it can be effectively inactivated with cooking or other heat processes, such as roasting.</p>  |    |  |
| S2 | <p><b>Inadequate time and temperature during reheating of food</b></p> <p><b>Description</b><br/>The time and temperature during <u>reheating or heat processing of a previously cooked food</u> (which may have been cooled overnight) was inadequate to kill or reduce the pathogen population to below an infectious dose.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>Reheating of sauces or roasts to a temperature insufficient to reduce the level of contamination to below an infectious dose</li> </ul> <p><b>Notable Exceptions</b><br/>Citation of S2 does not include inactivation of preformed heat-stable toxins, such as <i>Bacillus cereus</i>. Please cite the appropriate proliferation factor instead.</p>  | S2 | <p><b>Insufficient time and/or temperature during reheating (e.g., sauces, roasts):</b><br/>Time/temperature exposure during reheating or heat processing of a previously cooked or heated food (which has often been cooled overnight) inadequate to kill the pathogens.</p> <p>S2 does not include inactivation of preformed heat-stable toxins.</p>   |
| S3 | <p><b>Inadequate time and temperature control during freezing of food designed for pathogen destruction</b></p> <p><b>Description</b><br/>The time and temperature during <u>freezing</u> was inadequate to kill or reduce the pathogen population to below an infectious dose. A freezing process may be used in order to ensure the destruction of certain parasites before raw service of some foods, such as fish.</p> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>Pacific red snapper was not sufficiently frozen before served in raw sushi, or an investigation revealed that the time and temperature requirements to kill parasites were not achieved.</li> </ul> <p><b>Notable Exceptions</b></p> <ul style="list-style-type: none"> <li>Some species of tuna do not harbor parasites of concern and thus freezing is not necessary. Care should be taken in determining if freezing would have been an appropriate pathogen destruction</li> </ul> | S3 | <p><b>Insufficient time and/or temperature control during freezing:</b> Insufficient time and/or temperature control during freezing of foods such as fish, which may be frozen before raw service.</p> <p>One example of this type of contributing factor is when there is insufficient time and/or temperature control during freezing: Pacific red snapper is the implicated food in an outbreak of Anisakis infection. The snapper was not frozen before service in raw sushi or the investigation revealed that the time and temperature required to kill parasites (-31°F for 15 hours or 4°F for 7 days) was not used.</p> <p>Freezing is currently used for parasite destruction in fish served raw. In the future if it is determined that freezing can be used for</p> |

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|    | <p>process for the fish in question before this factor is cited.</p> <p>Norovirus in food cannot be inactivated by freezing.</p>   |    | <p>pathogen destruction in other situations, this factor would be cited if established procedures are not implemented or are implemented incorrectly. Some species of tuna are not susceptible to harboring parasites of concern, so freezing is not necessary.</p> <p>Care should be taken in determining if freezing would have been an appropriate pathogen destruction process for the fish in question before citing S3.</p>  |
| S4 | <p><b>Inadequate non-temperature dependent processes (e.g., acidification, water activity, fermentation) applied to a food to prevent pathogens from surviving</b></p> <p><b>Description</b></p> <p>Non-temperature depending processes (e.g., acidification, water activity, fermentation) designed to kill or reduce the pathogen population to below an infectious dose were inadequate or improperly used, allowing pathogens to survive. This situation is more of a concern for pathogenic bacteria with low infectious doses, making pathogen survival more often the cause for illness rather than pathogen proliferation.</p> <p>Please note:</p> <ol style="list-style-type: none"> <li>1) Though chemicals may be added to foods to inhibit bacterial growth, at normal levels of use, most chemicals cause inhibition rather inactivation.</li> <li>2) Though pH is considered primarily a means of growth inhibition and not a method of destruction of existing pathogens, at low pH values, many bacterial pathogens will be destroyed if held at that pH for a significant amount of time, even if their growth is already inhibited. If the acidification procedures are inadequate, pathogenic bacteria can survive. <i>E. coli</i> O157:H7 and <i>Listeria monocytogenes</i>, in particular, are able to survive acidic conditions.</li> </ol> <p><b>Examples</b></p> <ul style="list-style-type: none"> <li>• Inadequate acidification of seafood when preparing ceviche, allowing for pathogen survival</li> <li>• Inadequate acidification of unpasteurized juice, in which the inappropriately high pH allowed survival of <i>E. coli</i></li> <li>• Inadequate salting of fresh water fish, allowing for parasite survival</li> <li>• Inadequate fermentation of sauerkraut, allowing for survival of <i>Listeria monocytogenes</i></li> <li>• Inadequate chlorine concentration used for</li> </ul> | S4 | <p><b>Insufficient or improper use of chemical processes designed for pathogen destruction:</b></p> <p>Insufficient or improperly used chemical processes (such as acidification, salting, and cold smoking) allow pathogens to survive.</p> <p>Examples of this type of contributing factor include</p> <ul style="list-style-type: none"> <li>• Inadequate acidification (such as insufficient quantity or concentration of acid) of canned tomatoes results in pathogen survival.</li> <li>• Inadequate cold smoking of meat (such as insufficient time of contact of the smoke with the meat) results in pathogen survival.</li> </ul> |

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|    | washing lettuce, allowing for survival of <i>E. coli</i> .<br><b>Notable Exceptions</b><br>Norovirus in food cannot be inactivated by acidification.  |    |   |
| S5 | <b>No attempt was made to inactivate the contaminant through initial cooking/thermal processing, freezing, or chemical processes</b><br><b>Description</b><br>No attempt was made to inactivate the contaminant through initial cooking/thermal processing, freezing, or chemical processes.<br><b>Examples</b> <ul style="list-style-type: none"> <li>• Unpasteurized milk or cider</li> <li>• Oysters served raw</li> </ul> | -- | --  |
| S6 | <b>Other process failures that permit pathogen survival (specify)</b><br><br><b>Description</b><br>A form of survival that does not fit into the above categories.  | S5 | <b>Other process failures that permit the agent to survive (please describe):</b> Other forms of survival. A form of survival that does not fit into the above categories; the factor should be specified. Failures of other processes (such as subjecting foods to irradiation, high pressure, drying conditions) that then permits pathogens to survive. Specify the survival factor. |

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| <b>Att6 NEARS Data Recording (paper form) (revisions)</b>   |                          |  |                           |
| <b>Part II- Establishment characterization, categorization, and menu review:</b>  |                          |  |                           |
| 14. What is the most recent CDC/ATSDR SVI overall score for establishment's census tract (based on the establishment's street address)? Go to: <a href="https://svi.cdc.gov/map.html">https://svi.cdc.gov/map.html</a> .  |                          | SVI Score: _____<br><br>(Possible scores range from <b>0</b> (lowest vulnerability) to <b>1</b> (highest vulnerability). |                           |
| <b>Part VII—Contributing factors:</b> Complete this section for EACH contributing factor identified in this outbreak. Contributing factors are defined in the Definitions of Factors Contributing to Outbreaks section of the <i>NEARS Instruction Manual</i> . |                          |  |                           |
| Contributing factor #:  |                          |  |                           |
| 1. Which contributing factor was identified?  | <input type="radio"/> C1 | <input type="radio"/> P1   | <input type="radio"/> S1  |
|   | <input type="radio"/> C2 | <input type="radio"/> P2   | <input type="radio"/> S2  |
|   | <input type="radio"/> C3 | <input type="radio"/> P3   | <input type="radio"/> S3  |
|   | <input type="radio"/> C4 | <input type="radio"/> P4   | <input type="radio"/> S4  |
|   | <input type="radio"/> C5 | <input type="radio"/> P5   | <input type="radio"/> S54 |

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|  | o C6  | o P6  | o S65 |
|  | o C7  | o P7  |       |
|  | o C8  | o P8  |       |
|  | o C9  | o P9  |       |
|  | o C10 | o P10 |       |
|  | o C11 | o P11 |       |
|  | o C12 | o P12 |       |
|  | o C13 |       |       |

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

Based on our experience over the past six years, we anticipate an increase of 10 reporting sites from 34 to 44 registered food safety programs. Therefore, we have added one hour for new NEARS registrations to the annual time burden estimate. We also estimate that each site will report up to seven outbreaks each year. The total estimated annual burden for this information collection is 1,371 hours. This reflects an increase in time burden of 21 hours over the previously approved 1,350 hours. The total number of respondents is 1,951 per year. This reflects an increase of 51 respondents over the previously approved 1,900 respondents.

## 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         |
|---|--------------------|
| 9 <sup>th</sup> year (2022) data collection                   | 2022               |
| 9 <sup>th</sup> year (2022) data verification and correction  | completed May 2023 |
| 10 <sup>th</sup> year (2023) data collection                  | 2023               |
| 10 <sup>th</sup> year (2023) data verification and correction | completed May 2024 |
| 11 <sup>th</sup> year (2024) data collection                  | 2024               |
| 11 <sup>th</sup> year (2024) verification and correction      | completed May 2025 |

|  |                    |
|--|--------------------|
| 12 <sup>th</sup> year (2025) data collection   | 2025               |
| 12 <sup>th</sup> year (2025) data verification and correction                                      | completed May 2026 |
| <b>Activity- Data analysis and publication</b>   |                    |
| 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 |
| 10 <sup>th</sup> year (2023) data analysis and annual report                                       | completed Dec.2026 |
| 11 <sup>th</sup> year (2024) data analysis and annual report                                       | completed Dec.2027 |
| 12 <sup>th</sup> year (2025) data analysis and annual report                                       | completed Dec.2028 |
| 10 <sup>th</sup> -12 <sup>th</sup> year (2023-2025) aggregate data analysis and report publication | completed Dec.2029 |

## B. Publication plan

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

- Operational Antecedents Associated with *Clostridium perfringens* Outbreaks in Retail Food Establishments, United States, 2015-2018 (2022) *Foodborne Pathogens and Disease*
- Retail Establishment Policies and Practices Related to Norovirus Outbreak Size and Duration (2020) *J Food Protection*
- 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, 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**

- 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.
- Hoover ER, Hedeem N, Freeland A, Kambhampati A, Dewey-Mattia D, Scott KW, Hall A, Brown L. Restaurant Policies and Practices Related to Norovirus Outbreak Size and Duration. *J Food Prot.* 2020 Sep 1;83(9):1607-1618
- 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.