

Supporting Statement A

**National Voluntary Environmental Assessment Information System (NVEAIS)**

**NEW**

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**Laura Brown, Ph.D.**  
**Centers for Disease Control and Prevention**  
**National Center for Environmental Health**  
**Emergency and Environmental Health Services**  
**Environmental Health Services Branch**  
**4770 Buford Highway, NE F – 58**  
**Atlanta, GA 30341-3724**  
**lrg0@cdc.gov**  
**770-488-4332**

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## **National Voluntary Environmental Assessment Information System (NVEAIS)**

### **A. Justification**

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

##### **Background**

Foodborne illness is a significant problem in the U.S.--an estimated 47.8 million foodborne illnesses occur annually in the United States, resulting in 127,839 hospitalizations, and 3,037 deaths annually (Scallan, Hoekstra et al., 2011; Scallan, Griffin et al., 2011). Many of these illnesses result from foodborne illness outbreaks- an average of 1,329 foodborne illness outbreaks occur in the United States every year (Lynch, Painter, Woodruff and Braden, 2006).

Reducing the number of outbreaks requires identification and understanding of the etiology of outbreaks. We need to know the pathogen, food, and the pattern of illness associated with each outbreak. We also need to identify the environmental factors associated with each outbreak; in other words, we need to know how and why the food became contaminated with pathogens and how and why these pathogens were not eliminated before ingestion. This information can then be used to develop effective foodborne illness outbreak response and preventative controls.

As part of their public health practice, local, state, territorial, and tribal public health personnel conduct foodborne illness outbreak investigations for the purpose of identifying and understanding the etiology and environmental factors associated with outbreaks. These investigations are multi-pronged, and often involve multiple data collection activities and multi-disciplinary teams. For example, epidemiologists in epidemiology or communicable disease control programs (hereafter referred to as epidemiology programs) working on these investigations will focus on identifying the pathogen, food, and pattern of illness associated with the outbreak. To do this, they interview persons who may be associated with the outbreak to determine if they are ill, what their symptoms were, and what and where they ate. They will also take stool samples to identify the pathogen that caused the outbreak.

Environmental health specialists in environmental health or food safety programs (hereafter referred to as food safety programs) also typically conduct foodborne illness outbreak investigations, and they focus on identifying the environmental factors associated with the outbreak. They may participate in joint investigations with communicable disease control programs or they may conduct their investigations independently. The investigation process and the level of coordination between communicable disease control programs and food safety programs varies considerably among agencies.

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

environmental assessments, which involve a thorough assessment of the environment in which the outbreak occurred. These assessments typically involve: interviews with food service establishment managers to determine characteristics of the establishment and food safety policies and practices; interviews with food preparers to determine their individual food handling practices, hygiene practices, and other circumstances (e.g., are they ill, do they have any ill family members, etc.); review of records on food source, shipping and handling; and environmental sampling (samples from floors, food preparation equipment, etc.).

The environmental factors identified during these environmental assessment activities include *contributing factors* and *environmental antecedents*. A contributing factor is an immediate cause of the outbreak. Based on data from previous outbreaks, FDA and CDC have developed a list of contributing factors and have grouped them into three categories:

- Contamination factors- those associated with contamination of food with foodborne illness pathogens (e.g., a worker with a foodborne illness handles ready-to-eat food bare-handed and contaminates the food with pathogens)
- Proliferation factors- those associated with proliferation of foodborne illness pathogens in food (e.g., cold food is not held at a temperature cold enough to prevent proliferation of pathogens)
- Survival factors- those associated with survival of foodborne illness pathogens in food (e.g., raw meat is not cooked to a temperature hot enough to kill the pathogens with which it is contaminated).

The list of contributing factors, along with definitions, can be found in Attachment 2.

Environmental antecedents are those factors in the environment that led to the contributing factor. For example, a worker may have been handling food when they were ill because no policies or practices were in place that would have allowed management to determine that the worker was ill and prevent the worker from working.

Environmental antecedents are typically classified into 5 categories: economics, equipment, food, people, and process.

- *Economic* environmental antecedents are those associated with the costs and profit margins of food facilities. For example, poor profit margins may contribute to inadequate staffing, training or equipment maintenance.
- *Equipment* environmental antecedents are those associated with the physical layout and equipment of food facilities. For example, poor equipment maintenance can lead to food being stored and cooked at improper temperatures.
- *Food* environmental antecedents are those associated with the inherent qualities of food, such as, pH levels, texture, and viscosity. For example, the texture of leafy greens makes them difficult to clean; the thickness of some foods may require specialized cooling practices for those foods.
- *People* environmental antecedents are those associated with the individuals working in food facilities and the food safety culture in which they work. Examples of people antecedents include workers' cultural background, gender, education, experience, and food safety attitudes. Examples of food safety culture antecedents include management emphasis on food safety and reinforcement of safe food preparation through reward or punishment systems.

- *Process* environmental antecedents are those associated with the characteristics of the processes used to grow, store, prepare, and cook food. For example, the complexity of the food process (i.e., how many steps are involved in the process) is associated with food safety risk.

**Foodborne Illness Outbreak Surveillance.** Epidemiological and clinical data obtained through foodborne illness outbreak investigations conducted by communicable disease control programs, such as the number of ill people associated with individual outbreaks and the pathogen involved, are reported by communicable disease control programs to the National Outbreak Reporting System (NORS). This system is maintained by CDC's National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) under the National Disease Surveillance Program II - Disease Summaries (OMB Control Number: 0920-0004, expiration date August 31, 2014). NORS is a mature surveillance system primarily designed to capture epidemiological and clinical information about outbreaks, and data are typically reported into this system through state epidemiology programs. Very little environmental factor data are reported in this system. The names of contributing factors identified in outbreak investigations are reported, but no details on these contributing factors are reported (e.g., when the factor occurred, how it was identified, etc.), nor is any other information obtained from environmental assessments (e.g., environmental antecedents) reported.

High quality environmental factor data obtained from environmental assessments are essential to improving food safety. These environmental data can be used to support public health regulators' efforts to respond more effectively to foodborne illness outbreaks and to prevent foodborne illness outbreaks--they can be used guide developing implementation and evaluation of foodborne illness prevention and intervention activities. National surveillance data on foodborne illness outbreak environmental factors are needed.

To meet this need, the CDC developed the National Voluntary Environmental Assessment Information System (NVEAIS). Through NVEAIS, detailed national surveillance data on foodborne illness outbreak environmental factors, collected through environmental assessments routinely conducted by food safety programs in response to foodborne illness outbreaks, can be reported to CDC. Data will be reported into this system by those who collected the data--environmental health specialists working in food safety programs. The NVEAIS data reporting instrument was developed by the Environmental Health Specialists Network (EHS-Net), a network of environmental health specialists and epidemiologists from CDC, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and several local and state health departments. The NVEAIS data will be reported through a web-based information system developed by CDC and will provide valuable data on how and why foodborne illness outbreaks occur. Reporting will be voluntary; however, CDC's long-term goal is to establish NVEAIS as the reporting system for foodborne illness outbreak environmental factor data for all food safety programs.

The implementation of NVEAIS will result in two foodborne illness outbreak surveillance systems at CDC--NORS and NVEAIS. NORS will focus on collecting epidemiological and clinical data; NVEAIS will focus on collecting environmental factor data. Both NORS and NVEAIS data are critical to food safety efforts. Although CDC's long-term goal is to have one

foodborne illness outbreak surveillance system that will collect these two sets of data, it is currently not feasible. As indicated earlier, data reported into NORS are typically collected by communicable disease control programs, and data to be reported into NVEAIS are typically collected by food safety programs. In many jurisdictions, the coordination and communication across these two types of programs that would be required to report all foodborne illness surveillance data into one system currently does not exist. CDC will be working to improve coordination and communication between these two types of programs at the local, state, territorial, and tribal level so that we can meet the goal of one foodborne illness outbreak surveillance system. However, this will be a long-term process, and environmental factor data are needed now. The collection of environmental factor data through NVEAIS and efforts to improve coordination and communication across communicable disease control programs and food safety control programs needs to occur simultaneously.

### **National Food Safety Context**

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

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

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

To identify and understand environmental factors associated with foodborne illness outbreaks through improved surveillance, a task essential to decreasing outbreaks, CDC is requesting a three-year approval of NVEAIS. Public health personnel who conduct environmental assessments during foodborne illness outbreak investigations are the respondent group for this data collection and reporting data to NVEAIS will be a voluntary decision made by these personnel.

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

**Other Federal Food Safety Data Collection Efforts.** In 1998, the FDA began its multi-phase Retail Food Risk Factor Study to measure the occurrence of practices and behaviors commonly identified as contributing factors to foodborne illness outbreaks in retail food establishments. These data are collected in retail establishments that are not associated with foodborne illness outbreaks. (Because these data are collected in retail establishments that are not associated with outbreaks, these practices and behaviors are referred to as risk factors rather than contributing factors.) The data from this study allow FDA to identify risk factors most in need of intervention efforts, and to assess trends in the occurrence of these risk factors.

CDC and FDA have discussed how the datasets collected through the Risk Factor Study and NVEAIS can inform and influence one another. Data collected through NVEAIS will identify contributing factors of particular concern (e.g., the most common contributing factors; contributing factors that increase over time); FDA can then ensure that their data collection focuses on those factors. Conversely, data collected through the Risk Factor Study can identify factors that may need to be focused on in NVEAIS.

Additionally, the data collected through these two systems will need to be reviewed and interpreted in light of one another. The Risk Factor Study provides data on practices and behaviors that occur on a normal, day-to-day basis in retail food establishments, while NVEAIS provides data on practices and behaviors that occur in an abnormal situation- a foodborne illness outbreak. To fully understand contributing/risk factors, these two sets of data need to be examined in an integrated fashion.

CDC and FDA will work together to develop a data collection and analysis plan that ensures that the data collected from the Risk Factor Study and NVEAIS will be used in an integrated and coherent fashion. CDC and FDA will work to finalize this plan in 2014. This plan will include joint CDC-FDA periodic reviews of the data collected through the two data collections and joint discussions of how the two data collections may need to be modified in light of review findings.

### **Privacy Impact Assessment**

**Overview of the Data Collection System.** State, local, tribal, and territorial food safety program officials are the primary respondents for this data collection. The data to be reported into this system are currently collected by respondents as part of their routine public health activities. Thus, respondents will be reporting data on the basis of their role as public health officials. This OMB information collection request (ICR) is *not* requiring the collection of these data. Instead, this ICR is requesting that respondents voluntarily report the information collected in their routine public health activities to the CDC.

These routine environmental assessment data collected by food safety program officials will be reported to CDC through a web-based information system. Because these data will be used to identify trends over time, these data will be stored for at least ten years.

The only data collection activity that is not necessarily conducted as part of the food safety program respondents' routine activities is the structured manager interview, conducted with pen and paper. Although food safety program officials typically conduct manager interviews during their environmental assessments, they are not typically structured interviews, as this one is. The respondents to this interview are the retail food managers of the facilities in which the outbreak investigations occur.

NVEAIS is composed of seven data collection parts (Parts I-VII). These parts can be found in Attachment 4, with the exception of Part III, the manager interview, which can be found in Attachment 5. This part of the instrument is listed separately because it poses a burden to retail food managers of outbreak establishments and not just food program personnel, as with the rest of the instrument.

Attachments 4 and 5 contain the Word versions of NVEAIS. These are the documents with which NVEAIS participants will use to collect their data. Attachment 7 contains sample screenshots of the web-based version of NVEAIS, through which NVEAIS data will be entered and transmitted to CDC. This web-based version is currently under development and will be finalized upon receipt of OMB approval.

**Items of Information to be Collected.** This system will collect information obtained from routine environmental assessments conducted during foodborne illness outbreak investigations. A description of the seven parts of NVEAIS can be found below.

- *Part I: General characterization of the outbreak and the outbreak response:* This section collects descriptive data on the outbreak and the outbreak response (e.g., number of locations associated with the outbreak, number of establishments involved, number of environmental assessments conducted, etc.).
- *Part II: Establishment description, categorization and menu review:* This section collects descriptive data on the outbreak response and environmental antecedents (e.g., type of establishment, type of menu, sewage disposal method, source of potable water, etc.).
- *Part III: Manager interview:* This section collects descriptive data on establishments associated with the outbreak, with a focus on environmental antecedents associated with establishment food handling policies and practices and food worker practices (e.g., training, cleaning policies, etc.).
- *Part IV: Establishment observation:* This section collects observation data on environmental antecedents associated with the kitchen environment and food handling practices in establishments associated with the outbreak (e.g., hand sink locations, temperatures of cold storage units, glove use).
- *Part V: Suspected/Confirmed food:* This section collects detailed environmental antecedent data on the foods associated with the outbreak (e.g., form of food- frozen, raw, etc.).
- *Part VI: Sampling:* This section collects any available data on food and environmental sampling to help describe the outbreak.
- *Part VII: Contributing Factors:* This section collects data on a pre-existing list of contributing factors to outbreaks (e.g., contaminated raw product, cross-contamination of ingredients, etc.). As discussed earlier, these contributing factors are organized into three categories: factors associated with pathogen contamination of food/environment, factors



associated with pathogen proliferation in food/environment and factors associated with pathogen survival in food/environment. Attachment 2 lists the specific contributing factors examined.

No IIF will be collected.

**Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age.** Information will be reported through a web-based system. This system is password protected- only people given access to the system by CDC can access it. The system does not contain any content directed at children under 13 years of age.

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

The information reported to NVEAIS will primarily be used by the CDC to identify and understand environmental factors (contributing factors and environmental antecedents) associated with foodborne illness outbreaks. Below is a brief description of the purpose and use of each section of the instrument. The instrument can be found in Attachments 4 and 5.

*Part I: General characterization of the outbreak and the outbreak response:* The purpose of this section is to collect descriptive data on the outbreak and the outbreak response. This information will be used to describe the outbreaks in the data set and connect environmental assessments that were conducted in the same outbreak response. The section will also collect the number assigned to the outbreak when the epidemiological and clinical data were reported into other national surveillance systems, such as NORS. These reporting numbers will be used to link those dataset with NVEAIS data, when appropriate.

*Part II: Establishment description, categorization and menu review:* The purpose of this section is to collect descriptive data on the outbreak response and environmental antecedents associated with the outbreak establishments. Additionally, some of the descriptive variables included in this section can be used to assist in the identification contributing factors. For example, the information collected on whether customers have direct access to food could provide evidence for a determination that contamination of food by a non-food worker was a contributing factor to the outbreak.

*Part III: Manager interview:* The purpose of this section is to collect interview data to describe environmental antecedents associated with outbreak establishments, with a focus on establishment food handling policies and practices and food worker practices (i.e., people and process environmental antecedents).

Although those conducting environmental assessments typically conduct manager interviews that collect information similar to that collected in this manager interview, they are not typically structured interviews. We developed a structured interview to ensure that data were collected systematically on specific important data points related to environmental antecedents. Thus, participating NVEAIS food safety program respondents may conduct their manager interviews slightly differently than they would if they were not participating in NVEAIS. For this reason, and for the purposes of this OMB package, the manager interview is presented as a separate document (Attachment 4) from the NVEAIS data collection instrument.

*Part IV: Establishment observation:* The purpose of this section is to collect observation data to describe environmental antecedents associated with outbreak establishments, with a focus on the kitchen environment and food handling practices in outbreak establishments (i.e., equipment and people environmental antecedents). For example, this section collects information on the equipment environmental antecedents of the number and status of kitchen hand sinks. It also collects information to help identify contributing factors. For example, information collected on whether cold foods are held at appropriate temperatures could provide evidence for a determination that improper cold holding was a contributing factor to the outbreak.

*Part V: Suspected/Confirmed food:* The purpose of this section is to collect detailed environmental antecedent data on the foods associated with the outbreak. These data will also allow us to determine which foods are associated with which environmental factors. Detailed data on foods associated with outbreaks is currently lacking, yet is critical to the development of preventative controls.

*Part VI: Sampling:* In some outbreak investigations, investigators conduct food and environmental sampling; the purpose of this section is to collect these data on food and environmental sampling. These data will provide additional information on the nature of the outbreak. For example, environmental sampling can determine if pathogens are found in the food service environment (e.g., food preparation surfaces and equipment).

*Part VII: Contributing Factors:* The purpose of this section is to collect data on contributing factors to outbreaks. These data will allow us to determine the frequency of each contributing factor, and which foods and environmental antecedents are associated with each contributing factor.

To synthesize, data collected through NVEAIS will be used to:

- *Describe outbreaks and outbreak responses.* NVEAIS will collect 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.* NVEAIS will collect 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.* NVEAIS will collect 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.

The data collected in NVEAIS will be invaluable in determining and understanding the ultimate causes of outbreaks and are critically important to outbreak response and prevention efforts, because they answer the how and why questions about the causes of outbreaks. CDC will use data from NVEAIS to develop specific recommendations for food safety programs responsible for 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 implementation of such policies. Other public health agencies (FDA, USDA, state and local food safety programs, industry) may use the data in this way.

CDC will periodically publish these data through relevant sources. These disseminations will also allow food safety programs, food industries, and academia to access and use the information gained from NVEAIS 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.

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.

### **Generalizability of Results**

Programs that participate in NVEAIS will be expected to report data on all outbreaks occurring in their jurisdictions. Thus, we will not be sampling outbreaks. All food safety programs in the United States will be invited to participate; however, participation is voluntary. 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 NVEAIS.

### **Privacy Impact Assessment**

The information reported in NVEAIS is collected on outbreaks, not respondents. No individually identifiable information on people is being collected.

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

Participating food safety programs will engage in two activities for NVEAIS. First, participating programs will report the data they collect through their environmental assessment activities to CDC through an electronic information system. This eliminates the need to copy data collection forms or to mail or fax forms to CDC. Instead, respondents will enter all their data into a web-based system designed to make data entry easy for respondents. Second, they will conduct a manager interview at establishments associated with outbreaks. They will collect manager answers in paper and pen format, as many food safety programs do not have access to equipment that would allow them to collect data in the field electronically.

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

Through examination of the activities of other organizations, such as FDA, and organizations within CDC, such as NCEZID, we have confirmed that no national, state, or local 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 NVEAIS can be linked when appropriate, NVEAIS will collect information related to whether epidemiological or laboratory information has been reported to other surveillance systems and the reporting numbers associated with those systems for each outbreak.

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

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

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

State, local, tribal, and territorial food safety program officials are the primary respondents for this data collection. As indicated earlier, the foodborne illness outbreak investigation data reported into NVEAIS by these officials is collected as part of routine public health practice. Food safety programs do vary in size; some of them are small, with few staff (estimate: 30%). Reporting to NVEAIS may be difficult for some of these small programs. However, reporting into NVEAIS 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. 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

As indicated earlier, CDC’s current mature foodborne illness outbreak reporting system collects epidemiological and clinical information on outbreaks. However, it does not adequately address questions about the environmental causes of outbreaks. Without a full understanding of the environmental context and causes of outbreaks, it will be difficult to develop effective prevention measures. If this data collection is not conducted, this major gap in overall foodborne illness surveillance will remain, hampering efforts to develop these effective prevention measures. Thus, it would also be difficult for CDC to fully address CDC’s research agenda goal of decreasing health risks from environmental exposures. There are no legal obstacles to reduce the burden.

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

There are no special circumstances for this data collection. It fully complies with 5 CFR 1320.5.

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

- A. The 60-Day *Federal Register* notice was published on August 1, 2012 in Volume 77, Number 148, Pages 45615-45616 (Attachment 2) (citation: 77 FR 45615). We did not receive any comments.
- B. The data collection instrument was developed by EHS-Net, a collaborative network of federal, state, and local epidemiologists and environmental health specialists. This network developed the instrument in 2004 and 2005 and revised and tested it extensively from 2006 through 2009. Federal and state consultants are listed in Table A.8.1.

**Table A.8.1**

| <b>Federal Consultants</b>  |  |  |
|---|--|--|
| <p><b>Jack Guzewich, RS, MPH</b><br/>           Director-Emergency<br/>           Coordination &amp; Response<br/>           U.S. Food and Drug<br/>           Administration<br/>           Center for Food Safety and<br/>           Applied Nutrition<br/>           MS HFS-600 Bld. CPK1<br/>           College Park, MD 20740<br/>           301-436-1608<br/>           john.guzewich@cfsan.fda.gov</p> | <p><b>Morris Potter, DVM</b><br/>           U.S. Food and Drug<br/>           Administration<br/>           60 Eighth Street, NE<br/>           Atlanta, GA 30309<br/>           404-253-1225<br/>           mpotter@cfsan.fda.gov</p> | <p><b>Shirley Bohm</b><br/>           Consumer Safety Officer<br/>           U.S. Food and Drug<br/>           Administration<br/>           Center for Food Safety and<br/>           Applied Nutrition<br/>           5100 Paint Branch Parkway,<br/>           MS HFS-627<br/>           College Park, MD 20740<br/>           301-436-2096<br/>           shirley.bohm@cfsan.fda.gov</p> |

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|---|---|---|
| <p><b>Glenda Lewis</b><br/>Team Leader, Retail Food Protection Team<br/>U.S. Food and Drug Administration<br/>Center for Food Safety and Applied Nutrition<br/>5100 Paint Branch Parkway, MS HFS-627<br/>College Park, MD 20740<br/>(301) 436-1608<br/>glenda.lewis@fda.hhs.gov</p> | <p><b>Moshe Dreyfuss</b><br/>Branch Chief<br/>U.S. Department of Agriculture<br/>Food Safety and Inspection Service<br/>Microbiology Issues Branch<br/>1400 Independence Ave, SW<br/>Room 344 Aerospace Center<br/>Washington, DC 20250<br/>202-690-6379<br/>moshe.dreyfuss@fsis.usda.gov</p> | <p><b>Kristen Holt, DVM</b><br/>Epidemiologist<br/>U.S. Department of Agriculture<br/>Food Safety and Inspection Service<br/>Foodborne Disease Investigations Branch<br/>1924 Building, Suite 3R90A<br/>100 Alabama Street, SW<br/>Atlanta, Georgia 30303<br/>404-562-5936<br/>kristen.holt@fsis.usda.gov</p> |
| <p><b>State Consultants</b></p>   |   |   |
| <p><b>Susan Strong</b><br/>Retail Food Program Specialist<br/>California Department of Health Services, Food and Drug Branch<br/>Sacramento, CA 95899<br/>(916) 650-6617<br/>sstrong1@dhs.ca.gov</p>  | <p><b>Roberta Frick</b><br/>Environmental Health Specialist<br/>Department of Health Services<br/>Food and Drug Branch<br/>850 Marina Bay Parkway, Building P, 1st Floor<br/>Richmond, CA 94804<br/>(510) 620-3482<br/>rfrick@dhs.ca.gov</p>  | <p><b>Dawn Norton</b><br/>Senior Epidemiologist, FoodNet<br/>Connecticut FoodNet<br/>1611 Telegraph Avenue, Suite 1200<br/>Oakland, CA 94612<br/>(510) 625-7974<br/>dnorton@ceip.us</p>   |
| <p><b>Ruthanne Marcus, MPH</b><br/>Epidemiologist<br/>CT FoodNet<br/>1 Church Street 7th Floor<br/>New Haven, CT 06510<br/>203-764-4363<br/>Ruthanne.marcus@yale.edu</p>  | <p><b>Lisa Bushnell</b><br/>Environmental Sanitarian 2<br/>Connecticut Dept of PH<br/>Food Protection Program<br/>Division of Environmental Health<br/>410 Capital Avenue, MS # 11<br/>Hartford, CT 06134<br/>(860) 509-7297<br/>lisa.bushnell@po.state.ct.us</p>                             | <p><b>Nelle Couret</b><br/>Environmental Health Specialist<br/>GA Dept of Human Resources<br/>Division of Public Health<br/>Notifiable Disease Section<br/>2 Peachtree St. NW<br/>Suite 14.267<br/>Atlanta, GA 30303<br/>(404) 657-2588<br/>necouret@dhr.state.ga.us</p>                                      |
| <p><b>Melissa Tobin-D'Angelo, MD</b><br/>State Epidemiologist<br/>GA Department of Human Resources<br/>Division of Public Health<br/>Notifiable Disease Section<br/>2 Peachtree St. NW<br/>Suite 14.267</p>   | <p><b>Tim Wickam, MPH</b><br/>EHS-Net Coordinator<br/>Iowa Dept. of Public Health<br/>Bureau of Environmental Health Services<br/>Division of Environmental Health<br/>321 E. 12th Street</p>   | <p><b>Ken Sharp</b><br/>Iowa Department of Public Health<br/>Division of Environmental Health<br/>Des Moines, IA 50319<br/>(515) 281-7462<br/>ksharp@idph.state.ia.us</p>   |

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| Atlanta, GA 30303<br>404-657-1105<br>mtdangelo@dhr.state.ga.us  | Des Moines, IA 50319<br>515-281-7462<br>twickam@idph.state.ia.us   |   |
| <b>Dave Reimann, RS</b><br>Public Health Sanitarian III<br>MN Dept of Health<br>410 Jackson St. Suite 500<br>Mankato, MN 56001<br>507-389-2203<br>david.reimann@health.state.mn.us  | <b>Kirk Smith, DVM</b><br>State Epidemiologist<br>Minnesota Department of Health<br>625 Robert St N<br>Minneapolis, MN 55164<br>612-676-5414<br>Kirk.smith@state.mn.us                                 | <b>Karen Everstine</b><br>Epidemiologist<br>MN Dept of Health<br>625 Robert St N<br>Minneapolis, MN 55164<br>(651) 201-5746<br>karen.everstine@health.state.mn.us   |
| <b>Steven Diaz</b><br>Environmental Health Specialist<br>Environmental Health Services<br>Snelling Office Park<br>1645 Energy Park Drive<br>St. Paul, MN 55108<br>651-643-2167<br>steven.diaz@state.mn.us   | <b>Dave 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>dcn01@health.state.ny.us                 | <b>Dale Morse</b><br>Office of Science and Public Health NYS Department of Health ESP<br>625 Robert Street North<br>St. Paul, MN 55155<br>(518) 472-4959<br>dlm04@health.state.ny.us                            |
| <b>Paul Cieslak</b><br>Section Manager<br>Acute and Communicable Disease Program, Oregon Public Health Division,<br>Department of Human Services<br>800 NE Oregon Street, Suite 772<br>Portland, OR 97232<br>(971) 673-1111<br>paul.r.cieslak@state.or.us | <b>Lore Lee, MPH</b><br>Epidemiologist<br>Acute and Communicable Disease Program<br>Oregon Health Services<br>800 NE Oregon Street<br>Portland, Oregon 97323<br>503-731-3122<br>Lore.e.lee@state.or.us | <b>Matt Jaqua</b><br>Environmental Health Specialist<br>Oregon Department of Human Services<br>Tower Building, Room 1482<br>Albany, NY 12237<br>971-673-0449<br>Matthew.J.Jaqua@state.or.us                     |
| <b>Ernest Julian</b><br>Director, Environmental Health Program<br>Rhode Island Department of Health<br>Office of Food Protection<br>3 Capitol Hill<br>Providence, RI 02908<br>(401) 222-2749<br>erniej@doh.state.ri.us                                    | <b>Henry Blade</b><br>Rhode Island Department of Health<br>Office of Food Protection<br>3 Capitol Hill<br>Providence, RI 02908<br>(401) 222-7735<br>Henry.Blade@health.ri.gov                          | <b>Rand Carpenter Epidemiologist</b><br>State of Tennessee<br>Department of Health<br>Cordell Hull Bldg. 6th Floor<br>425 5th Ave. North<br>Nashville, TN 37247<br>615-741-6075<br>L.Rand.Carpenter@state.tn.us |

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| <p><b>Danny Ripley</b><br/> Food Safety Investigator<br/> Food Division<br/> Metro Public Health<br/> Department<br/> 311 23rd Ave. North<br/> Nashville, TN 37203<br/> 615-340-2701<br/> danny.ripley@nashville.gov</p> | <p><b>Ryan Mason</b><br/> Environmental Health<br/> Specialist 5<br/> State of Tennessee<br/> Department of Health<br/> Cordell Hull Bldg. 6th Floor<br/> 425 5th Ave. North<br/> Nashville, TN 37247<br/> 615-741-6075<br/> Ryan.mason@state.tn.us</p> | <p><b>Neculai Codru</b><br/> Research Scientist<br/> New York Department of<br/> Health<br/> 547 River Street<br/> Flanigan Square, Room 400<br/> Troy, NY 12180<br/> 518-402-7711<br/> <a href="mailto:nxc09@health.state.ny.us">nxc09@health.state.ny.us</a></p> |
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Since EHS-Net’s inception, we have also consulted with CDC’s NCEZID, which is responsible for NORs. This consultation has included discussions about availability of data, data elements to be recorded, and minimizing duplication. Information on our primary contacts at NCEZID is below.

Dana Cole  
Enteric Diseases Epidemiology Branch  
Centers for Disease Control and Prevention  
1600 Clifton Road  
Atlanta, GA 30329  
404-639-3315

**A.9. Explanation of Any Payment or Gift to Respondents**

There will be no payments or gifts to respondents.

**A.10. Assurance of Confidentiality Provided to Respondents**

Data are being collected on outbreaks, not respondents. The information reported into NVEAIS will be obtained through environmental assessments routinely conducted by local, state, territorial, or tribal environmental health specialists working in food safety programs during foodborne illness outbreak investigations. These outbreak investigations are public health practice. Food safety program personnel participating in NVEAIS will report the data collected through their environmental assessments into NVEAIS. No IIF is being collected. Per the CDC Human Subjects Protection Office policies and procedures, this data collection system is classified as non-research, and does not require human subjects review beyond the National Center level (Attachment 6). Full CDC Institutional Review Board (IRB) review is not required.

**Privacy Impact Assessment Information**

- A. It has been determined that the Privacy Act does not apply. Respondents will not be providing individually identifiable data.
- B. No paper files will be collected at CDC. The paper-based interview data will be entered into a web-based information system. All electronic data will be stored on secure CDC



networks. Access to the data will be limited to those with a bonafide need-to-know in order to perform job duties related to the project.

- C. Respondents to this information collection are providing data in their roles as food safety program officials and as retail establishment managers. As they are not providing personal data on themselves, respondent consent is not needed.
- D. Reporting by food safety program personnel into this system is voluntary, and respondents are informed of this.

#### **A.11. Justification for Sensitive Questions**

There are no sensitive questions in this data collection.

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

State, local, tribal, and territorial food safety programs are the primary respondents for this data collection- one official from each participating program will report environmental assessment data on outbreaks. These programs are typically located in public health or agriculture agencies. There are approximately 3,000 such agencies in the United States. Thus, although it is not possible to determine how many programs will choose to participate, as participation in NVEAIS is *voluntary*, the maximum potential number of program respondents is approximately 3,000.

However, these programs will be reporting data on outbreaks, not their programs or personnel. It is not possible to determine exactly how many outbreaks will occur in the future, nor where they will occur. However, we can estimate, based on existing data, that a maximum of 1,400 foodborne illness outbreaks will occur annually. Only programs in the jurisdictions in which these outbreaks occur would report to NVEAIS. Thus, not every program will respond every year. Consequently, we have based our respondent burden estimate on the number of outbreaks likely to occur each year. Assuming each outbreak occurs in a different jurisdiction, there will be one respondent per outbreak.

There are two data collection activities. The first activity is entering all requested environmental assessment data into NVEAIS (Attachment 4). The respondents for this activity are the food safety program personnel participating in NVEAIS. This will be done once for each outbreak. This will take approximately 60 minutes per outbreak. Assuming a maximum number of outbreaks of 1,400, the estimated annual burden is 1,400 hours (1 hour \* 1,400 outbreaks).

The second activity is the manager interview that will be conducted at each establishment associated with an outbreak (Attachment 5). 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 NVEAIS will conduct a structured interview and will thus conduct their interviews slightly differently than they would if they were not participating in NVEAIS. For this reason, we have presented the burden for this interview separately. Most outbreaks are associated with only one establishment; however, some are associated with multiple establishments. We estimate that a maximum of 4 manager interviews will be conducted per outbreak. Each interview will take about 20 minutes. Again

assuming a maximum number of outbreaks of 1,400, the estimated annual burden is 1,867 hours (20/60 hours \* 4 interviews per outbreak \* 1,400 outbreaks).

Additionally, food safety program personnel participating in NVEAIS will be required to attend a LiveMeeting (i.e., webinar) training session conducted by CDC staff. This training will cover identifying environmental factors, logging in and entering data into the web-based NVEAIS data entry system, and troubleshooting problems. There will be no website, form, or presentation document associated with this training. Instead, CDC personnel will be walking participants through the NVEAIS data entry system. Attachment 8 contains a brief description of the training. We estimate the burden of this training to be a maximum of 2 hours. Respondents will only have to take this training one time. Assuming a maximum number of outbreaks of 1,400, the estimated burden for this training is 2,800.

The total estimated annual burden is 6,067 hours (see Table A.12-1).

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

| <b>Type of Respondent</b>     | <b>Form Name</b>                              | <b>No. of Respondents</b> | <b>No. of Responses per Respondent</b> | <b>Average Burden per Response (in hours)</b> | <b>Total Burden Hours</b> |
|-------------------------------|---|---------------------------|--|---|---------------------------|
| Food safety program personnel | NVEAIS Data Reporting Instrument              | 1,400                     | 1                                      | 1   | 1,400                     |
| Retail food personnel         | NVEAIS Manager Interview                      | 5,600                     | 1                                      | 20/60   | 1,867                     |
| Food safety program personnel | NVEAIS Food safety program personnel training | 1,400                     | 1                                      | 2   | 2,800                     |
| <b>Total</b>                  |   |                           |  |   | <b>6,067</b>              |

**A.12-2- Annualized Cost to Respondents**

The maximum total annualized cost of this data collection to respondents is estimated to be \$167,669 (See Table A.12-2). This figure is based on an estimated mean hourly wage of \$15.39 for retail food workers and \$33.08 for food safety program personnel. This estimate was obtained from the U.S. Department of Labor’s 2011 national occupational employment and wage estimates report (supervisors of food preparation and serving workers:

<http://stats.bls.gov/oes/current/oes351012.htm> environmental health scientists/specialists; and food safety program personnel: <http://stats.bls.gov/oes/current/oes192041.htm>).

**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 | NVEAIS Data Reporting Instrument              | 1,400              | \$33.08          | \$46,312               |
| Retail food personnel         | NVEAIS Manager Interview                      | 1,867              | \$15.39          | \$28,733               |
| Food safety program personnel | NVEAIS Food safety program personnel training | 2,800              | \$33.08          | \$92,624               |
| <b>Total</b>                  |   |                    |                  | <b>\$167,669</b>       |

**A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

There are no other costs to respondents or record keepers.

**A.14. Annualized Cost to the Federal Government**

Costs to the government include the costs of CDC personnel and contractors who maintain the system and assist respondents in data entry.

**Table A.14.1**

| Expenditure  | Cost             |
|--|------------------|
| 1 CDC fellow to assist respondents with data entry and data quality (100% of time) | \$50,000         |
| 1 contractor to maintain system  | \$100,000        |
| 1 CDC FTE to ensure data quality and analyze data (50% of time)                    | \$65,000         |
| <b>Total</b>   | <b>\$215,000</b> |

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

This is a new data collection.

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

**A. Time schedule for the project**

A three-year clearance is requested for this annual data collection. Data collection will begin once OMB clearance is received. Although respondents will be asked to report data on an annual basis, they will be able to enter data year round. CDC verification and program correction of

reported data will occur in the three months following the annual reporting deadline. Data analysis will occur in the three months following that.

**A.16.1 – Project Time Schedule**

| <b>Activity</b>                                       | <b>Time Frame</b>                         |
|---|---|
| 1 <sup>st</sup> year data collection                  | 3 -12 months after OMB clearance received |
| 1 <sup>st</sup> year data verification and correction | 13-15 months after OMB clearance received |
| 1 <sup>st</sup> year analysis                         | 16-18 months after OMB clearance received |
| 1 <sup>st</sup> year report                           | 19 months after OMB clearance received    |
| 2 <sup>nd</sup> year data collection                  | 13-24 months after OMB clearance received |
| 2 <sup>nd</sup> year data verification and correction | 25-27 months after OMB clearance received |
| 2 <sup>nd</sup> year analysis                         | 28-30 months after OMB clearance received |
| 2 <sup>nd</sup> year report                           | 31 months after OMB clearance received    |
| 3 <sup>rd</sup> year data collection                  | 25-36 months after OMB clearance received |
| 3 <sup>rd</sup> year data verification and correction | 37-39 months after OMB clearance received |
| 3 <sup>rd</sup> year analysis                         | 40-42 months after OMB clearance received |
| 3 <sup>rd</sup> year report                           | 43 months after OMB clearance received    |
| Analysis of 1 <sup>st</sup> 3 years of data           | 44-49 months after OMB clearance received |
| Publication of 1 <sup>st</sup> 3 years of data        | 50 months after OMB clearance received    |

**B. Publication plan**

Each year, CDC will prepare and distribute a report to participating programs following analysis. This report will also be available on CDC’s public website. A publication based on the first three years of data will also be developed.

**C. Analysis plan**

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

**A.17. Reason(s) Display of OMB Expiration Date is Inappropriate**

We are not requesting an exemption to the display of the expiration date.

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

There will be no exceptions to certification for Paperwork Reduction Act.

## References

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

## **List of Attachments**

Attachment 1- Regulation Authorizing Data Collection (Public Health Service Act and Food Safety Modernization Act)

Attachment 2- FDA/CDC List of Contributing Factors to Foodborne Illness Outbreaks

Attachment 3- 60-day Federal Register Notice

Attachment 4- NVEAIS Data Reporting Instrument

Attachment 5- NVEAIS Manager Interview

Attachment 6- NVEAIS IRB Determination

Attachment 7- Sample Screenshots of the Web-based NVEAIS Data Reporting Instrument and Manager Interview

Attachment 8- NVEAIS Food Safety Program Training