requested for one year. The total estimated annualized burden hours are 512.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Quantitative:					
Healthcare Professionals (POC)	Survey	50	1	20/60	17
IT Staff	EMR data	50	1	7.5	375
Qualitative:					
Healthcare Professionals	Key Informant Interview	12	1	1	12
	Focus Groups	72	1	1.5	108
Total					512

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–0980; Docket No. CDC–2019–0011]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Environmental Assessment Reporting System (NEARS) to collect data from foodborne illness outbreak environmental assessments routinely conducted by local, state, territorial, or tribal food safety programs during outbreak investigations.

DATES: CDC must receive written comments on or before May 6, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0011 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

National Environmental Assessment Reporting System (NEARS) (OMB Control No. 0920–0980, Exp. 8/31/2019)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting OMB approval for the National Environmental Assessment Reporting System (NEARS) (0920–0980) to collect data from foodborne illness outbreak environmental assessments routinely conducted by local, state, territorial, or tribal food safety programs during outbreak investigations. Prior to the development of NEARS, environmental assessment data were not collected at the national level. The data reported through this surveillance system provides timely information on the causes of outbreaks, including environmental factors associated with

outbreaks, and are essential to environmental public health regulators' efforts to respond more effectively to outbreaks and prevent future, similar outbreaks. This surveillance system was specifically designed to link to CDC's National Outbreak Reporting System (NORS), a disease (*e.g.* enteric diseases transmitted by food) outbreak surveillance system. NEARS was developed by the Environmental Health Specialists Network (EHS–Net), a collaborative network of CDC, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and nine state food safety programs (California, Connecticut, Georgia, Iowa, New York, Minnesota, Oregon, Rhode Island, and Tennessee). The network consists of environmental health specialists (EHSs), epidemiologists, and laboratorians. EHS-Net developed a standardized protocol for identifying, reporting, and analyzing data relevant to foodborne illness outbreak environmental assessments.

While conducting environmental assessments during outbreak investigations is routine for food safety program officials, reporting information from the environmental assessments to CDC is not routine. Local, state, federal, territorial, and tribal food safety programs are the primary respondents for this data collection. One official from each participating program will report environmental assessment data on outbreaks. These programs are typically located in public health or agriculture agencies. In the U.S., there are approximately 3,000 such agencies. Currently, 31 state and local health departments are registered to report data on outbreaks to NEARS. Based on our experience over the past five years, we expect up to 10 additional local and state public health departments to register to report outbreak data to NEARS over the next three years. It is not possible to determine exactly how many outbreaks will occur in the future, nor where they will occur. Based on past trends, it is likely that up to 300 foodborne illness outbreaks may be reported annually to NEARS from up to 41 entities for the duration of the next PRA clearance. Only programs in the jurisdictions in which these outbreaks occur would report to NEARS. Thus, not every program of the approximate 3,000 programs will respond every year. Assuming each outbreak occurs in a different jurisdiction, there will be one respondent per outbreak.

The activities associated with NEARS that require a burden estimate consist of training, observing, data recording, and data reporting events. The first activity is the training for the food safety program personnel participating in NEARS. These staff will be encouraged to attend a Skype Meeting (*i.e.,* webinar) training session conducted by CDC staff. 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. We estimate the burden of this training to be a maximum of two hours. Respondents will only be required to take this training one time. Assuming a maximum participation of up to 10 programs and about five staff being trained at each participating program, the total estimated burden associated with this training is 100 hours.

Food safety program personnel participating in NEARS will also be encouraged to complete CDC's Environmental Assessment Training Series (EATS). This eCourse provides training to staff on how to use a systems approach in foodborne illness outbreak environmental assessments. We estimate the burden of this training to be a maximum of 10 hours. Respondents will only have to take this training one time. Assuming a maximum participation of up to 10 programs and approximately five staff being trained at each program, the estimated burden associated with this training is 500 hours.

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

The manager interview 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. 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. Assuming a maximum of 300 outbreaks, the estimated annual burden is 400 hours. Web-based data entry for both data recording and the manager interview will be combined. Data entry into the NEARS system is expected to take approximately 40 minutes for the combined activities, for a total of 200 burden hours. The total estimated annual burden for this information collection is 1,350 hours.

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 Training.	50	1	2	100
	NEARS e-Learning (screenshots)	50	1	10	500
	NEARS Data Recording (paper form).	300	1	30/60	150
	NEARS Data reporting and manager's interview (web entry).	300	1	40/60	200
Retail food personnel	NEARS Manager Interview	1200	1	20/60	400
Total					1,350

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1398]

Mitigation Strategies To Protect Food Against Intentional Adulteration; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' The revised draft guidance supersedes the version of the intentional adulteration draft guidance that we announced on June 20, 2018. This draft guidance document, when finalized, will help food facilities that manufacture, process, pack, or hold food, and that are required to register under the Federal Food, Drug, and Cosmetic Act (FD&C Act) comply with the requirements of our regulation entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration.''

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1398 for ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ryan Newkirk, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–3712, *ryan.newkirk@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur.

FSMA added to the FD&C Act several new sections that reference intentional adulteration. For example, section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food, and that are required to register under section 415 (21 U.S.C. 350d). Section 420 of the FD&C Act (21 U.S.C. 350i) addresses intentional adulteration in the context of high-risk foods and exempts farms except for farms that produce milk.

We are announcing the availability of a revised draft guidance for industry entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' This revised draft guidance supersedes the version of