United States Food and Drug Administration

National Agriculture and Food Defense Strategy Survey

OMB Control No. 0910-0855

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA, the agency, us or we) is seeking OMB approval of the National Agriculture and Food Defense Strategy (NAFDS) Survey under section 108 of the Food Safety Modernization Act (FSMA). This is a voluntary survey of State, local, territorial, and tribal (SLTT) governments intended to gauge government activities in food and agriculture defense from intentional contamination and emerging threats. The collected information will be included in the mandatory NAFDS follow-up Report to Congress. The authority for us to collect the information derives from the Commissioner of Food and Drugs' authority provided in section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(C)).

Protecting the nation's food and agriculture supply against intentional contamination and other emerging threats is an important responsibility shared by SLTT governments as well as private sector partners. FSMA focuses on ensuring the safety of the U.S. food supply by shifting the efforts of Federal regulators from response to prevention and recognizes the importance of strengthening existing collaboration among all stakeholders to achieve common public health and security goals. FSMA identifies some key priorities for working with partners in areas such as reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Section 108 of FSMA–NAFDS requires the Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA), in coordination with the Department of Homeland Security (DHS), to work together with SLTT to monitor and measure progress in food defense. In 2015, the initial NAFDS Report to Congress detailed the specific Federal response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined in FSMA. The survey includes questions about all activities related to objectives, goals, initiatives, and activities completed by each state, locality, tribe, or territory. FDA is unlikely to survey SLTT governments directly as the States will decide.

We therefore request extension of OMB approval for the NAFDS Survey as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The NAFDS charts a direction for how the Federal agencies, in cooperation with SLTT governments and private sector partners, protect the nation's food supply against intentional contamination. Not later than 4 years after the initial NAFDS Report to Congress (2015), and every 4 years thereafter (i.e., 2019, 2023, 2027, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

FDA is the agency primarily responsible for obtaining the information from Federal and SLTT partners to complete the NAFDS Report to Congress. An interagency working group will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

The survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or SLTT agencies have completed (or are planning) from 2024 to 2028. Planning for the local, territorial, and tribal information collections will commence during this period of renewal. The survey will continue to be repeated approximately every 2 to 4 years, as described in section 108 of FSMA. The NAFDS survey is being administered for the purpose of monitoring progress in food and agricultural defense by government agencies.

A purposive sampling strategy is employed, such that the government agencies participating in food and agricultural defense are asked to respond to the voluntary survey. Food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdiction are identified and will receive an emailed invitation to complete the survey online; they will be provided with a web link to the survey. The survey will be conducted electronically on the FDA.gov web portal, and results will be analyzed by the interagency working group.

Description of Respondents: Respondents to this collection are SLTT government representatives (survey respondents) who are food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdictions.

3. Use of Improved Information Technology and Burden Reduction

To reduce respondent burden, the survey will be administered electronically, and responses accepted electronically. Targeted respondents will receive a link by email to complete the survey online using survey application software designed for highly private information. The survey will be administered by FDA contractors using an internal server for data capture. The survey will be conducted electronically via FDA's webpage, FDA.gov, and the results will be analyzed by the interagency working group. The percentage of respondents completing the survey electronically is expected to be 100%.

4. Efforts to Identify Duplication and Use of Similar Information

The NAFDS Survey is a unique survey instrument. No other survey of Federal and State NAFDS cooperative agreement partners on monitoring food and agriculture defense goals, objectives, key initiatives, and activities related to achieving the goals outlined in the NAFDS is being conducted. Of the Federal agencies responsible for accomplishing the NAFDS, FDA has the primary responsibility for collecting the information that will be used in the follow-up Report to Congress about the status of the national strategy.

5. Impact on Small Businesses or Other Small Entities

No small businesses are involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements. This data collection is important because it is a follow-up to the NAFDS Report to Congress. The collection will be the among the indicators of Federal and State response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders plan to

accomplish to meet the objectives outlined within FSMA. If the information from the survey is not collected, FDA will be unable to complete the mandatory NAFDS follow-up Reports to Congress.

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

There are no special circumstances associated with this information collection.

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

In accordance with 5 CFR 1320.8(d), we published a 60-day notice requesting public comment on the proposed collection of information in the *Federal Register* of March 26, 2024 (89 FR 20980). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via the NAFDS Survey access page is name, work email address, work telephone number, and agency name. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Based on our experience with the survey, we estimate the burden as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
SLTT Survey	500	1	500	0.33 (20 minutes)	165

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

12b. Annualized Cost Burden Estimate

The annualized burden hour cost to respondents for the survey is $10,927.95 (165 hours x $66.23) using the May 2023 hourly mean wage rate for those in management occupations in the United States.[1] To account for overhead, we have doubled the hourly mean wage rate to $132.46, with the total estimated annual burden cost to be $21,855.90.

Table 2.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Responding to Survey	165	$132.46	$21,855.90

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal government is $11,500. This cost reflects the increase in government wages since 2021 and includes FDA staff time to develop the study materials, obtain clearances, contact the sample, collect the survey data, create a database of the data, tabulate and summarize the survey data, and prepare a final report.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

Activities associated with the outcomes of this survey will consist only of a top-line report summarizing the survey findings included in the NAFDS follow-up Report to Congress. The planned schedule for project activities is shown below.

Table 3.--Project Schedule

Date	**Activity**	**Audience**
Within 3 days after receipt of OMB approval of collection of information	Notification to FDA staff to proceed with data collection activities	Not applicable
Within 60 days after staff notification	Completion of data collection	Not applicable
Within 6 months after receipt of final data files	Insertion of findings into NAFDS follow-up Report to Congress	U.S. Congress

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

[1] U.S. Bureau of Labor Statistics, Management Occupations – 11-000, http://www.bls.gov/oes/current/oes_nat.htm, accessed June 2024.

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.