

# UNITED STATES FOOD & 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

This information collection request supports the National Agriculture and Food Defense Strategy (NAFDS) Survey, administered by the Food and Drug Administration (FDA, the agency, us or we), consistent with section 1003(d)(2)(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(c)). This is a voluntary survey of State 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 2021 NAFDS follow-up Report to Congress.

Protecting the nation's food and agriculture supply against intentional contamination and other emerging threats is an important responsibility shared by Federal, State, local, tribal, and territorial governments as well as private sector partners. Section 108 of Food Safety Modernization Act (FSMA) 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 State, local, territorial, and tribal (SLTT) governments 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 National Agriculture and Food Defense Survey.

#### 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. Section 108 of FSMA directs FDA to coordinate with the agencies to obtain information to complete the NAFDS report. An interagency working group consisting of representatives from HHS, USDA, and DHS conducts the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

HHS/FDA is the agency primarily responsible for obtaining the information from Federal and SLTT partners to complete the NAFDS Report to Congress. The voluntary survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or State agencies have completed (or are planning) from 2019 to 2023. Planning for the local, territorial, and tribal information collections will commence after the collection and reporting of Federal and State agency level data.

This voluntary survey will be repeated approximately every 2 to 4 years, as described in section 108 of FSMA (NAFDS) for the purpose of monitoring progress in food and agricultural defense by government agencies.

*Description of Respondents:* Respondents to this collection are SLTT 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 number 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 first follow-up Report to Congress (estimated 2021) 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 2015 and 2019 Report to Congress. The collection will be 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 2021 and 2023 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 January 4, 2021 (86 FR 104). One comment was received questioning the utility of the survey but did not proffer alternative burden estimates and therefore no adjustments were made to the information collection.

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

All data will be collected with an assurance that the respondents' answers will be kept secure to the extent provided by law. The survey questionnaire and screener contain a statement that responses will be kept secure to the extent provided by law. Private information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). Identifying information will not be included in the data files received by the agency.

All data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35.

*Privacy Act*

Additionally, we have consulted with our Privacy Office and confirmed this ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports "*FDA Food Safety Modernization Act National Agriculture and Food Defense Strategy State Survey on Food Defense Activities*" and does not require the collection of PII. We also determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply.

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<sup>1</sup>

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

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

### 12b. *Annualized Cost Burden Estimate*

The annualized cost to all respondents for the hour burden for the collection of information is \$10,033.65 (165 hours x \$60.81) at the 2020 mean wage rate for those in management occupations in the United States.<sup>1</sup>

Table 2. --Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Responding to Survey	165	\$60.81	\$10,033.65

## 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 \$10,000. This cost 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

We have adjusted our burden estimate to reflect the total number of states and possible number of local, tribal, and territorial entities that may complete the survey. This results in an increase of 149 hours and 451 respondents annually.

## 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
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<sup>1</sup> [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm), accessed June, 2021.

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

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.