



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1129]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; National Agriculture and Food Defense Strategy Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title “National Agriculture and Food Defense Strategy Survey.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

National Agriculture and Food Defense Strategy Survey

OMB Control Number--0910-NEW

We are seeking OMB approval of the National Agriculture and Food Defense Strategy (NAFDS) under the FDA Food Safety Modernization Act (FSMA), section 108. 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 2019 NAFDS followup Report to Congress. The authority for FDA 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 Federal, State, local, tribal, and territorial governments as well as private sector partners. On January 4, 2011, the President signed FSMA. 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 U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA), in coordination with the Department of

Homeland Security (DHS), to work together with State, local, territorial, and tribal 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 NAFDS charts a direction for how the Federal Agencies, in cooperation with State, local, territorial, and tribal 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, 2017, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

HHS/FDA is primarily responsible for obtaining the information from Federal and State, local, territorial, and tribal 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 proposed 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 2015 to 2019. Planning for the local, territorial, and tribal information collections will commence after the collection and reporting of Federal and State Agency level data.

This 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.

A purposive sampling strategy will be employed, such that the government agencies participating in food and agricultural defense cooperative agreements with FDA (22 State

Agencies) and USDA (27 State Agencies) will be asked to respond to the voluntary survey. Food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdiction will be 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.

In the *Federal Register* of March 28, 2018 (83 FR 13284), we published a notice inviting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State Survey	49	1	49	0.33 (20 minutes)	16.17

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

The total burden for this collection of information, therefore, is 16.17 hours.

The FDA Office of Partnerships reviewed the questionnaire and provided the amount of time to complete the survey. The total burden is based on our previous experiences conducting surveys.

Dated: June 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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