



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0734]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) 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 submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0601. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@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.

Manufactured Food Regulatory Program Standards

This information collection helps implement FDA's "Manufactured Food Regulatory Program Standards" (MFRPS). Section 1012 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399c) authorizes FDA to administer training and education programs for employees of State, local, Territorial, and Tribal food safety authorities relating to regulatory programs. Also, under section 205 of the FDA Food Safety Modernization Act (codified in 21 U.S.C. 2224), FDA, together with the Centers for Disease Control and Prevention, is directed to enhance foodborne illness surveillance to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses. As part of this effort, we have initiated programs that include developing and instituting regulatory standards intended to reduce the risk of foodborne illness through coordinated efforts with our strategic partners. Regulatory program standards establish a uniform foundation for the design and management of State, local, Tribal, and Territorial programs that have the responsibility for regulating human and animal food. Partnering with other regulatory officials also helps maximize limited resources in administering FDA regulations pertaining to manufacturing/processing, packing, or holding of food for consumption in the United States.

The MFRPS are the result of external collaboration and coordination with the Association of Food and Drug Officials (AFDO) and State manufactured food regulatory programs. FDA, AFDO, and states worked collaboratively to develop the content of the MFRPS. A copy of the standards and accompanying worksheets and forms is available in the *Federal Register* docket for this notice. We recommend that State manufactured food regulatory programs use these program standards as the framework to design and manage their manufactured food regulatory programs. The States that assisted in the development of MFRPS were representative of the 42 State programs enrolled currently conducting manufactured food inspections via funding from a cooperative agreement grant entitled "RFA-FD-18-001: Flexible Funding Model--Infrastructure Development and Maintenance for State Manufactured Food Regulatory Programs (U18)." For

more information on this cooperative agreement, visit our website at:

<https://www.fda.gov/food/regulatory-program-standards-food/manufactured-food-regulatory-program-standards-mfrps>.

The regulatory program standards provide a uniform and consistent approach to manufactured food regulation in the United States. States may implement the program standards on a voluntary basis. The MFRPS is the framework that each participating State should use to design, manage, and improve its manufactured food regulatory program. The MFRPS provides for the following standards: (1) regulatory foundation; (2) training program; (3) inspection program; (4) inspection audit program; (5) food-related illness, outbreak, and hazards response; (6) compliance and enforcement program; (7) industry and community relations; (8) program resources; (9) program assessment; and (10) laboratory support. For more information, including access to the program standards and appendices, visit our website at:

<https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/integrated-food-safety-system-ifss-programs-and-initiatives/regulatory-program-standards>.

The MFRPS includes appendices to help the State program assess and meet the program elements in the standard. State programs are not obligated to use the appendices provided with the standards. Other manual or automated forms, worksheets, and templates may be used if the pertinent data elements are present. Records and other documents specified in the standards must be current and fit for use by the State program and must be available to verify the implementation of each standard. As set forth in the standards, the State program is expected to develop or update a strategic improvement plan that aids the State program in achieving and maintaining conformance with the program elements of each standard and addresses any necessary corrective actions.

*Description of Respondents:* Respondents are State Departments of Agriculture or Health regulatory officials who enroll in the MFRPS. We estimate 42 respondents to the information collection based on current participation.

In the *Federal Register* of June 16, 2025 (90 FR 25309), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1--Estimated Annual Recordkeeping Burden<sup>1,2</sup>

Type of Respondent; Information Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State Governments; Maintenance of data records consistent with the MFRPS	42	11	462	88.09	40,698

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

<sup>2</sup> Totals may not sum due to rounding.

One State program is no longer participating in the MFRPS and two enrolled state agencies have been reorganized into one state agency since our last evaluation. We have consolidated our estimates from the previous request for renewal of this information collection to account for burden attributable to reporting tasks in the recordkeeping table. This consolidation of reporting and recordkeeping hours results in an increase in the average burden per recordkeeping. Due to the decrease in respondents, the total estimated burden for this collection has decreased by 1,938 hours.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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