

U.S. Food and Drug Administration

Manufactured Food Regulatory Program Standards

OMB Control No. 0910-0601

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration (FDA, us or we) “Manufactured Food Regulatory Program Standards.” We recommend that States use these program standards as the framework to design and manage their manufactured food programs. The Secretary is authorized under the FDA Food Safety Modernization Act (Pub. L. 111-353) to collect and share information with the States. The collection is necessary to determine and develop inspection programs when jurisdiction overlaps between FDA and State agencies.

We request OMB approval of the information collection contained in the Manufactured Food Regulatory Program Standards.

2. Purpose and Use of the Information Collection

The goal of the Manufactured Food Regulatory Program Standards (MFRPS) is to implement a nationally integrated, risk-based, food safety system focused on protecting public health. The MFRPS establish a uniform basis for measuring and improving the performance of prevention, intervention, and response activities of manufactured food regulatory programs in the United States. The development and implementation of the standards will help Federal and State programs better direct their regulatory activities toward reducing foodborne illness. Additional information is available on our website at: <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/regulatory-program-standards/manufactured-food-regulatory-program-standards-mfrps>

FDA recommends that a State program enrolled in the MFRPS use the worksheets and forms contained in the standards; however, alternate forms that are equivalent may be used. The State program maintains documentation (guidance, procedures, documents, and forms) required by the 10 standards, which must be current and fit for use. In the first year of implementing the program standards, the State program conducts a baseline self-assessment of the documentation to determine if it meets the elements of each standard. The State program must participate in additional verification audits in subsequent years. After 5 years, FDA will conduct a comprehensive program audit of the documentation. As part of the program audit, the auditor reviews the records and supporting documents

required by the criteria in each standard to determine if the self-assessment and improvement plan accurately reflect the State program's level of conformance with each of the standards. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) the individual element of documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, and (3) projected completion dates for each task.

Description of Respondents: Respondents are State Departments of Agriculture or Health enrolled in the MFRPS (State Governments). There are 44 State programs enrolled in the MFRPS under cooperative agreements.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 98 percent of the respondents will use electronic means to fulfill the agency's requirement or request. Current practices allow the reporting and recordkeeping requirements to be met through electronic means. The fill-in forms and worksheets will be in Portable Document Format (PDF), Excel or Word Format and available on the internet.

4. Efforts to Identify Duplication and Similar Information

The information described is not duplicative and must be obtained from the States.

5. Impact on Small Business or Other Small Entities

FDA does not anticipate responses from small businesses and does not believe it will adversely affect small businesses or other small entities. The Manufactured Food Standards do not impact business or small entities.

6. Consequences of Collecting the Information Less Frequently

Collecting the information solicited in this collection less frequently would negatively impact FDA's ability to evaluate annual grantee performance. The annual collection is proportionate and appropriate.

There are no technical or legal obstacles to the collection of this information.

7. Consistency with the Guidelines in 5 CFR 1320.5

There are no special circumstances for this collection of this information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of 1/13/2022 (87 FR 2162) to which the agency received no comments.

Subsequent to the publication of the 60-day notice, in collaboration with the State Governments, FDA completed a revision of the program standards. In an effort to improve program effectiveness, understanding and clarity, changes include those to program definitions, inspection procedures, appendices and assessment worksheets that may be used by the States who have adopted the MFRPS. The revised program standards are available in docket FDA-2010-N-0414-0006.

The revision of the program standards is the result of external collaboration and coordination between FDA and the Association of Food and Drug Officials (AFDO) Manufactured Food Regulatory Program Alliance (MFRPA) and the Partnership for Food Protection (PFP) Governing Council (GC). We consider any formal comments received on the previous edition of the program standards and feedback obtained from our collaboration with the States.

The FDA worked closely with state agencies participating in the MFRPS program through the AFDO Manufactured Food Regulatory Program Alliance Board to review and evaluate the program standards. The changes were proposed by the FDA, or by the regulatory state programs, and provided to the PFP-GC for review and comment. Comments received from the States, the MFRPA Board, and the PFP were reviewed and incorporated into a final draft. The final draft standards were provided to all participating state agencies for review before the MFRPA Board voted on accepting proposed revisions.

9. Explanation of any Payment or Gift to Respondents

No gift or payment is offered to respondents for completing the information collection. The standards do correspond to a grant program that conforms to federal regulations.

States can apply for a cooperative agreement allowing them to receive up to \$300,000 each year for a period of five years to work toward significant conformance with the ten standards. The States will conduct a baseline self-assessment and develop a strategic plan to fully implement the program standard within five years. States apply for additional funds for continual improvement and enhancement projects for the next awarded cooperative agreement being offered to support the enrollment of the MFRPS after they have met full conformance.

10. Assurance of Confidentiality Provided to Respondents

This ICR is not collecting personally identifiable information (PII) or other data of a personal nature. Information collected is about state food safety programs through the

Manufactured Food Regulatory Program Standards which ranges from information about state laws and regulations to procedures for dealing with foodborne illness outbreaks.

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.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA determined that PII is not collected, and the Privacy Act does not apply to this collection.

11. Justification of Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The total estimated annual reporting burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the ten standards contained in the MFRPS. The hours per respondent will average the same to account for continual improvement and self-sufficiency in the program.

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

Table 1.—Estimated Annual Reporting Burden ¹					
Respondent; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State Governments; Development and reporting of data consistent with MFRPS	44	1	44	569	25,036

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

The annual recordkeeping burden associated with documenting conformance to the program standards average to 40 hours per record.

Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Record-keeping	Total Hours
State Governments; Maintenance of data records consistent with the MFRPS	44	10	440	40	17,600

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

One additional State has enrolled in the program since our last evaluation. The total estimated burden for this collection has increased by 969 hours to 42,636 hours among 44 respondents, from a previous total of 41,667 hours among 43 respondents. The burden increase is due to the one additional respondent.

13. Estimate of the Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

Staff needs specific to this collection include effort to review report submissions, provide technical guidance to program participants on using the forms, and facilitation of periodic review and updates to the MFRPS when needed.

Government Personnel	Effort Commitment	Average Annual Salary	Total Costs
GS-12 (1)	5%	\$79,363	\$3,968.15
GS-13 (5 @ 25% each)	125%	\$100,664	\$125,830
GS-14 (1)	10%	\$118,955	\$11,895.50
GS-15 (1)	5%	\$139,923	\$6,996.15
Total			\$148,659.80

15. Explanation for Program Changes or Adjustments

We have adjusted the number of respondents to the information collection to reflect the enrollment of an additional State since our last evaluation.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

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

Not applicable.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.