

# UNITED STATES FOOD & DRUG ADMINISTRATION

## Federal-State Food Regulatory Program Standards

OMB Control No. 0910-0760

### SUPPORTING STATEMENT – **Part A: Justification**

#### 1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) Animal Food (formerly Feed) Regulatory Program Standards (AFRPS) and Egg Regulatory Program Standards (ERPS). The current submission seeks to revise this information collection related to the ERPS. No revisions were made to the AFRPS.

The Food Safety Modernization Act (FSMA) (P.L.111-353) provides FDA with tools to better protect public health by strengthening the human and animal food safety system. In the United States, federal and state government agencies ensure the safety of human and animal food. FDA is responsible for ensuring that all human and animal food moving in interstate commerce, except those under the U.S. Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. States are responsible for conducting inspections and regulatory activities that help ensure human and animal food and produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. States primarily perform inspections under their own regulatory authority. Some States conduct inspections of human or animal food facilities under contract with FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect human and animal food.

Section 205(c) of FSMA (codified in 21 U.S.C. 2224) calls for enhanced partnerships and provides a legal mandate for developing an Integrated Food Safety System (IFSS). FDA is committed to implementing an IFSS thereby optimizing coordination of human and animal food safety efforts with federal, state, local, tribal, and territorial regulatory and public health agencies. Model standards provide a consistent, underlying foundation that is critical for uniformity across state and federal agencies to ensure credibility of human and animal food programs within the IFSS.

The regulatory program standards provide a uniform and consistent approach to human and animal food regulation in the United States. States may implement the program standards on a voluntary basis. The AFRPS and ERPS are the frameworks that each participating state should use to design, manage, and improve its animal food or egg regulatory programs. The AFRPS provide for the following eleven standards: (1) regulatory foundation; (2) training program; (3) inspection program; (4) audit program; (5) animal food-related illnesses or death and emergency response; (6) compliance and enforcement program; (7) outreach program; (8)

planning and resources; (9) assessment and improvement; (10) laboratory services; and (11) sampling program. The ERPS include equivalent standards for egg regulatory programs except they do not include a separate standard 11 sampling program.

We therefore request OMB approval for the information collection provisions associated with AFRPS and ERPS and the revision of the AFRPS as discussed in this supporting statement.

## 2. Purpose and Use of the Information Collection

This information collection will be used by both FDA and the states to maximize the use of resources and better direct their regulatory activities to help ensure human and animal food produced, processed, and distributed within their jurisdiction are safe and in compliance with state laws and regulations.

## 3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 99 percent of the respondents will use electronic means to provide the information requested. We collect information from respondents via appendices which contain fill-in forms and worksheets. The forms and worksheets are made available on our website (AFRPS - <https://www.fda.gov/media/136030/download?attachment>) (ERPS - <https://www.fda.gov/media/154954/download?attachment>). They are fillable and fileable, but not signable. Respondents submit the forms and worksheets annually via email to the appropriate FDA program manager.

## 4. Efforts to Identify Duplication and Similar Information

We are unaware of duplicative information collection.

## 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 Animal Food and Egg Regulatory Program Standards do not impact business or small entities.

## 6. Consequences of Collecting the Information Less Frequently

Respondents will respond to the information collection on occasion and/or annually. Collecting the information less frequently than that would degrade FDA's ability to measure progress and adjust resource allocations accordingly.

## 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 August 22, 2025 (90 FR 41083). Two comments were received. Both comments were unrelated to the Paperwork Reduction Act.

9. Explanation of any Payment of 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 annual grant funds for a period of five years to work toward significant conformance with the standards. The states will conduct a baseline self-assessment and develop a strategic plan to fully implement the program standard in five years.

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 does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports the Food and Drug Administration's implementation of its Federal-State Regulatory Program standards, specifically the Animal Feed Regulatory Program Standards (AFRPS) and the Egg Regulatory Program Standards (ERPS). Information collected is about state food safety programs through the AFRPS and ERPS, which range from information about state laws and regulations to procedures for dealing with foodborne illness outbreaks. All records are maintained at the facility. Because neither FDA nor any party acting on behalf of the agency collects PII, the ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act such as displaying a Privacy Act Statement on a collection form do not apply.

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 makes 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 of Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

*12a. Annualized Hour Burden Estimate*

Table 1. – Estimated Annual Reporting Burden<sup>1</sup>

Type of Respondents; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	2	1	2	569	1,138
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with AFRPS	25	1	25	569	14,225
Total					15,363

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

Table 2. – Estimated Annual Recordkeeping Burden<sup>1</sup>

Type of Respondents; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State, local, Territorial and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	2	10	20	40	800
State, local, Territorial and/or Tribal Governments; submission of data elements to FDA consistent with AFRPS	25	11	275	40	11,000
Total					11,800

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

The total annual recordkeeping and reporting burden is 27,163 hours.

12b. Annualized Cost Estimate

FDA assumes an average hourly wage rate of \$45.04 per hour<sup>1</sup>. Doubling that to approximate a “fully loaded” cost estimate produces \$90.08/hr. We therefore calculate respondent costs to be \$2,446,843.04 (27,163 x \$90.08).

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 AFRPS and ERPS when needed.

Table 3. – Estimated Government Costs<sup>2</sup>

Government Personnel	Effort Commitment	Average Annual Salary	Total Costs
GS-12 (1)	5%	\$102,415	\$5,120.75
GS-13 (2 @ 30% each)	60%	\$121,785	\$73,071.00
GS-14 (1)	10%	\$143,913	\$14,391.30
GS-15 (1)	2%	\$169,279	\$3,385.58
Total			\$95,968.63

15. Explanation for Program Changes or Adjustments

Collection Activity	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Reason for Change
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	1,138	1,138	0	N/A

<sup>1</sup> Per U.S. Bureau of Labor Statistics May 2024 National Occupational Employment and Wage Estimates for Business and Financial Operations occupations: [https://www.bls.gov/oes/current/oes\\_nat.htm#13-0000](https://www.bls.gov/oes/current/oes_nat.htm#13-0000)

<sup>2</sup> Per U.S. Office of Management and Budget 2026 Washington, D.C. Metro Area GS Pay Table: <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2026/DCB.pdf>

Collection Activity	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Reason for Change
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with AFRPS	14,225	14,225	0	N/A
State, local, Territorial and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	800	800	0	N/A
State, local, Territorial and/or Tribal Governments; submission of data elements to FDA consistent with AFRPS	11,000	11,000	0	N/A
<b>TOTAL</b>	<b>27163</b>	<b>27163</b>	<b>0</b>	

The change in estimated burden for the information collection is net-zero (27,163 total hours), as enrollment and participation in both programs remains steady.

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

There are no reasons why display of the expiration date for OMB approval of information collection would be inappropriate.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.