

UNITED STATES FOOD & DRUG ADMINISTRATION

Production, Storage, and Transportation of Shell Eggs
(Preventing Salmonella Enteritidis (SE))

OMB Control No. 0910-0660 - Extension

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) regulations in part 118 (21 CFR part 118), Production, Storage, and Transportation of Shell Eggs, and Form FDA 3733, Shell Egg Producer Registration Form. The Public Health Service Act (PHS Act) authorizes the Secretary of Health and Human Services to make and enforce such regulations as “are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States . . . or from one State . . . into any other State” (section 361(a) of the PHS Act (42 U.S.C. 264(a))). This authority has been delegated to the Commissioner of Food and Drugs. Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)), a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

Under part 118, shell egg producers are required to implement measures to prevent *Salmonella Enteritidis* (SE) from contaminating eggs on the farm and from growth during storage and transportation. Shell egg producers also are required to maintain records concerning their compliance with part 118 and to register with FDA. As described in more detail about each information collection provision of part 118, each farm site with 3,000 or more egg-laying hens that sells raw shell eggs, other than directly to the consumer, must refrigerate, register, and keep certain records. Farms that do not send all of their eggs to treatment are also required to have an SE prevention plan and to test for SE.

Form FDA 3733

As provided for in the regulations, respondents must use Form FDA 3733, “*DHHS/FDA Shell Egg Producer Registration*,” to complete the required registration under § 118.1(a). The term “*Form FDA 3733*” refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at <http://www.access.fda.gov>.

We therefore request extension of OMB approval for the information collection provisions found in the regulations at 21 CFR part 118, and associated Form FDA 3733, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Section 118.10 of FDA's regulations requires recordkeeping for all measures a farm takes to prevent SE in its flocks. Since many existing farms participate in voluntary egg quality assurance programs, those respondents may not have to collect any additional information. Records are compiled and retained at each farm site and examined there periodically by FDA inspectors.

Section 118.10 also requires each farm site with 3,000 or more egg-laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, and does not have all of the shell eggs treated, to design and implement an SE prevention plan. Section 118.10 requires recordkeeping for each of the provisions included in the plan and for plan review and modifications if corrective actions are taken.

Finally, § 118.11 of FDA's regulations requires that each farm covered by § 118.1(a) register with FDA using Form FDA 3733. We strongly encourage electronic registration because it is faster and more convenient. The system accepts electronic registrations 24 hours a day, 7 days a week. A registering shell egg producer receives confirmation of electronic registration instantaneously once all the required fields on the registration screen are completed. However, paper registrations also are accepted. Form FDA 3733 is available for download for registration by mail, fax, or CD-ROM. More information is available at our website at <https://www.fda.gov/food/shell-egg-producer-registration/shell-egg-producer-registration-step-step-instructions> and <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ShellEggProducerRegistration/ucm217952.htm>.

Recordkeeping and registration are necessary for the success of the SE prevention measures. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Further, they are essential for us to be able to determine compliance. Information provided under these regulations helps us to quickly notify the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support our enforcement activities.

Description of Respondents: Respondents to this information collection include farm sites with 3,000 or more egg-laying hens that sell raw eggs, other than directly to the consumer. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

Companies are free to use whatever forms of information technology that best assist them in retaining the appropriate records. We encourage, but do not mandate, the use of electronic recordkeeping.

As noted above, the term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at <http://www.access.fda.gov>. The agency strongly encourages electronic registration because it is faster and more convenient for both FDA and the registrant. In addition, registration updates and

cancellations may be accomplished electronically. The system accepts electronic registrations 24 hours a day, 7 days a week, 365 days a year. The individual registering a facility receives confirmation of electronic registration and the facility's registration number instantaneously once all the required fields on the registration screen are completed. However, we will continue to accept paper registrations. Form FDA 3733 is available for download for registration by mail, fax, or CD-ROM. Registration by mail may take several weeks to several months, depending on the speed of the mail system and the number of paper registrations needed to be entered manually.

Based on submissions received during the past three years, the agency estimates that about ninety percent (90%) of registrations will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. There is no duplication of recordkeeping requirements as a result of FDA's regulation and regulations issued by the U.S. Department of Agriculture (USDA). USDA requires records on some of the egg products it regulates, but these will not overlap in information with the records required by FDA's regulation of shell egg production.

Farms that have packing facilities integrated on the farm will already be registered by USDA under the Egg Product Inspection Act (EPIA) and some may also be registered by FDA under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which added section 415 of the Act (21 U.S.C. 350d), and §§ 1.230 - 1.235 of FDA's regulations (21 CFR 1.230 - 1.235). However, these two registration programs are not a substitute for the Shell Eggs Registration information collection because information required by this regulation, namely the size of operation, including the number of houses on the farm and the number of layers per house, are not provided under EPIA or the Bioterrorism Act. Farms already registered under EPIA or the Bioterrorism Act will need to fully reregister under this regulation.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately seventy percent (70%) of respondents are small businesses. We assist small businesses by exempting farms with fewer than 3,000 layers from the recordkeeping and registration provisions of this regulation.

We also provide assistance with the registration requirements to small businesses through the HFP small business office. In addition, the FDA Industry Systems Help Desk can answer computer system and technical questions, as well as general questions about registration and will attempt to assist small businesses to register. The Help Desk is available Monday through Friday from 7:00 a.m. to 11:00 p.m. Eastern Time. We strongly encourage electronic registration, but provide registration through postal mail, which can reduce the burden on small entities. We aid small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. Assistance is also available for small businesses via the agency's website at <https://www.fda.gov/industry/small-business-assistance>.

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden. Data collection occurs occasionally. If a farm is not registered or the registration for a farm is not updated when necessary, we may not be able to contact the farm in case of a known or potential threat to the food supply or other food-related emergency. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Without written plans and records of actions taken due to each provision, the SE prevention plan would not be effective. Further, recordkeeping and registration are essential for FDA to be able to determine compliance.

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 for public comment in the *Federal Register* of June 27, 2025 (90 FR 27614). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Privacy Act

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed as either the facility owner or operator, or an individual authorized to submit on behalf of the facility owner or operator. The PII submitted via Form FDA 3733 (DHHS/FDA Shell Egg Producer Registration) includes: name, address, telephone number, fax number, and email address. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Freedom of Information Act

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.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Recordkeeping Burden¹

Collection Activity; 21 CFR Section	No. of Recordkeepers ²	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
Refrigeration Records; § 118.10(a)(3)(iv)	2,600	52	135,200	0.5 (30 mins.)	67,600
Testing, Diversion, and Treatment Records; § 118.10(a)(3)(v) through (viii) (positive) ³	343	52	17,836	0.5 (30 mins.)	8,918
Egg Testing; § 118.10(a)(3)(vii)	331	7	2,317	8.3	19,231
Environmental Testing; § 118.10(a)(3)(v) ³	6,308	23	145,084	0.25 (15 mins.)	36,271
Testing, Diversion, and Treatment Records; § 118.10(a)(3)(v) through (viii) (negative) ³	5,965	1	5,965	0.5 (30 mins.)	2,983
Prevention Plan Review and Modifications; § 118.10(a)(4)	331	1	331	10	3,310
Chick and Pullet Procurement Records; § 118.10(a)(2)	4,731	1	4,731	0.5 (30 mins.)	2,366
Rodent and Other Pest Control; § 118.10(a)(3)(ii), and Biosecurity Records; § 118.10(a)(3)(i)	9,462	52	492,024	0.5 (30 mins.)	246,012
Prevention Plan Design; § 118.10(a)(1)	350	1	350	20	7,000
Cleaning and Disinfection Records; § 118.10(a)(3)(iii)	331	1	331	0.5 (30 mins.)	166
TOTAL			0		0

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

²Some records are kept on a by-farm basis and others are kept on a by-house basis.

³Calculations include requirements for pullet and layer houses.

Table 2.--Estimated Annual Reporting Burden¹

Collection Activity; 21 CFR Section	Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Registrations or Updates; § 118.11	FDA 3733 ²	350	1	350	2.3	805
Cancellations; § 118.11	FDA 3733	30	1	30	1	30
Total						835

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

² The term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at <http://www.access.fda.gov> per § 118.11(b)(1).

Our estimates for the recordkeeping and reporting burdens are based on our experience with similar recordkeeping activities and the number of registrations and cancellations received in the past 3 years.

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately \$14,595,710 per year. We estimate that the average hourly wage for the employee engaged in recordkeeping, testing, and registration would be equivalent to a GS-6/Step-1 level in the locality pay area of Washington-Baltimore in 2025, which is \$24.65/hour. Adding fifty percent (50%) to this wage to account for overhead costs, we estimate the average hourly cost to respondents to be \$36.98/hour. Thus, the overall estimated cost incurred by the respondents is \$14,595,710 (394,692 burden hours x \$36.98/hr).

Table 3.--Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Support employee	394,692	\$36.98	\$14,595,710

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 collection.

14. Annualized Cost to the Federal Government

Our review of the registration documents would generally occur as part of the registration process. We devote approximately 2 hours per registration to the inspection of the documents; cancellations require only a nominal amount of processing time, which has been factored into the registration process. We estimate the annualized cost to the Federal government for the review of records retained by a firm to be \$145.77 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation at a GS-12, step 1 wage for the locality pay area of Washington-Baltimore for 2025 of \$48.59/hour. Two hours multiplied by \$48.59 per hour equals \$97.18. To account for overhead, this cost is increased by 50 percent, making the cost to the Federal government \$145.77 per review. As noted above, we estimate that we will receive an average of 350 registrations per year over the next 3 years, and an average of 30 registration cancellations annually. Thus, the cost to the government to review the registration documents is estimated to be \$51,020 per year (350 registrations per year x \$145.77 per review).

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimates for the recordkeeping and reporting burdens are based on our experience with similar recordkeeping activities and the number of registrations and cancellations received in the past 3 years.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish data from this information collection.

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

We will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.