United States Food and Drug Administration

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

OMB Control No. 0910-0660

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) 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 (21 CFR 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 with regard to each information collection provision of part 118, 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, 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 to the table egg market, 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

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 CFSAN 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 January 19, 2022 (87 FR 2797). Two comments were received, however only one was responsive to the four information collection topics solicited and is discussed here.

One comment suggested that farms could save money by pooling samples while conducting environmental testing, proffering a 2015 research article. FDA reviewed the 2015 research article by Kinde et al.[1] and had additional questions about the equivalency of pooled versus non-pooled samples. This led to a subsequent 2020 study conducted and published by Jones et al.,[2] which found that analysis of pooled samples was not equivalent to that of single samples. In environmental samples, the level of background microflora plays a role in the ability to detect SE, if present. When samples are pooled, the amount of background microflora is amplified, potentially causing the inability to detect SE by masking its presence. This is further exacerbated based on the number of pooled samples (e.g., 2 vs 4 samples per collection bag) and could result in false negative test results. After consideration of the science, FDA determined that at this time, there is not sufficient data to consider pooled samples equivalent to single samples, as required by the reference methods cited in § 118.8. While we understand cost considerations are important, the primary concern should always be the ability to detect SE if it is present.

The comment also suggested adjusting the egg testing protocol to two 1,000-egg samples instead of four 1,000-egg samples. Testing four 1,000-egg samples over an 8-week period results in approximately a 95% probability that a positive egg will be detected from a flock that is producing SE-contaminated eggs with a prevalence of 1 in 1,400. Testing fewer than 4,000 eggs over a period of 8 weeks, as required by § 118.7, would result in less than a 95% probability that a positive egg would be detected from a flock that is producing SE-contaminated eggs at that rate.

We find that the required testing established under 21 CFR 118.7 and 118.8 best protects the public health and that relaxing the current testing requirements, whether or not in an effort to reduce costs, would not provide the same level of protection necessary to ensure the public health.

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

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work that they perform as either the facility owner or operator, or an individual authorized to submit on behalf of the facility owner

[1] Hailu Kinde, Helen A. Goodluck, Maurice Pitesky, Tom D. Friend, James A. Campbell, and Ashley E. Hill, 2015. Validation of Single and Pooled Manure Drag Swabs for the Detection of Salmonella Serovar Enteritidis in Commercial Poultry Houses. Avian Diseases 59(4):548-553.

[2] Deana R. Jones, Richard K. Gast, Prafulla Regmi, Garrett E. Ward, Kenneth E. Anderson, and Darrin M. Karcher, 2020. Pooling of Laying Hen Environmental Swabs and Efficacy of Salmonella Detection. Journal of Food Protection 83(6):943-950.

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 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.

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 questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Recordkeeping Burden[1]

Activity; 21 CFR Section	No. of Recordkeepers[2]	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Refrigeration Records; § 118.10(a)(3)(iv)	2,600	52	135,200	0.5 (30 minutes)	67,600
Testing, Diversion, and Treatment Records; § 118.10(a)(3)(v) through (viii) (positive)[3]	343	52	17,836	0.5 (30 minutes)	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 minutes)	36,271
Testing, Diversion, and Treatment Records; § 118.10(a)(3)(v) through (viii) (negative)[3]	5,965	1	5,965	0.5 (30 minutes)	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 minutes)	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 minutes)	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 minutes)	166
Total					393,857

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Some records are kept on a by-farm basis and others are kept on a by-house basis.
[3]Calculations include requirements for pullet and layer houses.

Table 2.--Estimated Annual Reporting Burden[1]

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 $12,930,110 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 2022, approximately $21.84/hour. Adding fifty percent (50%) to this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $32.76/hour. Thus, the overall estimated cost incurred by the respondents is $12,930,110 (394,692 burden hours x $32.76/hr).

Table 3.--Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Support employee	394,692	$32.76	$12,930,110

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 $129.12 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation at a GS-12, step 1 salary for the locality pay area of

Washington-Baltimore for 2022 of $43.04/hour. Two hours multiplied by $43.04 per hour equals $86.08. To account for overhead, this cost is increased by 50 percent, making the cost to the Federal Government $129.12 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 $45,192 per year (350 registrations per year x $129.12 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. However, burden costs were inadvertently entered into OMB's ROCIS automated system for this collection the last time this collection was approved by OMB, and those costs should be revised from $12,002,584 to zero.

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.