UNITED STATES FOOD & DRUG ADMINISTRATION

Production, Storage, and Transportation of Shell Eggs:
21 CFR part 118

OMB Control No. 0910-0660

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

Shell eggs contaminated with *Salmonella Enteritidis* (SE) are responsible for more than 140,000 illnesses per year. 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). 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)), the Food and Drug Administration (FDA or we) is authorized to issue regulations for the efficient enforcement of the FD&C Act.

Accordingly, regulations are established under part 118 (21 CFR part 118), requiring shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further 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.

We strongly encourage electronic registration because it provides for more efficient processing. The system the agency has developed can accept electronic registrations 24 hours a day, 7 days a week. A registering shell egg producer will receive confirmation of electronic registration instantaneously once all the required fields on the registration screen are completed. However, paper registrations will also be accepted. Form FDA 3733 is available for download for registration for submission by mail, fax, or CD-ROM (see 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 the agency has developed can accept electronic registrations 24 hours a day, 7 days a week, 365 days a year. The individual registering a facility will receive 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 that we will have to enter 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 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 ninety-nine percent (99%) of respondents are small businesses. Farms with more than 3,000 layers are considered small by Small Business Administration (SBA) standards. The SBA defines chicken and egg producers to be small if their total revenues are less than $11.5 million. A producer that receives $0.45 per dozen eggs and has layers that produce 265 eggs per year would have to have over 1,100,000 layers in production to earn revenues of over $11.5 million. Because only about 400 farms fall into the category of 100,000 or more layers, more than 99 percent of the farms with more than 3,000 layers are considered small by SBA standards, and account for roughly 60 percent of all production. We assist small businesses by providing small farms (farms with between 3,000 and 49,999 laying hens) up to three years to comply with the recordkeeping and registration provisions of the regulation; and by exempting very small

farms (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 provides 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. We also provide a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

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 March 26, 2019 (84 FR 11309). 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. While we are aware of the referenced study, we decline to adopt the alternative methodology.

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 percent 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 percent 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

The regulation does not specify confidentiality. However, records that may be consulted during FDA farm inspections are subject to FDA's regulations on the release of information, 21 CFR part 20. Confidential commercial information is protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). To the extent 21 CFR 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

Privacy Act

This ICR does not request any personally identifiable information. It does include a form, but that form does not require a Privacy Act Statement under 5 U.S.C. § 552a(e)(3).

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 Costs

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

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

Description and 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 mins.)	67,600
Testing, Diversion, and Treatment Records, § 118.10(a)(3)(v) to (a)(3)(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) to (a)(3)(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			804,169		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.

We are basing our estimates for the recordkeeping burden and the reporting burden on our experience with similar recordkeeping activities and the number of registrations and cancellations received in the past 3 years.

The number of recordkeepers estimated in column 2 of Table 1 is drawn from estimates of the total number of layer and pullet houses affected by part 118. We assume that those farms that were operating according to recognized industry or State quality assurance plans prior to their compliance date under 21 CFR part 118 were already largely in compliance with the plan design and recordkeeping provisions discussed in this section, and therefore are not experiencing additional costs to comply with recordkeeping provisions. We found that 59 percent of farms with more than 50,000 layers are members of State or industry quality assurance plans. Fewer than 8 percent of farms with fewer than 50,000 layers were members of quality assurance plans. Thus, we estimate the number of layer farms incurring a new recordkeeping burden because of part 118 to be 2,600, and the number of houses affected to be 4,731.

Prevention plan design (§ 118.10(a)(1)) records are kept on a per farm basis, so we assume that new prevention plan design is only undertaken by new entrants to the industry. Refrigeration records (§ 118.10(a)(3)(iv)) are also kept on a per farm basis so the estimated number of recordkeepers for this provision is 2,600.

Records of chick and pullet procurement (§ 118.10(a)(2)), rodent and other pest control (§ 118.10(a)(3)(ii)), and biosecurity (§ 118.10(a)(3)(i)) are kept on a per house basis, so the estimated number of recordkeepers for these provisions is 4,731.

Records of cleaning and disinfection (§ 118.10(a)(3)(iii)) are also kept on a per house basis, but only need to be kept in the event that a layer house tests environmentally positive for SE. Prevention plan review and modifications (§ 118.10(a)(4)) also need to be performed every time a house tests positive, which we estimate that 7.0 percent tests positive. Therefore, the number of recordkeepers for these provisions is estimated to be 331 (4,731 houses x 0.070) annually.

Records of testing, diversion, and treatment (118.10(a)(3)(v) to (a)(3)(viii)) are kept on a per house basis and include records on flocks from pullet houses. We estimate that there are one-third as many pullet houses as there are layer houses. Therefore, the total number of recordkeepers for these provisions is 6,308 (4,731 + (4,731/3)). The number of annual records kept depends on whether or not houses test positive for SE. Annually, 343 layer and pullet houses ((4,731 layer houses x 0.070) + ((4731/3 pullet houses) x 0.0075)) are expected to test positive and 5,965 are expected to test negative ((4,731 layer houses x 0.930) + ((4731/3 pullet houses) x 0.9925)).

We assume that refrigeration records are kept on a weekly basis on a per farm basis under § 118.10(a)(3)(iv)). We estimate that 2,600 recordkeepers maintain 52 records each for a total of 135,200 records and that it takes approximately 0.5 hour per recordkeeping. Thus, the total annual burden for refrigeration records is estimated to be 67,600 hours (135,200 x 0.5 hour).

We assume that records of testing, diversion, and treatment under § 118.10(a)(3)(v) to (a)(3)(viii)) are kept weekly in the event a layer house tests environmentally positive for SE. We estimate that 343 layer and pullet houses test positive and thus 343 recordkeepers maintain 52 records each for a total of 17,836 records and that it takes approximately 0.5 hour per recordkeeping. Thus, the total annual burden for testing, diversion, and treatment records in the event of a positive test result is calculated to be 8,918 hours (17,836 x 0.5 hour).

Given a positive environmental test for SE, we estimate the weighted average number of egg tests per house under § 118.10(a)(3)(vii)) to be 7. We estimate that 331 recordkeepers maintain 7 records each for a total of 2,317 records and that it takes approximately 8.3 hours per recordkeeping. Thus, the total annual burden for egg testing is calculated to be 19,231 hours (2,317 x 8.3 hours).

We estimate that all 1,577 pullet and 4,731 layer houses not currently testing (6,308 recordkeepers) incur the burden of a single environmental test annually under § 118.10(a)(3)(v)). The number of samples taken during the test depends on whether a farm employs the row-based method (an average of 12 samples per house) or the random sampling method (32 samples per house). We estimate that roughly 50 percent of the houses affected employ a row-based method and 50 percent employ a random sampling method, implying an average of 23 samples per house. Thus, we estimate that 6,308 recordkeepers take 23 samples each for a total of 145,084 samples. The time burden of sampling is estimated on a per swab sample basis. We estimate that it takes approximately 15 minutes to collect and pack each sample. Thus, the total annual burden for environmental testing is estimated to be 36,271 hours (145,084 records x 0.25 hour).

We estimate that records of testing, diversion, and treatment under § 118.10(a)(3)(v) to (a)(3)(viii)) are kept annually in the event a layer house tests environmentally negative for SE. We estimate that 5,965 layer and pullet houses test negative and thus 5,965 recordkeepers maintain one record of that testing that take approximately 0.5 hour per record. Thus, the total annual burden for testing, diversion, and treatment records in the event of a negative test result is estimated to be 2,983 hours (5,965 records x 0.5 hour).

Prevention plan review and modifications under § 118.10(a)(4)) need to be performed every time a house tests positive. We estimate that 331 layer houses test positive requiring plan review and modifications and that it takes 10 hours to complete this work. Thus, the total annual burden for prevention plan review and modifications in the event of a positive test result is calculated to be 3,310 hours (331 records x 10 hours).

We estimate that chick and pullet procurement records under § 118.10(a)(2) is kept roughly once annually per layer house basis. We estimate that 4,731 layer houses maintain 1 record each and that it takes approximately 0.5 hour per recordkeeping. Thus, the total annual burden for chick and pullet procurement recordkeeping is calculated to be 2,366 hours (4,731 records x 0.5 hour).

We estimate that rodent and other pest control records under § 118.10(a)(3)(ii)) and biosecurity records under § 118.10(a)(3)(i) are kept weekly on a per layer house basis. We assume that 4,731 layer houses maintain a weekly record under each provision. Thus, we estimate 9,462 recordkeepers maintain 52 records each for a total of 492,024 records. We estimate a recordkeeping burden of 0.5 hours per record for a total of 246,012 burden hours (492,024 records x 0.5 hour).

New prevention plan design required by § 118.10(a)(1) is only undertaken by new farms and records are kept on a per farm basis. We estimate that there are 350 new farm registrations annually and we assume that this reflects 350 new farms requiring prevention plan design. This is an increase from our previous estimate based on new registrations received. We estimate that it takes 20 hours to complete this work. Thus, the total annual burden for prevention plan design is calculated to be 7,000 hours (350 records x 20 hours).

Cleaning and disinfection recordkeeping under § 118.10(a)(3)(iii) needs to be performed every time a house tests positive. We estimate that 331 layer houses will test positive requiring 1 record each and that it takes approximately 0.5 hour per recordkeeping. Thus, the total annual burden for cleaning and disinfection recordkeeping in the event of a positive test result is calculated to be 166 hours (331 records x 0.5 hour).

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

Description and 21 CFR Section	Form FDA	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Registrations or Updates, § 118.11	3733[2]	350	1	350	2.3	805
Cancellations, § 118.11	3733	30	1	30	1	30
Total				380		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).

This estimate is based on the average number of new shell egg producer registrations and cancellations received in the past 3 years under § 118.11. We estimate that we will receive 350 registrations or updates per year over the next 3 years and that it takes the average farm approximately 2.3 hours to register, taking into account that some respondents completing the registration may not have readily available Internet access. Thus, the total annual burden for new shell egg producer registrations or updates is estimated to be 805 hours (350 respondents x 2.3 hours).

We estimate that we will receive approximately 30 cancellations per year over the next 3 years and that cancelling a registration, on average, requires a burden of approximately 1 hour, taking into account that some respondents may not have readily available Internet access. Thus, the total annual burden for cancelling shell egg producer registrations is calculated to be 30 hours (30 cancellations x 1 hour).

We estimate that the burden for this information collection will increase since the last OMB approval due to the estimated annual increase of 50 new farm registrations and recordkeeping. As a result, the total annual recordkeeping burden will increase from 392,857 to 393,857 hours, and the total annual reporting burden will increase from 720 to 835 hours.

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $12,002,584 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 2019, approximately $20.27/hour. Adding fifty percent (50%) to this wage to account for overhead costs, we estimate the average hourly cost to

respondents to be $30.41/hour. Thus, the overall estimated cost incurred by the respondents is $11,122,486 (394,692 burden hours x $30.41/hr = $12,002,584).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Support Employee	394,692	$30.41	$12,002,584

13. Estimates of 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.

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 in to the registration process. We estimate the annualized cost to the Federal Government for the review of records retained by a firm to be $119.88 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation at a base GS-12, step 1 salary for the locality pay area of Washington-Baltimore-Northern Virginia for 2019 of $39.96/hour. Two hours multiplied by $39.96 per hour equals $79.92. To account for overhead, this cost is increased by 50 percent, making the cost to the Federal Government $119.88 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. Thus, the cost to the government to review the registration documents is estimated to be $41,958 per year (350 registrations per year x $119.88 per review).

15. Explanation for Program Changes or Adjustments

This information collection reflects adjustments. We have increased our estimate based on an increase in registrations, resulting in 100 additional responses and 1,115 additional burden hours. We have also uploaded cost information to appear at www.reginfo.gov, and have changed the title of the collection to align with the underlying regulations.

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.