



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0297]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prevention of Salmonella Enteritidis in Shell Eggs During Production; Recordkeeping and Registration Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0660. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prevention of Salmonella Enteritidis in Shell Eggs During Production--Recordkeeping and
Registration Provisions--21 CFR 118.10 and 118.11

OMB Control Number 0910-0660--Extension

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 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)), 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 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.

Section 118.10 of FDA's regulations requires recordkeeping for all measures the 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 maintained on file 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. 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 strongly encourage electronic registration because it is faster and more convenient. The system can accept 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 will also be accepted. Form FDA 3733 is available for download for registration by mail or CD-ROM.

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

notify quickly 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.

In the Federal Register of January 28, 2016 (81 FR 4923), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments in response, both of which supported the collection of information by FDA to ensure that farms are in compliance with the FD&C Act and regulations, and that adequate control measures for prevention of SE are being implemented.

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

Table 1.--Estimated Annual Recordkeeping Burden¹

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	.5 (30 minutes)	67,600
Testing, Diversion, and Treatment Records, § 118.10(a)(3)(v) through (viii) (positive) ³	343	52	17,836	.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	.25 (15 minutes)	36,271
Testing, Diversion, and Treatment Records, § 118.10(a)(3)(v) through (viii) (negative) ³	5,965	1	5,965	.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	.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	.5 (30 minutes)	246,012
Prevention Plan Design, § 118.10(a)(1)	300	1	300	20	6,000

Cleaning and Disinfection Records, § 118.10(a)(3)(iii)	331	1	331	.5 (30 minutes)	166
Total hours					392,857

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 are operating according to recognized industry or State quality assurance plans are 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 are 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 percent tests positive. Therefore, the number of recordkeepers for these provisions is calculated to be 331 ($4,731 \text{ houses} \times 0.070$) annually.

Records of testing, diversion, and treatment (§ 118.10(a)(3)(v) through (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 ($(4,731 \text{ layer houses} \times 0.070) + (4,731 / 3 \text{ pullet houses}) \times 0.0075$) are expected to test positive and 5,965 are expected to test negative ($(4,731 \text{ layer houses} \times 0.930) + (4,731 / 3 \text{ pullet houses}) \times 0.9925$).

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 calculated to be 67,600 hours ($135,200 \times 0.5 \text{ hour}$).

We assume that records of testing, diversion, and treatment under § 118.10(a)(3)(v) through (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 ($17,836 \times 0.5 \text{ hour}$).

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 ($2,317 \times 8.3$ 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 employs 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 calculated to be 36,271 hours ($145,084 \times 0.25$ hour).

We estimate that records of testing, diversion, and treatment under § 118.10(a)(3)(v) through (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 1 record of that testing that takes 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 calculated to be 2,983 hours ($5,965 \times 0.5$ 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 (331×10 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 ($4,731 \times 0.5$ 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 ($492,024 \times 0.5$ 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 300 new farm registrations annually and we assume that this reflects 300 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 6,000 hours (300×20 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 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 (331×0.5 hour).

Table 2.--Estimated Annual Reporting Burden¹

Description and 21 CFR Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Registrations or Updates, § 118.11	Form FDA 3733 ²	300	1	300	2.3	690
Cancellations, § 118.11	Form FDA 3733	30	1	30	1	30
Total						720

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 an average of 300 registrations or updates per year over the next 3 years. Based on the number of cancellations previously received, we estimate that we will receive approximately 30 cancellations per year over the next 3 years.

We estimate that it takes the average farm 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 calculated to be 690 hours (300×2.3 hours).

We estimate 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 \times 1 hour).

Dated: June 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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