4164-01-P

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

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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0660. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, 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.

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

OMB Control Number 0910-0660--Extension--21 CFR 118.10 and 118.11

This information collection supports Agency 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) (42 U.S.C. 264) 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 (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 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 about 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 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 https://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, fax, or CD-ROM. For more information, we invite you to visit our websites at: https://www.fda.gov/food/registration-food-facilities-and-other-submissions/shell-egg-producer-registration 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.

In the *Federal Register* of January 19, 2022 (87 FR 2797), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received, however only one was responsive to the four information collection topics solicited.

The 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. 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., 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., two vs. four 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 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.

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).

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

Dated: July 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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