4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 118

[Docket No. FDA-2000-N-0190 (formerly Docket No. 2000N-0504)]

Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Access to Areas Outside the Poultry House): Questions and Answers Regarding the Final Rule; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Access to Areas Outside the Poultry House): Questions and Answers Regarding the Final Rule." The guidance is intended to provide information to egg producers on certain provisions contained in FDA's final rule entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" (the egg rule) that reference the "poultry house." Specifically, the document provides guidance to shell egg producers whose production systems provide laying hens with access to areas outside of a "poultry house" as that term is defined in the egg rule.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2000-N-0190 for "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Access to Areas Outside the Poultry House): Questions and Answers Regarding the Final Rule." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Plant and Dairy Food Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition, Food

and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Nancy Bufano, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1493; or Marquita Steadman, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Access to Areas Outside the Poultry House): Questions and Answers Regarding the Final Rule." We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on how to interpret the requirements in the egg rule with regard to production systems that provide laying hens with access to areas outside of a "poultry house" as that term is defined in 21 CFR 118.3, including questions and answers on coverage; definitions; *Salmonella* Enteritidis (SE) prevention measures; and environmental sampling for SE. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the *Federal Register* of July 9, 2009 (74 FR 33030), FDA issued the egg rule requiring shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and requiring these producers to maintain records concerning their compliance with the egg rule and to register with FDA. The egg rule became effective September 8, 2009, with a compliance date of July 9, 2010, for

producers with 50,000 or more laying hens. For producers with fewer than 50,000, but at least 3,000 laying hens, the compliance date was July 9, 2012. Producers with fewer than 3,000 laying hens and those that sell all of their eggs directly to consumers are exempt from requirements in the egg rule. The egg rule is codified at part 118 (21 CFR part 118).

In the *Federal Register* of July 24, 2013 (78 FR 44483), we made available a draft guidance entitled "Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Outdoor Access)" and gave interested parties an opportunity to submit comments by September 23, 2013, for us to consider before beginning work on the final version of the guidance. We received more than 3,000 comments on the draft guidance and have modified the content, where appropriate, for this final guidance. In the draft guidance, we indicated that we consider porches to be part of the poultry house because we considered them to be part of a structure used to house poultry. However, comments to the draft guidance indicated that, from a structural perspective, the difference between a porch and an outdoor run (whether an outdoor run-row style or an outdoor run-attached run style) was the presence of a roof, in some cases concrete flooring, and the height of the fence. We considered these comments and upon further analysis determined those differences do not warrant considering one of these systems different from the other two. We have concluded that our initial interpretation did not fully consider how the term "structure" is used within the context of 21 CFR 118.3, particularly with respect to the goal of housing poultry and considering factors such as protection from the elements and from predation and control of temperature, humidity, and lighting. Accordingly, in this final guidance, we consider a porch to be an area outside the poultry house rather than part of the poultry house. Other changes to the guidance include listing additional guidance documents that egg producers should be aware of, and adding additional references to support the statement that wild birds are common vectors of SE. In addition, we made editorial changes

to improve clarity and removed certain recommendations based on practicality. The guidance announced in this notice finalizes the draft guidance dated July 2013.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in part 118 have been approved under OMB control number 0910-0660.

III. Electronic Access

Persons with access to the internet may obtain the guidance at https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: August 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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