

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2000N-0504] (formerly Docket No. 00N-0504)

**Prevention of Salmonella Enteritidis in Shell Eggs During Production;  
Reopening of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; reopening of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is reopening until *[insert date 30 days after date of publication in the Federal Register]*, the comment period for the agency's proposed rule entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production" that published in the **Federal Register** of September 22, 2004 (69 FR 56824). FDA is reopening the comment period to receive comments and other information regarding industry practices and programs that prevent *Salmonella* Enteritidis (SE)-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into laying hen houses.

**DATES:** Submit written or electronic comments by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** You may submit comments, identified by Docket No. 2000N-0504, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Display Date	5-9-05
Publication Date	5-10-05
Certifier	L. CLAWSON
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- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov). Include Docket No. 2000N-0504 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:  
Division of Dockets Management (HFA-305), Food and Drug Administration,  
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the agency name and docket number or regulatory information number for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the relevant docket number, 2000N-0504, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Lou Carson, Center for Food Safety and Applied Nutrition (HFS-032), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2130.

**SUPPLEMENTARY INFORMATION:**

## **I. Background**

In the **Federal Register** of September 22, 2004 (69 FR 56824), FDA proposed regulations that would require egg safety measures to prevent the contamination of shell eggs with SE during egg production. The proposal would reduce SE prevalence in the egg production environment and consequently in the eggs themselves. The proposed SE prevention measures include: (1) Provisions for procurement of chicks and pullets, (2) a biosecurity program, (3) a pest and rodent control program, (4) cleaning and disinfection of poultry houses that have had an environmental sample or egg test positive for SE, and (5) refrigerated storage of eggs at the farm. In addition, the proposal would require that producers test the environment for SE in poultry houses. If the environmental test is positive, the proposal would require that egg testing for SE be undertaken, and that if an egg test is positive, eggs be diverted from the table egg market to a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or to processing in accordance with the Egg Products Inspection Act. The proposed rule had a 90-day comment period, which ended December 21, 2004. To discuss the proposed rule and solicit comments from interested stakeholders, FDA held three public meetings in 2004: October 28 in College Park, MD; November 9 in Chicago, IL; and November 16 in Los Angeles, CA.

## **II. Request for Comments**

Based on comments received in response to the proposal, FDA is seeking further comment and information on industry practices and programs that prevent SE-monitored chicks from being infected by SE during the period of pullet rearing until placement into laying hen houses. Specifically, FDA seeks

additional comment and supportive data or other information on the following questions:

1. How many pullet growing facilities are there in the United States? What is the range in the number of houses on those facilities?

- What percentage of pullet growers are under programs or have practices aimed at preventing SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into layer hen houses?

- Do State or regional Egg Quality Assurance Programs include provisions to prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into layer hen houses? How effective have the pullet programs (whatever the programs entail—cleaning, testing, etc.) been in reducing the prevalence of SE in layer flocks? How is effectiveness measured?

2. During pullet rearing, what programs or industry practices are currently taken to prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into layer hen houses?

- Are pullets, or their environment, tested for SE between the time they are procured as chicks and the time they enter layer houses? If so, when? When tested, approximately how often do pullets or pullet environments test positive? What happens after a positive test?

- Is vaccination used as a preventive measure, if so, when and how?

- What cleaning and disinfecting practices are common?

- Are measures taken to reduce the prevalence of rodents and pests in the pullet rearing houses?

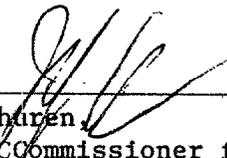
### **III. Comments**

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit

a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify

comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/3/05  
May 3, 2005.

  
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Jeffrey Shuren  
Assistant Commissioner for Policy.

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