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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 16 and 118

[Docket Nos. 1996P–0418, 1997P–0197, 1998P–0203, and 2000N–0504]

RIN 0910–AC14

Egg Safety; Proposed Rule for Prevention of *Salmonella* Enteritidis in Shell Eggs During Production; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meetings.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of public meetings to discuss the proposed rule for prevention of *Salmonella* Enteritidis (SE) in shell eggs during production. On September 22, 2004, FDA published in the **Federal Register** a proposed rule for egg safety national standards. The purpose of these meetings is to solicit public comments on the proposed rule and provide the public an opportunity to ask questions.

DATES: Meetings will be held on October 28, 2004, in College Park, MD; on November 9, 2004, in Chicago, IL and on November 16, 2004, in Los Angeles, CA from 9 a.m. to 1 p.m. and registration will begin at 8 a.m.

FDA provided 90 days for submission of comments on the September 22, 2004 proposal. Written and electronic comments are due by December 21, 2004, and should be submitted in the manner prescribed in the **ADDRESSES** section of this document.

ADDRESSES: The following are a list of the upcoming meeting locations:

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1. Thursday, October 28, 2004, Harvey W. Wiley Federal Building, Auditorium, 5100 Paint Branch Pkwy., College Park, MD.

2. Tuesday, November 9, 2004, Chicago Marriott Downtown Magnificent Mile, 540 North Michigan Ave., Chicago, IL.

3. Tuesday, November 16, 2004, Los Angeles Airport Marriott, 5855 West Century Blvd., Los Angeles, CA.

You may submit comments, identified by [Docket Nos. 1996P–0418, 1997P–0197, 1998P–0203, and 2000N–0504], by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- 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*. Include [Docket Nos. 1996P–0418, 1997P–0197, 1998P–0203, and 2000N–0504 and RIN number 0910–AC14] 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket Nos. or Regulatory Information Number (RIN) 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 **ADDRESSES** 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

docket number(s), found in brackets in the heading of this document, 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: Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2428, FAX 301–436–2605, e-mail: *marion.allen@fda.hhs.gov* for general questions only about the meeting.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 22, 2004 (69 FR 56823), FDA proposed to establish measures to prevent SE contamination of shell eggs during egg production. The motivation for this proposal is a farm-to-table risk assessment of SE in eggs which identified implementation of on-farm prevention measures as a very important step that could reduce the occurrence of SE infections from eggs. While voluntary quality assurance (QA) programs for egg production have led to meaningful reductions in SE illnesses, these programs are not always uniformly administered or uniformly comprehensive in their prevention measures.

Moreover, the most recent data from the Centers for Disease Control and Prevention (CDC) show that SE illnesses have essentially remained steady for the past several years. CDC estimated that 118,000 illnesses were caused by consumption of SE-contaminated eggs in 2001. Accordingly, FDA believes that further actions to improve egg safety, building upon the safe consumer handling labeling and egg refrigeration at retail rule of 2000, are the most effective way to achieve our public health goals of a 50 percent reduction in overall salmonellosis and a 50 percent reduction in SE outbreaks by 2010.

The proposed rule for SE prevention measures includes:

Provisions for procurement of chicks and pullets;

- A biosecurity program;
- A pest and rodent control program;
- Cleaning and disinfection of poultry houses that have had an environmental sample or egg test positive for SE before new laying hens are added to the house;
- Refrigerated storage of eggs at the farm;
- Producer testing of the environment for SE in poultry houses, if the environmental test is positive, FDA proposes that egg testing for SE be undertaken, and that, if an egg test is positive, the eggs be diverted from the table egg market;
- Identification of a person responsible for SE prevention at each farm;
- Recordkeeping requirements for environmental and egg sampling and testing and for egg diversion; and
- *Exemptions*: the proposed rule would not apply to producers who sell all of their eggs directly to consumers or producers with fewer than 3,000 laying hens. In addition, if a producer has 3,000 or more laying hens and all eggs at a farm are to be given a treatment that will achieve at least a 5-log destruction of SE or processed into egg products, then only the proposed refrigeration requirements would apply.

The proposed rule and fact sheet are available on FDA's Web site at: *http://www.cfsan.fda.gov/~dms/fs-eggs6.html* and *http://www.fda.gov/OHRMS/DOCKETS/98fr/1996p-0418-npr0002.pdf.*

II. Registration

Please submit your registration information (including name, title, firm name, address, telephone number, e-mail address, and fax number) at least 7

business days before the meeting date. We encourage you to register online at *http://www.cfsan.fda.gov/~dms/egg0904.html,* or by fax at 202–479–6801. We will accept registration on-site. Space is limited, and registration will be closed at each site when maximum seating capacity for that site is reached. If you need special accommodations due to a disability, including a sign language interpreter, please notify the contact person as listed under **FOR FURTHER INFORMATION CONTACT** in this announcement at least 7 business days in advance of the meeting. All participants must present a valid photo ID when entering a federal building and parking facility.

Attendees are encouraged to present their comments, concerns, and recommendations regarding the proposed rule at the public meeting. Attendees wishing to make a presentation will be allowed 5 minutes each. Please indicate when registering if you wish to make a presentation. Individuals and organizations that do not pre-register to make a presentation may have the opportunity to speak if time permits. While oral presentations from specific individuals and organizations will be limited during the public meeting, the written comments submitted as part of the administrative record may contain a discussion of any issues of concern. All relevant data and documentation should be submitted with the written comments.

III. Transcripts

A transcript of the proceedings from these public meetings, as well as all information and data submitted voluntarily to FDA during the public meetings, will become part of the administrative record and will be available to the public under 21 CFR 20.111 from FDA's Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 at a cost of 10 cents per page. Summaries of the public meetings will also be available for

public examination at FDA's Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/29/04

September 29, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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