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**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

[Docket No. 98-045N3]

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00N-0504]

**Egg Safety Action Plan; Public Meetings**

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**AGENCIES:** Food Safety and Inspection Service, USDA; Food and Drug Administration, HHS.

**ACTION:** Notice of public meetings.

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**SUMMARY:** The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) are announcing two joint public meetings to solicit and discuss information for reducing or eliminating the risk of *Salmonella Enteritidis* (SE) in shell eggs and egg products using a farm-to-table approach. The current status of the Egg Safety Action Plan also will be discussed.

**DATES:** The first meeting will be held on Thursday, March 30, 2000, from 8:30 a.m. to 5 p.m. in Columbus, Ohio. The second meeting will be held on Thursday, April 6, 2000, from 8:30 a.m. to 5 p.m. in Sacramento, California. Comments must be submitted no later than April 20, 2000.

**ADDRESSES:** The first meeting will be held at the Hyatt Regency Columbus at the Greater Columbus Convention Center, 350 North High St., Columbus, OH 43215. Telephone: 614-463-1234. The second meeting will be held in the Auditorium of the California Department of Food and Agriculture Building, 1220 N St., Sacramento, CA 95814. Telephone: 916-654-0561.

**FOR FURTHER INFORMATION CONTACT:**

For registration for the Columbus, OH meeting: Linda Russell, FSIS, 202-501-7249 or FAX 202-501-7615.

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For registration for the Sacramento, CA meeting: Mary Harris, FSIS, 202-501-7315 or FAX 202-501-7615. Persons requiring a sign language interpreter or other special accommodations should notify Ms. Russell or Ms. Harris 1 week before the meeting.

For general information regarding either meeting: Nancy Bufano, FDA, 202-401-2022, FAX 202-205-4422, or e-mail: [nbufano@bangate.fda.gov](mailto:nbufano@bangate.fda.gov); Alice Thaler, FSIS, 202-690-2683, FAX 202-720-8213; or Martha Workman, FSIS, 202-720-3219, FAX 202-690-0824.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background and Information Solicitation**

The President's Council on Food Safety was established in August 1998 to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs. The Council on Food Safety was charged with developing a comprehensive long-range strategic plan that can be used to set priorities, improve coordination and efficiency, identify gaps in the current system, recommend ways to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify or develop measures to show progress.

The Council has identified egg safety as one component of the public health issue of food safety that warrants immediate Federal, interagency action. In July 1999, FDA and FSIS committed to developing an action plan to address the presence of SE in shell eggs and egg products using a farm-to-table approach.

As part of this action plan, FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on the draft goals, as well as to further develop the objectives and action items. The Egg Safety Action Plan, announced by the President on December 11, 1999, was developed, in part, from the input received at the meeting. The Egg Safety Action Plan is available on the Internet at [www.foodsafety.gov](http://www.foodsafety.gov) or from Alice Thaler, FSIS, or Nancy Bufano, FDA (see contact persons).

In this notice, FSIS and FDA are announcing two joint public meetings to solicit and discuss information related to the implementation of the Egg Safety Action Plan. Therefore, the agencies invite comments on the following general questions regarding the Action Plan:

1. Does the Egg Safety Action Plan comprehensively cover the problem of SE in eggs and measures for reducing this hazard? If not, what should the Plan include to be more complete?
2. What are the costs and benefits of implementing each risk reduction component in the Action Plan?
3. What training should be associated with respect to each component of the Action Plan?

However, the specific purpose of the public meetings is to gather information for reducing or eliminating the risk of SE in eggs. In 2000, FDA will propose regulations for egg producers that the States and FDA will enforce; FSIS will propose regulations with performance standards for packers and egg products processors that the States and USDA (FSIS and Agricultural Marketing Service) will enforce. The information shared at the public meetings and during the comment period for the public meetings will be carefully considered as the new regulations are crafted. After the proposed rules are published, the agencies plan to hold additional public meetings to discuss, among other issues, enforcement strategies, as well as strategies to effectively communicate between State and Federal governments.

To obtain public comment on components of the Egg Safety Action Plan, the agencies developed the series of questions posed in this notice. These questions are offered to focus both the discussions at the public meetings and the written comments to be submitted to the docket. Some of the questions reference possible components of an SE-reduction program. An outline of these components will be provided as a handout at the public meetings, and is available on the Internet at [www.usda.fsis.gov](http://www.usda.fsis.gov) or from Alice Thaler, FSIS (see contact person above).

FDA envisions that the on-farm risk reduction measures may include several mandatory components, including the requirement for a risk reduction plan. Environmental testing may be used to verify that this risk reduction plan is effectively controlling SE in the environment. In

order to develop appropriate and adequate on-farm standards, the agency has the following questions regarding shell egg production:

4. Are the following appropriate and adequate components for a nationwide SE reduction program: Bio-security, SE-negative feed, chicks from SE-monitored breeders, flock health monitoring program, cleaning and disinfection of houses, rodent/pest control, monitored water supply?
5. How effective do you think each component would be? Which component(s) do you think will provide the most risk reduction?
6. Is environmental testing an appropriate verification step to ensure that the risk reduction plan is working? If so, how often and when should testing be performed to ensure that the plan is working and that the consumer is protected from consuming SE-contaminated eggs?
7. In the event that an environmental sample for SE is positive, what, if any, additional steps should a producer be required to take with the positive flock/house and with the next flock that will be placed in that house?
8. Where vaccines have been used, is there a correlation between vaccine use and reduction of SE in eggs?

FSIS envisions that packer/processor risk reduction measures may include several mandatory components of a risk reduction plan. In order to propose appropriate and adequate packer/processor performance standards, the agency has the following questions regarding shell egg packing and egg products processing:

9. In the event eggs from an SE-positive layer flock are diverted from the table egg market, what measures should be implemented to ensure those eggs are pasteurized?
10. In the event eggs from an SE-positive flock are diverted to the production of liquid, frozen, or dried egg products, should the eggs be handled or processed differently? Indicate the cost associated with the described process.

11. Do customer specifications exist that prohibit the processing of SE-positive eggs for egg products? Considering your production volume and available market for egg products, will this influence the price for SE-positive eggs?

12. What is an estimated cost to implement the proposed components of a HACCP-based system, including adequate good manufacturing practices to minimize the growth of SE and prevent cross contamination, for each of the following processing operations (include only the new costs incurred such as record keeping, company verification on a continuing basis, and revised processing procedures for conformance):

- a. Packer of shell eggs for the consumer?
- b. In-shell pasteurization of eggs?
- c. HACCP in egg products establishments?

13. For the development of a performance standard(s) for the thermal processing of liquid eggs and other egg products, we are requesting information regarding the enumeration of SE in liquid eggs prior to pasteurization.

14. What is the cost of maintaining refrigerated storage (maximum temperature 60 °F) for eggs received that are destined for grading and packaging or in-shell pasteurization, when time to processing will exceed 24 hours from time of lay?

15. Are there any methods by which a packer/processor can determine how old eggs are when they are received?

16. When packing shell eggs for the consumer, will the use of only new primary packing materials increase your marketing costs? If so, what is the estimated cost? Is there a way to clean plastic containers to prevent cross contamination so they can be re-used?

17. Are the proposed components of the national standards for packing and processing of shell eggs and egg products appropriate and adequate to reduce the risk associated with SE?

In addition to standards for shell egg production and packer/processor standards, the Egg Safety Action Plan includes measures to reduce SE contamination of eggs during distribution and

at retail and includes plans to accelerate SE research. The agencies have the following questions related to retail and research:

18. Do the provisions in the 1999 Food Code which apply to shell eggs adequately protect at-risk consumers in retail establishments? If not, what other provisions are necessary for their protection? (Note: The 1999 Food Code is available on the Internet under "Federal/State Food Programs" at [www.cfsan.fda.gov](http://www.cfsan.fda.gov).)

19. Rewashing of shell eggs is a wide-spread industry practice. Are there data or research to support it? If it is disallowed, what economic effect will it have on the shell egg industry?

20. What research on SE in eggs is already underway and what additional research is needed to assist producers, packer/processors, and retailers in proper practices?

To assess the economic impact of any proposed risk reduction plan, FDA's economics team would like information on the shell egg industry. Useful information which egg farm operators can provide include answers to the following questions:

21. To what extent are you already engaging in the following practices:

- a. Use of chicks from National Poultry Improvement Plan (NPIP) SE-monitored breeders?
- b. Rodent/pest control?
- c. Bio-security?
- d. Cleaning and disinfecting?
- e. Use of monitored water supply?
- f. Use of SE-controlled feed?

22. Testing for verification on the on-farm plan. We are interested in your answers to the following questions for both environmental testing and egg testing:

- a. To what extent are you currently testing?
- b. What is the sampling plan for the tests you conduct?
- c. What tests do you use? Do you test for the presence of Salmonella, SE, SE stereotypes, etc.?
- d. How much do these tests cost (include separately both lab costs and on-farm labor costs)?

23. How much would it cost you to implement each of the proposed components of the risk reduction plan? (Note: The costs you estimate should be the new costs you will bear in excess of what you are already spending on risk reduction.)

24. What are the current market prices or costs you pay or get for the following:

- a. Chicks from NPIP SE-monitored breeders versus chicks from noncertified sources?
- b. Grade A/B eggs versus breaker eggs?
- c. Dry cleaning versus dry, wet disinfecting poultry houses?
- d. SE-controlled feed versus noncontrolled feed?

25. Can you get replacement chicks/pullets at a time different from your usual lay cycle?

If so, what price premium, if any, would you have to pay to get these birds?

26. Do you currently vaccinate your layers for SE? At what time(s)? What does it cost?

27. Before processing or shipping for processing, are your eggs stored on the farm in an environment that is not temperature controlled? For how long? If so, what temperatures are the eggs stored at and how long do they stay in storage?

28. When you ship your eggs from the farm to the processor/ packer, do you reuse packing materials? What steps are taken to minimize any bio-security hazards that may arise from such a practice? How much would it cost to sanitize or use new packing materials for each egg shipment?

29. To help us understand the viewpoint from which you are making your comments, it would be helpful for us to have some information about the structure of your firm. This will help us to determine whether your comment represents an additional perspective that we should consider.

Answers to the following questions would be useful:

- a. In what State(s) do you currently operate?
- b. How many layer houses do you have?
- c. What style of house(s) is typical for your operation?
- d. What is the average number of layers in each house?
- e. Is yours an in-line or an off-line operation?
- f. Do you currently molt your layers? If molting is used, when is it used?

## II. Five Segments of the Public Meetings

The agenda for both public meetings will address the following five segments of the farm-to-table egg safety continuum:

1. On-farm production;
2. Packer shell egg processing;
3. Egg products processing;
4. Retail, food service, and consumer; and
5. Research.

The format of both public meetings will involve discussion of the questions posed in the previous section of this notice. The discussion will be led by a panel composed of stakeholders representing industry, Federal and State government, academia, and consumer interests, and it will include all meeting participants. In addition, there will be time at the end of each meeting for general public comment. However, attendees must request time in advance to participate in this public comment session. Time allotted for comment will be approximately 5 minutes for each participant, but will depend on the number of people participating.

## III. Agenda for Public Meetings Implementing the Egg Safety Action Plan in Columbus, OH (March 30, 2000) and Sacramento, CA (April 6, 2000)

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|------------|---|
| 8:30 a.m.  | Opening presentation—current status of the Egg Safety Action Plan (FDA/FSIS)  |
| 8:45 a.m.  | Significance and prevalence of SE infection associated with eating raw or undercooked eggs (Centers for Disease Control and Prevention) |
| 9:00 a.m.  | On-farm production—overview of the issues (FDA)   |
| 9:10 a.m.  | Discussion—issues for on-farm production  |
| 10:10 a.m. | Break   |
| 10:25 a.m. | Packer/shell egg processing—overview of the issues (FSIS)   |
| 10:35 a.m. | Discussion—issues for packer/shell egg processing   |
| 11:35 a.m. | Lunch—1 hour  |

- 12:35 p.m. Egg products processing—overview of the issues (FSIS)
- 12:45 p.m. Discussion—issues for egg products processing
- 1:45 p.m. Retail/food service/consumer—overview of the issues (FDA)
- 1:55 p.m. Discussion—issues for retail/food service/consumer
- 2:25 p.m. Regulatory impact analysis—the role of economics in rulemaking (FDA)
- 2:35 p.m. Research—overview of the issues (FDA)
- 2:45 p.m. Discussion—issues for research
- 3:15 p.m. Break
- 3:30 p.m. Open microphone—participants must sign in to request a slot
- 4:30 p.m. Closing remarks (FDA/FSIS)

#### **IV. Additional Public Notification**

Public awareness of and involvement in all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce the notice and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the congressional and Public Affairs Office, at 202-720-5704.

## **V. Public Dockets and Submission of Comments**

The agencies have established public dockets to which comments may be submitted.

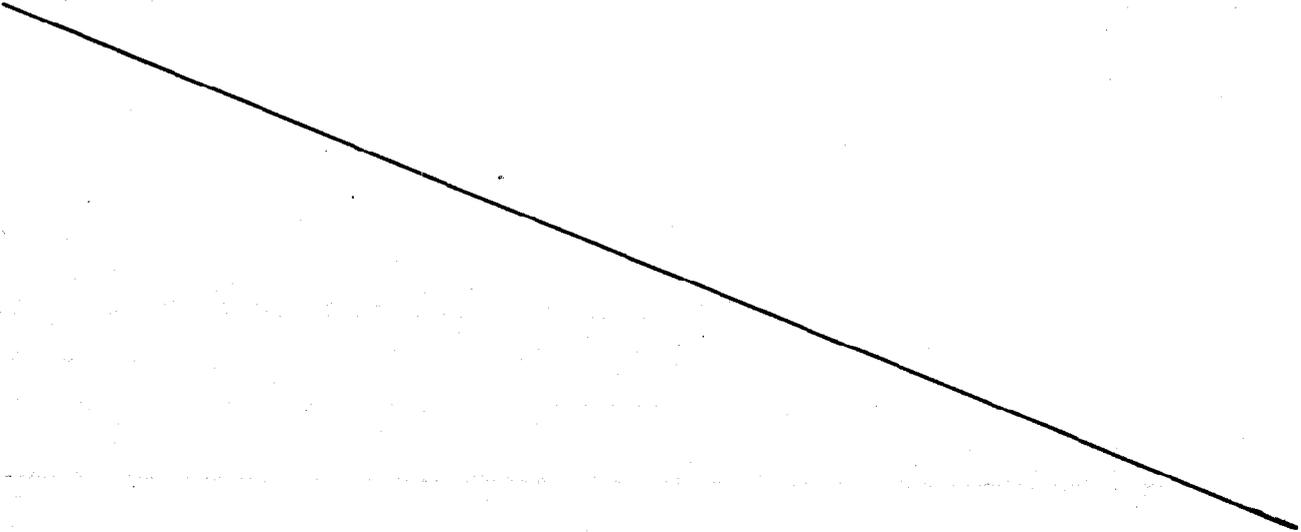
Comments should be directed either to FSIS, Docket No. 98-045N3, or to FDA, Docket No. 00N-0504. All comments must include the appropriate docket number. Submit written comments in triplicate to:

USDA/FSIS Hearing Clerk, 300 12th St. SW., rm. 102, Cotton Annex, Washington, DC 20250-3700, or to

FDA/Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may also send comments to the Dockets Management Branch at the following e-mail address: [FDADockets@oc.fda.gov](mailto:FDADockets@oc.fda.gov) or via the FDA Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>.

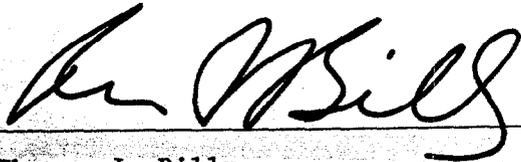
## **VI. Meeting Summaries**

Summaries of the proceedings of the public meetings will be posted on the Internet at [www.foodsafety.gov](http://www.foodsafety.gov). This website is a joint FDA, USDA, and Environmental Protection Agency food safety homepage. It is linked to each agency for persons seeking additional food safety information. Summaries of the proceedings of the public meetings may also be requested in writing from the Dockets Management Branch, FDA (address above) approximately 30 business days after the meetings, at a cost of 10 cents per page. The summaries of the public meetings will be available



for public examination at the Docket Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 2000



Thomas J. Billy,

Administrator

*Food Safety and Inspection Service, United States Department of Agriculture.*



William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

*Food and Drug Administration, Department of Health and Human Services.*

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