

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 308, 310, 318, 320, 325, 326, 327, and 381

[Docket No. 95-039N]

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems—Issue-Focused Public Meetings on the Proposed Regulation

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Meeting notice; closing of comment period.

SUMMARY: The U.S. Department of Agriculture is holding a series of issue-focused public meetings on FSIS' proposed rule, "Pathogen Reduction, Hazard Analysis and Critical Control Point (HACCP) Systems." The purpose of the meetings is to provide an opportunity for interested persons to directly discuss the key concerns that were raised during the comment period on the proposed rule, as well as the Agency's thinking about options under consideration in response to those concerns.

DATES: The issue-focused meetings will be held September 13-15 and September 27-29, 1995, from 9:00 a.m. to 5:30 p.m.

The comment period for the proposed rule, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems" (60 FR 6674, February 3, 1995), which reopened August 11, 1995 (60 FR 41029, August 11, 1995), will close on October 30, 1995.

ADDRESSES: The meetings will be held at the U.S. Department of Agriculture, Back of the South Building Cafeteria (between the 2nd and 3rd wings), 14th Street and Independence Avenue, SW, in Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Charles Danner, Director, Planning Office, Policy Evaluation and Planning Staff, FSIS, USDA, Room 6904, Franklin

Court, Washington, DC 20250, (202) 501-7138. Anyone wishing to attend should contact Ms Lisa Parks at (202) 501-7138. Anyone wishing to obtain copies of the brief issue papers on agenda topics should contact Mr. Andrew Moss at (202) 690-3774. Anyone requiring a sign language interpreter or other special accommodations should make this known to Ms. Parks. The proceedings will be transcribed, and the transcripts will be made a part of the rulemaking record.

SUPPLEMENTARY INFORMATION: On August 23, 1995, USDA held a public scoping session to discuss the agenda and format for the series of issue-focused public meetings being held September 13-15 and 27-29, 1995, on the proposed rule, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems." Based on the discussion that took place at the scoping session, the following format will be observed for the issue-focused meetings:

Format

- The issue-focused public meetings will be held on September 13, 14, 15 and 27, 28, and 29 in the South Building of the U.S. Department of Agriculture, Washington, DC.
- The meetings are open to all interested parties. No concurrent sessions will be held.
- The meetings will be transcribed and made part of the rulemaking record. It is, therefore, unnecessary for oral comments to be duplicatively submitted in written form.
- Interested parties may also provide written comments on issues addressed in the meetings until October 30, 1995.
- Each meeting will focus on the specific set of issues provided in the agenda, below.
- Interested parties with common concerns and positions on a particular issue are encouraged to designate a representative to speak for them on that issue.
- Appropriate FSIS staff will attend and participate in the meetings.
- The moderator of the issue-focused public meetings will be Thomas J. Billy, Associate Administrator, USDA Food Safety and Inspection Service. The role of the moderator will be to foster substantive and focused discussion and dialogue among attendees on agenda items. The moderator will encourage an

open and balanced exchange of views while ensuring that discussions stay generally within announced time frames, remain on the designated subject, and avoid repetitious statements previously provided.

- Based on meeting discussions, the moderator will determine what additional issues will be included on the September 29 agenda.

- Brief issue papers on agenda topics will be provided. See Information Contact above.

- Several issues raised in the scoping session, which did not fall within the HACCP rulemaking, will be included for discussion at the Secretary's Food Safety Forum in October.

Based on the discussion that took place at the scoping session, the following agenda has been adopted:

Agenda

September 13, 1995

Overview of HACCP Proposal

A. Near-Term Measures

- Role and rationale for sanitation standard operating procedures (SOPs), antimicrobial treatments, carcass cooling requirements for red meat as a transition to HACCP

B. HACCP Program

- A tool for process control by industry
- A regulatory tool for FSIS and States
- The role of performance standards
- Application to different segments of industry

—slaughter

—processing, including canned, frozen, and specialty foods

—small plants

- Relationship to farm-to-table food safety strategy

C. Merging HACCP and Current System

- Refocus of inspection tasks
- Shift from command-and-control to performance standards

D. Timing

- Agency implementation
- Industry adoption of HACCP

FSIS Oversight of HACCP*A. Changing the Relationship Between FSIS and Inspected Plants**B. FSIS Inspection Under HACCP*

- Focus on industry's process control system and other systems such as standard operating procedures (SOP's) for sanitation
- Focus on government safety standards

C. Ensuring Compliance With HACCP Requirements

- FSIS and plant accountability
- Enforcement
- Appeal process
- Public access to HACCP records
- Whistleblower protection for FSIS and plant employees

Changing Role of Inspectors Under HACCP

- Focus on industry process control and other systems
- Changing inspection tasks related to product and production to focus on safety
- Inspection outside plants
- Training of inspectors for new roles

September 14

Regulatory Shift to Performance Standards—"Layering"*A. Eliminating Unnecessary and Redundant Regulations and Prior Approval Requirements to Increase Industry's Ability to Innovate to Improve Food Safety**B. Specific Changes Needed for Bringing FSIS Requirements Into Harmony With HACCP**C. FSIS Role in Facilitating Development of HACCP Plans*

- Model plans
- Guidance
- Pilot demonstrations in small plants

September 15

Performance Standards and Microbial Testing*A. Establishing Performance Standards*

- Scientific and policy basis for establishing targets
 - Whether *Salmonella* is the appropriate organism for some or all species
 - Whether other pathogens would be preferable for some or all species
 - Utility of targets for *E. coli* or other non-pathogenic indicator organisms as a means of controlling and reducing pathogenic microorganisms
 - Advantages and disadvantages of targets based on the incidence of detectable contamination (as proposed by FSIS) vs. targets based on the number of organisms present

- Need for pathogen reduction targets for raw ground products in general, and in plants that both slaughter animals and produce ground product

B. Measuring Achievement

- Purpose of testing (verifying process control adequate to achieve target consistently over time vs. enforcement of lot release criterion)

- Frequency of testing
- Who should test (the plant, FSIS, third-party laboratories, or a combination of the three); who should pay

- Laboratory accreditation

September 27

Carcass Cooling Standards for Red Meat and Poultry*A. Feasibility of Proposal**B. Alternatives, Including Performance Standards***Antimicrobial Treatments in Slaughter Plants***A. Should Antimicrobial Treatments be Mandated**B. Alternatives**C. FSIS Role in Specifying Efficacy Standards**D. FSIS Role in Approving Substances/Processes**E. International Considerations***Sanitation Standard Operating Procedures (SOP's)***A. How SOP's Relate to HACCP**B. Alternatives**C. Need for FSIS Sanitation Guidelines**D. Clarification of Acceptable Format, Records**E. Implications of SOPs for FSIS Inspectors in Daily Commencement of Plant Operations**F. Enforcement*

September 28

Specific Economic and Product Considerations*A. General Economic Impact**B. Minimizing Economic Impact Without Compromising Food Safety Goals**C. Taking Account of Impacts on Small Business*

- Definition of small business
- Options to minimize impact and assist small business
- Implementation schedule

D. Taking Account of Impacts on Religious and Ethnic Slaughter and Processing Practices

September 29

Remaining Issues and Review*A. International Considerations*

- Export issues
- Import issues

*B. Incentive-Based Alternatives, Such as Marketing Claims on Labels**C. Animal Producer Considerations**D. Any Issues That Need Further Discussion**E. Summary*

Done at Washington, DC, on: August 28, 1995.

Michael R. Taylor,*Acting Under Secretary for Food Safety.*

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DEPARTMENT OF ENERGY**10 CFR Parts 830 and 834**

[Docket Nos. NE-RM-91-830 and EH-RM-93-834]

RIN 1901-AA34 and 1901-AA38

Nuclear Safety Management and Radiation Protection of the Public and the Environment

AGENCY: Department of Energy.

ACTION: Notice of limited reopening of comment periods.

SUMMARY: On December 9, 1991, the Department of Energy (DOE) published a Notice of Proposed Rulemaking to add regulations establishing a body of rules for DOE contractor and subcontractor activities to ensure safe operation of DOE's nuclear facilities. On March 25, 1993, DOE published a Notice of Proposed Rulemaking to add regulations establishing standards for the protection of the public and the environment against radiation from DOE activities. The purpose of this notice is to reopen the comment periods in these two rulemakings for 30 days in order to solicit comments on options now being considered in light of (1) public comments received during the initial comment periods, (2) comments received from the Defense Nuclear Facilities Safety Board (DNFSB), and (3) comments raised in connection with Departmental initiatives concerning the management of the DOE complex. This notice also announces the availability of current draft language for these regulations, as well as a draft discussion