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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 430

[Docket No. 97–013FE]

RIN 0583–AC46

Control of *Listeria Monocytogenes* in Ready-to-Eat Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule; extension of comment period.

SUMMARY: The Food Safety and Inspection Service (FSIS) is extending the public comment period on the interim final rule ''Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products'' (68 FR 34208; June 6, 2003). The comment period on the rule will end on the same date as the comment period on the Agency report ''Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule'' announced in a document published elsewhere in this issue of the **Federal Register**.

DATES: Comments on the interim final rule must be received on or before January 31, 2005.

ADDRESSES: Comments may be submitted by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send the written comment to FSIS Docket Clerk Docket No. 97–013F, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW., Washington DC 20250–3700. Please state that your comment refers to Docket No. 97–013F. Comments may also be sent electronically. If you use e-mail, address your comment to *FSIS.RegulationsComments@usda.gov*. For more information on e-rulemaking, or to view all open regulations, go to Regulations.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and include the Docket No. 97–013F on the subject line. All comments will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays. The comments may also be viewed on the Agency's Web site at *http://www.fsis.usda.gov/regulations/Federal_Register_Publications_&_Related_Documents/*.

FOR FURTHER INFORMATION CONTACT: Lynn E. Dickey, Ph.D., Director, Regulations and Petitions Policy Staff, Office of Policy, Program, and Employee Development, Food Safety and Inspection Service, U.S. Department of Agriculture, (202) 720–5627.

Done in Washington, DC, on November 15, 2004.

Barbara J. Masters,

Acting Administrator.

[FR Doc. 04–26516 Filed 12–1–04; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 430

[Docket No. 04–032N]

Availability of the Food Safety and Inspection Service Report on Assessing the Effectiveness of the *Listeria Monocytogenes* Interim Final Rule

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of the report ''Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule.'' The report was written by the Agency's *Listeria monocytogenes* (*L. monocytogenes*) Assessment Team (Team) and presents the findings and recommendations of the Team which was responsible for assessing and measuring the effectiveness of the regulation to control *L. monocytogenes* in certain ready-to-eat (RTE) meat and poultry products. FSIS requests comments on the report. FSIS will consider the report and the comments on it, along with the comments that we receive on the interim final rule itself, in deriving a final rule on *L. monocytogenes*.

DATES: To receive full consideration, comments should be submitted by January 31, 2005.

ADDRESSES: FSIS invites interested persons to submit comments on the report ''Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule''. Comments may be submitted by any of the following methods:

- Mail, including floppy disks or CD-ROM's, and hand-or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.

All submissions received must include the Agency name and docket number 04–032N. All comments submitted in response to the report, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/regulations/2004_Notices_Index/*

FOR FURTHER INFORMATION CONTACT: Dr. Arshad Hussain, Director, Data Analysis and Statistical Support Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, (202) 720–3219.

SUPPLEMENTARY INFORMATION:

Background

FSIS published an interim final rule, ''Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products'', on June 6, 2003 (68 FR 34208) that was effective on October 6, 2003. The comment period on the interim final rule is being extended until January 31, 2005, by another document published elsewhere in this issue of the **Federal Register**. The interim final rule requires that official establishments that produce certain ready-to-eat (RTE) meat and poultry

products prevent product adulteration by the pathogenic environmental contaminant *L. monocytogenes*. In particular, under the interim final rule, establishments that produce RTE meat and poultry products that are exposed to the environment after lethality treatments and that support the growth of *L. monocytogenes* will be required to have, in their hazard analysis and critical control point (HACCP) plans or in their sanitation standard operating procedures or other prerequisite programs, controls that prevent product adulteration by *L. monocytogenes*. The establishments must share with FSIS data and information relevant to their controls for *L. monocytogenes*. The establishments also must furnish FSIS with information on the production volume of products affected by the regulations. The establishments may make claims on the labels of their RTE products regarding the processes that they use to eliminate or reduce *L. monocytogenes* or to suppress or limit its growth in the products.

Purpose of the L. Monocytogenes Interim Final Rule Assessment Team

The *L. monocytogenes* Assessment Team (Team) was assembled to assess and measure the effectiveness of the *L. monocytogenes* interim final rule and to report on what the rule has accomplished, what could be done to improve it, and what criteria should be used for long-term evaluations.

The Team's report, ''Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule'', presents the Team's major findings and recommendations. The Agency will use information from this report in deciding whether to modify the interim final rule. FSIS wants to ensure that the *L. monocytogenes* regulations that are in place at the end of this process are as well-designed as they can possibly be as a tool to protect the public health. The Agency also wants to know what it can do to enhance the impact of initiatives associated with the rule, such as consumer education, retail outreach, and public health surveillance.

The Structure of the L. Monocytogenes Interim Final Rule Assessment Team

Out of the main assessment Team, FSIS formed seven smaller teams called Project Assessment Teams (PAT) to review various aspects of the interim final rule and related issues. Three teams, the Public Health team, the Economic Impact team, and the Labeling and Consumer Education team focused on the impact of the interim final rule. Two teams (Sampling Verification and Training) focused on the Agency's on-going verification of the rule. The teams focused on how the Agency verifies that the requirements of the interim final rule are met, and on how it is preparing its inspection program personnel to verify that the requirements of the interim final rule are met. The Small Plant Guidance Team and the Retail Team focused on activities that support the effective implementation of the interim final rule, *i.e.*, the teams focused on what FSIS can do to facilitate compliance.

Each PAT prepared a report of its findings and recommendations. A summary of the findings of each of the seven PATs follows. Also, the PAT reports were presented to the National Advisory Committee on Meat and Poultry Inspection (NACMPI). NACMPI made recommendations that were considered and addressed by each PAT.

Summary of the Findings of Each of the PAT's Reports on ''Assessing the Effectiveness of the Listeria Monocytogenes Interim Final Rule''

Public Health Team

The Public Health team focused on whether it is possible to assess the effects of the rule on public health. The team recognized that it is early to judge these effects. The team investigated whether the rule has affected the alternatives chosen by establishments to control *L. monocytogenes* in post-lethality exposed RTE products. To assess whether there have been changes, FSIS conducted a survey of 1,490 Inspectors-in-Charge (IIC) who cover over 2,900 establishments that produce RTE meat and poultry products. FSIS found that more than 87% of the establishments have changed their operations to more effectively control *L. monocytogenes*. For example, about 59% have started to test for *Listeria* or *Listeria*-like organisms on direct food contact surfaces; 27% have started using an antimicrobial agent to inhibit the growth of this organism; and over 17% have started using post-lethality treatments in RTE products.

Economic Impact Team

The Economic Impact team assessed the assumptions that the Agency made in preparing the economic assessment that was part of the interim final rule. It also gathered data on the costs and benefits of the rule as implemented. For example, the team considered whether the rule is disproportionately affecting small establishments. It found that 56% of the *L. monocytogenes*-related FSIS noncompliance records (NRs) have gone to very small plants, but that this is not a disproportionate share given that very small plants represent about 51% of the plants that produce RTE product. The team found that most of the establishments that received a NR had chosen the least protective alternative to control *L. monocytogenes* available to establishments.

Labeling and Consumer Education Team

The Labeling and Consumer Education Team focused in part on incentive labeling. The interim final rule stated that establishments can declare any processing methodology that they use to address *L. monocytogenes* on their label. The team found that no establishments are using incentive labeling. The team recommended that FSIS use focus group research to help develop statements that would provide flexibility in conveying the fact that RTE product has undergone post-lethality treatment to destroy *Listeria*.

Sampling Verification Team

The Sampling Verification team assessed the *L. monocytogenes* sampling that the Agency performs and determined whether improvements in that sampling are needed. The team recommended that the Agency complete the development of a risk-based sampling regime, including an intensified sampling program in response to positive findings. The Agency's work on this risk-based sampling will begin shortly using the information that FSIS collects on the volume of RTE products produced by establishments.

Training Team

The Training team was responsible for ensuring that the Agency's inspection program personnel are appropriately trained to enforce the interim final rule. The team recommended that FSIS' Food Safety Regulatory Essentials (FSRE) course be given to all FSIS Consumer Safety Inspectors (CSI), and that it be supplemented with compact disc (CD) training that focuses on the interim final rule. FSIS has trained more than half of its 1,700 CSIs on FSRE, and it continually updates the course. The FSRE course has already been updated to reflect the interim final rule. The team also recommended that the work of the CSIs be supplemented by training of the FSIS Enforcement, Investigations, and Analysis Officers (EIAO) on the performance of specialized sampling.

Small Plant Guidance Team

The Small Plant Guidance team found that the Agency needs to develop better ways of ensuring that FSIS Compliance

Guides reach small and very small establishments. The team also suggested that, to be useful to small and very small plants, the guidelines be simplified.

Retail Team

Finally, the Retail team focused on possible means of controlling *L. monocytogenes* in RTE products at retail establishments. This team found that slicing and packaging deli meats at retail establishments represents a significant source of exposure of *L. monocytogenes.* The team suggested two possible strategies for dealing with this problem: (1) education and outreach, and (2) use of antimicrobial agents in products to be sliced and sold at retail establishments. The team also pointed to efforts already underway in the Agency to compare the risk of listeriosis from product sliced in plants with the risk from those sliced at retail establishments. The results of this assessment will be used by the Agency in developing its strategy for retail establishments.

Availability of the Complete Team Report

The report on ''Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule'', with each of the Project Assessment Team's individual reports, is available on the Agency Web site at *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/Docs_97–013F.htm*.

The complete report may also be viewed in the FSIS Docket Room, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC, 20250 between 8:30 a.m. to 4:30 p.m.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

Done in Washington, DC, on October 29, 2004.

Barbara J. Masters,

Acting Administrator.

[FR Doc. 04–26515 Filed 12–1–04; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–18827; Airspace Docket No. 04–ACE–53]

Modification of Class E Airspace; Hannibal, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of the direct final rule which revises Class E airspace at Hannibal, MO.

DATES: *Effective* 0901 UTC, January 20, 2005.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on October 8, 2004 (69 FR 60286). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on January 20, 2005. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO, on November 16, 2004.

Anthony D. Roetzel,

Acting Area Director, Western Flight Services Operations.

[FR Doc. 04–26524 Filed 12–1–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Sulfadiazine/Pyrimethamine Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Animal Health Pharmaceuticals, LLC. The NADA provides for veterinary prescription use of an oral suspension of sulfadiazine and pyrimethamine for the treatment of equine protozoal myeloencephalitis (EPM).

DATES: This rule is effective December 2, 2004.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *melanie.berson@fda.gov*.

SUPPLEMENTARY INFORMATION: Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506, filed NADA 141–240 for veterinary prescription use of REBALANCE (sulfadiazine/pyrimethamine) Antiprotozoal Oral Suspension for the treatment of EPM caused by *Sarcocystis neurona*. The NADA is approved as of November 5, 2004, and 21 CFR part 520 is amended by adding new § 520.2215 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Animal Health Pharmaceuticals, LLC, is not currently listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to