# Proposed Rules

**Federal Register**
Vol. 64, No. 42
Thursday, March 4, 1999

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

### Animal and Plant Health Inspection Service

### 9 CFR Parts 1 and 3

**[Docket No. 98–106–2]**

### Animal Welfare; Petition for Rulemaking

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of extension of comment period.

**SUMMARY:** We are extending the comment period for our notice of a petition for rulemaking received by the Secretary of Agriculture. The petition, sponsored by several petitioners, requests that the Secretary amend the definition of ''animal'' in the Animal Welfare Act regulations to remove the current exclusion of rats and mice bred for use in research and birds and ''grant such other relief as the Secretary deems just and proper.'' This extension will provide interested persons with additional time to prepare and submit comments on the petition.

**DATES:** Consideration will be given only to comments on Docket No. 98–106–1 that are received on or before May 28, 1999.

**ADDRESSES:** Please send your comment and three copies to: Docket No. 98–106–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Please state that your comment refers to Docket No. 98–106–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

Any person who wishes to submit a comment electronically must use a form located on the Internet at http://comments.aphis.usda.gov. Electronically submitted comments need only be submitted once. These comments are available for public viewing at the same Internet address.

**FOR FURTHER INFORMATION CONTACT:** Dr. Jerry DePoyster, Senior Veterinary Medical Officer, AC, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737–1228, (301) 734–7833.

**SUPPLEMENTARY INFORMATION:**

#### Background

On January 28, 1999, we published in the **Federal Register** (64 FR 4356–4367, Docket No. 98–106–1) a notice of petition and request for comments regarding a petition for rulemaking received by the Secretary of Agriculture. The petition, sponsored by several petitioners, requests that the Secretary take two actions: (1) Initiate rulemaking proceedings to amend the definition of ''animal'' in the Animal Welfare Act (AWA) regulations to remove the current exclusion of rats and mice bred for use in research and birds, and (2) ''grant such other relief as the Secretary deems just and proper.'' The AWA regulations are contained in title 9 of the Code of Federal Regulations (CFR), parts 1 through 3; the definitions of terms used in the AWA regulations are at 9 CFR 1.1.

Comments on the petition were required to be received on or before March 29, 1999. We have received a request to extend the period during which comments will be accepted. In response, we are extending the comment period on Docket No. 98–106–1 for an additional 60 days. This action will allow interested persons additional time to prepare and submit comments.

**Authority:** 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.2(g).

Done in Washington, DC, this 26th day of February 1999.

**Joan M. Arnoldi,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 99–5359 Filed 3–3–99; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 9 CFR Part 113

**[Docket No. 97–103–1]**

### Viruses, Serums, Toxins, and Analogous Products; Update of Incorporation by Reference for Rabies Vaccine

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to amend the regulations pertaining to the standard requirements for rabies vaccine, killed virus, so that they incorporate the latest edition of a guide to laboratory techniques. The regulations currently refer to the previous edition of that guide, which was published in 1973. This proposed action would ensure that the latest edition of the guide is incorporated by reference and used in conducting potency tests during the production of rabies vaccines.

**DATES:** Consideration will be given only to comments received on or before May 3, 1999.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 97–103–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 97–103–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. David A. Espeseth, Special Assistant to

the Deputy Administrator, Veterinary Services, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231, (301) 734–8245.

**SUPPLEMENTARY INFORMATION:**

## Background

The regulations in 9 CFR part 113 pertain to standard requirements for the preparation of veterinary biological products. A standard requirement consists of test methods, procedures, and criteria established by the Animal and Plant Health Inspection Service (APHIS) to determine that a veterinary biological product is pure, safe, potent, and efficacious and not worthless, dangerous, contaminated, or harmful.

''Laboratory Techniques in Rabies,'' which is a guide to laboratory techniques for rabies research and diagnosis and for the production of vaccine and immunoglobulin and which is published by the World Health Organization (WHO), is incorporated by reference into the Code of Federal Regulations at 9 CFR 113.209(b)(1). In 1996, the WHO published a fourth edition of ''Laboratory Techniques in Rabies'' (edited by F.X. Meslin, M.M. Kaplan, and H. Koprowski), but the incorporation by reference in § 113.209(b)(1) still refers to the 1973 third edition of that guide. Therefore, we are proposing to amend the regulations in § 113.209(b)(1) so that they refer to the fourth edition of ''Laboratory Techniques in Rabies'' in order for the latest version to be incorporated by reference and used.

The regulations in § 113.209(b)(1) currently refer to potency tests conducted in accordance with the ''NIH Test For Potency'' contained in the third edition of ''Laboratory Techniques in Rabies.'' Because the fourth edition of ''Laboratory Techniques in Rabies'' provides two different methods of conducting the NIH test—a ''standard test'' and a ''modified NIH test''—we would amend § 113.209(b)(1) to specify that it is the standard NIH test for potency that must be used.

With regard to potency tests, the third sentence of § 113.209(b)(1) currently states that the volumetric method of calculation must be used and that the challenge dose must contain between 5 and 50 $LD_{50}$. The required challenge dose has been changed in the fourth edition and is now between 12 and 50 $LD_{50}$. That change in the international standard came about as a result of extensive statistical work that showed the 12 and 50 $LD_{50}$ range to be a more sound measurement for the challenge dose in an animal test system. Because the standard NIH test is a volumetric method, it is not necessary to specify that the volumetric method of calculation be used. Further, because the criteria for an appropriate challenge are fully described in the fourth edition of ''Laboratory Techniques in Rabies,'' it is also not necessary to describe the challenge dose. Therefore, we are proposing to remove the third sentence of § 113.209(b)(1).

The fourth edition of ''Laboratory Techniques in Rabies'' states that the Challenge Virus Standard (CVS) to be used as the challenge in the NIH test is available from the national control authority, which in the United States is APHIS' Center for Veterinary Biologics-Laboratory (CVB–L). A pool of CVS material at a given passage level is established at the CVB–L, which supplies seed from this pool to all producers of inactivated veterinary rabies vaccine. For use as the challenge material, the producer makes one mouse passage from the seed supplied by the CVB–L. This ensures that all producers are using challenge material at the same passage level. As stated in the fourth edition, in a valid NIH test for calculating potency, the reference vaccine dilutions must be such that at the lowest dilution (highest dose) 70 percent of the mice survive after challenge, and at the highest dilution (lowest dose) 70 percent of the mice die after challenge.

The fourth edition of ''Laboratory Techniques in Rabies'' also indicates that each country's national control authority should supply the reference vaccine for the NIH test. The national control authority is responsible for preparing a national reference vaccine that is calibrated against the International Standard. For U.S. producers of veterinary rabies vaccine, the supplier of the reference vaccine is the CVB–L. The reference produced by the CVB–L is calibrated against the current WHO International Standard to a final potency of 1.0 International Unit per mL (IU/mL). This reference vaccine is available upon request from the CVB–L.

## Miscellaneous

In updating the incorporation by reference, we would also revise § 113.209(b)(1) so that it conforms to the requirements of the Office of the Federal Register (OFR) regarding the proper language of incorporation. Specifically, we would amend that paragraph to provide, in accordance with the OFR's regulations in 1 CFR 51.9(b), information regarding the publication's authors and its reference number; state that the incorporation by reference has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a); and state that copies of ''Laboratory Techniques in Rabies'' may be obtained from WHO and may be reviewed at APHIS' offices in Riverdale, MD, or at the Office of the Federal Register in Washington, DC.

We would also remove an outdated footnote in § 113.209(d)(3). That outdated footnote refers the reader to ''footnote 1 to § 113.129(b),'' but § 113.129 and its footnote no longer exist in part 113. (Section 113.129 was redesignated as § 113.209 in a final rule published in the **Federal Register** on August 31, 1990 (55 FR 35556–35563, Docket No. 89–151).) However, the now-absent footnote did provide details regarding the incorporation by reference that is the subject of this proposed rule. Therefore, we are proposing to replace the footnote in § 113.209(d)(3) with text informing the reader that the fourth edition of ''Laboratory Techniques in Rabies'' is incorporated by reference at § 113.209(b)(1).

## Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have considered the potential impacts of this proposed action on small entities. We have identified four producers of rabies vaccine as the entities potentially affected by this proposed rule. Those producers fall into one of two standard industrial classification (SIC) categories, either SIC 2836 (Biological Products, Except Diagnostic Substances) or SIC 2834 (Pharmaceutical Preparations). According to Small Business Administration (SBA) criteria, a business in SIC 2836 is considered to be a small entity if it has 500 or fewer employees, and a business in SIC 2834 is considered to be a small entity if it has 750 or fewer employees. Under those criteria, none of the four producers identified are small entities.

''Laboratory Techniques in Rabies'' is a guide to laboratory techniques for rabies research and diagnosis and for the production of vaccine and immunoglobulin that is incorporated by reference into the standard requirements regulations in 9 CFR 113.209(b)(1). This proposed rule would amend those regulations so that the language used in the guide's incorporation by reference is correct and to ensure that the current

edition of the guide is incorporated by reference and used.

The testing required under § 113.209(b)(1) would remain the same as is currently conducted. However, some retesting may be required due to change in the international standard for the $LD_{50}$ of the challenge dose. We expect that the cost of a retest, which is estimated to be approximately $2,400 for the mice and animal care, would have minimal economic impact on the producers of rabies vaccines, none of which are small entities under SBA criteria.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

**Executive Order 12372**

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

**Executive Order 12988**

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. The Virus-Serum-Toxin Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

**Paperwork Reduction Act**

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**List of Subjects in 9 CFR Part 113**

Animal biologics, Exports, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

Accordingly, we would amend 9 CFR part 113 as follows:

## PART 113—STANDARD REQUIREMENTS

1. The authority citation for part 113 would continue to read as follows:

**Authority:** 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

2. In § 113.209, paragraphs (b)(1) and (d)(3) would be revised to read as follows:

**§ 113.209 Rabies Vaccine, Killed Virus.**

* * * * *

(b) * * *

(1) The preinactivation virus titer must be established as soon as possible after harvest by at least five separate virus titrations. A mean relative potency value of the vaccine to be used in the host animal potency test must be established by at least five replicate potency tests conducted in accordance with the standard NIH test for potency in chapter 37 of ''Laboratory Techniques in Rabies,'' Fourth Edition (1996), edited by F.X. Meslin, M.M. Kaplan, and H. Koprowski, World Health Organization, Geneva, Switzerland (ISBN 92 4 154479 1). The provisions of chapter 37 of ''Laboratory Techniques in Rabies,'' Fourth Edition (1996), are the minimum standards for achieving compliance with this section and are incorporated by reference. These provisions state that the challenge virus standard to be used as the challenge in the NIH test and the reference vaccine for the test are available from the national control authority. In the United States, that authority is the Animal and Plant Health Inspection Service's Center for Veterinary Biologics-Laboratory, located at 1800 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 239–8331; fax (515) 239–8673. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the World Health Organization Publications Center USA, 49 Sheridan Avenue, Albany, NY 12210. Copies may be inspected at the Animal and Plant Health Inspection Service, Center for Veterinary Biologics, Licensing and Policy Development, 4700 River Road, Riverdale, MD, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

* * * * *

(d) * * *

(3) *Potency test.* Bulk or final container samples of completed product from each serial must be tested for potency by tests conducted in accordance with the standard NIH test for potency in Chapter 37 of ''Laboratory Techniques in Rabies,'' Fourth Edition (1996), which is incorporated by reference at paragraph (b)(1) of this section. The relative potency of each serial must be at least equal to that used in an approved host animal immunogenicity test.

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Done in Washington, DC, this 26th day of February 1999.

**Joan M. Arnoldi,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 99–5358 Filed 3–3–99; 8:45 am]

BILLING CODE 3410–34–P

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

### 9 CFR Part 391

**[Docket No. 98–052P]**

### Fee Increase for Inspection Services

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is proposing to increase the fees that FSIS charges meat and poultry establishments, plants, importers, and exporters for providing voluntary inspection, identification, and certification services; laboratory services; and overtime and holiday services. These fee increases are based on the Agency's analysis of its projected costs for Fiscal Year 1999, which identified increased FSIS expenses as a result of national and locality pay raises for Federal employees, and increased travel and overhead costs. The fee increases are being proposed in order to generate the additional revenue that FSIS is required to recover as a result of its projected increased costs.

FSIS also is proposing to reduce the fee it charges for the Accredited Laboratory Program. The Agency's analysis of projected costs for calendar year 1999 has identified decreased operational costs for this program. The Agency is proposing to reduce its fee so that only the actual costs of this program are recovered from the industry.

**DATES:** Written comments must be received by April 5, 1999.

**ADDRESSES:** Submit an original and two copies of written comments concerning this proposed rule to: FSIS Docket Clerk, Docket #98–052P, Room 102-Cotton Annex Building, FSIS, U.S. Department of Agriculture, Washington, DC 20250–3700. Persons that want to present oral comments should, as permitted under the Poultry Products Inspection Act, contact Michael B. Zimmerer at (202) 720–3367. FSIS' cost analysis and the comments that it receives will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 1 p.m. and 2 p.m. to 4:30 p.m., Monday through Friday.