

policies and procedures of the Department. At the conclusion of an investigation of an allegation or complaint of violation of § 287.8, the investigative report shall be referred promptly for appropriate action in accordance with the policies and procedures of the Department.

(d) *Unsubstantiated complaints.*

When an investigative report does not support the allegation, the employee or officer against whom the allegation was made shall be informed in writing that the matter has been closed as soon as practicable. No reference to the allegation shall be filed in the official's or employee's official personnel file.

(e) *Jurisdiction of Department of Justice organizations.* Nothing in this section alters or limits, is intended to alter or limit, or shall be construed to alter or limit, the jurisdiction or authority conferred upon the Federal Bureau of Investigation, the United States Attorneys, the Criminal Division or the Civil Rights Division, or any other component of the Department of Justice that may have jurisdiction regarding criminal violations of law.

■ 20. Section 287.12 is revised to read as follows:

**§ 287.12 Scope.**

With regard to this part, these regulations provide internal guidance on specific areas of law enforcement authority. These regulations do not, are not intended to, and shall not be construed to exclude, supplant, or limit otherwise lawful activities of the Department or the Secretary. These regulations do not, are not intended to, shall not be construed to, and may not be relied upon to create any rights, substantive or procedural, enforceable at law by any party in any matter, civil or criminal. The Secretary shall have exclusive authority to enforce these regulations through such administrative and other means as he may deem appropriate.

Dated: June 6, 2003.

**Tom Ridge,**

*Secretary of Homeland Security.*

[FR Doc. 03-14931 Filed 6-10-03; 3:25 pm]

**BILLING CODE 4410-10-P**

**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**9 CFR Part 113**

[Docket No. 01-091-2]

**Viruses, Serums, Toxins, and Analogous Products; Standard Requirements for Determination of Residual Free Formaldehyde Content of Biological Products**

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

**ACTION:** Final rule.

**SUMMARY:** We are amending the Virus-Serum-Toxin Act regulations for the determination of residual free formaldehyde in veterinary biologics to specify that such determinations be made using the ferric chloride method, and that the residual free formaldehyde content be measured in grams per liter. The ferric chloride method has been adopted as an international standard by scientific experts and regulatory authorities in the United States, Canada, Japan, and the European Union. The effect of this rule will be to reduce the differences in technical requirements for veterinary biologics among regulatory agencies in different countries and further ensure the safety and shelf life of veterinary biologics by adopting a method that has been standardized and accepted internationally.

**EFFECTIVE DATE:** July 14, 2003.

**FOR FURTHER INFORMATION CONTACT:** Dr. Albert P. Morgan, Chief Staff Officer, Operational Support Section, 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 Virus-Serum-Toxin Act regulations in 9 CFR part 113 (referred to below as the regulations) prescribe standard requirements for the preparation and testing of veterinary biological products. Standard requirements consist of test methods, procedures, and criteria that define the standards for purity, safety, potency, and efficacy for a given type of veterinary biological product. When a standard procedure for testing veterinary biological products is validated and approved by the Animal and Plant Health Inspection Service (APHIS) for general use, it is proposed for codification in the regulations. Sections 113.100 and 113.200 of the

regulations prescribe the requirement for determination of residual free formaldehyde content in inactivated bacterial products and killed virus vaccines, respectively.

On April 5, 2002, we published in the **Federal Register** (67 FR 16327-16329, Docket No. 01-091-1) a proposal to amend to amend the regulations for determination of residual free formaldehyde content in inactivated bacterial products and killed virus vaccines to specify that such determinations be made using the ferric chloride method, and that the residual free formaldehyde content be measured in grams per liter. The proposed rule was intended to reduce the differences in technical requirements for veterinary biologics among regulatory agencies in different countries and further ensure the safety and shelf life of veterinary biologics by adopting a method which has been standardized and accepted internationally.

We solicited comments concerning our proposal for 60 days ending on June 4, 2002. We received one comment by that date, from a national trade association representing veterinary biologics manufacturers. The commenter expressed support for the efforts of APHIS and the International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) to harmonize the technical requirements for product registration among the participating regions and recommended that APHIS adopt the provisions of the proposed rule.

Therefore, for the reasons given in the proposed rule, we are adopting the proposed rule as a final rule, without change.

**Executive Order 12866 and Regulatory Flexibility Act**

This 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.

We are amending the Virus-Serum-Toxin Act regulations for determination of residual free formaldehyde content in biological products to require that such free formaldehyde determinations be made using the ferric chloride method, which determines residual free formaldehyde content by measuring the quantity of coloring matter in solution by the quantity of light absorbed in passing through the solution. In addition, this rule provides that the maximum allowable residual free formaldehyde content of veterinary

biologics be measured in grams per liter, rather than equivalent percent or parts per million. The effect of this action will be to provide a standardized method that has been shown to be more accurate than the basic fuchsin method and that has been standardized and adopted internationally.

This rule will affect all licensed manufacturers of veterinary biologics that test inactivated bacterial products and killed virus vaccines for free formaldehyde content. Currently, there are approximately 135 veterinary biologics establishments, including permittees. According to the standards of the Small Business Administration, most veterinary biologics establishments would be classified as small entities.

We do not expect that this rule will impose any additional testing or economic burden on these manufacturers because manufacturers currently test their products for free formaldehyde content using the basic fuchsin and other methods, and the reagents and equipment necessary to perform the ferric chloride test for free formaldehyde content that will be required under this rule are expected to be comparable in cost.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will 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 final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. The 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 final rule contains no new information 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, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 113 as follows:

#### PART 113—STANDARD REQUIREMENTS

■ 1. The authority citation for part 113 continues to read as follows:

**Authority:** 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 113.100, paragraph (f) is revised to read as follows:

#### § 113.100 General requirements for inactivated bacterial products.

\* \* \* \* \*

(f) If formaldehyde is used as the inactivating agent, and the serial has not been found satisfactory by the viricidal activity test, bulk or final container samples of completed product from each serial must be tested for residual free formaldehyde content using the ferric chloride test.<sup>2</sup> Firms currently using tests for residual free formaldehyde content other than the ferric chloride test have until July 14, 2004 to update their Outline of Production to be in compliance with this requirement.

(1) The residual free formaldehyde content of biological products containing clostridial antigens must not exceed 1.85 grams per liter (g/L).

(2) The residual free formaldehyde content of bacterins, bacterin-toxoids, and toxoids, other than those containing clostridial antigens, must not exceed 0.74 grams per liter (g/L).

■ 3. In § 113.200, paragraph (f) is revised to read as follows:

#### § 113.200 General requirements for killed virus vaccines.

\* \* \* \* \*

(f) *Formaldehyde content.* If formaldehyde is used as the killing agent, the residual free formaldehyde content must not exceed 0.74 grams per liter (g/L) as determined using the ferric chloride test.<sup>3</sup> Firms currently using tests for residual free formaldehyde content other than the ferric chloride test have until July 14, 2004 to update

<sup>2</sup> The procedures for performing the ferric chloride test for residual free formaldehyde may be obtained from USDA, APHIS, Center for Veterinary Biologics-Laboratory, 1800 Dayton Road, P.O. Box 844, Ames, IA 50010.

<sup>3</sup> The procedures for performing the ferric chloride test for residual free formaldehyde may be obtained from USDA, APHIS, Center for Veterinary Biologics-Laboratory, 1800 Dayton Road, P.O. Box 844, Ames, IA 50010.

their Outline of Production to be in compliance with this requirement.

Done in Washington, DC, this 10th day of June 2003.

**Peter Fernandez,**

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

[FR Doc. 03–14957 Filed 6–12–03; 8:45 am]

BILLING CODE 3410–34–P

#### DEPARTMENT OF THE TREASURY

#### Office of the Comptroller of the Currency

#### 12 CFR Part 37

[Docket No. 03–11]

RIN 1557–AB75

#### Debt Cancellation Contracts and Debt Suspension Agreements; Change in Compliance Date and Request for Comment

**AGENCY:** Office of the Comptroller of the Currency, Treasury.

**ACTION:** Notice of delay in compliance date; request for comment.

**SUMMARY:** The Office of the Comptroller of the Currency (OCC) has determined to delay the date when compliance is required with certain provisions of the final rule governing debt cancellation contracts (DCCs) and debt suspension agreements (DSAs) in order to allow the OCC to consider issues that have recently been brought to our attention concerning the application of the DCC/DSA rule in the context of closed-end consumer loan transactions where DCCs and DSAs are offered through unaffiliated, non-exclusive agents. The delay of the compliance date applies only to the extent and to the types of transactions described in this document. In all other circumstances, national banks are required to comply with the DCC/DSA rule as of June 16, 2003, which is the date on which the rule takes effect. The OCC also is inviting comment on issues raised by national banks related to the sale of DCCs and DSAs in connection with closed-end consumer loans offered through such non-exclusive agency relationships.

**DATES:** *Compliance date:* The compliance date for certain provisions in 12 CFR part 37 published at 67 FR 58962 (September 19, 2002) is delayed indefinitely. See **SUPPLEMENTARY INFORMATION** for details. OCC will publish a document in the **Federal Register** announcing the compliance date.

*Comment date:* Comments must be received by July 14, 2003.