

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 propose to 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 371.4.

2. Section 113.31 would be revised to read as follows:

§ 113.31 Detection of extraneous replicating avian leukosis virus.

A test that will detect extraneous replicating avian leukosis virus and that is acceptable to the Animal and Plant Health Inspection Service (APHIS) shall be conducted on all biological products containing virus that has been propagated in substrates of chicken origin: *Provided*, An inactivated viral product will be exempt from this requirement if the licensee can provide data that demonstrates to APHIS that the agent used to inactivate the vaccine virus would also inactivate lymphoid leukosis virus.

(a) Propagation of extraneous lymphoid leukosis viruses shall be done in chick embryo cell cultures or other substrate acceptable to APHIS.

(1) Each vaccine virus cytopathic to the cell culture being used shall be effectively neutralized, inactivated, or separated so that minimal amounts of extraneous replicating lymphoid leukosis virus can be propagated during the specified growth period. If the product cannot be tested for extraneous replicating lymphoid leukosis virus because the vaccine virus cannot be effectively neutralized, inactivated, or separated, an alternative procedure acceptable to APHIS shall be specified in the filed Outline of Production.

(2) When cell cultures are tested, 5 mL of the final cell suspension as prepared for seeding of production cell cultures shall be used as inoculum. When vaccines are tested, the equivalent of 200 doses of cytopathic vaccine viruses, including Newcastle disease vaccine, bursal disease vaccine, tenosynovitis vaccine, and reovirus vaccine, or 500 doses of other vaccines for use in poultry, or 1 dose of vaccine for use in other animals shall be used as inoculum. Control cultures shall be prepared from the same cell suspension as the cultures for testing the vaccine.

(3) Uninoculated chick embryo fibroblast cell cultures shall act as negative controls. One set of chick fibroblast cultures inoculated with subgroup A virus and one set of chick fibroblast cultures inoculated with subgroup B virus shall act as positive controls A and B, respectively.

(4) The cell cultures shall be passed when necessary to maintain viability, and samples harvested from each passage shall be tested for group-specific antigen.

(b) A test that will detect extraneous replicating lymphoid leukosis virus and that is acceptable to APHIS shall be used.

(1) All test materials, including positive and negative controls, shall be stored at –60 °C or colder until used in the test.

(2) The test procedure, including the cutoff value indicative of a positive test for extraneous replicating lymphoid leukosis virus, shall be specified in a filed Outline of Production or Special Outline.

(3) The detection of extraneous replicating lymphoid leukosis virus at the first passage shall be considered suspicious and the sample shall be further subcultured and tested to determine the presence of extraneous replicating lymphoid leukosis virus.

(4) Biological products or primary cells that are found contaminated with lymphoid leukosis viruses are unsatisfactory. Source flocks from which contaminated material was obtained are also unsatisfactory.

Done in Washington, DC this 25th day of January 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–1528 Filed 1–30–07; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. APHIS–2006–0079]

RIN 0579–AC30

Viruses, Serums, Toxins, and Analogous Products; Standard Requirements for Live Vaccines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations

for certain live bacterial and viral vaccines by removing the requirement to retest the Master Seeds for immunogenicity 3 years after the initial qualifying immunogenicity test. In addition, we are proposing to amend the requirement concerning mouse safety tests prescribed for a biological product recommended for animals other than poultry. These proposed changes would update the standard requirements by eliminating unnecessary testing of Master Seed bacteria and viruses and other forms of bulk or completed biological product.

DATES: We will consider all comments that we receive on or before April 2, 2007.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>, select “Animal and Plant Health Inspection Service” from the agency drop-down menu, then click “Submit.” In the Docket ID column, select APHIS–2006–0079 to submit or view public comments and to view supporting and related materials available electronically. Information on using [Regulations.gov](http://www.regulations.gov), including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site’s “User Tips” link.

- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2006–0079, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2006–0079.

Reading Room: 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief Staff Officer, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, APHIS, USDA, 4700

River Road Unit 148, Riverdale, MD 20737-1228; (301) 734-8245.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 113 (referred to below as the regulations) contain standard procedures and requirements that are used to establish the purity, safety, potency, and efficacy of veterinary biological products. Current standard requirements in the regulations for certain live bacterial and viral vaccines require each lot of Master Seed virus or bacteria used for vaccine production to be tested for the ability to provoke an immune response (immunogenicity) prior to licensure. In addition, the regulations require such Master Seed virus and bacteria to be retested 3 years after completion of the initial immunogenicity test to confirm persistence of the ability to provoke an immune response.

The requirement to periodically confirm the immunogenicity of a Master Seed has been in place since the adoption of the master seed concept for vaccine production; and had been considered necessary by APHIS until such time that an accumulation of data derived from such confirmatory testing established the antigenic stability of Master Seed bacteria and viruses over extended periods of storage. APHIS' analysis of data submitted by veterinary biologics licensees over several years has shown that the immunogenicity of the Master Seed is not adversely affected over extended periods of storage. Therefore, the requirement to retest Master Seed bacteria and viruses for immunogenicity 3 years after completion of the initial immunogenicity test is no longer considered necessary and would be removed. The elimination of such testing would result in a reduction in testing costs for veterinary biologics licensees and permittees.

Mouse Safety Tests

Safety tests are conducted to ensure that veterinary biologicals are free from properties causing undue local or systemic reactions. When the mouse safety test is prescribed in a standard requirement or filed Outline of Production for veterinary biologicals, the current regulations in § 113.33 specify that vaccine must be tested by inoculating one group of eight mice intracerebrally with 0.03 mL of vaccine and a second group of eight mice intraperitoneally with 0.5 mL of vaccine. Recent data, however, show that inoculating mice subcutaneously with 0.5 mL of vaccine is as effective as

intracerebral inoculation with 0.03 mL. Therefore, we are proposing to amend the regulations regarding the mouse safety test by removing the reference to intracerebral inoculation with 0.03 mL of vaccine and replacing it with a reference to subcutaneous inoculation with 0.5 mL of vaccine. The subcutaneous and intraperitoneal routes of inoculation are considered equally sensitive for the purposes of the mouse safety test. Therefore, we are also proposing to amend the regulations to provide that only one route of inoculation—either the subcutaneous route or intraperitoneal route—be used in the test, rather than two routes as is currently required, and that the test be performed on a single group of eight mice, rather than the two groups of eight currently required. Although this proposed change would reduce the level of testing required by the regulations, we do not anticipate that the reduction in the number of mice used in the safety test would result in an increased number of vaccine-associated local or systemic reactions.

These proposed amendments would update the standard requirements for veterinary biological products by eliminating test procedures which are no longer necessary to ensure the safety of veterinary biologics.

Executive Order 12866 and Regulatory Flexibility Act

This proposed 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 proposing to amend the regulations for certain live bacterial and viral vaccines to eliminate the requirement to retest the Master Seed for immunogenicity 3 years after the initial qualifying immunogenicity test. In addition, this proposed amendment would update the regulations concerning mouse safety tests by requiring either intraperitoneal or subcutaneous inoculation of mice in place of the current requirement to inoculate mice intracerebrally and intraperitoneally. These proposed amendments, if adopted, would remove test procedures that do not provide additional assurance that such products are not worthless, contaminated, dangerous, or harmful.

This proposed rule would affect veterinary biologics licensees and permittees producing live bacterial and viral vaccines and/or conducting the mouse safety test. According to the 2006 Current Veterinary Biologics Product Catalog, there are approximately 122 licensed and 21 permittee veterinary

biologics establishments. The majority of these establishments produce veterinary products and would be affected by this proposal. The entities are classified under North American Industrial Classification System (NAICS) code 325414, Biological Product Manufacturing, and NAICS code 541710, Research and Development in the Physical, Engineering and Life Sciences. The small entity size standard for both groups is 500 or fewer employees.

According to the Small Business Administration, most veterinary biologics establishments would be classified as small entities. In 2002, there were 296 establishments in the Biological Product Manufacturing subsector, 96 percent of which had fewer than 500 employees. However, APHIS does not have the 2006 information on the sizes of all potentially affected entities.

The proposed changes would reduce testing costs for those entities by eliminating the requirement to retest the Master Seed for immunogenicity 3 years after the initial qualifying immunogenicity test. The proposed changes would also reduce, by half, the number of mice used in mouse safety tests by requiring either intraperitoneal or subcutaneous inoculation of mice in place of the current requirement to inoculate mice both intracerebrally and intraperitoneally. By revising the mouse safety test, it would only be necessary to test mice by requiring inoculation either intraperitoneally or subcutaneously. Reducing the number of mice needed for inoculation would therefore decrease the total cost of laboratory testing.

This proposal would not impose any additional economic burden upon the establishments because it actually eliminates testing requirements for the Master Seed and reduces the number of mice, by half, to be tested. The overall effects of this action would be to reduce the costs associated with producing and testing veterinary and biological products. APHIS has been unable to quantify the potential cost savings, and welcomes public comment on the savings that would be afforded by the proposed rule. While the overall effect of this action would be to reduce the costs associated with producing and testing veterinary biological products, we do not expect the amount saved would represent a significant percentage of overall costs.

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 proposed 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 propose to 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 371.4.

2. In § 113.8, paragraph (d) would be amended as follows:

- a. By revising the heading to paragraph (d).
- b. By removing paragraph (d)(1).
- c. By removing the paragraph designation “(d)(2)”.

§ 113.8 In vitro tests for serial release.

* * * * *

(d) *Extending the dating of a reference.* * * *

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3. In § 113.33, paragraphs (a)(1) and (a)(2) would be revised to read as follows:

§ 113.33 Mouse safety tests.

* * * * *

(a) * * *

(1) Vaccine prepared for use as recommended on the label shall be

tested by inoculating eight mice intraperitoneally or subcutaneously with 0.5 mL, and the animals observed for 7 days.

(2) If unfavorable reactions attributable to the product occur in any of the mice during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated: *Provided*, That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

* * * * *

§§ 113.66, 113.68, and 113.69 [Amended]

4. In §§ 113.66, 113.68, and 113.69, paragraph (b)(6) would be removed and paragraph (b)(7) would be redesignated as paragraph (b)(6).

§ 113.67 [Amended]

5. In § 113.67, paragraph (b)(7) would be removed and paragraph (b)(8) would be redesignated as paragraph (b)(7).

§ 113.70 [Amended]

6. In § 113.70, paragraph (b)(5) would be removed.

§§ 113.71, 113.306, and 113.318 [Amended]

7. In §§ 113.71, 113.306, and 113.318, paragraph (b)(4) would be removed and paragraph (b)(5) would be redesignated as paragraph (b)(4).

§ 113.303 [Amended]

8. In § 113.303, paragraph (c)(6) would be removed.

§ 113.302, 113.304, 113.314, 113.315, 113.317, 113.327, 113.331, and 113.332 [Amended]

9. In §§ 113.302, 113.304, 113.314, 113.315, 113.317, 113.327, 113.331, and 113.332, paragraph (c)(4) would be removed and paragraph (c)(5) would be redesignated as paragraph (c)(4).

§ 113.305 [Amended]

10. In § 113.305, paragraphs (b)(1)(iii) and (b)(2)(iii) would be removed and paragraph (b)(2)(iv) would be redesignated as paragraph (b)(2)(iii).

§§ 113.308 and 113.316 [Amended]

11. In §§ 113.308 and 113.316, paragraph (b)(5) would be removed and paragraph (b)(6) would be redesignated as paragraph (b)(5).

§ 113.309 [Amended]

12. In § 113.309, paragraph (c)(9) would be removed and paragraph (c)(10) would be redesignated as paragraph (c)(9).

§ 113.310 [Amended]

13. In § 113.310, paragraph (c)(8) would be removed and paragraph (c)(9) would be redesignated as paragraph (c)(8).

§ 113.311 [Amended]

14. In § 113.311, paragraph (c)(7) would be removed and paragraph (c)(8) would be redesignated as paragraph (c)(7).

§ 113.312 [Amended]

15. In § 113.312, paragraphs (b)(5) and (b)(6) would be removed and paragraph (b)(7) would be redesignated as paragraph (b)(5).

§§ 113.313 and 113.328 [Amended]

16. In §§ 113.313 and 113.328, paragraph (c)(6) would be removed and paragraph (c)(7) would be redesignated as paragraph (c)(6).

§§ 113.325 and 113.326 [Amended]

17. In §§ 113.325 and 113.326, paragraph (c)(5) would be removed and paragraph (c)(6) would be redesignated as paragraph (c)(5).

§ 113.329 [Amended]

18. In § 113.329, paragraph (c)(5) would be removed and paragraphs (c)(6) and (c)(7) would be redesignated as paragraphs (c)(5) and (c)(6), respectively.

Done in Washington, DC, this 25th day of January 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2006–0973; FRL–8274–8]

Approval and Promulgation of Implementation Plans; State of Kansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a request to revise the State Implementation Plan (SIP) made by the state of Kansas to include updates to its Prevention of Significant Deterioration (PSD) of Air Quality rule. The Kansas revision adopts by reference provisions of 40 CFR 52.21 as in effect July 1, 2004, except for subsections with references to Clean Unit Exemptions, Pollution Control Projects, and the record keeping