without appreciable loss of antigenicity as measured by suitable tests, and which is nontoxic as demonstrated by acceptable tests written into the filed Outline of Production.

(o) *Bacterin-toxoid.* An inactivated bacterial product which is either:

(1) A suspension of organisms, representing a whole culture or a concentrate thereof, with the toxic growth products from the culture which has been inactivated without appreciable loss of antigenicity as measured by suitable tests, the inactivation of organisms and toxins being demonstrated by acceptable tests written into the filed Outline of Production: *Provided,* That it shall contain cellular antigens and shall stimulate the development of antitoxin; or

(2) A combination product in which one or more toxoids or bacterin-toxoids is combined with one or more bacterins or one or more bacterin-toxoids.

(p) *Bacterial extract.* An inactivated bacterial product which consists of the sterile, nontoxic, antigenic derivatives extracted from bacterial organisms or from culture medium in which bacterial organisms have grown.

PART 113—STANDARD REQUIREMENTS

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

Authority: 21 U.S.C. 151–159; 7 CFR 217, 2.51, and 371.2(d).

4. In § 113.100, the heading, introductory paragraph, and paragraphs (a) through (d) are revised to read as follows:

§ 113.100 General requirements for inactivated bacterial products.

Unless otherwise prescribed in an applicable Standard Requirement or in the filed Outline of Production, an inactivated bacterial product shall meet the applicable requirements in this section.

(a) *Purity tests.* (1) Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(2) Each lot of Master Seed Bacteria shall be tested for the presence of extraneous viable bacteria and fungi in accordance with the test provided in § 113.27(d).

(b) *Safety tests.* Bulk or final container samples of completed product from each serial shall be tested for safety in young adult mice in accordance with the test provided in § 113.33(b) unless:

(1) The product contains material which is inherently lethal for mice.

In such instances, the guinea pig safety test provided in § 113.38 shall be conducted in place of the mouse safety test.

(2) The product is recommended for poultry. In such instances, the product shall be safety tested in poultry as defined in the specific Standard Requirement or Outline of Production for the product.

(3) The product is recommended for fish, other aquatic species, or reptiles. In such instances, the product shall be safety tested in fish, other aquatic species, or reptiles as required by specific Standard Requirement or Outline of Production for the product.

(c) *Identity test.* Methods of identification of Master Seed Bacteria to the genus and species level by laboratory tests shall be sufficient to distinguish the bacteria from other similar bacteria according to criteria described in the most recent edition of ''Bergey's Manual of Systematic Bacteriology'' or the American Society for Microbiology ''Manual of Clinical Microbiology''. If Master Seed Bacteria are referred to by serotype, serovar, subtype, pilus type, strain or other taxonomic subdivision below the species level, adequate testing must be used to identify the bacteria to that level. Tests which may be used to identify Master Seed Bacteria include, but are not limited to:

(1) Cultural characteristics,

(2) Staining reaction,

(3) Biochemical reactivity,

(4) Fluorescent antibody tests,

(5) Serologic tests,

(6) Toxin typing,

(7) Somatic or flagellar antigen characterization, and

(8) Restriction endonuclease analysis.

(d) *Ingredient requirements.* Ingredients used for the growth and preparation of Master Seed Bacteria and of final product shall meet the requirements provided in § 113.50. Ingredients of animal origin shall meet the applicable requirements provided in § 113.53.

* * * * *

Done in Washington, DC, this 13th day of March 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–6648 Filed 3–16–95; 8:45 am]

BILLING CODE 3410–34–M

9 CFR Part 113

[Docket No. 93–057–2]

Viruses, Serums, Toxins, and Analogous Products; Sampling of Biological Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations concerning the number of representative samples of product that a firm is required to submit to the Animal and Plant Health Inspection Service for testing at the National Veterinary Services Laboratories, Ames, Iowa. The amendment is applicable to diagnostic test kits and Master Seeds and Cells, and will codify provisions which are not currently in the regulations.

EFFECTIVE DATE: April 17, 1995.

FOR FURTHER INFORMATION CONTACT: Dr. Richard E. Pacer, Senior Staff Veterinarian, Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Veterinary Biologics, 4700 River Road, Unit 148, Riverdale, MD 20737–1228, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR Part 113 contain standard requirements for evaluating veterinary biological products that are licensed by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, under the Virus-Serum-Toxin Act of 1913, as amended by the Food Security Act of 1985. Licenses are required to show that biological products are pure, safe, potent, and efficacious.

Purity and identify tests are performed by the licensee and the National Veterinary Services Laboratories (NVSL) on master seed(s) and master cell stock(s) used in the production of veterinary biological products. The licensee is also required to perform tests on the completed veterinary biological product for purity, safety, and potency as prescribed in a filed outline of production or applicable standard requirements for the product in accordance with § 113.5. The licensee's test results may be confirmed by NVSL personnel using representative biological product samples that the manufacturer is required to submit to APHIS in accordance with § 113.3.

Section 113.3 currently provides licensees and permittees with criteria for selection and submission of veterinary biological products, such as

vaccines, bacterins, antiserums, and toxoids to NVSL. Section 113.3, however, does not state the number of samples of diagnostic test kits and master seeds and cells required by NVSL for product evaluation. These amendments specify that a minimum of 1 sample of a diagnostic test kit, 10 samples of bacterial master seeds, 13 samples of viral master seeds, and 36 milliliters of master cell stocks will be required for evaluation at NVSL.

Finally, minor editorial changes are made in § 113.309 to reflect organizational changes within APHIS.

On March 24, 1994, we published in the **Federal Register** (59 FR 13896–13897, Docket No. 93–057–1) the proposal to amend § 113.3.

We solicited comments for a 60-day period ending May 23, 1994. Two comments were received by that date. Both comments were from licensed manufacturers of veterinary biological products. The commenters were in favor of the proposed rule, but suggested certain changes.

The first commenter felt that the 1 milliliter (ml) sample volume for master seeds and cells was too restrictive and suggested that a volume of ''1 ml or larger'' be specified along with a minimum total volume. Proposed paragraph (c) of § 113.3 specified that ''a minimum individual volume of 1 ml shall be submitted.'' The proposed wording thus did not restrict the total volume to only 1 ml. In response to the commenter, we have amended § 113.3(c)(3) as follows:

> Thirty-six samples of at least 1 ml each or six samples of at least 1 ml each, one sample of at least 20 ml, and one sample of at least 10 ml of Master Cell Stocks. In the case of Master Cell Stocks which are persistently infected with a virus, an additional four samples of at least 1 ml each are required. If these persistently infected cell stocks are intended for use in more than one species, an additional two samples of at least 1 ml are required for each additional species.

The second commenter requested clarification regarding diagnostic test kits when the final product packages contains more than one microtiter test plate. Several diagnostic test kits are designed to use 96-well microtiter test plates or 12- or 16-well microtiter test strips. The proposed rule (§ 113.3(b)(7)) specified the submission of ''two samples of diagnostic test kits'' as a general rule and ''a minimum of one diagnostic kit'' in the preamble of the rule. As the commenter pointed out, multiple test plates or test strips may be packaged together with other test reagents in a single product. In the case of a product with multiple microtiter test plates or test strips, APHIS would not need to test all of the test plates or test strips for proper evaluation of the product. In response to the commenter, we have amended § 113.3(b)(7) and § 113.3(e)(1) to require the submission of a specified number of test plates or test strips along with all other test reagents as prescribed in a filed Outline of Production when a diagostic test kit contains multiple microtiter test plates or test strips.

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 purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget.

There are currently no criteria in the regulations which specify the number of samples needed by NVSL to evaluate diagnostic test kits and Master Seeds and Cells. Almost all of the 114 licensed veterinary biologics companies currently submit samples of Master Seeds and Cells to NVSL for testing. In addition, at least 25 of these companies produce veterinary diagnostic test kits and submit samples of them to NVSL for testing. Many of these companies would be considered small entities. This rule will benefit these entities by clarifying the current requirements.

This rule will reduce the licensees' time and expense in submitting samples to the NVSL by specifying the number of samples required, by increasing the uniformity of sample submissions, and by allowing for more efficient handling of samples by licensees and APHIS personnel. In addition, this amendment could increase revenues for manufacturers of veterinary diagnostic test kits by allowing them to return unrequested samples to inventory for sale.

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 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform: This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq*.).

List of Subjects in 9 CFR Part 113

Animal biologics Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 113 is amended 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 2.17, 2.51, and 371.2(d).

2. In § 113.3, paragraphs (b)(7), (b)(8) and (b)(9) are revised, paragraph (b)(10) is removed, paragraph (c) is revised, and new paragraphs (d) and (e) are added to read as follows:

§ 113.3 Sampling of biological products.

* * * * *

(b) * * *

(7) *Diagnostic test kits:* Two samples of diagnostic test kits. The licensee or permittee will hold one of these selected samples at the storage temperature recommended on the label while awaiting a request by the animal and Plant Health Inspection Service to submit the additional sample. If submission is not requested by the Animal and Plant Health Inspection Service, the additional sample may be returned to the serial inventory after the serial is released. In the case of diagnostic test kits in which final packaging consists of multiple microtiter test plates or strips, the licensee or permittee may submit a specified number of test plates or strips along with all other test reagents as prescribed in a filed Outline of Production and retain a similar amount as a second sample for submission upon request. When the initial sample is not representative of final packaging by the licensee of permittee, e.g., does not consist of all the microtiter test plates or strips, the second sample is not eligible to be returned to serial inventory after the serial is released.

(8) *Autogenous biologics:* Ten samples shall be selected from each serial of autogenous biologic that exceeds 50 containers. No samples, other than those

required by paragraph (e) of this section, are required for a serial of autogenous biologic with 50 or fewer containers.

(9) *Miscellaneous:* The number of samples from products not in the categories provided for in paragraphs (b)(1) through (b)(8) of this section shall be prescribed in the filed Outline of Production for the product.

(c) Prelicensing and Outline of Production changes: Samples needed to support a license application or a change in the Outline of Production for a licensed product shall be submitted only upon request from the animal and Plant Health Inspection Service. Except for miscellaneous products specified in paragraph (b)(9) of this section, the number of such samples shall be at least one and one-half times the number prescribed for such product in paragraph (b) of this section. Samples of Master Seeds and Master Cell Stocks with a minimum individual volume of 1 ml shall be submitted as follows:

(1) Ten samples of Bacterial Master Seeds.

(2) Thirteen samples of viral Master Seeds or nonviral Master Seeds requiring cell culture propagation. For Master Seeds isolated or passed in a cell line different from the species of intended use, an additional 2 samples are required for each additional species. For Master Seeds grown in cell culture and intended for use in more than one species, an additional 2 samples are required for each additional species.

(3) Thirty-six samples of at least 1 ml each or six samples of at least 1 ml each, one sample of at least 20 ml, and one sample of at least 10 ml of Master Cell Stocks. In the case of Master Cell Stocks which are persistently infected with a virus, an additional four samples of at least 1 ml each are required. If these persistently infected cell stocks are intended for use in more than one species, an additional two samples of at least 1 ml each are required for each additional species.

(4) Four samples of the Master Cell Stock + n (highest passage) cells.

(d) Sterile diluent: A sample of Sterile Diluent shall accompany each sample of product, other than Marek's Disease Vaccine, if such diluent is required to rehydrate or dilute the product before use. The volume of diluent shall be an appropriate amount to rehydrate or dilute the product. Samples of Sterile Diluent prepared for use with Marek's Disease Vaccine shall be submitted upon request from the Animal and Plant Health Inspection Service.

(e) Reserve samples shall be selected from each serial and subserial of biological product. Such samples shall be selected at random from final containers of completed product by an employee of the Department, of the licensee, or of the permittee, as designated by the administrator. Each sample shall:

(1) Consist of 5 single-dose packages, 2 multiple-dose packages, or 2 diagnostic test kits, except that, in the case of diagnostic test kits in which final packaging consists of multiple microtiter test plates or strips, a sample may consist of a specified number of test plates or strips along with all other test reagents as prescribed in a filed Outline of Production;

(2) Be adequate in quantity for appropriate examination and testing;

(3) Be truly representative and in final containers;

(4) Be held in a special compartment set aside by the licensee or permittee for holding these samples under refrigeration at the storage temperature recommended on the labels for 6 months after the expiration date stated on the labels. The samples that are stored in this manner shall be delivered to the Animal and Plant Health Inspection Service upon request.

(Approved by the Office of Management and Budget under control number 0579–0013)

§ 113.309 [Amended]

3. In § 113.309, paragraph (c)(4), the words ''Veterinary Services'' are removed and the words ''Animal and Plant Health Inspection Service'' are added in their place.

Done in Washington, DC, this 13th day of March 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–6649 Filed 3–16–95; 8:45 am]

Billing Code 3410–34–M

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9 CFR Part 113

[Docket No. 92–132–2]

Viruses, Serums, Toxins, and Analogous Products; Revision of Standard Requirements

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the Standard Requirements concerning Dog Safety Testing; Canine Distemper Vaccine, Killed Virus; Canine Hepatitis Vaccine, Killed Virus; Canine Adenovirus Type 2 Vaccine, Killed Virus; Mink Enteritis Vaccine, Killed Virus; Canine Hepatitis Vaccine, Live Virus; Canine Adenovirus Type 2 Vaccine, Live Virus; and Canine Distemper Vaccine, Live Virus. The amendments are necessary because new test methods and procedures have been developed that can replace current test requirements and increase the validity of test results. The effect of the amendments is to provide new test methods and procedures and to relax some of the restrictions currently in effect. Also, the Standard Requirement for Canine Distemper Vaccine (Ferret Virulent) is removed because this vaccine is no longer manufactured.

EFFECTIVE DATE: April 17, 1995.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Veterinary Biologics, 4700 River Road Unit 148, Riverdale, MD 20737–1228, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 113 ''Standard Requirements'', (referred to below as the regulations) consist of test methods, procedures, and criteria established by the Animal and Plant Health Inspection Service (APHIS) for the evaluation of veterinary biological products based upon their purity, safety, potency, and efficacy. The Agency periodically reviews the regulations and amends test methods and procedures as required to ensure that they are consistent with current scientific knowledge. On July 23, 1993, we published in the **Federal Register** (*see* 58 FR 39467–39473, Docket No. 92–132–1) a proposed rule to update the regulations based upon current scientific knowledge.

We solicited comments concerning our proposal for a 60-day comment period ending September 21, 1993. We received four comments by that date. One commenter fully supported the proposal as written. Three commenters suggested changes to certain sections related to the Standard Requirements. These comments are discussed below.

Two commenters suggested changes to § 113.204. Both commenters indicated that the portion of the regulations dealing with the time(s) of feces collection for virus detection required clarification, and suggested that feces collection at some point from day 4 to 8 would be appropriate.

APHIS believes that the above comments have merit. APHIS agrees that feces collection early or late in the collection period, or more than once, is unnecessary. Therefore, APHIS has revised the regulations in § 113.204(b)(2) to specify that feces are