

sale, which are intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity; or

(iii) Substances, at any stage of production, shipment, distribution, or sale, which resemble or are represented as biological products intended for use in the treatment of animals through appearance, packaging, labeling, claims (either oral or written), representations, or through any other means.

(3) The term "treatment" shall mean the prevention, diagnosis, management, or cure of diseases of animals.

* * * * *

Guidelines. Guidelines establish principles or practices related to test procedures, manufacturing practices, product standards, scientific protocols, labeling, and other technical or policy considerations. Guidelines contain procedures or standards of general applicability that are usually not regulatory in nature, but that are related to matters that fall under the Virus-Serum-Toxin Act. Guidelines issued by the agency include Veterinary Biologics Licensing Considerations, Memoranda, Notices, and Supplemental Assay Methods.

* * * * *

Done in Washington, DC, this 3rd day of June 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97-14997 Filed 6-6-97; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. 92-090-2]

Viruses, Serums, Toxins, and Analogous Products; Revision of Standard Requirements for *Clostridium Perfringens* Types C and D Toxoids and Bacterin-Toxoids

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations pertaining to the Standard Requirements for *Clostridium Perfringens* Type C and *Clostridium Perfringens* Type D toxoids and bacterin-toxoids. The amendments will reduce the minimum number of rabbits required in order to pool their serum for testing. This amendment will also

clarify the method of determining the test vaccine dose in rabbits based on the recommended vaccine dosage in cattle and other host animal species.

These amended regulations will not change the accuracy of the assays and, under certain circumstances, will reduce the number of required tests as well as the number of mice needed for testing. The amendment is necessary to make the potency assays conform more closely to the revised standard requirements for *Clostridium Novyi* and *Clostridium Sordellii* Bacterin-Toxoids and more economical to run when combination products containing these fractions are tested.

EFFECTIVE DATE: July 9, 1997.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Director, Licensing and Policy Development, Center for Veterinary Biologics, VS, APHIS, USDA, 4700 River Road Unit 148, Riverdale, MD 20737-1237, (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.

These regulations concerning potency testing of *Clostridium Perfringens* Type C Toxoid and Bacterin-Toxoid in § 113.111 and *Clostridium Perfringens* Type D Toxoid and Bacterin-Toxoid in § 113.112 reduce certain test requirements and decrease the cost of performing these tests. This has been accomplished without affecting the accuracy and reliability of the tests.

On March 22, 1993, we published a proposed rule in the **Federal Register** (58 FR 15301-15303, Docket No. 92-090-1) to amend the regulations in § 113.111 pertaining to *Clostridium Perfringens* Type C Toxoid and Bacterin-Toxoid and in § 113.112 pertaining to *Clostridium Perfringens* Type D Toxoid and Bacterin-Toxoid.

We proposed to reduce the number of mice needed for serum neutralization testing in certain circumstances. Also, the current test method uses half of the recommended cattle or sheep dose. The proposed rule provided for potency testing of product recommended for use in host animal species other than cattle and sheep. The test method in the proposed rule provided for recommendations for a variety of host

animal species by prescribing the use of half of the smallest host animal dose.

Current regulations in §§ 113.111(c) and 113.112(c) provide for at least four of eight rabbits which are initially injected to be bled in the potency determination of *Clostridium Perfringens* Type C Toxoid and Bacterin-Toxoid and *Clostridium Perfringens* Type D Toxoid and Bacterin-Toxoid. The amount of antitoxin found in the rabbit sera after injection with the toxoid or bacterin-toxoid is proportional to the potency of the antigen in the product tested.

The antitoxin response of vaccinated rabbits is measured by a toxin neutralization assay in mice. A standard amount of *Clostridium perfringens* Beta or Epsilon toxin is mixed with a designated amount of the test rabbits' sera. The mixture is allowed to neutralize for one hour. Swiss white mice are then injected with this toxin-sera mixture to determine if the standard amount of toxin was neutralized by the test rabbit sera. Since mice are particularly sensitive to these toxins, the absence of mouse mortality indicates sufficient toxin neutralization and thus an adequate antitoxin response in the rabbits tested. The result would indicate an acceptable potency for the toxoid or bacterin-toxoid antigen in the product tested.

Under the current regulations in §§ 113.111(c) and 113.112(c), if four to seven rabbits are bled for potency testing, the sera from each rabbit must be assayed individually. This requires the use of at least 20 to 35 mice (each rabbit serum is tested in a minimum of 5 mice) for serum neutralization testing as compared to a minimum of 5 mice with the single pooled serum sample which was proposed.

The proposed rule required the use of at least seven rabbits in order for the sera to be pooled into a single sample. The potency test would then be conducted on the single pooled sample. Pooling the serum samples of seven instead of eight rabbits would reduce the number of toxin-antitoxin neutralization tests required, the number of mice needed, the time spent, and the expense of the procedure.

We solicited comments concerning our proposal for 60 days ending May 21, 1993. We received six comments by that date from manufacturers of animal health products and a national trade association. One of the commenters supported the proposed rule as written, while five raised specific issues concerning the proposed rule. Those comments are discussed below.

One commenter expressed concern that, as proposed, the rule had the

unintended effect of making the potency test requirements more stringent. As a cure, the commenter recommended the use of half the cattle dose for testing the potency of all *Clostridium Perfringens* Toxoids.

Five other commenters also expressed concern about the proposed reduction in the volume of rabbit inoculum to half the smallest host animal dose. One firm indicated it would be forced to increase antigen content in order to pass the more stringent requirement resulting from a reduced volume of rabbit inoculum, with the possible negative effect on host animal safety.

Three commenters indicated that the proposed inoculum volumes would be incompatible with those in the recently revised standard requirements for *Clostridium Novyi* and *Clostridium Sordellii*, which permitted utilization of the same group of rabbits for testing of sheep and cattle product fractions, the only two species addressed under that standard requirement. One commenter indicated that there is no need to change the volume of the rabbit inoculum under the current regulations.

Yet another commenter suggested that the volume of rabbit inoculum should be half of the largest dose indicated on the label for any species of animal for which the product is recommended. The commenter argued that this suggestion would not affect the potency test procedure for any licensed product, while it would address the dosage to be used for alternate species not specifically addressed under the current regulations, i.e., goats and swine.

In response to these comments, APHIS agrees that a volume of rabbit inoculum that is half the largest host animal dose for any species of animal for which the product is recommended is reasonable and also provides for more general indications that are appropriate for products not recommended for cattle or sheep. Reference to half of the largest host animal dose would, in most cases, result in the same rabbit test dosage that is used for testing these products in the current standard requirement. The proposal to require half the smallest host animal dose would have unnecessarily raised the potency requirement for some products and, in contrast to statements made in the proposed rule, would have resulted in test procedures that were not consistent with recent standard requirements for products containing *Clostridium novyi* and *Clostridium sordellii*. Therefore, in response to these comments, we are amending the regulations in §§ 113.111 and 113.112, paragraph (c)(2), to allow the use of half the largest recommended dose in host animals for the rabbit

potency testing for any species of animal for which the product is recommended. The change in the proposed rule will, in most cases, retain the potency test requirement for these products at the same level as in the current standard requirement while recognizing products that would be used in animals other than cattle or sheep.

In further response to the comment that the standard requirement for *Clostridium Perfringens* should be consistent with those of *Clostridium Novyi* and *Clostridium Sordellii*, APHIS notes that the recently amended standard requirements for *Clostridium Novyi* and *Clostridium Sordellii* require that the strain of rabbit used for potency testing be acceptable to APHIS. APHIS believes that, for consistency, the requirement should apply equally to *Clostridium Perfringens*. Therefore, in response to this comment, we are adding the requirement in §§ 113.111 and 113.112, paragraph (c)(2), that the strain of rabbit used for potency testing *Clostridium Perfringens* be acceptable to APHIS.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This 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.

There are currently some 19 veterinary biologics establishments that may be affected by this rule. According to the Small Business Administration regulations, many of them would be classified as small entities.

This rule will result in a reduction of the number of mice required to perform potency assays. The reduction in the number of mice needed will result in a reduction in the total cost of the assays. Therefore, the rule should provide an economic benefit to producers of veterinary biologics. In addition, this rule clarifies the dosage of rabbit inoculum to be used in potency tests for products recommended for species other than cattle or sheep.

Retests may be indicated if less than 80 percent of control mice, inoculated with standard antitoxin and 10 L₊ doses of standard toxin, die in the neutralization test. However, since the testing of the pooled serum sample requires fewer mice as compared to testing individual serum samples, the

number of mice required for a retest will be less.

Manufacturers, as well as the National Veterinary Services Laboratories, will benefit from the revisions since they will improve efficiency and reduce costs but will not change the accuracy of the assays.

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 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. There are no 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 record keeping 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, 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 2.22, 2.80, and 371.2(d).

2. Section 113.111 is amended by revising paragraphs (c)(2), (c)(3)(i), (c)(3)(ii), (c)(3)(iii), and (c)(5)(iii) to read as set forth below, and by removing paragraph (c)(5)(iv).

§ 113.111 *Clostridium Perfringens* Type C Toxoid and Bacterin-Toxoid.

* * * * *

(c) * * *

(2) Each of at least eight rabbits of a strain acceptable to APHIS, each

weighing 4–8 pounds, shall be injected subcutaneously with not more than half of the largest recommended dose for any species indicated on the product label. A second equivalent dose shall be given not less than 20 days nor more than 23 days after the first dose.

(3) * * *

(i) At least seven rabbits are required to make an acceptable serum pool.

(ii) Equal quantities of serum from each rabbit shall be combined and tested as a single pooled serum.

(iii) If less than seven rabbits are available, the test is invalid and shall be repeated: *Provided*, That, if the test is not repeated, the serial shall be declared unsatisfactory.

* * * * *

(5) * * *

(iii) If any mice inoculated with the mixture of serum with 10 L₅ doses of Standard Toxin die, the serum is considered to contain less than 10 International Units per ml, and the serial is unsatisfactory.

3. Section 113.112 is amended by revising paragraphs (c)(2), (c)(3)(i), (c)(3)(ii), (c)(3)(iii), and (c)(5)(iii) to read as set forth below, and by removing paragraph (c)(5)(iv).

§ 113.112 Clostridium Perfringens Type D Toxoid and Bacterin-Toxoid.

* * * * *

(c) * * *

(2) Each of at least eight rabbits of a strain acceptable to APHIS, each weighing 4–8 pounds, shall be injected subcutaneously with not more than half of the largest recommended dose for any species indicated on the product label. A second equivalent dose shall be given not less than 20 days nor more than 23 days after the first dose.

(3) * * *

(i) At least seven rabbits are required to make an acceptable serum pool.

(ii) Equal quantities of serum from each rabbit shall be combined and tested as a single pooled serum.

(iii) If less than seven rabbits are available, the test is invalid and shall be repeated: *Provided*, That, if the test is not repeated, the serial shall be declared unsatisfactory.

* * * * *

(5) * * *

(iii) If any mice inoculated with the mixture of serum with 10 L₅ doses of Standard Toxin die, the serum is considered to contain less than 2 International Units per ml, and the serial is unsatisfactory.

Done in Washington, DC, this 3rd day of June 1997.

Donald W. Luchsinger,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97-14996 Filed 6-6-97; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97-NM-70-AD; Amendment 39-10045; AD 97-12-03]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes two existing airworthiness directives (AD) that are applicable to certain Boeing Model 747 series airplanes. One of those AD's currently requires inspections for cracking, corrosion, and fracturing of the lower horizontal clevis of the strut midspar fittings, and replacement of discrepant parts with new or serviceable parts, or repair, if necessary. That AD also requires inspection for removal of broken sealant of the clevis and the fasteners, and various follow-on actions. It also provides for optional terminating actions for the inspections. The other AD currently requires inspection for cracking of certain fastener holes of the upper and lower horizontal clevis legs. This amendment continues to require inspections to detect cracking, corrosion, and fracturing of the lower horizontal clevis; and adds corresponding inspections of the upper horizontal clevis, and replacement of discrepant parts with new parts, or rework, if necessary. This amendment also removes certain optional terminating actions. This amendment is prompted by reports of cracking of the lower and upper leg of the horizontal clevis of the midspar fitting. The actions specified in this AD are intended to detect and correct cracking and fracturing of the clevis, which could result in drooping of the strut at the strut-to-wing interface, and consequent separation of the engine and strut from the airplane.

DATES: Effective June 24, 1997.

The incorporation by reference of Boeing Alert Service Bulletin 747-

54A2179, Revision 1, dated November 27, 1996, as listed in the regulations, is approved by the Director of the Federal Register as of June 24, 1997.

The incorporation by reference of the following publications listed in the regulations was approved by the Director of the Federal Register as of the specified dates:

Referenced service bulletin and date	Approval date and Federal Register citation
747-54A2157, January 12, 1995.	July 28, 1995 (60 FR 33333, June 28, 1995).
747-54A2158, November 30, 1994.	July 28, 1995 (60 FR 33336, July 28, 1995).
747-54A2159, November 3, 1994.	June 21, 1995 (60 FR 27008, May 22, 1995).

The incorporation by reference of certain other publications listed in the regulations also was approved previously by the Director of the Federal Register as of January 22, 1997 (60 FR 66201, December 12, 1996).

Comments for inclusion in the Rules Docket must be received on or before August 8, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 97-NM-70-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tamara Dow, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington; telephone (425) 227-2771; fax (425) 227-1181.

SUPPLEMENTARY INFORMATION: On January 13, 1988, the FAA issued AD 87-04-13 R1, amendment 39-5836 (53 FR 2005, January 26, 1988), applicable to certain Boeing Model 747 series airplanes. That AD revised an existing AD to require inspection for cracking, and repair or replacement, as necessary, of the horizontal clevis of the pylon midspar attach fitting. That action was prompted by reports of cracking and corrosion in the fastener holes of the