

# Proposed Rules

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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 50, 51, 77 and 78

[Docket No. 95-006-1]

#### Tuberculosis and Brucellosis in Cattle and Bison; Identification Requirements

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

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to amend the tuberculosis and brucellosis regulations by requiring brands for certain cattle and bison to be placed on the hip rather than the jaw. This action would reduce distress to cattle and bison that need to be identified with a brand by moving the brand to a less sensitive location, but would allow them to continue to be clearly identified. We are also proposing to allow certain cattle and bison to be moved interstate to slaughter without branding if they are accompanied directly to slaughter by an Animal and Plant Health Inspection Service or State representative or are moved in vehicles closed with official seals. This proposed rule responds to increasing public concern that branding on the jaw causes unnecessary distress to cattle and bison.

**DATES:** Consideration will be given only to comments received on or before June 16, 1995.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 95-006-1, 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. 95-006-1. 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. J.D. Kopec, Senior Staff Veterinarian, Cattle Diseases and Surveillance, VS, APHIS, Suite 3B08, 4700 River Road Unit 36, Riverdale, MD 20737-1231; (301) 734-6188.

#### SUPPLEMENTARY INFORMATION:

##### Background

Bovine tuberculosis is a serious communicable disease of cattle, bison, and other species, including humans, caused by *Mycobacterium bovis*. Tuberculosis causes weight loss, general debilitation, and sometimes death.

Brucellosis, also called Bang's disease or undulant fever, is a serious infectious disease of cattle, bison, and other species, including humans, caused by bacteria of the genus *Brucella*. Brucellosis in cattle and bison is characterized by the birth of weak or stillborn calves, slow breeding, abortion, and loss of milk production.

In accordance with the regulations in 9 CFR parts 50, 51, 77, and 78 (referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) administers programs designed to control and eradicate tuberculosis and brucellosis in cattle and bison. As part of these programs, hot-iron branding on the jaw and on the tailhead is used to identify certain cattle and bison. Specifically, hot-iron branding on the jaw is required or allowed in the following cases: (1) To identify cattle or bison that have contracted or been exposed to tuberculosis or brucellosis; (2) to identify certain cattle or bison to be moved interstate to slaughter because of tuberculosis or brucellosis; and (3) to identify adult cattle or bison that have been immunized against brucellosis.

There has been increasing public concern that hot-iron branding on the jaw may cause undue distress to cattle and bison. A number of animal rights groups and other members of the public have requested that APHIS remove hot-iron branding on the jaw from our regulatory programs. In response to their concerns, we are in this document proposing to remove hot-iron branding on the jaw from the regulations in 9 CFR parts 50, 51, 77, and 78. In places where branding is required to be on the jaw, we would move the required location of the brand to high on the hip near the tailhead. In places where the regulations

offer an owner the option of branding either on the jaw or on the hip, we would remove the option of branding on the jaw, but would retain the brand on the hip.

We also considered proposing identification options such as freeze branding, by requiring that the cattle and bison be identified by a brand or by another distinct, permanent, and legible mark. We chose not to propose these options. A limitation of freeze branding is that the brand takes a minimum of 18 to 21 days to become visible. In order that we may continue to prevent the spread of tuberculosis and brucellosis, it is imperative that exposed and affected animals be instantly recognizable from the time of their identification until they are slaughtered, so that they are not commingled with healthy animals. In most cases, exposed or affected cattle or bison would be identified, shipped, and slaughtered before the freeze brand becomes visible. To date, an acceptable alternative to hot-iron branding has not been found for marking exposed or affected cattle or bison that satisfies the criteria of being instantly visible upon application, as well as distinct, permanent, and legible. Until an acceptable alternative is developed, we have chosen to continue to require that branding of cattle and bison under the brucellosis and tuberculosis regulations be with a hot iron. We believe that moving the location of the brand from the jaw to the hip would reduce distress to cattle and bison, but would allow them to continue to be identified distinctly, permanently, legibly, and instantly.

We are, however, proposing several alternatives to branding certain cattle and bison that are to be moved interstate for slaughter. We would allow brucellosis reactor and exposed cattle or bison moving directly to slaughter to be moved without branding if they are accompanied directly to slaughter by an APHIS or State representative. We would also allow brucellosis reactor and exposed cattle or bison moving interstate in slaughter channels (e.g. to a quarantined feedlot, a specifically approved stockyard, or an approved intermediate handling facility, and then to slaughter) to be moved without branding if they are moved in vehicles closed with official seals applied and removed by an APHIS representative, a State representative, an accredited

veterinarian, or an individual authorized for this purpose by an APHIS representative. For movement in sealed vehicles, cattle and bison moving interstate to slaughter because of brucellosis would have to be accompanied by a permit or "S" brand permit, and the official seal numbers would have to be recorded on the accompanying permit or "S" brand permit. (*Permit* and "*S*" brand permit are defined in the regulations, and, in accordance with the definitions, must list: The points of origin and destination, the number of animals covered, the purpose of movement, and one of several possible identification numbers.)

We would allow tuberculosis exposed cattle and bison moving directly to slaughter to be moved without branding if they are accompanied directly to slaughter by an APHIS or State representative. We would allow tuberculosis exposed cattle or bison moving interstate in slaughter channels to be moved without branding if they are moved in vehicles closed with official seals applied and removed by an APHIS representative, a State representative, an accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. For tuberculosis reactor cattle and bison, we would allow the same movement without branding as for tuberculosis exposed cattle and bison, but we would require that the reactors be identified by a permanent and legible "TB" tattooed on the left ear, and by spraying the left ear with yellow paint. Unlike brucellosis reactor cattle and bison, tuberculosis reactor cattle and bison can only be sold for consumption if the meat is cooked. Presently, there are only four slaughtering facilities in the United States that have the capacity to cook the meat, so this option is not available to the majority of cattle and bison owners. Consequently, most tuberculosis reactor cattle and bison sent to slaughter constitute a monetary loss of \$500 or more to the owner. Such monetary loss could provide an incentive to substitute less valuable tuberculosis-free animals for more valuable infected animals, or to otherwise divert valuable tuberculosis infected animals from slaughter channels, impeding tuberculosis eradication efforts in the United States. We believe that requiring tuberculosis reactors to have their left ear tattooed with a "TB" and spray painted yellow would make it difficult for these reactors to be diverted.

These options would provide owners of cattle and bison with an alternative to branding, while helping to ensure

that brucellosis- and tuberculosis-affected cattle and bison are handled and moved to slaughter in a manner that prevents dissemination of these diseases.

#### Miscellaneous

The branding requirements in the regulations are currently inconsistent, providing different size specifications and different descriptions for the location of the brand. This proposed rule would revise the branding requirements not only to remove the option for branding on the jaw, but to make the descriptions consistent. All brands would be required to be positioned high on the left hip near the tailhead and to be at least 5 by 5 centimeters (2 by 2 inches) in size.

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

We do not anticipate that this proposed rule would have an economic impact on any entities, large or small. Cattle and bison that have contracted or been exposed to tuberculosis or brucellosis, or that have been immunized against brucellosis, are already required to be identified by a brand; this rule would simply change the location of the brand. Under the tuberculosis and brucellosis eradication programs, the Animal and Plant Health Inspection Service (APHIS) and cooperating States bear the costs of branding cattle and bison, and changing the location of the brand would not result in any change in costs to APHIS or the States. Further, although branding is generally done on the ranch or farm where the cattle or bison are located, no new equipment would be necessary for branding the cattle or bison on the hip, so there would be no new costs to the owner of the animals.

This rule would also allow certain cattle and bison to be moved interstate to slaughter without branding if they are accompanied directly to slaughter by an APHIS or State representative, or if they are moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. Such movement would be a voluntary alternative to branding, and would not impose any additional costs to owners

of cattle or bison that are to be moved interstate.

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 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

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

#### List of Subjects

##### 9 CFR Part 50

Animal diseases, Bison, Cattle, Hogs, Indemnity payments, Reporting and recordkeeping requirements, Tuberculosis.

##### 9 CFR Part 51

Animal diseases, Cattle, Hogs, Indemnity payments, Reporting and recordkeeping requirements.

##### 9 CFR Part 77

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

##### 9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 9 CFR parts 50, 51, 77, and 78 would be amended as follows:

#### PART 50—ANIMALS DESTROYED BECAUSE OF TUBERCULOSIS

1. The authority citation for part 50 would continue to read as follows:

**Authority:** 21 U.S.C. 111–113, 114, 114a, 114a-1, 120, 121, 125, and 134b; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 50.6, paragraphs (a) and (b) would be revised to read as follows:

##### § 50.6 Identification of animals to be destroyed because of tuberculosis.

\* \* \* \* \*

(a) *Reactor cattle and bison.* Reactor cattle and bison shall be identified by

branding the letter "T," at least 5 by 5 centimeters (2 by 2 inches) in size, high on the left hip near the tailhead and by attaching to the left ear an approved metal eartag bearing a serial number and the inscription "U.S. Reactor", or a similar State reactor tag. Reactor cattle and bison may be moved interstate to slaughter without branding if they are permanently identified by the letters "TB" tattooed legibly on the left ear, they are sprayed on the left ear with yellow paint, and they are either accompanied by an APHIS or State representative or moved directly to slaughter in vehicles closed with official seals. Such official seals must be applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

(b) *Exposed cattle and bison.* Exposed cattle and bison shall be identified by branding the letter "S," at least 5 by 5 centimeters (2 by 2 inches) in size, high on the left hip near the tailhead and by attaching to the left ear an approved metal eartag bearing a serial number. Exposed cattle and bison may be moved interstate to slaughter without branding if they are either accompanied by an APHIS or State representative or moved directly to slaughter in vehicles closed with official seals. Such official seals must be applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

\* \* \* \* \*

**PART 51—ANIMALS DESTROYED BECAUSE OF BRUCELLOSIS**

3. The authority citation for part 51 would continue to read as follows:

**Authority:** 21 U.S.C. 111–113, 114, 114a, 114a-1, 120, 121, 125, and 134b; 7 CFR 2.17, 2.51, and 371.2(d).

4. In § 51.5, paragraph (b) would be revised to read as follows:

**§ 51.5 Identification of animals to be destroyed because of brucellosis.**

\* \* \* \* \*

(b) Except as in paragraph (b)(4), cattle and bison to be destroyed because of brucellosis shall be individually identified prior to moving interstate by attaching to the left ear a metal tag bearing a serial number and the inscription "U.S. Reactor," or a similar State reactor tag, and must be:

(1) "B" branded (as defined in § 78.1); or

(2) Accompanied directly to slaughter by an APHIS or State representative; or

(3) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit.

(4) Reactor and exposed cattle and bison in herds scheduled for herd depopulation may be moved interstate without eartagging or branding if they are identified by USDA approved backtags and either accompanied directly to slaughter by an APHIS or State representative or moved directly to slaughter in vehicles closed with official seals. Such official seals must be applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

\* \* \* \* \*

**PART 77—TUBERCULOSIS**

5. The authority citation for part 77 would continue to read as follows:

**Authority:** 21 U.S.C. 111, 114, 114a, 115–117, 120, 121, 134b, and 134f; 7 CFR 2.17, 2.51, and 371.2(d).

6. In § 77.5, the heading would be amended by removing the word "containing" and adding the word "containing" in its place, and paragraphs (a)(1) and (b)(1) would be revised to read as follows:

**§ 77.5 Interstate movement of cattle and bison that are exposed, reactors, or suspects, or from herds containing suspects.**

(a) *Reactor cattle and bison.* \* \* \*

(1) Reactor cattle and bison must be individually identified by attaching to the left ear an approved metal eartag bearing a serial number and the inscription "U.S. Reactor", or a similar State reactor tag, and must be:

(i) Branded with the letter "T," at least 5 by 5 centimeters (2 by 2 inches) in size, high on the left hip near the tailhead; or

(ii) Permanently identified with the letters "TB" tattooed legibly on the left ear and sprayed on the left ear with yellow paint, and either accompanied directly to slaughter by an APHIS or State representative or moved directly to slaughter in vehicles closed with official seals. Such official seals must be applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

\* \* \* \* \*

(b) *Exposed cattle and bison.* \* \* \*

(1) Exposed cattle and bison must be individually identified by attaching to the left ear an approved metal eartag bearing a serial number, and must be:

(i) Branded with the letter "S," at least 5 by 5 centimeters (2 by 2 inches) in size, high on the left hip near the tailhead; or

(ii) Accompanied directly to slaughter by an APHIS or State representative; or

(iii) Moved directly to slaughter in vehicles closed with official seals. Such official seals must be applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

\* \* \* \* \*

**PART 78—BRUCELLOSIS**

7. The authority citation for part 78 would continue to read as follows:

**Authority:** 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, and 134f; 7 CFR 2.17, 2.51, and 371.2(d).

**Subpart A—General Provisions**

**§ 78.1 [Amended]**

8. Section 78.1 would be amended as follows:

a. In the definition for "B" *branded*, the phrase "at least 5 sq. cm. (2 × 2 inches) in size on the left jaw" would be removed and "high on left hip near the tailhead and at least 5 by 5 centimeters (2 by 2 inches) in size" would be added in its place.

b. In the definition for *Official adult vaccinate*, paragraph (b)(1) would be amended by removing "on the right jaw or" and by adding "at least 5 by 5 centimeters (2 by 2 inches) in size" immediately after "tailhead".

c. In the definition for "S" *branded*, the phrase "at least 5 sq. cm. (2 × 2 inches) in size on the left jaw or high on the tailhead (over the fourth to the seventh coccygeal vertebrae)" would be removed and "high on left hip near the tailhead and at least 5 by 5 centimeters (2 by 2 inches) in size" would be added in its place.

**Subpart B—Restrictions on Interstate Movement of Cattle Because of Brucellosis**

9. In § 78.7, paragraph (b) would be revised to read as follows:

**§ 78.7 Brucellosis reactor cattle.**

\* \* \* \* \*

(b) *Identification.* Brucellosis reactor cattle must be individually identified prior to moving interstate by attaching to the left ear a metal tag bearing a serial number and the inscription "U.S.

Reactor," or a metal tag bearing a serial number designated by the State animal health official for identifying brucellosis reactors, and must be:

(1) "B" branded (as defined in § 78.1); or

(2) Accompanied directly to slaughter by an APHIS or State representative; or

(3) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit.

10. Section 78.8 would be amended by removing the period at the end of paragraphs (a)(3)(iii)(C), (a)(5)(iii)(C), and (b)(3)(ii) and adding "; or" in its place; and by adding new paragraphs (a)(3)(iii)(D), (a)(5)(iii)(D), and (b)(3)(iii) to read as follows:

§ 78.8 Brucellosis exposed cattle.

\* \* \* \* \*

- (a) \* \* \*
(3) \* \* \*
(iii) \* \* \*

(D) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit or "S" brand permit.

\* \* \* \* \*

- (5) \* \* \*
(iii) \* \* \*

(D) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit or "S" brand permit.

\* \* \* \* \*

- (b) \* \* \*
(3) \* \* \*

(iii) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit or "S" brand permit.

\* \* \* \* \*

11. Section 78.9 would be amended by removing the period at the end of paragraphs (c)(1)(v)(C), (c)(1)(vii)(C), (c)(2)(i)(C), (c)(2)(ii)(B), (d)(1)(v)(C),

(d)(1)(vii)(C), (d)(2)(i)(C), and (d)(2)(ii)(B) and adding "; or" in its place; and by adding new paragraphs (c)(1)(v)(D), (c)(1)(vii)(D), (c)(2)(i)(D), (c)(2)(ii)(C), (d)(1)(v)(D), (d)(1)(vii)(D), (d)(2)(i)(D), and (d)(2)(ii)(C) to read as follows:

§ 78.9 Cattle from herds not known to be affected.

\* \* \* \* \*

- (c) \* \* \*
(1) \* \* \*
(v) \* \* \*

(D) They are accompanied by an "S" brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying "S" brand permit.

\* \* \* \* \*

- (vii) \* \* \*

(D) They are accompanied by an "S" brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying "S" brand permit.

\* \* \* \* \*

- (2) \* \* \*
(i) \* \* \*

(D) A quarantined feedlot, a specifically approved stockyard and then directly to a quarantined feedlot, or an approved intermediate handling facility and then directly to a quarantined feedlot if the cattle are accompanied by an "S" brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying "S" brand permit.

\* \* \* \* \*

- (ii) \* \* \*

(C) They are accompanied by an "S" brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying "S" brand permit.

\* \* \* \* \*

- (d) \* \* \*
(1) \* \* \*
(v) \* \* \*

(D) They are accompanied by an "S" brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying "S" brand permit.

\* \* \* \* \*

- (vii) \* \* \*

(D) They are accompanied by an "S" brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying "S" brand permit.

\* \* \* \* \*

- (2) \* \* \*
(i) \* \* \*

(D) A quarantined feedlot, a specifically approved stockyard and then directly to a quarantined feedlot, or an approved intermediate handling facility and then directly to a quarantined feedlot if the cattle are accompanied by an "S" brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying "S" brand permit.

\* \* \* \* \*

- (ii) \* \* \*

(C) They are accompanied by an "S" brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying "S" brand permit.

\* \* \* \* \*

Subpart C—Restrictions on Interstate Movement of Bison Because of Brucellosis

12. In § 78.22, paragraph (b) would be revised to read as follows:

§ 78.22 Brucellosis reactor bison.

\* \* \* \* \*

(b) Identification. Brucellosis reactor bison must be individually identified

prior to moving interstate by attaching to the left ear a metal tag bearing a serial number and the inscription "U.S. Reactor," or a metal tag bearing a serial number designated by the State animal health official for identifying brucellosis reactors, and must be:

(1) "B" branded (as defined in § 78.1); or

(2) Accompanied directly to slaughter by an APHIS or State representative; or

(3) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit.

\* \* \* \* \*

Done in Washington, DC, this 11th day of May 1995.

**Lonnie J. King,**

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

[FR Doc. 95-12150 Filed 5-16-95; 8:45 am]

BILLING CODE 3410-34-P

## 9 CFR Parts 101 and 113

[Docket No. 94-051-1]

RIN 0579-AA66

### Viruses, Serums, Toxins, and Analogous Products; In Vitro Tests for Serial Release

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

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to amend the regulations regarding the use of in vitro potency tests in place of animal tests for immunogenicity to: change the title of the section; prescribe requirements for in vitro immunoassays used to determine the relative antigen content of inactivated biological products; require that such immunoassays be parallel line assays based upon unexpired reference preparations; require that in vitro tests for relative antigen content be converted to parallel line assays within 2 years; specify procedures and requirements for qualifying or requalifying reference preparations for inactivated products; and add certain definitions to the regulations.

The effect of the amendment would be to standardize the methods used to determine the relative potency of inactivated biological products.

**DATES:** Consideration will be given only to comments received on or before August 15, 1995.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 94-051-1, 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. 94-051-1. 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 (202) 690-2817 to facilitate entry into the comment reading room.

**FOR FURTHER INFORMATION CONTACT:**

Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1237, (301) 734-8245.

**SUPPLEMENTARY INFORMATION:**

**Background**

The regulations pertaining to the testing of biologics provide that no biological product shall be released (for sale) prior to the completion of tests prescribed to establish the product to be pure, safe, potent, and efficacious (9 CFR 113.5). Efficacy refers to the specific ability of the product to effect the result for which it is offered when used as recommended by the manufacturer. Studies conducted to establish efficacy include immunogenicity tests in host animals using product manufactured according to specific requirements which include specifications for antigen content and/or animal potency. These requirements apply to every serial of product which is produced. Therefore, if a product has been tested for immunogenicity in animals and shown to have the desired effect, it follows that subsequent serials (batches) of the product manufactured to the same specifications should also have the same effect.

Once immunogenicity is established in relation to a specific minimum antigen content in a product, it should no longer be necessary to test every subsequent serial for potency in animals if an evaluation can be made with reasonable certainty of the relative antigen content by testing the serial or subserial in an acceptable in vitro test system. Therefore, when properly qualified and validated, in vitro immunoassays that determine relative antigen content of the product can serve as acceptable substitutes for potency tests that otherwise would need to be performed in animals.

The regulations in 9 CFR 113.8 pertain to the use of in vitro tests in

place of animal tests for determining the potency of veterinary biological products. Currently, the in vitro tests prescribed in § 113.8 which include determining the log<sub>10</sub> virus titer and performing live bacterial counts are only applicable to veterinary biologicals which contain live microorganisms. The changes and test procedures prescribed in this proposal would make § 113.8 applicable to both live and inactivated products by prescribing validity requirements for in vitro test systems used, in place of animal tests, to test for the potency of inactivated products.

We are proposing to amend the title of § 113.8 to read: "In vitro potency tests for serial release." This change is intended to clarify the fact that the in vitro procedures described in § 113.8 are applicable to in vitro tests used to release serials or subserials of veterinary biological products after the prescribed animal protection studies required for licensing have been completed. In the case of inactivated products, the proposal specifies that in vitro immunoassays (test systems) which compare the relative antigen content (relative potency) of a test serial to a reference preparation must be parallel line assays using an unexpired reference preparation whose potency has been correlated directly or indirectly to immunogenicity in host animals.

In addition, the proposal would require: confirming the accuracy of the protective dose established for live products 3 years after the initiation of the host animal immunogenicity study; and confirming the immunogenicity of reference preparations used in immunoassays for inactivated biological products prior to their expiration. The expiration date for a reference would be equal to the dating of the product or as supported by data acceptable to APHIS.

APHIS is proposing these amendments because current requirements for many of the immunoassays being used to release serials or subserials of product do not have uniform validity criteria and do not include a provision to confirm periodically the immunogenicity of the reference used in such immunoassays. The proposed amendment would standardize the requirements for in vitro potency tests for relative antigen content and update and improve the reliability of such tests that are currently included in filed outlines of production. The proposed amendment does not specify a particular immunoassay provided that it is a parallel line assay using an unexpired reference preparation. While there is not a generally accepted "best" immunoassay, there is general agreement that an acceptable