IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

| HTS No. | Conversion factor | Cents per kg |
|---|---|---|
| 6210109010 | 0.2291 | 0.2949 |
| 6210403000 | 0.0391 | 0.0503 |
| 6210405020 | 0.4556 | 0.5865 |
| 6211111010 | 0.1273 | 0.1639 |
| 6211111020 | 0.1273 | 0.1639 |
| 6211118010 | 1.1455 | 1.4747 |
| 6211118020 | 1.1455 | 1.4747 |
| 6211320007 | 0.8461 | 1.0893 |
| 6211320010 | 1.0413 | 1.3406 |
| 6211320015 | 1.0413 | 1.3406 |
| 6211320030 | 0.9763 | 1.2569 |
| 6211320060 | 0.9763 | 1.2569 |
| 6211320070 | 0.9763 | 1.2569 |
| 6211330010 | 0.3254 | 0.4189 |
| 6211330030 | 0.3905 | 0.5027 |
| 6211330035 | 0.3905 | 0.5027 |
| 6211330040 | 0.3905 | 0.5027 |
| 6211420010 | 1.0413 | 1.3406 |
| 6211420020 | 1.0413 | 1.3406 |
| 6211420025 | 1.1715 | 1.5082 |
| 6211420060 | 1.0413 | 1.3406 |
| 6211420070 | 1.1715 | 1.5082 |
| 6211430010 | 0.2603 | 0.3351 |
| 6211430030 | 0.2603 | 0.3351 |
| 6211430040 | 0.2603 | 0.3351 |
| 6211430050 | 0.2603 | 0.3351 |
| 6211430060 | 0.2603 | 0.3351 |
| 6211430066 | 0.2603 | 0.3351 |
| 6212105020 | 0.2412 | 0.3105 |
| 6212109010 | 0.9646 | 1.2418 |
| 6212109020 | 0.2412 | 0.3105 |
| 6212200020 | 0.3014 | 0.388 |
| 6212900030 | 0.1929 | 0.2483 |
| 6213201000 | 1.1809 | 1.5203 |
| 6213202000 | 1.0628 | 1.3682 |
| 6213901000 | 0.4724 | 0.6082 |
| 6214900010 | 0.9043 | 1.1642 |
| 6216000800 | 0.2351 | 0.3027 |
| 6216001720 | 0.6752 | 0.8693 |
| 6216003800 | 1.2058 | 1.5523 |
| 6216004100 | 1.2058 | 1.5523 |
| 6217109010 | 1.0182 | 1.3108 |
| 6217109030 | 0.2546 | 0.3278 |
| 6301300010 | 0.8766 | 1.1285 |
| 6301300020 | 0.8766 | 1.1285 |
| 6302100010 | 1.1689 | 1.5048 |
| 6302215010 | 0.8182 | 1.0534 |
| 6302215020 | 0.8182 | 1.0534 |
| 6302217010 | 1.1689 | 1.5048 |
| 6302219010 | 0.8182 | 1.0534 |
| 6302217020 | 1.1689 | 1.5048 |
| 6302219020 | 0.8182 | 1.0534 |
| 6302217050 | 1.1689 | 1.5048 |
| 6302219050 | 0.8182 | 1.0534 |
| 6302222010 | 0.4091 | 0.5267 |
| 6302222020 | 0.4091 | 0.5267 |
| 6302313010 | 0.8182 | 1.0534 |
| 6302313050 | 1.1689 | 1.5048 |
| 6302315050 | 0.8182 | 1.0534 |
| 6302317010 | 1.1689 | 1.5048 |
| 6302317020 | 1.1689 | 1.5048 |
| 6302317040 | 1.1689 | 1.5048 |
| 6302317050 | 1.1689 | 1.5048 |
| 6302319010 | 0.8182 | 1.0534 |
| 6302319020 | 0.8182 | 1.0534 |
| 6302319040 | 0.8182 | 1.0534 |
| 6302319050 | 0.8182 | 1.0534 |
| 6302322020 | 0.4091 | 0.5267 |
| 6302322040 | 0.4091 | 0.5267 |

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

| HTS No. | Conversion factor | Cents per kg |
|---|---|---|
| 6302402010 | 0.9935 | 1.279 |
| 6302511000 | 0.5844 | 0.7524 |
| 6302512000 | 0.8766 | 1.1285 |
| 6302513000 | 0.5844 | 0.7524 |
| 6302514000 | 0.8182 | 1.0534 |
| 6302600010 | 1.1689 | 1.5048 |
| 6302600020 | 1.052 | 1.3543 |
| 6302600030 | 1.052 | 1.3543 |
| 6302910005 | 1.052 | 1.3543 |
| 6302910015 | 1.1689 | 1.5048 |
| 6302910025 | 1.052 | 1.3543 |
| 6302910035 | 1.052 | 1.3543 |
| 6302910045 | 1.052 | 1.3543 |
| 6302910050 | 1.052 | 1.3543 |
| 6302910060 | 1.052 | 1.3543 |
| 6303110000 | 0.9448 | 1.2163 |
| 6303910000 | 0.6429 | 0.8277 |
| 6304111000 | 1.0629 | 1.3684 |
| 6304190500 | 1.052 | 1.3543 |
| 6304191000 | 1.1689 | 1.5048 |
| 6304191500 | 0.4091 | 0.5267 |
| 6304192000 | 0.4091 | 0.5267 |
| 6304910020 | 0.9351 | 1.2038 |
| 6304920000 | 0.9351 | 1.2038 |
| 6505901540 | 1.181 | 1.5204 |
| 6505902060 | 0.9935 | 1.279 |
| 6505902545 | 0.5844 | 0.7524 |

* * * * *

3. In § 1205.510, paragraph (b)(6)(i) is revised to read as follows:

(6) * * *

(i) A request for such exemption must be submitted to the Cotton Board by the importer, prior to the importation of the cotton product. The Cotton Board will then issue, if deemed appropriate, a numbered exemption certificate valid for 1 year from the date of issue. The exemption number should be entered by the importer on the Customs entry documentation in the appropriate location as determined by the U.S. Customs Service.

* * * * *

Dated: June 14, 1996.

Lon Hatamiya,

*Administrator.*

[FR Doc. 96–15662 Filed 6–20–96; 8:45 am]

BILLING CODE 3410–02–P

## Animal and Plant Health Inspection Service

## 9 CFR Part 113

**[Docket No. 95–012–2]**

## Viruses, Serums, Toxins, and Analogous Products; Rabies Vaccine, Killed Virus and Rabies Vaccine, Live Virus

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

**ACTION:** Final rule.

**SUMMARY:** We are amending the standard requirements for establishing the immunogenicity of Rabies Vaccine, Killed Virus and Rabies Vaccine, Live Virus. The amendment changes and clarifies alternate test procedures which may be used in animals other than carnivores. Under the rule, when a reduced number of challenge animals is used in a rabies immunogenicity test, all vaccinates must survive challenge. If one or more of the challenged vaccinates die of rabies, all of the remainder of the vaccinates will have to be challenged or the test will be deemed unsatisfactory and terminated.

This action corrects a problem associated with rabies immunogenicity tests in the regulations and makes other changes deemed necessary for clarity and consistency.

**EFFECTIVE DATE:** July 22, 1996.

**FOR FURTHER INFORMATION CONTACT:** Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, 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.

The standard requirements for Rabies Vaccine, Killed Virus, and for Rabies Vaccine, Live Virus, appear in §§ 113.209 and 113.312, respectively. Sections 113.209(b)(4) and 113.312(b)(4) provide for an alternative immunogenicity test, for domestic species other than dogs and cats, that reduces the number of animals that must be challenged.

On November 16, 1995, we published in the Federal Register (60 FR 57549–57550, Docket No. 95–012–1) a proposed rule to amend the standard requirements for Rabies Vaccine, Killed Virus and Rabies Vaccine, Live Virus. The amendments specify: (1) that for an immunogenicity study in non-carnivores to be satisfactory, all animals must survive challenge when less than 25 vaccinates are challenged, and (2) that a reduced number of challenge animals may only be used for non-carnivores. The rule more clearly

defines which animals must be challenged when a reduced number of vaccinates is used.

We solicited comments for a 60-day comment period ending January 16, 1996. One comment was received by that date. The comment was from a licensed manufacturer of veterinary biological products. The comment addressed which animals should be challenged and the percent survival required for a reduced challenge. The commenter recommended that less than 100 percent survival be acceptable for a reduced challenge. The commenter requested that this be accomplished through a wording change to the rule.

In response to the commenter, APHIS believes that when the number of challenged animals is reduced, survival of less than 100 percent of the animals of the lowest titer would not provide adequate assurance that animals of higher titer would be protected against challenge. Because of this, no change to the regulations is made in response to this comment.

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 without change.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This rule amending §§ 113.209 and 113.312 is necessary to clarify the regulations regarding the rabies immunogenicity test. The amendment clarifies which animals are to be challenged in a reduced immunogenicity study and the procedures to follow when one or more of the vaccinates die of rabies. The amendment requires that additional vaccinates be challenged if one of the low titer vaccinates succumbs to rabies. In 7 of the last 10 rabies challenge tests of non-carnivores, firms elected to challenge 25 or more animals. In the remaining three cases in which a reduced number of animals were challenged in accordance with current § 113.209 or § 113.312, paragraph (b)(4), no additional animals were challenged and no additional animals would have been challenged under the amendment. The amendment, therefore, will have minimal economic effect.

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. 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 113.209 is amended by revising paragraph (b)(4) to read as follows:

**§ 113.209 Rabies Vaccine, Killed Virus.**

* * * * *

(b) * * *

(4) An alternative to challenging all surviving test animals in accordance with paragraph (b)(3)(iv) of this section may be used when the test animals are of species other than carnivores. Vaccinates shall be challenged at 1 year postvaccination. These shall include five vaccinates with the lowest SN titers at the 270th-day bleeding, five vaccinates with the lowest SN titers at the 365th-day bleeding, and all vaccinates with SN titers below 1:10 by the mouse SN test or below 1:16 by the rapid-fluorescent-focus-inhibition test at any bleeding. At least five SN-negative controls of each species shall be challenged at the same time as the vaccinates. All SN titers shall be titrated to an endpoint. All of the challenged vaccinates must remain well for a period of 90 days, and at least 80 percent of the controls must die of rabies for a satisfactory test without further challenge. If one or more of the vaccinates die from rabies, all the remaining vaccines, regardless of titer, along with the five controls shall be challenged. The cumulative results from the two challenges shall be evaluated for acceptance as specified in paragraph (b)(3)(v) of this section.

* * * * *

3. Section 113.312 is amended by revising the section heading and paragraph (b)(4) to read as follows:

**§ 113.312 Rabies Vaccine, Live Virus.**

* * * * *

(b) * * *

(4) an alternative to challenging all surviving test animals in accordance with paragraph (b)(3)(iv) of this section may be used when the test animals are of species other than carnivores. Vaccinates shall be challenged at 1 year postvaccination. These shall include five vaccinates with the lowest SN titers at the 270th-day bleeding, five vaccinates with the lowest SN titers at the 365th-day bleeding, and all vaccinates with SN titers below 1:10 by the mouse SN test or below 1:16 by the rapid-fluorescent-focus-inhibition test at any bleeding. At least five SN-negative controls of each species shall be challenged at the same time as the vaccinates. All SN titers shall be iterated to an endpoint. All of the challenged vaccinates must remain well for a period of 90 days, and at least 80 percent of the controls must die of rabies for a satisfactory test without further challenge. If one or more of the vaccinates die from rabies, all the remaining vaccinates, regardless of titer, along with the five controls shall be challenged. The cumulative results from the two challenges shall be evaluated for acceptance as specified in paragraph (b)(3)(v) of this section.

* * * * *

Done in Washington, DC, this 17th day of June 1996.

Lonnie J. King,

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 96–15854 Filed 6–20–96; 8:45 am]

BILLING CODE 3410–34–M