(b) Except as provided in paragraph (c) of this section, all breeding swine shall be tested for and show negative test results to brucellosis by a test prescribed in "Standard Agglutination Test Procedures for the Diagnosis of Brucellosis" or "Supplemental Test Procedures for the Diagnosis of Brucellosis." The test results shall be classified negative in accordance with the provisions prescribed in the Recommended Brucellosis Eradication Uniform Methods and Rules, chapter 2, part II, G, 1, 2, and 3.

(c) Breeding swine exported to a country that does not require breeding swine from the United States to be tested for brucellosis need not comply with the requirements of paragraph (b) of this section.

(Approved by the Office of Management and Budget under control number 0579-0020)

Done in Washington, DC, this 13th day of September 2010.

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2010–23235 Filed 9–16–10: 8:45 am]

BILLING CODE 3410–34–S

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 91

[Docket No. APHIS-2009-0078]

RIN 0579-AD25

Removal of the List of Ports of Embarkation and Export Inspection Facilities from the Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the live animal export regulations by removing the list of designated ports of embarkation and their associated export inspection facilities. As a result of this rulemaking, those ports and facilities would henceforth be listed on the Internet rather than in the regulations, thus enabling us to amend the list, when necessary, in a timelier manner than we can now and allowing us greater flexibility in regulating animal exports.

DATES: We will consider all comments that we receive on or before November 16, 2010.

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

- Federal eRulemaking Portal: Go to (*http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0078*) to submit or view comments and to view supporting and related materials available electronically.
- Postal Mail/Commercial Delivery: Please send one copy of your comment to Docket No. APHIS-2009-0078, 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-2009-0078.

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. Courtney Bronner Williams, Senior Staff Veterinarian, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD; 20737-1231; (301) 734-8364.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 91, "Inspection and Handling of Livestock for Exportation" (referred to below as the regulations), prescribe conditions for exporting animals from the United States. The regulations state, among other things, that all animals, except animals exported by land to Canada or Mexico, must be exported through designated ports of embarkation, unless the exporter can show that the animals would suffer undue hardship if they were required to be moved to a designated port of embarkation.

Paragraph (a) of § 91.14 lists ports that have been designated by the Animal and Plant Health Inspection Service (APHIS) as having met the requirements for use as ports of embarkation. To receive such a designation from APHIS, a port must have an export inspection facility available for the inspection, holding, feeding, and watering of animals prior to exportation. Approved export inspection facilities, along with their contact information, are also listed in § 91.14(a). Under the regulations, export inspection facilities must meet the standards contained in § 91.14(c) concerning physical construction requirements, facility size, inspection implements (e.g., pens and animal restraining devices), cleaning and disinfection, feed and water, access by inspectors, animal handling arrangements, testing and treatment of animals, facility location, disposal of animal wastes, lighting, office and restroom facilities, and walkways.

Because the designated ports of embarkation and associated export inspection facilities are now listed in the regulations, the list can only be amended to add or remove ports or export inspection facilities or to update contact information by means of rulemaking. In order to allow for more timely changes, we are proposing to remove this list from the regulations. In its place, we would add a new paragraph (a) stating that all ports that have export inspection facilities that an APHIS veterinarian has determined satisfy the requirements of § 91.14(c) would be designated as ports of embarkation. The proposed paragraph would further state that the list of designated ports and inspection facilities can be obtained from an APHIS Veterinary Services area office or viewed on the Internet on the APHIS Web site. Finally, proposed paragraph (a) would provide, as does the introductory text of the existing paragraph (a), that all animals, except animals being exported by land to Mexico or Canada, must be exported through the listed ports or through other ports designated in special cases by the Administrator, as provided in § 91.14(b).

We are also proposing some changes to § 91.14(d), which pertains to approval and denial, revocation, or suspension of approval of export inspection facilities. Currently, the paragraph states that approval of an export inspection facility will be denied or revoked if the facility fails to meet the standards contained in § 91.14(c). The operator of the facility is notified in writing if approval is denied or revoked, in the latter case, at least 60 days prior to the date of the proposed revocation. The written notice details the deficiencies of the facility, and the operator is given an opportunity to respond. Pending a final determination, approval of any facility may be denied or suspended by the Administrator when he has reason to believe that the facility does not meet the standards set forth in the regulations.

The paragraph, as currently written, is somewhat ambiguous regarding the circumstances that may trigger a revocation of approval. In order to clarify the regulations and ensure that standards are being maintained at ports

and facilities covered under these regulations, we are proposing to amend paragraph (d) to require that designated ports of embarkation and export facilities be reevaluated annually for compliance with § 91.14(c) by means of an APHIS inspection.

We would also remove the provisions pertaining to suspension and/or proposed revocation of approval, including the requirement that we notify the operator of the facility 60 days prior to the latter. For purposes of enforcement, the existing categories of suspension and revocation are essentially the same: In either case, the port or facility loses its eligibility for use as a designated port of embarkation. Moreover, there is no distinction between the requirements for reinstatement of a facility that has had its approval suspended and one that has had its approval revoked. In both the former case and the latter, the facility is reinstated when it can demonstrate that it meets the requirements of § 91.14(c). The elimination of the category of suspension, therefore, would not change the way the regulations are enforced but would simplify them. Under our proposed paragraph (d), if a facility were to fail an annual compliance inspection, it would be removed immediately from the list of designated facilities. Proposed paragraph (d) would also clarify the procedure for reinstatement by indicating that operators of facilities that fail either an initial inspection or an annual compliance inspection would have the opportunity to request another inspection after remedying the deficiencies listed in the written notice from APHIS. The existing regulations do not address the issue of reinstatement directly.

Finally, we would make minor editorial changes to §§ 91.14(b) and 91.15(a), the current text of which contains references to the list of ports in current § 91.14(a).

By eliminating the need for rulemaking each time the list of designated ports of embarkation and associated export inspection facilities needs to be changed, this proposed rule would allow revisions to that list to be made much more quickly than they can at present. Our ability to revise the list in a timely manner will make the process of regulating animal exports more flexible and efficient.

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.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

This proposed rule would amend the live animal export regulations by removing the list of designated ports of embarkation and their associated export inspection facilities. As a result of this rulemaking, those ports and facilities would henceforth be listed on the Internet rather than in the regulations, allowing us to amend the list, when necessary, in a timelier manner than we can now.

Those entities most likely to be economically affected by the rule would be exporters of live animals and domestic livestock producers. These entities either sell goods on their own account (import/export merchants) or arrange for the sale of goods owned by others (import/export agents and brokers). Affected entities could include beef cattle ranching and farming operations, dairy cattle and milk production operations, hog and pig farming operations, sheep and goat farming operations, and cattle feedlots.

The Small Business Administration has established guidelines for determining which businesses are to be considered small. Based on the most recent data we have regarding annual receipts, it is likely that most of the entities that could be affected by this proposed rule are small.

However, this proposal would only amend APHIS' administrative process for changing the list of designated embarkation ports and associated export inspection facilities. The proposed action would not make any changes in the status of any designated embarkation port or associated export inspection facility, nor would it alter the technical criteria by which designated embarkation ports and associated export inspection facilities are added to or removed from this list. We expect that this proposed rule will have little effect on U.S. entities other than benefits they could derive from timelier changes to the list of designated ports of embarkation and associated export inspection facilities.

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. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent 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 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 91

Animal diseases, Animal welfare, Exports, Livestock, Reporting and recordkeeping requirements, Transportation.

■ Accordingly, we propose to amend 9 CFR part 91 as follows:

PART 91—INSPECTION AND HANDLING OF LIVESTOCK FOR EXPORTATION

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 19 U.S.C. 1644a(c); 21 U.S.C. 136, 136a, and 618; 46 U.S.C. 3901 and 3902; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 91.14 is amended by revising paragraphs (a), (b), and (d) to read as follows:

§ 91.14 Ports of embarkation and export inspection facilities.

(a) All ports that have export inspection facilities which an APHIS veterinarian has determined satisfy the requirements of paragraph (c) of this section are hereby designated as ports of embarkation. A list of designated ports of embarkation can be viewed on the Internet at (*http://www.aphis.usda.gov/regulations/vs/iregs/animals/*) or obtained from a Veterinary Services area office. Information on area offices is available at (*http://www.aphis.usda.gov/animal_health/area_offices/*). All animals, except animals being exported

by land to Mexico or Canada, shall be exported through said ports or through ports designated in special cases under paragraph (b) of this section.

(b) In special cases, other ports may be designated as ports of embarkation by the Administrator, with the concurrence of the Commissioner of the Bureau of Customs and Border Protection, when the exporter can show to the satisfaction of the Administrator that the animals to be exported would suffer undue hardship if they are required to be moved to a port listed as a designated port of embarkation in accordance with paragraph (a) of this section. Ports shall be designated in special cases as ports of embarkation only if the inspection facilities are approved as meeting the requirements of paragraph (c) of this section.

* * * * *

(d) *Approval and denial or revocation of approval.* Approval of each export inspection facility for designation under paragraph (a) of this section, and in special cases under paragraph (b) of this section, shall be obtained from the Administrator. Approval of an export inspection facility under paragraph (a) or (b) will be denied or revoked for failure to meet the standards in paragraph (c) of this section. Designated ports of embarkation and export facilities shall be reevaluated annually, by means of an APHIS site inspection, for continued compliance with the standards contained in paragraph (c) of this section. If the port or facility fails to pass the annual inspection, its designation will be revoked, and it will be removed from the list of designated ports and facilities. A written notice of any proposed denial or revocation shall be given to the operator of the facility, and he will be given an opportunity to present his views thereon. Such notice shall list in detail the deficiencies concerned. After remedying the deficiencies, an operator may request another inspection. Approval of a port of embarkation in connection with the designation of an export inspection facility in special cases shall be limited to the special case for which the designation was made.

* * * * *

■ 3. In § 91.15, paragraph (a) is revised to read as follows:

§ 91.15 Inspection of animals for export.

(a) All animals offered for exportation to any foreign country, except by land to Mexico or Canada, shall be inspected within 24 hours of embarkation by an APHIS veterinarian at an export inspection facility at a port listed as a designated port of embarkation in accordance with § 91.14(a), or at a port or inspection facility designated by the Administrator in a special case under § 91.14(b).

* * * * *

Done in Washington, DC, this 13th day of September 2010.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2010–23245 Filed 9–16–10: 8:45 am]

BILLING CODE 3410–34–S

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101 and 114

[Docket No. APHIS-2009-0028]

RIN 0579-AD06

Viruses, Serums, Toxins, and Analogous Products; Expiration Date Required for Serials and Subserials and Determination of Expiration Date of Product

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; withdrawal and reproposal.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations concerning expiration dating to clarify that the expiration date of a serial or subserial of a veterinary biologic should be computed from the date of the initiation of the first potency test. We also propose to require the expiration dating period (stability) of a product to be confirmed by conducting a real-time stability study with a stability-indicating assay; require stability monitoring of products after licensing; and specify a single standard for determining the expiration date for veterinary biologics in place of the current standard that specifies different procedures for products contingent upon whether they consist of viable or nonviable organisms. These amendments would update and clarify the regulations concerning expiration dating and establish a single uniform standard for determining the stability of veterinary biological products. This proposed rule replaces a previously published proposed rule, which we are withdrawing as part of this document.

DATES: We will consider all comments that we receive on or before November 16, 2010.

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

- Federal eRulemaking Portal: Go to (*http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0028*) to submit or view comments and to view supporting and related materials available electronically.
- Postal Mail/Commercial Delivery: Please send one copy of your comment to Docket No. APHIS-2009-0028, 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-2009-0028.

Reading Room: You may read any comments that we receive on Regulations.gov (see the link above) or 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 of Operational Support, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; (301) 734-8245.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 114, "Production Requirements for Biological Products" (referred to below as the regulations), include requirements applicable to computing expiration dates and determining expiration dating periods (stability) for veterinary biologics. Currently, § 114.12 of the regulations requires each serial or subserial of veterinary biological product prepared in a licensed establishment to be given an expiration date, and § 114.13 provides that the expiration date for each product shall be computed from the date of the initiation of the potency test.

The computed expiration date of a serial or subserial of biological product is inextricably linked to the stability of such product. The expiration date of a veterinary biologic designates the end of the period during which such product, when properly stored and handled, can be expected with reasonable certainty to