Economic Impact on Small Entities

The Regulatory Flexibility Act requires that agencies consider the economic impact of their rules on small entities. The domestic entities most likely to be affected by our proposal to declare the Mexican State of Nayarit free of CSF are pork producers.

According to the 2002 Agricultural Census, there were about 66,036 hog and pig farms in the United States in that year, of which 93 percent received $750,000 or less in annual revenues. Agricultural operations with $750,000 or less in annual receipts are considered small entities, according to the Small Business Administration (SBA) size criteria.

We do not expect that U.S. hog producers, U.S. exporters of live hogs, or U.S. exporters of pork and pork products, small or otherwise, would be affected significantly by this proposed rule. This is because, for the reasons discussed above, the amount of live swine, pork, and other pork products imported into the United States from the Mexican State of Nayarit is likely to be small.

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 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.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with our proposal to list the Mexican State of Nayarit as free of CSF, we have prepared an environmental assessment. The environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment may be viewed on the Regulations.gov Web site or in our reading room. (Instructions for accessing Regulations.gov and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

This proposed rule contains no new 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 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 would continue to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

§ 94.9 [Amended]

2. In § 94.9, paragraph (a) would be amended by adding the word ''Nayarit,'' after the word ''Chihuahua,''.

§ 94.10 [Amended]

3. In § 94.10, paragraph (a) would be amended by adding the word ''Nayarit,'' after the word ''Chihuahua,''.

§ 94.25 [Amended]

4. In § 94.25, paragraph (a) would be amended by adding the word ''Nayarit,'' after the word ''Chihuahua,''.

Done in Washington, DC this 25th day of January 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–1530 Filed 1–30–07; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. APHIS–2007–0001]

RIN 0579–AC28

Viruses, Serums, Toxins, and Analogous Products; Detection of Avian Lymphoid Leukosis Virus

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations concerning testing for avian lymphoid leukosis in veterinary biologics to specify that the test is for the detection of extraneous replicating avian leukosis virus; require such testing to be conducted using a procedure that will detect extraneous replicating avian leukosis virus and that is acceptable to the Animal and Plant Health Inspection Service; require firms to develop a procedure to test for lymphoid leukosis virus contamination in the case of vaccine virus cytopathic to chick embryo cell cultures; and specify the equivalent inoculum dose of vaccine to be used when testing certain specified chicken vaccines for lymphoid leukosis virus. These proposed changes would update the testing for lymphoid leukosis virus contamination by prescribing a test procedure that increases the probability of detecting atypical lymphoid leukosis viruses such as those recently found in a contaminated vaccine.

DATES: We will consider all comments that we receive on or before April 2, 2007.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*, select ''Animal and Plant Health Inspection Service'' from the agency drop-down menu, then click ''Submit.'' In the Docket ID column, select APHIS–2007–0001 to submit or view public comments and to view supporting and related materials available electronically. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery:* Please send four copies of your

comment (an original and three copies) to Docket No. APHIS–2007–0001, 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–2007–0001.

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. Albert P. Morgan, Chief Staff Officer, Operational Support Section, Center for Veterinary Biologics, Licensing and Policy Development, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1228; (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 113 (referred to below as the regulations) contain standard procedures and requirements that are used to establish the purity, safety, potency, and efficacy of veterinary biological products. The regulations in §§ 113.200 and 113.300 specify general requirements for killed virus vaccine and live virus vaccine, respectively. The purity requirements for avian origin vaccine prescribed under these regulations specify that bulk or final container samples from each serial of avian origin vaccine must be tested for lymphoid leukosis virus contamination. Lymphoid leukosis viruses are ubiquitous in chickens, causing the disease lymphoid leukosis, and are considered to be potential contaminants of all biological products propagated in substrates of chicken origin. Inoculation of chickens and, possibly, other animals with veterinary biologics contaminated with lymphoid leukosis viruses may cause neoplastic diseases. Six subgroups (A, B, C, D, E, and J) of lymphoid leukosis viruses have been identified in chickens, with subgroups A (most often) and B (less frequently) being associated with disease. In order to ensure that biological products propagated in substrates of chicken origin are not contaminated with lymphoid leukosis viruses, veterinary biologics licensees and permittees are required to test such products for contaminating lymphoid leukosis viruses in accordance with the test procedure specified in § 113.31 of the regulations. The test procedure specified in § 113.31 is designed to detect contamination due to extraneous replicating subgroup A and B lymphoid leukosis viruses which are most often associated with disease in chickens. Biological products found contaminated with lymphoid leukosis viruses are unsatisfactory.

Currently, the standard test procedure in § 113.31 of the regulations prescribes the complement-fixation (CF) test for detecting lymphoid leukosis viruses in bulk pooled material or final container samples of biological products propagated in substrates of chicken origin. A negative CF test is considered evidence that the product is free of contaminating lymphoid leukosis viruses.

Recently, however, in response to a reported finding of lymphoid leukosis virus contaminated vaccine, the Center for Veterinary Biologics and other laboratories, using an enzyme-linked immunosorbent assay (ELISA), detected lymphoid leukosis virus in 7 out of 129 serials of a commonly used chicken vaccine. The lymphoid leukosis virus contaminant had not been detected when the serials were tested using the CF test procedure specified in § 113.31 of the regulations. Prior to the reported finding, and confirmation of lymphoid leukosis virus contamination in the seven serials mentioned above, the CF test procedure prescribed in § 113.31 had been considered suitable for detecting previously known and/or classified lymphoid leukosis viruses. However, the failure of the CF test to detect lymphoid leukosis virus contamination in the vaccine suggests that the contaminant most likely is a previously unknown and unclassified subgroup A-like (atypical) lymphoid leukosis virus that cannot be detected using the standard CF test procedure prescribed in § 113.31, but can be detected using an ELISA for the detection of avian leukosis virus. The inability of the CF test to detect the lymphoid leukosis virus contamination that was later found using an ELISA test procedure indicates that the ELISA has a broader spectrum of specificity as compared to the CF test, and may be more suitable for detecting previously unclassified atypical lymphoid leukosis viruses.

The requirement to use the CF test procedure specified in § 113.31 of the regulations to test for contaminating lymphoid leukosis viruses was promulgated prior to the development of ELISA methodology. Subsequent to the development of ELISA methodology and the licensing of ELISA based avian leukosis virus test kits, APHIS has approved the use of licensed ELISA kits to test for contaminating lymphoid leukosis viruses in place of the CF test procedure. Such approvals were based on side-by-side testing of the two methods that found the licensed ELISA kits to be equivalent to the CF test procedure for detecting lymphoid leukosis virus contamination in biological products.

However, because the contaminated vaccine test results indicate that an ELISA will detect lymphoid leukosis virus contamination that cannot be detected using the CF test procedure, APHIS has concluded that the CF test procedure should no longer be specified for the detection of lymphoid leukosis viruses in § 113.31. In place of the CF test procedure, veterinary biologics licensees and permittees would be required to conduct a test that will detect extraneous replicating avian leukosis virus and that is acceptable to APHIS as specified in the product's filed Outline of Production.

We are proposing to change the title of § 113.31 from ''Detection of avian lymphoid leukosis'' to ''Detection of extraneous replicating avian leukosis virus'' to clarify the fact that the test is for the detection of ''extraneous replicating'' avian leukosis virus that causes the disease ''lymphoid leukosis'' in chickens. We would also amend the introductory text of the section, where the current regulations specify that the CF test shall be conducted, to state simply that a test that will detect extraneous replicating avian leukosis virus and that is acceptable to APHIS shall be conducted. We expect that most manufacturers would specify a licensed ELISA kit for such testing, but other methods may be available and could be used provided they are acceptable to APHIS.

In the case of biological product containing virus that has been propagated in substrates of chicken origin that cannot be tested for lymphoid leukosis virus contamination because the vaccine virus is cytopathic to chick embryo fibroblast cells, we would amend the regulations to require the individual firm(s) to specify a procedure to test such product for contaminating lymphoid leukosis viruses in the filed Outline of Production.

Currently, § 113.31 of the regulations provides that in the case of cytopathic vaccine virus, the test for contaminating

lymphoid leukosis viruses may be performed using a sample of another (alternative) vaccine prepared the same week from material harvested from each source flock used for the preparation of the product that contains the cytopathic (questionable) vaccine virus. Because both the questionable vaccine and the alternative vaccine would have been prepared using common-source avian origin substrate, the expectation was that if contaminating lymphoid leukosis viruses are not detected in the alternative vaccine, there is a strong probability that the questionable vaccine also is free of contaminating lymphoid leukosis viruses. However, as we sought to determine the source of the lymphoid leukosis virus found in the contaminated vaccine, we tested samples of another vaccine prepared the same week from material harvested from the same source flock(s) that provided the substrate used in the preparation of the contaminated vaccine. Because the substrate used to prepare both the contaminated vaccine and the vaccine used for the alternative test were derived from a common source, we expected the alternative vaccine to test positive for contaminating lymphoid leukosis viruses; however, none of the alternative vaccine samples tested positive for lymphoid leukosis viruses. These results indicate that testing an alternative vaccine for contaminating lymphoid leukosis viruses in place of a questionable vaccine does not ensure that a contaminant, if present, will be detected and, thus, should be discontinued. Therefore, when a vaccine cannot be tested for contaminating lymphoid leukosis viruses because the vaccine virus is cytopathic to the cells used for viral propagation, we are proposing to require veterinary biologics manufacturers to specify a procedure to test such vaccine for contaminating lymphoid leukosis viruses in the product's filed Outline of Production. The specified procedure would have to be acceptable to APHIS.

In addition, we propose to specify that the equivalent of 200 doses of vaccine must be used as inoculum when testing bursal disease vaccine, tenosynovitis vaccine, and reovirus vaccine for contaminating lymphoid leukosis viruses. The current standard requirement specifies that when vaccines are tested for lymphoid leukosis virus contamination, the equivalent of 200 doses of Newcastle disease vaccine or 500 doses of other vaccine for use in poultry, or 1 dose of vaccine for use in other animals, shall be used as inoculum. Subsequent to codifying the requirement to use the equivalent of 200 doses as inoculum when testing Newcastle disease vaccine for contaminating lymphoid leukosis viruses, we have identified additional poultry vaccines for which the equivalent of 200 doses should be used as inoculum when testing for contaminating lymphoid leukosis viruses. APHIS now proposes to amend § 113.31 by specifying that the equivalent of 200 doses also shall be used as inoculum when testing bursal disease vaccine, tenosynovitis vaccine, and reovirus vaccine for contaminating lymphoid leukosis viruses.

These amendments are being proposed in order to update the procedure used to detect lymphoid leukosis virus contamination in biological products and ensure that such products are free of material that adversely affects their safe use in animals.

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.

We are proposing to amend the regulations for detection of avian lymphoid leukosis to require that a test that will detect extraneous replicating avian leukosis virus and that is acceptable to APHIS shall be conducted on all biological products containing virus that has been propagated in substrates (starting material) of chicken origin. Lymphoid leukosis is a disease of chickens caused by avian leukosis viruses. Veterinary biologics containing virus that has been grown in substrates of chicken origin are at risk for contamination with avian leukosis viruses which, if present, are referred to as extraneous replicating avian leukosis virus. Inoculation of chickens, and possibly other animals, with vaccine contaminated with avian leukosis virus may cause neoplastic disease. This proposed rule, if adopted, would allow any valid method to be used for testing veterinary biologics for extraneous replicating avian leukosis virus, provided that it is acceptable to APHIS.

The proposed changes would affect all licensed manufacturers of veterinary biologics who are required to test for the detection of extraneous replicating avian leukosis virus. There are approximately 125 veterinary biologics establishments, and approximately 15 of these establishments produce product that would be affected by this proposed rule. According to the standards of the Small Business Administration, most veterinary biologics establishments would be classified as small entities. The proposed changes, however, would not impose any additional economic burden since the regulations already require vaccine propagated in substrates of chicken origin to be tested for extraneous replicating avian leukosis virus; currently, the regulations require firms to use the CF test procedure for such testing. This proposed rule would discontinue required use of the CF test and instead require a test that will detect extraneous replicating avian leukosis virus and that is acceptable to APHIS to be conducted. In addition, the proposed rule would require firms to specify a procedure to test for extraneous replicating avian leukosis virus when questionable vaccine cannot be tested because the vaccine virus is cytopathic to chick embryo fibroblast cells; and would specify using the equivalent of 200 doses as inoculum when testing bursal disease, tenosynovitis, and reovirus vaccines for contaminating lymphoid leukosis viruses. The overall effect of this action would be to update the standard procedure for detecting extraneous replicating avian leukosis virus in biological products by prescribing a test procedure that has a greater probability of detecting an atypical lymphoid leukosis virus such as was recently found in contaminated vaccine.

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. 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. The Virus-Serum-Toxin Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This proposed rule contains no new 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 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 113 as follows:

PART 113—STANDARD REQUIREMENTS

1. The authority citation for part 113 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

2. Section 113.31 would be revised to read as follows:

§ 113.31 Detection of extraneous replicating avian leukosis virus.

A test that will detect extraneous replicating avian leukosis virus and that is acceptable to the Animal and Plant Health Inspection Service (APHIS) shall be conducted on all biological products containing virus that has been propagated in substrates of chicken origin: *Provided,* An inactivated viral product will be exempt from this requirement if the licensee can provide data that demonstrates to APHIS that the agent used to inactivate the vaccine virus would also inactivate lymphoid leukosis virus.

(a) Propagation of extraneous lymphoid leukosis viruses shall be done in chick embryo cell cultures or other substrate acceptable to APHIS.

(1) Each vaccine virus cytopathic to the cell culture being used shall be effectively neutralized, inactivated, or separated so that minimal amounts of extraneous replicating lymphoid leukosis virus can be propagated during the specified growth period. If the product cannot be tested for extraneous replicating lymphoid leukosis virus because the vaccine virus cannot be effectively neutralized, inactivated, or separated, an alternative procedure acceptable to APHIS shall be specified in the filed Outline of Production.

(2) When cell cultures are tested, 5 mL of the final cell suspension as prepared for seeding of production cell cultures shall be used as inoculum. When vaccines are tested, the equivalent of 200 doses of cytopathic vaccine viruses, including Newcastle disease vaccine, bursal disease vaccine, tenosynovitis vaccine, and reovirus vaccine, or 500 doses of other vaccines for use in poultry, or 1 dose of vaccine for use in other animals shall be used as inoculum. Control cultures shall be prepared from the same cell suspension as the cultures for testing the vaccine.

(3) Uninoculated chick embryo fibroblast cell cultures shall act as negative controls. One set of chick fibroblast cultures inoculated with subgroup A virus and one set of chick fibroblast cultures inoculated with subgroup B virus shall act as positive controls A and B, respectively.

(4) The cell cultures shall be passed when necessary to maintain viability, and samples harvested from each passage shall be tested for group-specific antigen.

(b) A test that will detect extraneous replicating lymphoid leukosis virus and that is acceptable to APHIS shall be used.

(1) All test materials, including positive and negative controls, shall be stored at −60 °C or colder until used in the test.

(2) The test procedure, including the cutoff value indicative of a positive test for extraneous replicating lymphoid leukosis virus, shall be specified in a filed Outline of Production or Special Outline.

(3) The detection of extraneous replicating lymphoid leukosis virus at the first passage shall be considered suspicious and the sample shall be further subcultured and tested to determine the presence of extraneous replicating lymphoid leukosis virus.

(4) Biological products or primary cells that are found contaminated with lymphoid leukosis viruses are unsatisfactory. Source flocks from which contaminated material was obtained are also unsatisfactory.

Done in Washington, DC this 25th day of January 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–1528 Filed 1–30–07; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. APHIS–2006–0079]

RIN 0579–AC30

Viruses, Serums, Toxins, and Analogous Products; Standard Requirements for Live Vaccines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations for certain live bacterial and viral vaccines by removing the requirement to retest the Master Seeds for immunogenicity 3 years after the initial qualifying immunogenicity test. In addition, we are proposing to amend the requirement concerning mouse safety tests prescribed for a biological product recommended for animals other than poultry. These proposed changes would update the standard requirements by eliminating unnecessary testing of Master Seed bacteria and viruses and other forms of bulk or completed biological product.

DATES: We will consider all comments that we receive on or before April 2, 2007.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* select ''Animal and Plant Health Inspection Service'' from the agency drop-down menu, then click ''Submit.'' In the Docket ID column, select APHIS–2006–0079 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2006–0079, 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–2006–0079.

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. Albert P. Morgan, Chief Staff Officer, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, APHIS, USDA, 4700