DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 97–021–1]

Change in Disease Status of Northern Ireland and Norway Because of Exotic Newcastle Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations by removing Northern Ireland and Norway from the list of countries that are considered to be free of exotic Newcastle disease. We are taking this action based on reports we have received from the Office International des Epizooties and the Governments of Northern Ireland and Norway, which confirm that outbreaks of exotic Newcastle disease have occurred in Northern Ireland and Norway. This action restricts the importation of live birds, poultry, and poultry products into the United States from Northern Ireland and Norway.

DATES: Interim rule effective April 15, 1997. Consideration will be given only to comments received on or before June 17, 1997.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 97–021–1, 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. 97–021–1. 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. John Cougill, Staff Veterinarian, Animal Products Program, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231, (301) 734–3399; or e-mail: jcougill@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation into the United States of specified animals and animal products in order to prevent the introduction into the United States of various animal diseases, including exotic Newcastle disease (END). END is a contagious, infectious, and communicable disease of birds and poultry.

Section 94.6(a)(1) of the regulations provides that END exists in all countries of the world except those listed in § 94.6(a)(2), which have been declared to be free of END. We will consider declaring a country to be free of END if there have been no reported cases of the disease in that country for at least the previous 1-year period.

The Office International des Epizooties (OIE) and the Governments of Northern Ireland and Norway have sent the Animal and Plant Health Inspection Service (APHIS) reports that outbreaks of exotic Newcastle disease have occurred in Northern Ireland and Norway. After reviewing the reports submitted by OIE and the Governments of Northern Ireland and Norway, APHIS has determined to remove Northern Ireland and Norway from the list of countries free of END.

Therefore, we are amending § 94.6(a)(2) by removing Northern Ireland and Norway from the list of countries declared to be free of END. This action prohibits the importation of live birds and poultry and restricts the importation into the United States of carcasses and products of poultry, game birds, and other birds from Northern Ireland and Norway. However, under the regulations in § 92.209(a)(2), hatching eggs from poultry are allowed to be imported into the United States from countries with END under certain conditions, including being quarantined from the time of arrival at the United States port of entry until not less than 30 days after they hatch.

Emergency Action

The Administrator of the Animal and Plant Health Inspection Service has determined that an emergency exists that warrants publication of this interim rule without prior opportunity for public comment. Immediate action is necessary to prevent the introduction of END into the United States.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make it effective upon signature. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This interim rule restricts the importation of live birds, game birds, poultry, and their products into the United States from Northern Ireland and Norway. We are taking this action in response to reports that END outbreaks have occurred in those two countries. If END were introduced into the United States, the disease could have severe economic consequences for poultry consumers and producers, and the government.

The United Kingdom, which includes Northern Ireland,[1] is not a significant source of U.S. poultry imports. During the first 11 months of 1996, the United Kingdom accounted for less than 2 percent of the total U.S. imports of poultry. The United Kingdom's principal poultry export to the United States is hatching eggs; however, importations of hatching eggs from Great Britain (England, Scotland, Wales, and the Isle of Man), will not be affected by the rule change. Importations of poultry hatching eggs from Northern Ireland will have to meet the quarantine and other requirements of § 92.209. Given the relatively small contribution to the U.S. poultry supply by the United Kingdom as a whole, even the complete loss of Northern Ireland's imports should have no significant effect on small entities in the United States.

The United States imports virtually no poultry or poultry products from Norway. During the first 11 months of 1996, the only poultry product imported from Norway was 0.1 metric ton of chicken liver. Also during the first 11 months of 1996, there were no live poultry imports at all from Norway. Because Norway is not a significant source of poultry or poultry products for the United States, the loss of Norway's imports should have no significant effect on small entities in the United States.

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.

[1] Trade data for Northern Ireland as a separate entity from the United Kingdom is not available. Northern Ireland is included in trade data for the United Kingdom.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This 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 94

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

Accordingly, 9 CFR part 94 is amended as follows:

PART 94—RINDERPEST, FOOT–AND–MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATION

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

Authority: 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

§ 94.6 [Amended]

2. In § 94.6, paragraph (a)(2) is amended by removing the words ''Northern Ireland, Norway,''.

Done in Washington, DC, this 15th day of April 1997.

Donald W. Luchsinger,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–10101 Filed 4–17–97; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101 and 113

[Docket No. 94–051–3]

RIN 0579–AA66

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

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations to provide for the use of in vitro potency tests when conducting immunoassays to determine the relative antigen content (potency) of a serial of inactivated veterinary biological product once immunogenicity is established using host animal tests. Such tests would be conducted using unexpired immunogenic reference preparations and parallel line assays, or other methods which demonstrate linearity, specificity, and reproducibility at least equivalent to the parallel line assay. Firms currently using immunoassays which do not meet the standard in this amendment will have 2 years from the effective date of this final rule to update their filed Outlines of Production. This amendment also changes the title of the section and adds definitions of ''Master reference,'' ''Working reference,'' ''Qualifying serial,'' and ''Immunogenicity'' to the regulations.

The effect of this action is to standardize requirements for in vitro immunoassay potency tests for inactivated products which cannot be evaluated on the basis of virus titer or bacterial counts.

EFFECTIVE DATE: May 19, 1997.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Director, Center for Veterinary Biologics, Licensing and Policy Development, VS, 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. Tests to establish efficacy include immunogenicity tests in host animals using product which is manufactured according to specified requirements which include specifications for antigen content and/or animal potency. If a product has been tested for immunogenicity in animals and shown to elicit the desired immune response, it should follow that subsequent serials (batches) of the product manufactured to the same specifications should also have the same effect. Based on this premise, once immunogenicity is established in relation to a specific minimum antigen content, it should no longer be necessary to test every subsequent product serial for potency in animals if an evaluation of the relative antigen content can be made 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 a 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 for determining the potency of serials and/or subserials of veterinary biological products after required animal tests are completed. Prior to this amendment, the in vitro test procedures prescribed in § 113.8 were only applicable to products containing live microorganisms. With these amendments § 113.8 will be applicable to both live and inactivated products.

On May 17, 1995, we published in the **Federal Register** (60 FR 26381–26384, Docket No. 94–051–1) a proposal to amend the regulations regarding the use of in vitro potency tests in place of animal tests for immunogenicity. The proposed rule provided for the use of a parallel line assay, or other valid method, and an unexpired reference preparation in an in vitro immunoassay for relative antigen content to determine the potency of a serial of inactivated product. In proposing the parallel line assay or equivalent valid method and the use of an unexpired reference as a standard for in vitro immunoassay potency tests for serial release, APHIS did not intend to preclude the validation of existing in vitro immunoassays or the adoption of technological advances in antigen quantitation.

We solicited comments concerning our proposal for 90 days ending August 15, 1995. We extended the comment period an additional 30 days ending September 14, 1995 (60 FR 36743–36744, Docket No. 94–051–2, July 18,