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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 53, 82, and 94

[Docket No. APHIS-2007-0014]

RIN 0579-AC47

Importation of Table Eggs From Regions Where Exotic Newcastle Disease Exists

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations to modify the requirements concerning the importation of eggs (other than hatching eggs) from regions where exotic Newcastle disease (END) exists. This action is necessary to provide a more efficient and equally effective testing option for determining the END status of flocks producing eggs (other than hatching eggs) for export to the United States.

DATES: *Effective Date:* May 22, 2009.

FOR FURTHER INFORMATION CONTACT: Dr. Christopher Robinson, Senior Staff Veterinarian, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; (301) 734-7837.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 prohibit or restrict the importation of certain animals and animal and poultry products into the United States to prevent the introduction of dangerous and destructive diseases of livestock and poultry. Section 94.6 contains requirements that apply to the importation of carcasses, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game

birds, or other birds from regions where exotic Newcastle disease (END) or highly pathogenic avian influenza subtype H5N1 is considered to exist.

On August 13, 2007, we published in the **Federal Register** (72 FR 45177-45181, Docket No. APHIS-2007-0014) a proposal¹ to modify the requirements concerning the importation of eggs (other than hatching eggs) from regions where END exists. We proposed this action to provide for a more efficient and effective testing option for determining the END status of flocks producing table eggs for export to the United States.

We solicited comments concerning our proposal for 60 days ending October 12, 2007. We received four comments by that date. They were from a private citizen, State agricultural agencies, and another agency in the U.S. Department of Agriculture (USDA). They are discussed below.

One commenter stated that commercial poultry farming methods were responsible for diseases in poultry. The commenter suggested that the abolition of these methods would remove the need to regulate movement of eggs and poultry.

We disagree. Poultry become infected with END when they are exposed to Newcastle disease virus (NDV), which can be spread by pet and wild birds as well as domestic poultry. For example, a 1971 outbreak of END started in pet birds in California and spread to commercial flocks. Wild double-crested cormorants were the source of an END outbreak in North Dakota in 1992. The 2002-2003 END outbreak in several western States was first detected in backyard poultry flocks in California, from whence it spread to commercial poultry houses. We are making no changes in response to this comment.

One commenter expressed concern that the proposed testing protocols would increase the risk to human health.

There is no public health risk from END. Human infection with NDV is rare and usually occurs only in people who have close direct contact with infected birds, such as veterinarians or laboratory staff. The resulting disease is usually limited to conjunctivitis, and

recovery is usually rapid. There are no known instances of NDV transmission to humans through handling or consumption of poultry products. In any case, as discussed in the proposed rule, the testing requirements in this final rule are as effective at detecting END as the requirements that were previously in place.

One commenter expressed concern that some countries may not have laboratories that can perform virus isolation testing and APHIS did not include provisions to ensure that the samples be transported and handled appropriately. Another commenter asked for assurance that the cull birds for sampling will be selected, and that the samples themselves will be collected, by a government salaried veterinarian. The commenter also stated that the samples should be from birds that died, not birds that were killed.

As we explained in the proposed rule, and as is true in the current regulations, the laboratory performing the testing must be in the region of origin of the eggs and must be approved by the veterinary services organization of the national government of the region. If a region lacks the necessary veterinary infrastructure to perform the appropriate tests and to transport and handle samples appropriately, it would not be eligible to export eggs to the United States. While there is always a risk of improperly handled samples returning a false negative, we will require that the samples be collected from cull birds chosen by a salaried veterinary officer of the national government of the region of origin or by a veterinarian accredited by the national government of Mexico. We are confident that these measures will ensure the appropriate handling of the samples.

It was our intent that samples be collected from sick birds or birds that died, not healthy birds that were killed. We have clarified this in the final rule. In addition, to be consistent with the other proposed changes, we have also made a minor change in our proposed regulatory text in paragraph (c)(1)(ix)(C) of § 94.6 by replacing the words "an accredited veterinarian" with the words "a veterinarian accredited by the national government of Mexico". We proposed to recognize only accreditation by the national government of Mexico, so the more specific form is appropriate.

¹ To view the proposed rule and the comments we received, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0014>.

Two commenters stated that the level of confidence associated with the proposed sampling rate was too low. One asked why we were not requiring a sampling rate that would detect low-level infection with 98 percent confidence.

As we explained in the proposed rule, the level of confidence associated with the proposed sampling rate is 95 percent. This is the same level of confidence associated with the current requirements under which 10 percent of the flock must be sampled. Our intent is to replace the current testing regimen with one that will be both timelier and more efficient while maintaining the same level of effectiveness.

We proposed to allow either hemagglutination inhibition (HI) or embryonated egg inoculation testing to be used. One commenter stated that in 9 CFR 53.1, END is defined as “any velogenic Newcastle disease,” and that this implies that lentogenic and mesogenic strains of NDV do not cause END. The commenter expressed concern that HI tests conducted on blood samples from sick birds would only identify whether or not a sample was positive or negative for NDV, since there is no serological test to detect specific strains of the END virus.

We agree with the commenter's concerns. While the current regulations allow for HI testing of sentinel birds, this is appropriate because sentinel birds are not vaccinated against END. For flocks that have been vaccinated against END, HI testing is not appropriate because it will not be able to distinguish between a bird that has been vaccinated against END and a bird that has died from disease. We have revised the risk assessment accordingly and will remove references to HI testing from the final rule. Embryonated egg inoculation testing, one of the options available under the current regulations, is an accepted diagnostic procedure for detecting NDV and will be effective for detecting the virus without additional HI testing. The revised risk assessment, titled “Justification for the changes to the regulations governing the importation of table eggs from regions where exotic Newcastle disease exists into the United States,” may be viewed on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov). In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

The commenter also noted that with new knowledge of NDV the classification and terminology of END has evolved; in fact, in a proposed rule published in the **Federal Register** on

August 28, 2007 (72 FR 49231–49236, Docket No. APHIS–2007–0033), we had proposed to change the definition of END in the select agent regulations in 9 CFR part 121 to replace the word “velogenic” with the word “virulent.” We published a final rule adding this change to 9 CFR part 121 on October 16, 2008 (73 FR 61325–61332). The commenter stated that if the new wording were adopted the definition in 9 CFR part 53 would have to be amended as well.

We agree with the commenter that amending the END definition to be consistent with our select agent regulations and with the World Organization for Animal Health (OIE) definition is appropriate. Therefore, we are amending the definition of “exotic Newcastle disease” in § 53.1, the definition of “END” in § 82.1, and the definition of “exotic Newcastle disease (END)” in § 94.0 to replace the word “velogenic” with the word “virulent.” This will bring those definitions in line with the definition of END in our select agents regulations in 9 CFR part 121 and the OIE definition of END.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

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.

The Regulatory Flexibility Act requires agencies to evaluate the potential effects of rules on small businesses, small organizations, and small governmental jurisdictions. Section 605 of the Act allows the head of an agency to certify that a rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Following is the factual basis for such certification of this final rule.

We are amending the regulations concerning the importation of eggs (other than hatching eggs) from regions where exotic Newcastle disease (END) exists. This action will provide a more efficient testing protocol for determining the END status of flocks producing eggs (other than hatching eggs) for export to the United States.

The goal of this rule is to make our testing requirements more efficient and equally effective while continuing to protect domestic poultry from END. One procedure by which foreign producers

located in regions affected with END can currently export table eggs into the United States is to place sentinel birds within their flocks and then test these birds for presence of the disease. As many of these foreign producers vaccinate their flocks for END, sentinel birds may produce false-positive results when tested for END, necessitating further testing to differentiate a vaccine-induced response from an actual infection. The second procedure currently authorized, testing 10 percent of the flock, is viewed by foreign egg producers as excessive. This final rule will replace the current options for flock testing with a less costly protocol that targets the birds most likely to be infected.

U.S. Table Egg Production and Imports

The United States is the world's largest producer of poultry meat and the second largest egg producer after China. Table egg production during the year ending November 30, 2007, totaled 77.3 billion eggs.² The largest table egg-producing States are Indiana, Iowa, and Pennsylvania.³

The cost of complying with flock testing requirements for foreign suppliers of table eggs from regions where END exists will likely decrease due to the lower number of birds required to be tested to demonstrate flock freedom from END. This reduction in cost could result in a small increase in the volume of table egg imports by the United States from END-affected regions. In 2007, table eggs were imported from two countries free of END, Canada and New Zealand. These imports totaled 94,241 dozen and were valued at \$345,000. The only other country from which table eggs were imported in 2007 was China, where END is considered to exist. These imports totaled 7,740 dozen and were valued at \$12,000.⁴ Between January and August of 2008, the United States' only table eggs imports were from Canada (60,700 dozen valued at \$80,020) and New Zealand (21,888

² USDA, *Chickens and Eggs 2007 Summary*. Washington, DC: National Agricultural Statistics Service, Table: Eggs; Production During the Month by Type 2006–2007, pg. 8. February 2008.

³ Production statistics for Alaska, Arizona, Delaware, Kansas, North Dakota, New Mexico, Nevada, and Rhode Island are not separately reported to avoid disclosing information on individual operations. <http://usda.mannlib.cornell.edu/usda/current/ChickEgg/ChickEgg-02-28-2008.pdf>.

⁴ USDA, *Harmonized System 10-Digit Imports*. Washington, DC: Foreign Agricultural Service, 2008. Import quantities and cash value estimates of table eggs for regions where END is considered to exist were approximated by subtracting the quantity and value of imports from regions free of END from the “world total” query.

dozen valued at \$148,991); no table eggs were imported from China or any other country where END is considered to exist. The 7,740 dozen table eggs imported from China in 2007 was a negligible quantity compared to the number produced domestically (less than 100,000, compared to 77.3 billion). Any increase in the U.S. supply of table eggs attributable to this final rule will likely be insignificant.

Impact on Small Entities

Companies engaged in chicken egg production are classified under the North American Industry Classification System code 112310. The Small Business Administration (SBA) defines a chicken egg-producing entity as small if it has annual receipts of not more than \$11.5 million per year. The 2002 Census of Agriculture reported that there were 83,381 domestic poultry and egg farms. While their size distribution is unknown, the census indicates that 29,393 of those poultry operations had annual sales of \$50,000 or more. Thus, the majority of operations engaged in table egg production are small entities by SBA standards.

As described, recent imports of table eggs from regions where END exists have come only from China and constitute an extremely small share of the U.S. supply. While this rule provides a more efficient and effective testing protocol for determining the END status of flocks producing table eggs for the United States, any effects on the supply of imported eggs will be minimal.

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 12988

This final 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

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579-0328.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

Lists of Subjects

9 CFR Part 53

Animal diseases, Indemnity payments, Livestock, Poultry and poultry products.

9 CFR Part 82

Animal diseases, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 94

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

■ Accordingly, we are amending 9 CFR parts 53, 82, and 94 as follows:

PART 53—FOOT-AND-MOUTH DISEASE, PLEUROPNEUMONIA, RINDERPEST, AND CERTAIN OTHER COMMUNICABLE DISEASES OF LIVESTOCK OR POULTRY

■ 1. The authority citation for part 53 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

§ 53.1 [Amended]

■ 2. In § 53.1, the definition for “Exotic Newcastle Disease (END)” is amended by removing the word “velogenic” and adding the word “virulent” in its place.

PART 82—EXOTIC NEWCASTLE DISEASE (END) AND CHLAMYDIOSIS

■ 3. The authority citation for part 82 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

§ 82.1 [Amended]

■ 4. In § 82.1, the definition for “END” is amended by removing the word “velogenic” and adding the word “virulent” in its place.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 5. The authority citation for part 94 continues 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.

■ 6. The heading of part 94 is revised to read as set forth above.

§ 94.0 [Amended]

■ 7. In § 94.0, the definition of “Exotic Newcastle disease (END)” is amended by removing the word “velogenic” and adding the word “virulent” in its place.

■ 8. In § 94.6, the introductory text of paragraph (c)(1), paragraph (c)(1)(v), paragraph (c)(1)(viii), the introductory text of paragraph (c)(1)(ix), paragraph (c)(1)(ix)(C), and the OMB citation at the end of the section are revised, and a new paragraph (c)(1)(ix)(D) is added to read as follows:

§ 94.6 Carcasses, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds; importations from regions where Exotic Newcastle disease or highly pathogenic avian influenza subtype H5N1 is considered to exist.

* * * * *

(c) * * *

(1) *With a certificate.* The eggs may be imported if they are accompanied by a certificate signed by a salaried veterinary officer of the national government of the region of origin or, if exported from Mexico, accompanied either by such a certificate or by a certificate issued by a veterinarian accredited by the national government of Mexico and endorsed by a full-time salaried veterinary officer of the national government of Mexico, thereby representing that the veterinarian issuing the certificate was authorized to do so, and:

* * * * *

(v) The certificate states that no more than 90 days before the certificate was signed, a salaried veterinary officer of the national government of the region of origin or, if exported from Mexico, by a veterinarian accredited by the national government of Mexico, inspected the flock of origin and found no evidence of communicable diseases of poultry.

* * * * *

(viii) Before leaving the premises of origin, the cases in which the eggs were

packed were sealed with a seal of the national government of the region of origin by the salaried veterinarian of the national government of the region of origin who signed the certificate or, if exported from Mexico, by the veterinarian accredited by the national government of Mexico who signed the certificate.

(ix) In addition, if the eggs were laid in any region where END is considered to exist (see paragraph (a) of this section), the certificate must also state:

* * * * *

(C) The eggs are from a flock of origin found free of END as follows: On the seventh and fourteenth days of the 21-day period before the certificate is signed, at least 1 cull bird (a sick or dead bird, not a healthy bird that was killed) for each 10,000 live birds occupying each poultry house certified for exporting table eggs was tested for END virus using embryonated egg inoculation technique. The weekly cull rate of birds of every exporting poultry house within the exporting farm does not exceed 0.1 percent. The tests present no clinical or immunological evidence of END by embryonated egg inoculation technique from tissues of birds that were culled and have been collected by a salaried veterinary officer of the national government of the region of origin or by a veterinarian accredited by the national government of Mexico. All examinations and embryonated egg inoculation tests were conducted in a laboratory located in the region of origin, and the laboratory was approved to conduct the examinations and tests by the veterinary services organization of the national government of that region. All results were negative for END.

(D) Egg drop syndrome is notifiable in the region of origin and there have been no reports of egg drop syndrome in the flocks of origin of the eggs, or within a 50 kilometer radius of the flock of origin, for the 90 days prior to the issuance of the certificate.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579-0015, 0579-0245, and 0579-0328)

§ 94.8 [Amended]

■ 9. In § 94.8 in the introductory text and paragraph (a)(4) introductory text footnotes 8 and 9 are redesignated as footnotes 7 and 8 respectively.

§ 94.9 [Amended]

■ 10. In § 94.9 (a), (c)(3), and (e)(2) introductory text footnotes 10 through 12 are redesignated as footnotes 9 through 11 respectively.

■ 11. Section 94.12 is amended as follows:

■ a. In paragraph (b)(1)(iii)(B), by redesignating footnote 13 as footnote 12.

■ b. In paragraph (b)(3), by redesignating footnote 14 as footnote 13 and revising newly redesignated footnote 13 to read as set forth below.

§ 94.12 Pork and pork products from regions where swine vesicular disease exists.

* * * * *

(b) * * *

(3) * * * 13

¹³ See footnote 9 in § 94.9.

§ 94.16 [Amended]

■ 12. In § 94.16 (b)(2) footnote 15 is redesignated as footnote 14.

■ 13. Section 94.17 is amended as follows:

■ a. In paragraph (e), by redesignating footnote 16 as footnote 15.

■ b. In paragraph (p)(1)(i), by redesignating footnote 17 as footnote 16 and revising newly redesignated footnote 16 to read as set forth below.

§ 94.17 Dry-cured pork products from regions where foot-and-mouth disease, rinderpest, African swine fever, classical swine fever, or swine vesicular disease exists.

* * * * *

(p) * * *

(1) * * *

(i) * * * 16

¹⁶ See footnote 15 in paragraph (e) of this section.

§ 94.18 [Amended]

■ 14. In § 94.18 in paragraphs (c)(2) and (d)(1) footnotes 18 and 19 are redesignated as footnotes (17) and (18) respectively.

§ 94.24 [Amended]

■ 15. In § 94.24 in paragraphs (a)(5) and (b)(6) footnotes 20 and 21 are redesignated as footnotes 19 and 20 respectively.

Done in Washington, DC, this 15th day of April 2009.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E9-9102 Filed 4-21-09; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2008-1259; Airspace Docket No. 08-ASO-1]

Modification of the Atlantic High and San Juan Low Offshore Airspace Areas; East Coast, United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action will amend the boundaries of the Atlantic High and San Juan Low Offshore Airspace Areas located off the east coast of the United States. The implementation of the West Atlantic Route System Plus (WATRS Plus) project modified the boundaries of the Miami Control Area (CTA)/Flight Identification Region (FIR), the San Juan CTA/FIR, and the New York Oceanic CTA/FIR. This action modifies the Atlantic High and San Juan Low Offshore Airspace Area boundaries to coincide with the CTA/FIR changes.

DATES: *Effective Date:* 0901 UTC, July 2, 2009. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace and Rules Group, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

History

On Thursday January 15, 2009, the FAA published in the **Federal Register** a notice of proposed rulemaking to modify the Atlantic High and San Juan Low Offshore Airspace Areas, East Coast, United States (74 FR 2427). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received. With the exception of editorial changes, this amendment is the same as that proposed in the NPRM.

High offshore airspace areas are published in paragraph 2003, and low offshore airspace areas are published in paragraph 6007, of FAA Order 7400.9S signed October 3, 2008, and effective October 31, 2008, which is incorporated by reference in 14 CFR 71.1. The offshore airspace areas listed in this