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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 92

[Docket No. 02–001–2]

RIN 0579–AB53

Procedures for Reestablishing a Region as Free of a Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the recognition of regions to establish procedures that we will follow when a region that we recognize as free of an animal disease experiences an outbreak of that disease. The procedures include steps we will take to prevent the introduction of disease from that region and steps we will take to further assess the region's animal health status. The procedures will allow for timely reinstatement of the region's disease-free status if supported by the reassessment.

EFFECTIVE DATE: June 9, 2004.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Director, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 92, ''Importation of Animals and Animal Products; Procedures for Requesting Recognition of Regions'' (referred to below as the regulations), set out the process by which a foreign government may request recognition of the animal health status of a region or approval to export animals or animal products to the United States from a region based on the disease risk associated with animals or animal products from that region. As provided in § 92.2, each request must include information about the region, including information on the authority, organization, and infrastructure of the veterinary services organization of the region; the extent to which movement of animals and animal products is controlled from regions of higher disease risk, and the level of biosecurity for such movements; livestock demographics and marketing practices in the region; diagnostic laboratory capabilities in the region; and the region's policies and infrastructure for animal disease control, *i.e.*, the region's emergency response capacity.

Recognition by the Animal and Plant Health Inspection Service (APHIS) of a region's animal health status makes exports of animals and animal products from that region subject to a certain set of import conditions, depending on that region's animal health status. These import conditions are intended to ensure that animals and animal products imported from the region will not introduce animal diseases into the United States.

While the regulations in part 92 have provided for what can be described as the original recognition of the animal disease status of a region with respect to a particular disease, they have not described the actions that we will take when a region that we already recognize as free of a disease experiences an outbreak of that disease, nor have they described a process by which the region's disease-free status may be restored following its eradication of the disease.

To address this need, on June 24, 2003, we published in the **Federal Register** (68 FR 37426–37429, Docket No. 02–001–1) a proposal to establish procedures that we will follow when a region that we recognize as free of disease experiences an outbreak of that disease. Those procedures, which we proposed to set out in a new § 92.4, included steps we would take to prevent the introduction of disease from that region and steps we would take to further assess the region's animal health status. We proposed this action to allow for timely reinstatement of the region's disease-free status if supported by the reassessment.

We solicited comments concerning our proposal for 60 days ending August 25, 2003. We received 11 comments by that date. The comments were from representatives of domestic and foreign animal industry organizations, State veterinarians, a foreign government association, a representative of State government, and an individual. Most of the comments were generally supportive, although several asked for clarifications or minor adjustments to the proposed procedures. Three commenters did not appear to support the proposal. Their comments and the clarifications and adjustments requested by others are described below.

One commenter who opposed the proposal objected to the concept of regionalization, arguing that an area smaller than an entire country should not be accorded a separate disease status. He expressed the concern that disease could spread into a regionalized area through, among other means, the unauthorized movement of animals into that area.

We will not be making any changes to the final rule in response to these comments. International trade agreements entered into by the United States—specifically, the North American Free Trade Agreement and the World Trade Organization Agreement on Sanitary and Phytosanitary Measures—obligate APHIS to recognize regions, rather than only countries, for the purpose of regulating the importation of animals and animal products into the United States, and we have been doing so for several years. Our procedures for recognizing a region's disease status, including a region smaller than an entire country, are set out in § 92.2. We consider a number of factors, including the extent to which movement of animals and animal products is controlled and the level of biosecurity regarding such movements, the extent of an active disease control program and disease surveillance activities in the region, and the authority, organization, and infrastructure of the veterinary services organization in the region. We believe that an evaluation of these factors can justify recognition of a region smaller than an entire country, in accordance with part 92, and provide assurance that the region has the means to prevent the spread of disease into and from that region.

Another commenter who opposed the proposal maintained that reinstatement of the disease-free status of a region

must be done in accordance with the existing regulations in part 92. The commenter also maintained that any further regionalization of a region (*e.g.*, recognizing a region within a country) following a disease outbreak should also be done in accordance with the existing regulations.

We will not be making any changes to the final rule in response to these comments. We disagree with the commenter's assertion that reinstatement of disease-free status should be done in strict accordance with the existing regulations for original recognition of such status. We did not intend for the regulations in § 92.2 to apply in circumstances where an outbreak of a disease, or an increased incidence of disease, in a foreign region makes it necessary for the United States to take interim measures to protect its livestock from the foreign animal disease. In these cases, APHIS must take immediate action to prohibit or restrict imports from the region of concern. Such action may include publishing an interim rule to provide an appropriate basis for enforcing prohibitions or restrictions that may initially be announced administratively. An interim rule of this type is intended to be just that, an ''interim'' or ''temporary'' measure which would provide the immediate protection needed for animal health purposes. Such a rule gives APHIS an opportunity to evaluate the effectiveness of emergency response measures taken in the subject region to deal with the outbreak and to determine whether the outbreak is indeed a temporary situation or indicates a fundamental change in the region's disease status. If a region takes immediate and effective steps to control and stamp out the disease and satisfies any other requirements that it may be necessary to apply to that particular region, it should be promptly returned to its previous status.[1] APHIS will also take into consideration whether the subject region has met the minimum Office International des Epizooties (OIE) standards for restoration of free status. Our obligations under international trade agreements compel us to take no more restrictive actions than necessary to prevent the introduction of disease. Regarding the commenter's second point, in many cases, the evaluation of a region that led to our initial recognition of it as disease free also provides us with the information we need to determine whether an administrative unit within that region (*e.g.*, a political subdivision of a country) has sufficient control mechanisms in place to be recognized as a region with a separate disease status. We are taking steps to inform the public about the basis for our determining the administrative unit that may be recognized as a region if there is an outbreak of a disease. This determination is country specific and based on the controls existing in that country. For example, a final rule recognizing regions of the European Union for classical swine fever (CSF) status, which was published in the **Federal Register** on April 7, 2003 (68 FR 16922–16941, Docket No. 98–090–5), set out what we considered to be the appropriate administrative units, *i.e.*, regions, for Germany and Italy. Similarly, a notice of availability of our recent reassessment of the disease status of France and Spain for CSF, published in the **Federal Register** on November 24, 2003 (68 FR 65869–65871, Docket No. 98–090–6), set out the administrative units we would recognize in those countries.

The third commenter who opposed the proposed rule represented the European Commission (EC). This commenter stated that, in failing to recognize regionalization decisions made by the EC, the proposed rule was inconsistent with the Veterinary Equivalency Agreement between the EC and the United States concerning sanitary measures in the trade of live animals and animal products (Council Decision 98/258/EC).

We will not be making any changes to the final rule in response to this comment. Article 16 of the Veterinary Equivalency Agreement states, among other things, that, ''Each Party shall implement the commitments and obligations arising from this Agreement in accordance with its laws and procedures.'' APHIS' customary regulatory procedures involve rulemakings such as this one. However, we are working to create mechanisms through rulemaking that will provide us with greater flexibility and reduce response time. This rulemaking is one example.

Several commenters suggested that our proposed procedures placed too much emphasis on the standards of the OIE, suggesting that OIE standards may not always reflect current science and may not be sufficient to protect U.S. livestock from disease. These commenters cited, in particular, the wording in both the preamble and rule text that said we intend to reassess the disease situation in a country ''in accordance with OIE standards.'' One commenter also cited our statement in the preamble that, ''If a region takes immediate and effective steps to control and stamp out the disease, we believe the region's disease-free status should be restored as quickly as possible once the region has met OIE requirements.'' That commenter noted that while OIE sets ''standards,'' those standards are not ''requirements.''

We agree that OIE standards are not requirements, and we did not intend to imply that we would base our evaluation of a region's disease status solely on whether the region has satisfied the criteria contained in those standards. APHIS uses OIE's waiting period as a guideline; however, APHIS' evaluation of a region's disease status will be based not only on whether the region has met OIE standards for reinstatement of disease-free status, but also on consideration of all relevant information, including information obtained through public comments on both the initial interim rule and the notice of availability of our reassessment and information collected by or submitted to us through other means. We have modified § 92.4 (b)(1) in this final rule to clarify that all these factors will be taken into account when we conduct such evaluations.

Two commenters cautioned that we should not rush the process of reinstating a region's disease-free status. We agree that the process should not be rushed; however, we will not be making any changes to the final rule as a result of these comments, since we continue to believe that the procedures originally contained in proposed § 92.4 will give us additional flexibility in evaluating a region's disease status without reducing the thoroughness of the evaluation process.

Some commenters suggested that the list of possible actions to be taken after the reassessment of a region's disease status should include a provision allowing APHIS to modify the scope of products affected by the initial interim rule. We believe that the proposed rule did include such a provision. Proposed § 92.4(c) listed three possible actions that APHIS may take following a reassessment: (1) Publish a final rule that reinstates the disease-free status of the region, or a portion of the region, covered by the interim rule; (2) publish an affirmation of the interim rule that imposed prohibitions or restrictions on the imports of animals and animal products from that region; or (3) publish another document in the **Federal Register** for comment. Under the third option, we could solicit comments on the scope of products to be covered in any subsequent rulemaking.

[1] APHIS does not plan to use the procedures established by this rule to upgrade a region's status with respect to bovine spongiform encephalopathy (BSE).

One commenter questioned how APHIS will address regions that have a cycle of disease outbreaks. APHIS will carefully consider a pattern of disease outbreaks as we conduct our reassessment. A cycle of disease outbreaks may indicate that the region does not have the safeguards or resources to prevent future outbreaks. Under no circumstances will we reestablish a region's disease-free status when we believe that our reassessment does not support such a decision.

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.

Below is a summary of the economic analysis for this final rule. The economic analysis provides a cost-benefit analysis and an analysis of the potential economic effects on small entities as required by the Regulatory Flexibility Act. A copy of the full economic analysis may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

This final rule establishes procedures that we will follow when a region that we recognize as free of a disease experiences an outbreak of that disease. The procedures include steps we will take to prevent the introduction of disease from that region and steps we will take to further assess the region's animal health status. The procedures will allow for a more timely reinstatement of the disease-free status of a region, or portion of a region, if supported by the reassessment.

As in the past, if a region that we recognize as free of a specified animal disease experiences an outbreak of that disease, we will take immediate action to prohibit or restrict imports of animals and animal products from that region to protect U.S. livestock. Restrictions and/or prohibitions may at first be announced administratively but are generally followed by an interim rule.

Previously, following the close of the comment period on the interim rule, we would publish an affirmation of the interim rule. Then, in order to restore the region's previous disease-free status, we would begin a new rulemaking with the publication of a proposed rule. After considering any comments we received during the comment period for the proposed rule, we would publish a final rule.

Under our new procedures, we will not proceed directly to an affirmation of the interim rule following the close of the comment period. As part of the reassessment process, we will consider all public comments we receive on the interim rule, as well as any additional information relevant to a decision to change the disease status of the region, including information collected by or submitted to us. Additionally, we will reassess the disease status of the region in the context of the standards of the OIE to determine whether it is necessary to continue the interim prohibitions or restrictions. Prior to taking any action to relieve or finalize prohibitions or restrictions imposed by the interim rule, we will make information regarding our reassessment of the region's disease status available to the public for comment. We will announce the availability of this information by publishing a notice in the **Federal Register**. Based on the reassessment, including the comments we receive in response to the notice we publish, we will publish one of the following:

- A final rule that reinstates the disease-free status of the region, or a portion of the region covered by the interim rule;
- An affirmation of the interim rule that imposed prohibitions or restrictions on imports of animals and animal products from that region;
- Another document in the **Federal Register** for comment, if neither a final rule or interim rule is considered appropriate at that time (*e.g.*, we could publish a notice providing additional information for comment).

The new procedures will improve the process for reinstating a region's disease-free status while still providing an effective opportunity for public participation.

U.S. entities potentially affected by these changes in procedures include importers, domestic producers, and consumers. In particular, importers and consumers may benefit because imports affected by the change in disease status may resume earlier than under previous procedures. Domestic producers of close substitutes of the imports, who may have benefitted during the period when imports were restricted or prohibited, may incur losses associated with a resumption of imports that could occur sooner than under past procedures. Because import levels of potentially regulated commodities from the majority of disease-free foreign regions are low relative to total imports and domestic availability of those commodities, the new procedures will likely not lead to significant benefits or losses. This projection is based on a review of economic analyses we prepared for recent rulemakings revoking and reinstating the disease-free status of foreign regions, as well as an analysis of the types and volumes of commodities currently imported from regions we currently recognize as free of specified diseases. We believe that the main benefits associated with the change in procedures will be improved trade relations between the United States and foreign governments.

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

This final 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 92

Animal diseases, Imports, Livestock, Poultry and poultry products, Region, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 92 as follows:

PART 92—IMPORTATION OF ANIMALS AND ANIMAL PRODUCTS: PROCEDURES FOR REQUESTING RECOGNITION OF REGIONS

■ 1. The authority citation for part 92 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. A new section 92.4 is added to read as follows:

§ 92.4 Reestablishment of a region's disease-free status.

This section applies to regions that are designated in this subchapter D as free of a specific animal disease and then experience an outbreak of that disease.

(a) *Interim designation.* If a region recognized as free of a specified animal

disease in this subchapter D experiences an outbreak of that disease, APHIS will take immediate action to prohibit or restrict imports of animals and animal products from that region. Such action may include publishing an interim rule that imposes prohibitions or restrictions that may be announced initially administratively. The interim rule may be given an effective date earlier than the date of signature or publication to affirm our authority for issuing previous administrative orders. The interim rule may impose prohibitions or restrictions on only a portion of the region previously recognized as free of a disease. In these cases, APHIS will provide information to the public as soon as possible regarding the basis for its decision to prohibit or restrict imports from the smaller area of that region previously recognized as free.

(b) *Reassessment of the disease situation.* (1) Following publication of an interim rule as described in paragraph (a) of this section, APHIS will reassess the disease situation in that region to determine whether it is necessary to continue the interim prohibitions or restrictions. In reassessing a region's disease status, APHIS will take into consideration the standards of the Office International des Epizooties for reinstatement of disease-free status, as well as all relevant information obtained through public comments on both the initial interim rule and the notice of availability of the reassessment or relevant information collected by or submitted to APHIS through other means.

(2) Prior to taking any action to relieve or finalize prohibitions or restrictions imposed by the interim rule, APHIS will make information regarding its reassessment of the region's disease status available to the public for comment. APHIS will announce the availability of this information by publishing a notice in the **Federal Register**.

(c) *Determination.* Based on the reassessment conducted in accordance with paragraph (b) of this section, including comments regarding the reassessment information, APHIS will take one of the following actions:

(1) Publish a final rule that reinstates the disease-free status of the region, or a portion of the region, covered by the interim rule;

(2) Publish an affirmation of the interim rule that imposed prohibitions or restrictions on the imports of animals and animal products from that region; or

(3) Publish another document in the **Federal Register** for comment.

Done in Washington, DC, this 4th day of May 2004.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–10523 Filed 5–7–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 95

[Docket No. 04–011–1]

Highly Pathogenic Avian Influenza; Additional Restrictions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations concerning the importation of animals and animal products to prohibit or restrict the importation of birds, poultry, and unprocessed bird and poultry products from regions that have reported the presence of the H5N1 subtype of highly pathogenic avian influenza and to establish additional permit and quarantine requirements for U.S. origin pet birds and performing or theatrical birds and poultry returning to the United States. This action is necessary to prevent the introduction of highly pathogenic avian influenza subtype H5N1 into the United States.

DATES: This interim rule was effective February 4, 2004. We will consider all comments that we receive on or before July 9, 2004.

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

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–011–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–011–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 04–011–1'' on the subject line.
- Agency Web site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS Web site.

Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

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: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: For information concerning bird and poultry products, contact Dr. Tracye Butler, Senior Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737–1231; (301) 734–3277.

For information concerning live birds and poultry, contact Dr. Julie Garnier, Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231; (301) 734–8364.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the Department) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. The regulations in 9 CFR parts 93, 94, and 95 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including avian influenza (AI).

There are many strains of AI virus that can cause varying degrees of clinical illness in poultry. AI viruses can infect chickens, turkeys, pheasants, quail, ducks, geese, and guinea fowl, as well as a wide variety of other birds. Migratory waterfowl have proved to be the natural reservoir for this disease.

AI viruses can be classified into low pathogenic (LPAI) and highly pathogenic (HPAI) forms based on the