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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 92

[Docket No. APHIS–2007–0158]

RIN 0579–AD30

Information From Foreign Regions Applying for Recognition of Animal Health Status

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations that govern the importation of animals and animal products by consolidating the list of factors APHIS considers when evaluating the animal health status of a foreign region and by setting out new factors APHIS will consider when evaluating a region as historically free of a specific disease. These changes will make clearer the types of information APHIS needs from a requesting region in order to conduct an evaluation.

DATES: *Effective Date:* August 27, 2012.

FOR FURTHER INFORMATION CONTACT: Dr. Kelly Rhodes, Regionalization Evaluation Services, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 851–3300.

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 forth the process by which a foreign government may request recognition of the animal health status of a region.

Section 92.2 of the regulations requires that such requests be accompanied by information regarding the region that will enable the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture to evaluate the request.

On December 28, 2011, we published in the **Federal Register** (76 FR 81404–81408, Docket No. APHIS–2007–0158) a proposal [1] to amend the regulations by consolidating the 11 factors listed in § 92.2(b) that APHIS considers when evaluating the animal health status of a foreign region into 8 factors. We also proposed to establish criteria for recognizing a region as historically free of a specific disease. Our intent was to make clearer the types of information APHIS needs from a requesting region to conduct an evaluation. Additionally, although our regulations focus on requests from foreign regions, we noted that APHIS could initiate an evaluation of the disease status of a foreign region and, if we did, would conduct the evaluation using these same factors. We also proposed to remove a statement in § 92.2(d) that supporting information submitted with country requests will be made available to the public prior to initiation of rulemaking. We proposed to replace it with a statement that a list of regions that have requested recognition of their animal health status will be available to the public, and to leave in place a statement in § 92.2(f) that when APHIS makes its evaluation available for public comment, the public will have access to the information upon which APHIS based its evaluation, as well as the evaluation itself.

We solicited comments concerning our proposal for 60 days ending February 27, 2012. We received 12 comments (including two from the same person) by that date. They were from an organization representing pork producers, an organization representing cattle farmers and ranchers, an organization representing U.S. consumers, a wildlife conservation society, a State board of animal health, foreign governments, and individuals.

Six commenters supported the proposed changes.

Three commenters objected to the proposed rule. Two of the three said that they oppose the concept of regionalization for animal health status. Two also said they were concerned about APHIS' ability to predict outbreaks or detect disease threats under the current 11 factors and oppose finalizing a rule predicated on those factors. They cited several instances where regions APHIS had recognized as free of a disease had subsequently experienced an outbreak of that disease. One commenter also said that APHIS should not adopt international criteria for evaluating a region as historically free of a disease until we have conducted a scientific study to determine whether such recommendations are, in fact, capable of adequately assessing whether a country is historically free of a disease.

We are making no changes to the proposed rule in response to these comments. Regionalization is an important principle of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO–SPS Agreement). Regionalization is based on recognition that pest and disease conditions may vary across a country as a result of ecological, environmental, and epidemiological factors, and on the premise that these differences should be taken into account in developing science-based regulatory measures. The United States has successfully applied the concept for decades in domestic disease control and eradication programs, and regionalization of the United States for bluetongue and other diseases has facilitated exports.

Our evaluations of regions for animal health closely consider a broad range of factors widely accepted by the international community for assessing the disease risks associated with a region. As discussed above, we provide an opportunity for the public to view and comment on our evaluations and the information upon which they are based prior to making a final determination. Finding that a region is free of a disease based on such an evaluation does not guarantee, however, that the region will always remain free of that disease. Our evaluations enable us to determine whether a disease is present in a region at a given time, ensure that the region has safeguards in place to protect against introduction of the disease, and ensure that the region is capable of detecting and containing

[1] To view the proposed rule and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0158.*

the disease should it be introduced despite these measures.

Two commenters did not speak for or against the specific changes, but raised other issues, as follows.

One expressed concern that the reason for the changes was to expedite the evaluations for animal health status. The commenter stated that this should not be done at the expense of preventing foreign animal disease introductions into the United States.

We agree and point out that we are not changing the way we conduct evaluations. Our goal is to expedite the process of a region supplying us with the necessary information to conduct an evaluation.

One commenter expressed concern that APHIS emphasizes geographic, or zonal, freedom from disease over other approaches to trade in animal products that effectively mitigate disease risks. He mentioned compartmentalization and commodity-based trade as two alternatives. As examples of the latter, he cited the international standards for trade in fresh beef from regions that vaccinate for foot-and-mouth disease and the international standards for trade in milk and deboned beef from regions where the risk of bovine spongiform encephalopathy is neither negligible nor controlled. He stated that eradication of livestock diseases may not always be realistic or feasible, especially in places like Africa, where the means for achieving zone freedom (fences, for example) can conflict with wildlife preservation efforts (e.g., ensuring wildlife have space and freedom to roam).

We are making no changes to the proposed rule in response to this comment. While this rulemaking addresses factors we consider when assessing the disease status of a geographic area, APHIS' regulations also include commodity-based requirements that allow for the importation of a variety of products from regions not considered free of diseases of concern. These requirements are contained largely in 9 CFR part 94. Inquiries regarding these requirements or requests for approval of new requirements may be directed to the National Center for Import and Export: Telephone (301) 851–3300 or email *AskNCIE.Products@aphis.usda.gov.*

Additionally, several of the commenters addressed specific provisions of the proposal.

One commenter objected to the proposal to allow APHIS to initiate an evaluation of a foreign country's disease status in the absence of a request from that foreign country, stating that multinational meat packers might lobby APHIS to conduct such evaluations in order to source meat and livestock.

We are making no changes to the proposed rule in response to this comment. If there is a U.S. market for meat or livestock from a foreign region but APHIS has not yet evaluated its disease risk, the foreign government of that region will likely request an evaluation because of the value those exports would have for the foreign region. In any case, as stated in the proposed rule, APHIS anticipates that most evaluations will be done at the request of a foreign country. There may be instances, however, when it will be beneficial for APHIS to initiate an evaluation, and we reserve the right to do so. Even in such cases, we could not conduct the evaluation without the cooperation of the foreign government, which would need to supply information and allow access for any necessary site visits. As with any evaluation, there would be opportunity for the public to review and comment on the evaluation and proposed disease status.

One commenter objected to our proposal to remove the statement in § 92.2(d) that supporting information submitted with country requests will be made available to the public prior to initiation of rulemaking. The commenter stated withholding such information will severely limit APHIS' transparency. Another commenter expressed concern that this change would reduce the amount of time that supporting information regarding a country's disease status is available to the public.

We are making no change in response to these comments. The intent of this statement was to assure the public that they will have access to, and opportunity to comment on, the information upon which APHIS bases its evaluation, as well as the evaluation itself. As discussed in the proposed rule, this has been our practice, and it will continue to be our practice. Moreover, there will be no change in when we make the supporting information available. We will continue to make both the supporting information and the evaluation available when we announce our intention to recognize the animal health status of a region and open the public comment period. We were concerned that the statement we proposed to remove suggested that the supporting information might be made available sooner, perhaps at the time of the initial submission of the request, when the information may be incomplete or inadequate. Additionally, this is not the only information APHIS relies upon to make its determination. In addition to information provided by the requesting country, we also gather information from literature, reports, and site visits and consider all of this in preparing our evaluation. We believe that the public should consider all of the information together, and that it could be confusing or misleading to release it in stages.

One commenter requested that, when we make available to the public a list of regions that have requested recognition of their animal health status, we include an indication of the animal species and diseases under evaluation with respect to each region. Another commenter recommended that we encourage foreign jurisdictions to specify the type of animal or product they wish to export and that we also make that information available to the public when we have it.

We agree with the suggestions. Paragraph § 92.2(d) in this final rule provides that APHIS will list on its Web site each region that has requested APHIS recognition of its animal health status, the disease(s) under evaluation, and, if the information is available, the animal(s) or product(s) the region wishes to export.

One commenter said that while the proposed changes would facilitate the work of foreign governments in submitting information, he remains concerned about the length of time it can take to complete assessments. The commenter referenced provisions in Annex C of the WTO–SPS Agreement that recommend that Members publish the standard processing period for evaluation requests or communicate the anticipated processing period to the applicant upon request.

We are making no changes to the proposed rule in response to this comment. Because the time required for each evaluation varies, estimates must be made on a case-by-case basis, which APHIS will communicate with the applicant upon request, consistent with Annex C.

One commenter asked what we mean by the wording ''safely granted'' in proposed § 92.2(e), which says: ''If, after review and evaluation of the information submitted in accordance with paragraph (b) or (c) of this section, APHIS believes the request can be safely granted, APHIS will indicate its intent and make its evaluation available for public comment through a document published in the **Federal Register**.''

We mean that APHIS has determined that imports from the region would present a low risk of introducing a particular disease into the United States and may be safely imported.

A few commenters also made suggestions or raised issues not directly

related to the changes we proposed, including expanding APHIS' oversight of other animals, including rodents; data sharing among regulatory agencies; conducting post-mortem examinations of a representative sample of imported livestock to rule out ''potential disease''; and the agreement between the European Commission and the United States on sanitary measures. Because these matters are outside the scope of this rulemaking, we are not addressing them here.

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 change discussed above.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

The economic analysis identifies importers and producers of animals and animal products as the small entities most likely to be affected by this action and considers the reduction in time between receipt of a request by APHIS and initiation of an evaluation.

Based on the information presented in the analysis, we expect that decreasing the amount of time and APHIS resources required to conduct such an evaluation would not have a significant economic effect on the entities affected.

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 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 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. In § 92.2, paragraphs (a) through (f) are revised to read as follows:

§ 92.2 Application for recognition of the animal health status of a region.

(a) The representative of the national government(s) of any country or countries who has the authority to make such a request may request that APHIS recognize the animal health status of a region.[1] Such requests must be made in English and must be sent to the Administrator, c/o National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231. (Where possible, include a copy of the request and accompanying information in electronic format.)

(b) Requests for recognition of the animal health status of a region, other than requests submitted in accordance with paragraph (c) of this section, must include, in English, the following information about the region. More detailed information regarding the specific types of information that will enable APHIS to most expeditiously conduct an evaluation of the request is available at *http://www.aphis.usda.gov/import_export/animals/reg_request.shtml* or by contacting the Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737.

(1) Scope of the evaluation being requested.

(2) Veterinary control and oversight.

(3) Disease history and vaccination practices.

(4) Livestock demographics and traceability.

(5) Epidemiological separation from potential sources of infection.

(6) Surveillance.

(7) Diagnostic laboratory capabilities.

(8) Emergency preparedness and response.

(c) Requests for recognition that a region is historically free of a disease based on the amount of time that has elapsed since the disease last occurred in a region, if it has ever occurred, must include, in English, the following information about the region. More detailed information regarding the specific types of information that will enable APHIS to most expeditiously conduct an evaluation of the request is available at *http://www.aphis.usda.gov/import_export/animals/reg_request.shtml* or by contacting the Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737. For a region to be considered historically free of a disease, the disease must not have been reported in domestic livestock for at least the past 25 years and must not have been reported in wildlife for at least the past 10 years.

(1) Scope of the evaluation being requested.

(2) Veterinary control and oversight.

(3) Disease history and vaccination practices

(4) Disease notification.

(5) Disease detection.

(6) Barriers to disease introduction.

(d) A list of those regions that have requested APHIS' recognition of their animal health status, the disease(s) under evaluation, and, if available, the animal(s) or product(s) the region wishes to export, is available at *http://www.aphis.usda.gov/import_export/animals/reg_request.shtml.*

(e) If, after review and evaluation of the information submitted in accordance with paragraph (b) or (c) of this section, APHIS believes the request can be safely granted, APHIS will indicate its intent and make its evaluation available for public comment through a document published in the **Federal Register.**

(f) APHIS will provide a period of time during which the public may comment on its evaluation. During the comment period, the public will have access to the information upon which APHIS based its evaluation, as well as the evaluation itself. Once APHIS has reviewed all comments received, it will make a final determination regarding

[1] Additionally, APHIS may choose to initiate an evaluation of the animal health status of a foreign region on its own initiative. In such cases, APHIS will follow the same evaluation and notification procedures set forth in this section.

the request and will publish that determination in the **Federal Register.**

* * * * *

Done in Washington, DC, this 23rd day of July 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2012–18324 Filed 7–26–12; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 29

[Docket No. FAA–2012–0785; Special Conditions No. 29–027–SC]

Special Conditions: Agusta S.p.A. Model AW139 and AB139 Helicopter, Installation of a Search and Rescue (SAR) Automatic Flight Control System (AFCS)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Agusta S.p.A. (Agusta) Model AW139 and AB139 helicopters. These model helicopters, as modified by Agusta, will have novel or unusual design features associated with installing an optional SAR AFCS. The applicable airworthiness standards do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards the Administrator considers necessary to show a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is July 18, 2012. We must receive your comments by September 25, 2012.

ADDRESSES: Send comments identified by docket number [FAA–2012–0785] using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery of Courier:* Deliver comments to the ''Mail'' address between 9 a.m., and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://regulations.gov,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov.*

Docket: You can read the background documents or comments received at *http://www.regulations.gov.* Follow the online instructions for accessing the docket or go to the Docket Operations in Room @12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m., and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: FAA, Aircraft Certification Service, Rotorcraft Directorate, Regulations and Policy Group (ASW–111), Attn: Stephen Barbini, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5196; facsimile (817) 222–5961.

SUPPLEMENTARY INFORMATION:

Reason for No Prior Notice and Comment Before Adoption

The substance of these special conditions has been subjected to the notice and comment period previously and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Further, a delay in the effective date of these special conditions would significantly delay issuance of the design approval and thus delivery of the helicopter, which is imminent. Therefore, the FAA has determined that prior public notice and comment are unnecessary, impracticable, and contrary to the public interest, and finds good cause exists for adopting these special conditions upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment.

Comments Invited

While we did not precede this with a notice of proposed special conditions, we invite interested people to take part in this action by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We will consider comments filed late if it is possible to do so without incurring additional expense or delay. We may change these special conditions based on the comments we receive.

Background and Discussion

On November 11, 2008, Agusta applied for a change to Type Certificate (TC) No. R00002RD to install an optional SAR AFCS in the Model AB139 and AW139 helicopters. The AB139 and AW139 models are transport category helicopters certificated to Category A and Category B requirements, and instrument flight certificated under the requirements of Appendix B to 14 CFR part 29, Amendment 29–40.

There is a need to use dedicated AFCS upper modes, in which a fully coupled autopilot provides operational SAR profiles, for SAR operations conducted over water in offshore areas clear of obstructions. The SAR modes enable the helicopter pilot to fly fully coupled maneuvers, to include predefined search patterns during cruise flight, and to transition from cruise flight to a stabilized hover and departure (transition from hover to cruise flight). The SAR AFCS also includes an auxiliary crew control that allows another crewmember (such as a hoist operator) to have limited authority to control the helicopter's longitudinal and lateral position during hover operations.

Flight operations conducted over water at night may have an extremely limited visual horizon with little visual reference to the surface even when conducted under Visual Meteorological Conditions. Consequently, the certification requirements for SAR modes must meet Appendix B to 14 CFR part 29 for helicopter instrument flight. While this appendix prescribes airworthiness criteria for instrument flight, it does not consider operations below instrument flight minimum speed (V_{MINI}), whereas the SAR modes allow for coupled operations at low speed, all-azimuth flight to zero airspeed (hover).

Since SAR operations have traditionally been a public use mission, the use of SAR modes in civil operations requires special airworthiness standards (special conditions) to maintain a level of safety