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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 92

[Docket No. APHIS-2017-0105]

RIN 0579-AE43

Establishment of Regulations for the Evaluation and Recognition of the Animal Health Status of Compartments

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are establishing standards to allow us to recognize compartments for animal disease status, consistent with World Organization for Animal Health international standards.

Under this action, when a foreign government submits a request for recognition of a compartment, we will conduct a compartmentalization evaluation based on a list of factors that parallel those we use when conducting regionalization evaluations, and will provide for public notice of and comment on the risk assessment. We are also adding provisions for imposing import restrictions or prohibitions when a compartment we have recognized as disease-free experiences an outbreak, and for lifting those sanctions once the outbreak has been controlled.

These standards for compartmentalization will provide a means for preserving international trade when regionalization is not feasible.

DATES: Effective [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Lisa Rochette, Staff Officer,
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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. In order to conduct a valid evaluation of a region’s animal health status and any risk that may be associated with the action requested, it is important for the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture to have pertinent information regarding the region, its disease history, its animal health practices and capabilities, and any effect its import practices or relationship to adjacent regions might have on disease risk.

When regionalization is not feasible, compartmentalization is a means that may be used to preserve trade. Under compartmentalization, a country may define and manage animal subpopulations of distinct health status and under common biosecurity management within its territory, in accordance with the guidelines in the World Organization for Animal Health (OIE) Terrestrial Animal Health Code, for the purpose of disease control and international trade. Compartmentalization is distinct from regionalization, which involves the recognition of geographical zones of a country that can be identified and characterized by their level of risk for different diseases, but the two are not mutually exclusive.

On April 3, 2019, we published in the *Federal Register* (84 FR 12955-12959, Docket No. APHIS-2017-0105) a proposal¹ to amend the regulations by establishing standards to allow us to recognize compartments for animal disease status, consistent with OIE international standards.

We solicited comments concerning our proposal for 60 days ending June 3, 2019. We received seven comments on the proposal. They were from a foreign government, meat and poultry trade organizations, an organization representing poultry veterinarians, and the public. All responses were in favor of the proposed rule, though one requested further information regarding issues largely related to implementation of the proposed regulations. The comments and APHIS' responses are discussed below.

Compartment Evaluation

The commenter asked how APHIS will prioritize the compartmentalization requests it receives.

Similar to regionalization evaluations, APHIS will evaluate compartmentalization requests in the order they are received and process them with the resources available.

The commenter wanted to know how long it will take for APHIS to begin evaluating a compartmentalization request after we receive it.

As with regionalization evaluations, the timeframe to initiate and complete a compartmentalization evaluation is subject to several factors, including the timely submission of supporting information by the country requesting the evaluation. Supporting information required as part of the request is listed in § 92.2(d) of this final rule.

The commenter asked how we plan to conduct compartmentalization evaluations. Specifically, the commenter asked whether APHIS will perform evaluations on each of the

¹ To view the proposed rule, the supporting document, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0105>.

compartments proposed by the country's national competent authority, or will APHIS instead recognize the competent authority's evaluation and approval of compartments presented by companies in that country.

Unlike regionalization, where the national competent authority of a country provides oversight and programs to all entities within the region, compartments are a function of the individual company that controls the compartment. We anticipate a limited number of compartments per country, and therefore expect to evaluate and approve the national competent authority's program and all individual compartment's controlling company and compartment components. We may also consider developing a compartmentalization systems approach if several compartments become approved in a country. This approach would be dependent on our assessment of the ability of the national competent authority of that country to administer and oversee a compartmentalization program.

A commenter asked if APHIS will conduct site visits to evaluate compartments and what the role of the requesting country's government would be in the evaluation process.

As one of the requirements for our evaluation of a country's compartmentalization program, we will conduct an initial site visit to compartments and associated facilities such as national competent authority offices and laboratories. We may also require additional site visits to approve compartments that become recognized by the country's national competent authority after our initial site visit, as well as visits to confirm ongoing satisfactory maintenance of the compartmentalization program or the status of an individual compartment. We intend to collaborate with the country's national competent authority when conducting each compartment evaluation.

The commenter asked what happens if APHIS does not approve a country's compartment request.

As with regionalization evaluations, we will use a risk assessment framework to document compartmentalization evaluations. The risk assessment draws upon eight factors, listed in § 92.2, required for a country's national competent authority to effectively administer a compartmentalization program, as well as technical criteria an individual compartment must meet. If during the evaluation we find minor deficiencies in the country's compartmentalization program or in an individual compartment, we may allow the requesting country's national competent authority and the company involved to correct the deficiencies. However, if we find major deficiencies in competent authority oversight or company implementation of a compartment, we will not approve the program or the compartment.

If we do not approve a compartmentalization program or individual compartment, we may not draft a formal risk evaluation document, but we will inform the requesting country of the reasons that the program or the compartment they have requested does not meet APHIS' criteria.

The commenter asked what the procedure would be for restoring a compartment's status after a disease outbreak.

A livestock or poultry disease outbreak involving animals for which the compartment was approved constitutes a major noncompliance. If a component² within a certified compartment is found to have a major noncompliance, the entire compartment is immediately suspended. To regain approved status, APHIS expects the country's national competent authority to investigate the noncompliance and submit a new request for APHIS to evaluate the compartment, as indicated in § 92.4. APHIS may elect to conduct its own evaluation, which may include a site visit. Finally, a disease outbreak within the compartment involving animals other

² A compartment is made up of at least two sites or facilities, known as components. For example, components of a compartment could include a feed mill, farm, hatchery, or egg depot.

than those for which the compartment is approved would be subject to regulations and conditions for export pertaining to that disease and the animals involved.

The commenter asked how APHIS will protect the privacy of business and confidential proprietary information submitted with compartmentalization requests, particularly considering that we intend to publish evaluations and supporting documents for public comment.

When providing information to APHIS, submitters must indicate that the provided information is confidential business information. Upon intake, APHIS will review this information to ensure that the provided information is not information that the submitter would ordinarily disclose to the public. APHIS intends to protect confidential business information in accordance with legal and regulatory obligations and practice.

Finally, the commenter asked if the consultations and decisions resulting from compartmentalization requests will be published on the APHIS website.

A list of countries requesting an APHIS compartmentalization evaluation and a description of each compartment requested will be available on the APHIS website.³ If our evaluation of the information submitted indicates that a request can be safely granted, we will post our evaluation and supporting documentation for public comment on www.regulations.gov and announce the availability of these documents through a notice in the *Federal Register*. Once we review all comments we receive on the evaluation, we will make a final determination regarding the compartmentalization request and announce our decision in a follow-up *Federal Register* notice. We will also maintain a list of approved national competent authority compartmentalization programs on the aforementioned APHIS website.

³The compartmentalization request list can be found at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Orders 12866 and 13771 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. This final rule is not an Executive Order 13771 regulatory action because this final rule is not significant under Executive Order 12866. Further, APHIS considers this rule to be a deregulatory action under Executive Order 13771 as the action is intended to minimize trade disruptions and could thereby provide benefits to producers and consumers.

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 by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov website (see ADDRESSES above for instructions for accessing Regulations.gov).

APHIS is establishing standards to allow us to recognize compartments for animal disease status, consistent with World Organization for Animal Health international standards. Like our existing process for recognizing foreign regions for disease status, our process will include information requirements for evaluating the animal health status of a compartment for which a market access request has been submitted. Under this rule, we will perform a risk assessment to evaluate the animal health status of a compartment. If after conducting the evaluation, we deem the risk of importing animals or animal products from that compartment to be acceptable, we will publish a *Federal Register* notice announcing the availability of the risk documentation for public review and comment.

This rule will add compartmentalization as an option for evaluating disease status, but not propose a specific implementation of this option. Compartmentalization may be used when regionalization's broader geographic requirements are more costly or simply not feasible. The potential economic effects of imports based on a compartmentalization approach depend on the disease status evaluation specific to the particular commodity and facility, and the expected volume of the commodity imported under this option.

This final rule sets forth compartmentalization as a means of minimizing trade disruptions and delineate the information requirements that will be used for the evaluation of compartments. There are no costs or cost savings that will directly result from this rule. Only in the application of compartmentalization might gains from related trade be realized.

The APHIS Administrator 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. If this final rule is adopted: (1) All State and local laws and regulations that are inconsistent with

this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection requirements included in this final rule have already been approved by the Office of Management and Budget under control number 0579-0040.

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 final rule, please contact Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851-2483.

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 AND COMPARTMENTS

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. The heading of part 92 is revised to read as set forth above.

3. Section 92.1 is amended by adding in alphabetical order a definition of *Compartment* to read as follows:

§ 92.1 Definitions.

* * * * *

Compartment. Any defined animal subpopulation contained in one or more establishments under a common biosecurity management system for which surveillance, control, and biosecurity measures have been applied with respect to a specific disease.

* * * * *

4. Section 92.2 is revised to read as follows:

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

(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 or a compartment.¹ Such requests must be made in English and must be sent to the Administrator, c/o Strategy and Policy, 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 information in paragraphs (b)(1) through (8) of this section about the region. More detailed information regarding the specific types of information that will enable APHIS to most

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

expeditiously conduct an evaluation of the request is available at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request or by contacting the National Director, Regionalization Evaluation Services, 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 information in paragraphs (c)(1) through (6) of this section 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: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request or by contacting the National Director, Regionalization Evaluation Services, 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) Requests for recognition of the animal health status of a compartment must include, in English, the information in paragraphs (d)(1) through (8) of this section about the compartment. 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:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request or by contacting the National Director, Regionalization Evaluation Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737.

- (1) Scope of the evaluation being requested.
- (2) Veterinary control and oversight of the compartment.
- (3) Disease history and vaccination practices.
- (4) Livestock or poultry commodity movement and traceability.
- (5) Epidemiologic separation of the compartment from potential sources of infection.
- (6) Surveillance.
- (7) Diagnostic laboratory capabilities.
- (8) Emergency preparedness and response.

(e) A list of those regions for which an APHIS recognition of their animal health status has been requested, the disease(s) under evaluation, and, if available, the animal(s) or product(s)

the region wishes to export, is available at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request.

(f) A list of countries that have requested an APHIS compartmentalization evaluation, and a description of the requested compartment is available at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request.

(g) If, after review and evaluation of the information submitted in accordance with paragraph (b), (c), or (d) 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*.

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

(i) If a region or compartment is granted animal health status under the provisions of this section, the representative of the national government(s) of any country or countries who has the authority to make a regionalization or compartmentalization request may be required to submit additional information pertaining to animal health status or allow APHIS to conduct additional information collection activities in order for that region or compartment to maintain its animal health status.

(Approved by the Office of Management and Budget under control number 0579-0040)

5. Section 92.4 is revised to read as follows:

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

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

(a) *Interim designation.* If a region or a compartment recognized as free of a specified animal disease in this subchapter experiences an outbreak of that disease, APHIS will take immediate action to prohibit or restrict imports of animals and animal products from the entire region, a portion of that region, or the compartment. APHIS will inform the public as soon as possible of the prohibitions and restrictions by means of a notice in the *Federal Register*.

(b) *Reassessment of the disease situation.* (1) Following removal of disease-free status from all or part of a region or a compartment, APHIS may reassess the disease situation in that region or compartment to determine whether it is necessary to continue the interim prohibitions or restrictions. In reassessing disease status, APHIS will take into consideration the standards of the World Organization for Animal Health (OIE) for reinstatement of disease-free status, as well as all relevant information obtained through public comments or collected by or submitted to APHIS through other means.

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

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

(1) Publish a notice in the *Federal Register* of its decision to reinstate the disease-free status of the region, portion of the region, or compartment;

(2) Publish a notice in the *Federal Register* of its decision to continue the prohibitions or restrictions on the imports of animals and animal products from that region or compartment; or

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

Done in Washington, DC, this 19th day of February 2020 .

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020-03719 Filed: 2/27/2020 8:45 am; Publication Date: 2/28/2020]