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Process for Foreign Animal Health Status Evaluations, Regionalization, Compartmentalization, Risk Analysis, and Rulemaking

Animal and Plant Health Inspection Service

Veterinary Services

Regionalization Evaluation Services

Background

In October 1997, the Animal and Plant Health Inspection Service's (APHIS) Veterinary Services (VS) published a final rule that described VS procedures for evaluating the animal health statuses of foreign regions and defining conditions under which animals and animal products may be imported into the United States [1]. The goal was to create a mechanism to establish regionalized, risk-based import requirements that are consistent with VS obligations under the World Trade Organization's Sanitary and Phytosanitary Agreement [2].

The regionalization rule stated that VS would recognize the animal health status of (a) a national entity (country); (b) part of a national entity (zone, county, Province, State, etc.); (c) part of several national entities combined into an area; or (d) a group of national entities (countries) combined into a single area [1]. The rule further clarified VS' intention to apply a science-based approach to regionalization using risk analysis in its decision-making process.

In 2012, APHIS published a rule to revise the regionalization factors in title 9, *Code of Federal* Regulations, section 92.2 (9 CFR 92.2) [3]. These are the factors that VS considers when evaluating the animal health status of a foreign region. The rule consolidated what had been 11 factors into 8 factors in order to clarify the type of information VS needs to expeditiously conduct regionalization evaluations. The rule also implemented criteria for considering a region to be historically free of a specific disease. The final rule became effective on August 27, 2012.

In February 2020, APHIS published a final rule that established standards to allow APHIS to recognize compartments for animal disease status [4]. The final rule described compartmentalization as a means for countries to preserve trade when regionalization is not feasible. Under compartmentalization, a country may define and manage animal subpopulations of distinct health statuses and under common biosecurity management within its territory, in accordance with guidelines published by the World Organization for Animal Health (OIE). The final rule became effective March 30, 2020. APHIS standards for evaluating compartments are consistent with OIE standards, and the processes APHIS uses to evaluate the animal health statuses of regions and compartments are similar.

This document provides guidance on VS' approach for evaluating the animal health statuses of foreign regions and compartments, and the ways in which VS applies risk analysis to inform decision-making.

Definitions

The following definitions are presented for clarity as they apply to the evaluation process.

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.

Lead Staff Officer (LSO): Staff Officer within Regionalization Evaluation Services (RES) with primary responsibility for coordinating and conducting evaluations of the animal health statuses of foreign regions or compartments, and assessing the risk of opening U.S. markets to commodities from those regions.

Region: Any defined geographic land area identifiable by geological, political, or surveyed boundaries.

Regionalization Evaluation Services (RES): An APHIS unit responsible for coordinating regionalization and compartmentalization evaluations, including gathering and analyzing data, generating official correspondence, conducting risk analyses, implementing decisions, and assisting in development of *Federal Register* publications relevant to the regionalization and compartmentalization processes. RES staff are located in Riverdale, MD, and Raleigh, NC.

Initiating a regionalization or compartmentalization evaluation

A regionalization or compartmentalization evaluation begins when the Office of the Deputy Administrator for VS receives a request from the Chief Veterinary Officer (CVO) of a foreign region for APHIS to recognize a particular animal health status or allow importation of certain animals and/or animal products into the United States. The request should be accompanied by information addressing the 8 factors listed in 9 CFR 92.2.

For a regionalization evaluation, those factors are:

1. Scope of the evaluation 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; and
8. Emergency preparedness and response.

Alternatively, requests from regions in which the disease under evaluation has never occurred, or has not occurred for at least the past 25 years, must be accompanied by information addressing the 6 factors defined in 9 CFR 92.2 for recognition of historically-free status:

1. Scope of the evaluation being requested;
2. Veterinary control and oversight;
3. Disease history and vaccination practices;
4. Disease reporting;
5. Disease detection; and
6. Barriers to disease introduction.

For a compartmentalization evaluation, those factors are:

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; and
8. Emergency preparedness and response.

Further guidance on the type and scope of information required is available on the APHIS website.

Information gathering process

The Deputy Administrator forwards the request and supporting information to the RES Director, who works with the RES Assistant Director to assign an LSO to the evaluation.

The LSO drafts an acknowledgement letter and conducts a preliminary review of the information for completeness. If the information is sufficient for an initial team review, the LSO, with input from RES management, assembles a team to conduct that review. Team members are drawn from various sources to obtain a wide range of technical expertise and program representation. Units represented on review teams may include the National Veterinary Services Laboratories (including the Foreign Animal Disease Diagnostic Laboratory), International Services (IS), the Center for Epidemiology and Animal Health, and other VS program units.

Team members evaluate the information submitted by the requesting government and provide comments to the LSO. The LSO synthesizes the comments and, if necessary, coordinates an official request for additional information. RES management reviews the response for technical content and consistency with Agency policies. The information gathering process is iterative: this cycle continues until RES has sufficient information to identify potential risk factors, to determine whether a site visit is necessary, and, if a site visit is necessary, to inform its itinerary.

Verification through site visits

RES conducts site visits to verify and complement the information provided by foreign veterinary officials, investigate potential risk factors, and review the local circumstances. The site visit occurs prior to completing the risk analysis. The site visit team typically includes members of the initial review team. The team may also include individuals with expertise in quantitative risk analysis, when such an analysis is being considered, as well as a laboratory specialist and a representative of a U.S. State.

In rare instances, a site visit is not necessary. This option is available if VS has thoroughly evaluated the region or compartment on previous occasions; has maintained contact with veterinary officials and the conditions in the region or compartment since the time of that evaluation; and considers that its knowledge of the circumstances in the region or compartment, together with new supporting information, is sufficient to assess the risk.

The LSO plans the site visit program in cooperation with personnel from IS field offices and officials of the requesting region. The schedule is designed to meet the data needs and assess risks identified through review of information provided by the foreign region. The visit is planned to address high risk issues as well as assist in understanding procedures, policies, surveillance and control measures, and other factors representative of the entire region. VS consults with IS field personnel to ensure that the sites visited are relevant to the assessment of risk.

Although most evaluations require only a single site visit, in certain circumstances follow-up visits may be necessary. For example, it may be necessary to conduct a second site visit if animal health conditions in the region or compartment change substantially during the course of an evaluation (e.g., an outbreak occurs). RES makes this decision on a case-by-case basis.

Risk analyses

RES coordinates a risk analysis that uses information provided by veterinary officials of the requesting region, obtained from the literature and unpublished reports, and gathered during the site visit. Following OIE guidelines, the risk analysis is prefaced by a hazard identification step and includes an entry assessment, an exposure assessment, a consequence assessment, and a risk estimation [5]. The risk analysis may conclude if the entry or exposure assessment demonstrates no significant risk.

In all cases, RES conducts a thorough qualitative evaluation based on the regionalization factors listed in 9 CFR 92.2. Quantitative modeling may occur concurrently to address specific risk concerns, test assumptions, and evaluate the effectiveness of defined risk mitigation measures.

Rulemaking

If the risk analysis concludes that the regionalization or compartmentalization request can be safely granted, APHIS indicates its intent to do so and makes the analysis available for public comment through a document published in the *Federal Register*. APHIS solicits comments for a defined period of time—usually 60 days—during which the public also has access to the information upon which APHIS based its evaluation. APHIS reviews all of the comments received, makes a final determination, and publishes that determination in the *Federal Register*. A decision to recognize an animal health status or open U.S. markets under certain conditions is typically effective 15-30 days later.

The rulemaking process may require legal and policy reviews within APHIS and other USDA offices, as well as the White House Office of Management and Budget.

Variations in the regulatory process

When a disease outbreak occurs in a region that APHIS previously considered free of that disease, VS issues an immediate administrative ban on imports of animals and products from the region, removes the region from the list of regions that APHIS recognizes as free of the disease, and publishes a notification in the *Federal Register* that APHIS removed the region from the list. When a disease outbreak occurs in a compartment that APHIS previously considered free of that disease, the compartment immediately loses its free status and outputs are no longer eligible for export to the United States. After the outbreak is eradicated, a suitable waiting period has passed with no new cases detected, and any other relevant

criteria for disease freedom are addressed, the foreign CVO may request a reevaluation of animal health status of a region or a compartment.

The reinstatement process is typically similar to that described above, including information gathering—with particular focus on effectiveness of the eradication and control measures taken—a site visit, a risk analysis, and rulemaking.

Time required for the process

The entire process—from the time of the original request to final *Federal Register* publication—can take several years. As outlined above, the process requires information gathering and evaluation; a site visit; a risk analysis; an initial *Federal Register* publication; consideration of the comments received; and a second *Federal Register* publication to address the comments received and announce APHIS's decision. The time to complete the process therefore depends on many factors, including the completeness of the initial request by the requesting region and responsiveness to additional information requests, the complexity of public comments, and the resources available.

Conclusion

APHIS is committed to accurately evaluating the animal health statuses of foreign regions and compartments and facilitating trade while protecting the health of animal populations in the United States. APHIS applies a rigorous, science-based, analytical process to regionalization and compartmentalization evaluations, identifying risks and developing effective mitigation measures.

Bibliography

1. Importation of Animals and Animal Products. 62 Federal Register 56000-56026, October 28, 1997.

2. World Trade Organization. General Agreement on Tariffs and Trade (For Goods), Annex IA: Multilateral Agreements on Trade in Goods, Agreement on the Application of Sanitary and Phytosanitary Measures, pp.69-83. 1995.

3. Information from Foreign Regions Applying for Recognition of Animal Health Status. 77 Federal Register 44107-44110, July 27, 2012.

4. Establishment of Regulations for the Evaluation and Recognition of the Animal Health Status of Compartments. 85 Federal Register 11833-11836, February 28, 2020.

5. World Organization for Animal Health (OIE). Chapter 2.1: Import Risk Analysis. In Terrestrial Animal Health Code, 28th Edition; Paris, 2019.