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

Animal and Plant Health Inspection Service
Veterinary Services
National Import and Export 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 status of foreign regions and defining conditions under which animals and animal products may be exported 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.

This document provides guidance on VS’ approach to implementing its regionalization process and the ways in which VS applies risk analysis to the decision-making process for regionalization.

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

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

National Import Export Services (NIES): A unit within VS responsible for issuing import permits for animals and animal products, negotiating with foreign governments on provisions for animal health certificates for animals and animal products, liaising with the World Organization for Animal Health (OIE), and coordinating regionalization evaluations.
Regionalization Evaluation Services (RES): A unit within NIES responsible for coordinating regionalization 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 process. LSOs for foreign regionalization activities are RES personnel. RES has units in Riverdale, MD, and Raleigh, NC.

Initiation of the regionalization process

The regionalization process 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 in 9 CFR 92.2:

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. Diagnostic laboratory capabilities;
7. Surveillance practices; and

Alternatively, requests from regions in which the disease under evaluation has never occurred, or has not occurred for at least 25 years, may 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.

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 National Director, who works with the Directors of the two RES units 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 a RES Director, 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 Centers 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 as a draft for technical content and consistency with Agency policies. This cycle continues until RES has sufficient information to identify potential risk factors and guide a site visit.

**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 the U.S. States.

In rare instances, a site visit is not necessary. This option is available if VS has thoroughly evaluated the region on previous occasions; has maintained contact with veterinary officials and the conditions in the region since the time of that evaluation; and considers that its knowledge of the circumstances in the region, 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 in the region 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 areas 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 change substantially during the course of an evaluation (e.g., an outbreak occurs). RES makes this decision is made 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 [4]. The risk analysis may conclude if the entry or exposure assessments demonstrate no significant risk.

The entry assessment may be either quantitative and/or qualitative. 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 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 *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 free 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, followed by notification in the *Federal Register* that APHIS is removing the region from the list of regions free of the disease. After the outbreak is eradicated successfully, 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.

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 status of foreign regions and facilitating trade while protecting the health of animal populations in the United States. APHIS applies a rigorous, science-based, analytical process to regionalization evaluations, identifying risks and developing effective mitigation measures.
Bibliography


