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

Animal and Plant Health Inspection Service
Veterinary Services
National Center for Import and Export
Sanitary Trade Issues Team
Regionalization Evaluation Services

Background and objective

In October 1997, the Animal and Plant Health Inspection Service's (APHIS) Veterinary Services (VS) published procedures for evaluating the animal health status of countries and regions to define conditions under which animals or animal products might be exported into the United States [1, 2]. The goal of these procedures, which have been referred to as the regionalization rule and policy statement, was to create a mechanism to establish regionalized, risk-based import requirements that were consistent with obligations of VS under the World Trade Organization's Sanitary and Phytosanitary Agreement [3].

The regionalization policy stated that VS would recognize the animal health status of (a) regions within countries; or (b) regions composed of groups of countries, rather than only recognizing regions defined by national boundaries [1], as VS had done in the past. In addition, the policy statement clarified in general terms the manner in which VS intended to implement the rule. In this regard, VS stated its intention to apply a science-based approach to regionalization using risk analysis in its decisionmaking process. The rule stated that regionalization requests would be considered on a region-by-region and commodity-by-commodity basis [2].

VS also made a commitment to provide guidance regarding its approach to implementation of its regionalization process. Specifically, VS stated that it would issue a public guideline describing its regionalization process. This document is intended to fulfill that commitment and to describe the way in which VS applies risk analysis to the decisionmaking process for regionalization.

Definitions

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

Case Manager: Staff Officer within Regionalization Evaluation Services - Import (RESI) or Regionalization Evaluation Services - Export (RESE), both of which are units within VS' National Center for Import and Export (NCIE). RESI is responsible for coordinating disease status evaluations for the purpose of opening trade in animals and animal products and responding to regionalization requests from foreign governments. RESE is responsible for domestic regionalization activities. The focus of this document is the activities of the RESI unit.

Centers for Epidemiology and Animal Health (CEAH): A VS unit based in Fort Collins, Colorado. CEAH has responsibilities for animal disease information gathering and analysis, animal health monitoring, and identification of emerging animal health issues. The unit has been designated as a risk analysis and surveillance collaborating center for the World Organization for Animal Health (OIE). Personnel from this unit participate in and conduct import risk analyses.

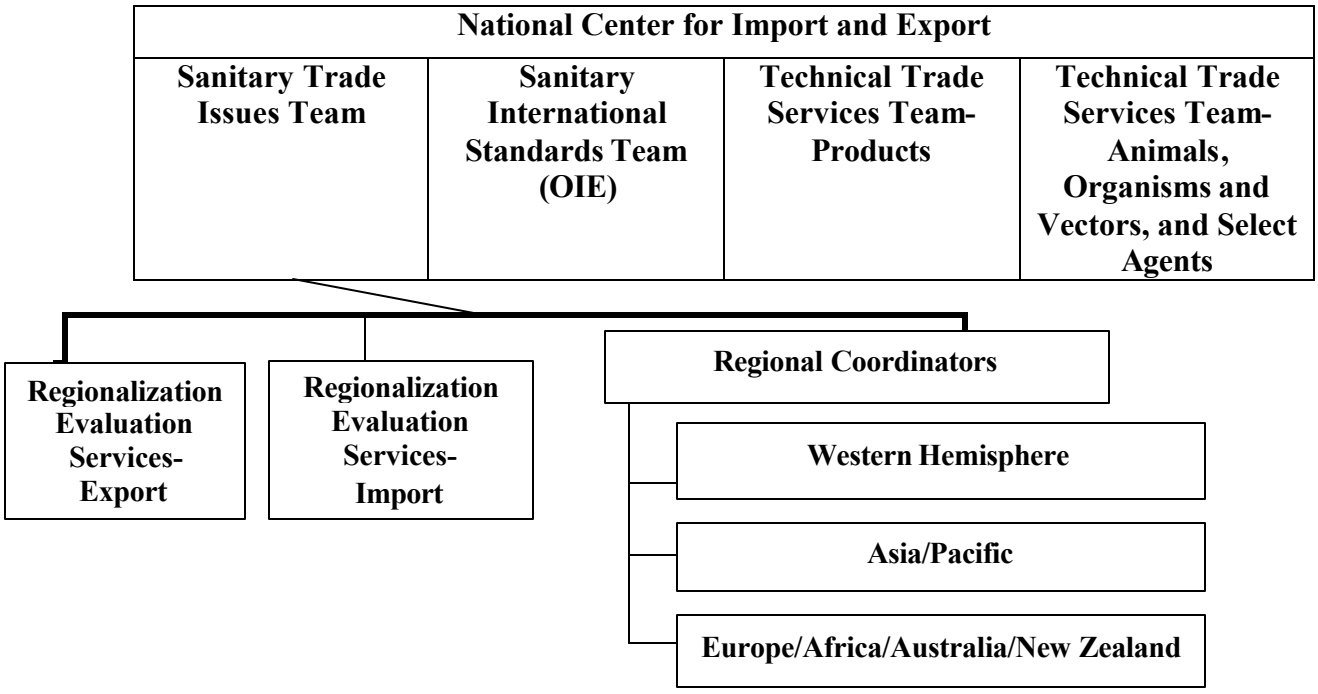
National Center for Import and Export (NCIE): A VS unit that has primary responsibility for issues relating to import and export of animals and animal products. These responsibilities include issuing import permits for animals and animal products, participating in negotiations with foreign governments on provisions for animal health certificates (both import and export) for animals and animal products, participating in trade negotiations, providing a liaison with the OIE, and coordinating evaluation of animal health status for regionalization requests.

Four units comprise NCIE: (1) the Sanitary Trade Issues Team (STIT); (2) the Sanitary International Standards Team (SIST); (3) the Technical Trade Services Team for Products; and (4) the Technical Trade Services Team for Animals, Organisms and Vectors, and Select Agents. Each of the four units is headed by a Director, and the staffs interact closely on a daily basis. The Supervisory Staff Officer for RESI reports to the Director of STIT, and coordinates regionalization activities relating to foreign countries with the other units. Regional Coordinators in STIT participate on a regional basis in both import and export issues. Personnel from each of the units within NCIE, as well as other APHIS units, participate in reviews and contribute to risk analyses. Figure 1 contains an organizational chart for NCIE illustrating the relationship among NCIE, STIT, SIST, and the Technical Trade Services Teams.

Regionalization Evaluation Services - Import (RESI): A unit within the STIT that is responsible for coordinating the evaluation of data, official communication, conduct of risk analyses, implementation of decisions, and publication of rules relevant to regionalization requests. Case Managers for foreign regionalization activities are RESI personnel.

Risk Analysis Systems (RAS), Policy and Program Development (PPD): A unit within APHIS with responsibility for conduct of risk analyses by request and coordination of Agency policy as it relates to risk analyses from other program units, including VS. The hierarchical level of PPD within the APHIS organizational structure is equivalent to that of VS.

Figure 1



Rulemaking:

1. Interim rule – A document published in the *Federal Register* that implements new regulations or changes to regulations, prior to providing the public with an opportunity to comment. Interim rules are published when the Agency finds that notice and public comment are impractical or contrary to the public interest, such as when a delay in implementation would pose risk to the animal health status of the United States. For example, an interim rule would be published to ban exports from a region previously considered as free in which a disease outbreak has occurred. In this case, the interim rule addresses an emergency situation. An interim rule is effective at a date designated in the rule. The interim rule may be given an effective date earlier than the date of signature or publication of the interim rule to affirm the Agency's authority for issuing previous administrative orders. Public comment will be accepted during a specified period after the date of publication [4]. The Agency may subsequently affirm the interim rule as a final rule, or change provisions of the interim rule, through another document published in the *Federal Register* based on public comment or other information obtained by the Agency.
2. Proposed rule – A document published in the *Federal Register* describing regulations, or changes to regulations, that the Agency is considering and inviting public comment for a specified period of time [4].
3. Final rule – A document published in the *Federal Register* implementing a proposed rule, with or without changes. The document includes a discussion of

public comments made on the proposed rule and any changes to the proposed rule that the Agency is making [4].

VS Risk Analysis Steering Committee (VSRASC): A committee providing guidance for regionalization activities and policy development. The committee is composed of the Directors of STIT and SIST; the Team Leader for Trade Risk Analysis, CEAH; and the Supervisory Staff Officers of RESI and RESE. The chair of the VSRASC is the Director of STIT.

Initiation of the regionalization process

The regionalization process begins when the Office of the Deputy Administrator, VS, receives a request from the Chief Veterinary Officer (CVO) of a government seeking authorization to export animals and/or animal products to the United States. The request should be accompanied by information addressing the 11 factors defined in title 9, *Code of Federal* Regulations (9 CFR), section 92.2 [2].

1. Authority, organization, and infrastructure of the veterinary services organization in the region.
2. Disease status of the region.
3. Status of adjacent regions with respect to the agent.
4. Extent of an active disease control program.
5. Vaccination status of the region.
6. Degree to which the region is separated from adjacent regions of higher risk through physical or other barriers.
7. Extent to which movement of animals and animal products is controlled from regions of higher risk and the level of biosecurity regarding such movements.
8. Livestock demographics and marketing practices in the region.
9. Type and extent of disease surveillance in the region.
10. Diagnostic laboratory capabilities.
11. Policies and infrastructure for animal disease control in the region, i.e., emergency response capacity.

Data evaluation process

The Deputy Administrator forwards the request and supporting data to the STIT Director and the RESI Supervisory Staff Officer. A Case Manager is assigned to the request, and VSRASC is informed of the request.

The Case Manager serves as the primary contact for the requesting country and is responsible for coordinating the evaluation, disseminating information regarding the request to relevant parties within and outside of VS, communicating with APHIS colleagues in International Services (IS) and veterinary officials of the requesting region, coordinating site visits to the region, conducting or coordinating risk analyses to use as a management tool for decisionmaking, providing information and direction for rulemaking related to the request, and generally coordinating all activities relevant to that request.

The Case Manager conducts a preliminary review of the information for completeness. If the information is sufficient for an initial team review, the Case Manager, with input from the VSRASC, assembles a team to conduct that review. Team members are drawn from various sources to obtain as wide a range of technical expertise and program representation as possible. The team is constructed to include individuals with technical expertise on the disease, commodity, and/or country making the request. Units typically represented on review teams include Staff Officers from TTST, the National Veterinary Services Laboratories (including the Foreign Animal Disease Diagnostic Laboratories), the IS field office in the region, and CEAH. Representatives may also be drawn from VS program staffs, if appropriate.

Team members evaluate the information submitted and provide comments to the Case Manager. The comments should address the history of disease in the region as it relates to risk of exporting the disease agent, identify both strengths and weaknesses of the veterinary system in place, and identify data gaps in the information.

The Case Manager synthesizes the comments and coordinates an official response to a designated contact in the requesting country. VSRASC members review the response as a draft for technical content and consistency with Agency policies. Often the initial response constitutes a request for additional information.

Verification through site visits

Once the initial review team considers the information to be sufficient to justify proceeding with the evaluation, a site visit is planned to verify and complement the information provided by foreign veterinary officials and review the local circumstances. The site visit occurs prior to conduct of a risk analysis. When possible, site visit team members include members of the initial review team.

In rare instances, a site visit is not considered 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 site visit program is planned in cooperation with personnel from IS field offices in the region and negotiated with officials of the requesting region. The schedule is designed to meet the data needs and assess risks identified in the initial review. The visit is planned to address high risk issues as well as assist in developing an understanding of the 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 being visited are relevant to the assessment of risk, and that all pertinent issues are identified during the visit. The objective is to gain an overall risk picture while targeting areas identified as potentially higher risk. VS assumes that, if the riskiest issues are sufficiently mitigated, the overall spectrum of risk issues should be acceptable.

As mentioned, consultation with IS and other field personnel is critical to this effort. Therefore, the site visit team includes technical personnel with field expertise in the areas in which verification is being requested as well as representation from IS and any other field personnel available (e.g., Foreign Agriculture Service). These individuals are critical to the success of the visit since they have the best knowledge of risk, circumstances, and cultural sensitivities in the region.

A State Veterinarian is invited to accompany any U.S. site visit team. In addition, sometimes veterinary officials from other countries (e.g., Canada or Mexico) join the team. If Canada or Mexico participates, the visit may be considered a North American Free Trade Agreement review effort.

The team also includes individuals with expertise in quantitative risk analysis, when such an analysis is being considered. Quantitative modeling is usually conducted by teams with membership from RESI, CEAH, and RAS. Quantitative modeling is most often used (a) when the qualitative evaluation is generally favorable but shows that some risk remains that may need to be addressed more precisely and (b) when risk of commodities is being considered specifically. An example of an instance in which a quantitative analysis is of particular usefulness is export of fresh (chilled or frozen) beef from a region that practices vaccination for foot-and-mouth disease (FMD).

The RESI Case Manager serves as a member of the quantitative modeling team as well as team leader for the site visit and risk analysis. The site visit is planned in order to obtain data to generate estimates of the appropriate data elements for the model to be used for the analysis.

Although most evaluations require only a single site visit, in certain circumstances, it is necessary to conduct more than one. This decision is made on a case-by-case basis as circumstances require. For example, it may be necessary to conduct a second site visit if disease circumstances in the region change substantially during the course of an evaluation (e.g., an outbreak occurs).

Risk analyses

Information provided by veterinary officials (in the name of the CVO) of the requesting region for the initial review, obtained from the literature and unpublished reports, and gathered during the site visit is used to conduct a risk assessment. The risk assessment is typically prefaced by a hazard identification step. Following OIE guidelines, the risk assessment itself consists of a release assessment, an exposure assessment, a consequence assessment, and a risk estimation.

The release assessment may be either quantitative and/or qualitative. The choice is made within the VSRASC and is dependent upon a preliminary characterization of the underlying disease risk in the requesting region. In all cases, the preliminary assessment is followed by a more thorough qualitative evaluation based on the 11 factors described

above. Quantitative modeling may occur concurrently to address specific risk concerns and the effectiveness of defined risk mitigation measures.

Historically, regions requesting to be considered free of a certain disease have been evaluated purely qualitatively. These regions typically have not reported an outbreak of the relevant disease in many years and do not allow vaccination which might mask disease. They often meet OIE criteria for disease freedom. In some instances, specific risk concerns identified during the qualitative assessment may be addressed through quantitative modeling.

In contrast, requests to export a specific product to the United States or exports from regions which vaccinate for disease have historically been approached quantitatively. Regions requesting to export such commodities are typically those that cannot be considered free of certain trade-limiting diseases due to recent outbreaks or continuing vaccination. These regions pose a higher level of risk. Quantitative modeling allows assessment of specific risk concerns, testing of assumptions, analysis of attendant uncertainty, and evaluation of the effectiveness of proposed mitigation measures.

As noted above, a qualitative evaluation of the 11 factors is conducted regardless of whether a quantitative model is developed. However, the veterinary infrastructure, surveillance and control measures, diagnostic approaches, and animal movement controls must be acceptable in order to provide confidence in the quantitative data. If the initial qualitative evaluation results are not generally favorable in this regard, there is little justification to proceed with the quantitative stage of the analysis.

The risk assessment may conclude if the release assessment demonstrates no significant risk. However, some form of exposure and consequence assessment is typically included for completeness. These assessments may be qualitative or quantitative.

Although coordination responsibility for a qualitative analysis is assigned to a single individual, the team leader works with review team members from the other units, soliciting input throughout the process. The finished product is subject to review by team colleagues as well as members of the VSRASC and technical experts as appropriate.

Quantitative analyses are conducted using a team approach. Team members are drawn from various APHIS units. Occasionally, teams have included independent experts or academicians from outside VS. This has occurred historically upon the recommendation from U.S. Department of Agriculture (USDA) units outside of APHIS. However, currently, the APHIS units forming the core of quantitative risk analysis teams are RESI, CEAH, and RAS. Teams are composed of at least one member from each unit, with representation from other units as applicable.

Historically, risk analyses, site visit reports, and supporting data have been made available to the public at the time of publication of a proposed rule or in association with a *Federal Register* notice announcing the availability of a risk analysis. VS is revising this policy and will post supporting information at the time of receipt.

Recommendations to management for rulemaking

Through its evaluation and risk analysis process, VS attempts to identify risks associated with opening markets with new trading partners. This process is based on a number of technical considerations in addition to the risk analysis, such as knowledge of (1) the relevant animal health situation existing in the region; (2) mitigations that have proven effective in similar situations; and (3) international standards. These types of considerations continue to be significant factors in the VS approach to developing rulemaking recommendations for management.

Quantitative models are an extension of the evaluation process and are not conducted unless the preliminary evaluation suggests that the risks identified for a particular situation can be mitigated appropriately. Quantitative models are intended to provide a quantitative estimate of the probability of an adverse event, the effect of certain mitigations on that probability, and estimates of consequences of adverse events.

The probability estimate alone is not sufficient to support a recommendation, however. In fact, VS has defined no threshold probability value in any type of analysis (release, exposure, consequence, or risk estimate) that would support conclusively a particular approach to rulemaking. When a very low risk can be estimated in a model of a situation in which the subjective assessment is generally favorable, rule-making is often recommended. The particular action recommended is based on the effect of the mitigations on the estimated risk and expert technical considerations.

Variations in the regulatory process

Prior disease status of the region

The approach to evaluation of a region previously considered as free of a disease and that subsequently experienced an outbreak of the disease and then eradicated it is different from the initial evaluation of a region that had never been considered as free. When a region previously considered as free has an outbreak, VS issues an administrative ban on imports of animals and products from the region. VS publishes an interim rule as soon as possible to affirm the ban. VS incorporates options into the interim rule that allow it to reevaluate the disease status of the region at a later date and then, based on that evaluation, (1) reinstate the disease-free status of the region through a final rule; (2) continue to prohibit or restrict exports from the region; or (3) take other action, such as further regionalizing the larger region because of the outbreak.

After an outbreak is eradicated successfully, the region meets OIE criteria for length of disease-free period, and any other relevant criteria for disease freedom are addressed, the foreign CVO may request a reevaluation of disease status. This reevaluation is based on information that addresses effectiveness of the eradication and control measures taken, involves a site visit to the region in question, and requires conduct of a risk analysis. The risk analysis results are reviewed by the VSRASC. A recommendation for action is then

submitted to VS Managers. If the risk analysis provides sufficient justification for reinstating the disease-free status of the region or for redefining the region from which imports are prohibited or restricted because of the outbreak, the risk analysis is released for public comment. Following the close of the comment period, the Agency will publish another document, which may be a final rule, reinstating the region's previous disease-free status or modifying the area from which imports are prohibited or restricted. Public comments on the risk analysis are addressed in the final rule. This process replaces the previous VS practice of affirming the initial interim rule revoking a region's disease-free status, and then beginning new notice-and-comment rulemaking (proposed rule, comment period, final rule) to restore it.

VS believes this process to be appropriate, rather than requiring the region to apply for disease-free status as if for the first time. This process is based on our knowledge of the veterinary infrastructure in the region, as well as the organization and authority, disease surveillance and control programs, movement controls on animals and animal products, and other factors that were considered in granting the region its previous disease-free status. The new process has allowed reinstatement of disease-free status for some regions several months sooner than would have been possible if it had been necessary to publish both proposed and final rules.

For an initial evaluation of a region that has not previously been considered free, VS conducts its initial review, site visit(s), and risk analysis; and the VSRASC provides a recommendation for regulatory action to VS management. The recommendation is implemented through a rulemaking process that involves a proposed rule, comment period, and, if appropriate, a final rule.

Risk classification for regions "free" of specific diseases

In the preamble to the final regionalization rule published in 1997, VS discussed three classifications of regions "free" of specific diseases [2]:

1. Regions in which the disease is deemed never to have existed or is deemed to have been eradicated. This class represents the lowest level of risk of the three classifications listed, and the regions have historically been evaluated using qualitative assessments;
2. Regions associated with a sufficient period of disease freedom to be classified as disease-free, but that present some risk due to trade or adjacency with affected regions. This class represents a higher level of risk than the previous class. However, the regulations define mitigations for that risk. In this classification, the mitigation operates primarily through certification requirements like those listed in 9 CFR 94.11 for certain FMD-free countries. Such regions have historically been evaluated and the mitigations applied through qualitative assessments; and
3. Regions that have experienced an outbreak, that have become free of a disease, but with which a measurable risk of residual infection remains. Such regions are likely to limit their request to authorization to export specified commodities. Risk

of these exports and the effectiveness of mitigations have historically been evaluated using quantitative modeling approaches.

Examples of each of these classifications are represented on the NCIE Web site. The address of this site is http://www.aphis.usda.gov/vs/ncie/country.html.

Time required for the process

The entire process—from the time of the original request to publication of a final rule—can take several years. The length of time depends on the specific situation. As outlined in detail earlier, APHIS' evaluation is a science-based and analytical process that culminates in a completed risk analysis and publication of a final rule.

Briefly, the process for original recognition of disease-free status requires data evaluation; a site visit; a risk analysis; an economic analysis; an environmental analysis; publication of a proposed rule with an opportunity for public comment; consideration of the comments received; and, if appropriate, publication of a final rule, which addresses comments received on the proposed rule. Reinstatement of disease-free status requires data evaluation; a site visit; a risk analysis; an announcement of availability of the risk analysis in the *Federal Register* with a period designated for public comment; consideration of those comments; and, if appropriate, publication of a final rule, which addresses any comments received on the risk analysis.

In addition to the analyses and consideration of comments, the rulemaking process requires legal and policy reviews within APHIS and other USDA offices and, sometimes, the Office of Management and Budget.

The time required to complete the process varies and is dependent upon several factors, especially the data provided by the requesting country, the complexity of public comments, and the resources available.

Conclusion

APHIS is committed to evaluating the foreign animal disease risk status and conditions that will allow safe exports of animals and animal products from foreign countries. APHIS applies a rigorous analytical process intended to identify risks and apply effective mitigations that can safeguard animal health in the United States while allowing trade to occur.

This document was made available to the public in 2004.

Bibliography

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