Fighting for the U.S. Cattle Producer!
R-CALF USA

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Docket No. APHIS-2010-0077
Regulatory Analysis and Development, PPD
U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Via Federal eRulemaking Portal

Re: R-CALF USA Comments in Docket No. APHIS-2010-0077: Availability of a Risk Analysis Evaluating the Foot-and-Mouth Disease Status of Japan

Dear Sir or Madam:

The Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF USA) appreciates this opportunity to submit comments to the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) regarding *Availability of a Risk Analysis Evaluating the Foot-and-Mouth Disease Status of Japan, notice of availability and request for comment* (Notice), published at 76 Fed. Reg. 44503-504 (July 26, 2011).

R-CALF USA is a non-profit association that represents thousands of U.S. cattle farmers and ranchers in 45 states. R-CALF USA works to sustain the profitability and viability of the U.S. cattle industry, a vital component of U.S. agriculture. R-CALF USA's membership consists primarily of cow-calf operators, cattle backgrounders and feedlot owners. Various main street businesses are associate members of R-CALF USA.

For the reasons stated below, R-CALF USA urges APHIS to reject Japan's request to be recognized as free of foot-and-mouth disease (FMD) and to continue disallowing the importation of whole cuts of boneless beef from Japan.

A. APHIS' Evaluation of the FMD Status of Japan Is Incomplete and Inadequate for Use in Determining the Risk of Introduction and Spread of FMD Into the United States from Japan

APHIS' 2004 *Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking* (Evaluation Process)[1] explains that quantitative risk modeling is typically used when a foreign country requests to export a specific product to the United State, which is the case here where the only product subject to a resumption of exports under the Notice is whole muscle cuts of boneless beef from Japan. APHIS' Evaluation Process further explains that quantitative risk modeling "allows assessment of specific risk concerns, testing of assumptions, analysis of attendant uncertainty, and evaluation of effectiveness of proposed mitigation measures."[2]

Although APHIS acknowledges in its *APHIS Evaluation of the Foot and Mouth Disease Status of Japan* (APHIS Evaluation) that outbreaks of FMD are not uncommon in previously free areas throughout the world,[3] and further acknowledges that Japan has a history of repeated outbreaks (Japan's 2010 outbreak followed it previous outbreak in 2000),[4] APHIS avoids completing a quantitative risk analysis that would, at a minimum, enable the public to test APHIS' numerous and overly optimistic assumptions contained in its APHIS Evaluation and analyze factors that contribute to the attendant uncertainty regarding FMD outbreaks that recur persistently throughout Asia.

Not only has APHIS avoided the completion of the more thorough and appropriate quantitative risk evaluation - which would be more commensurate with the known financial devastation caused by FMD (i.e., Japan's estimated losses from its 2010 FMD outbreak exceeded $3.5 billion[5]) – but also, APHIS has chosen to abrogate its duty to the U.S. livestock industry to prevent the introduction of FMD into the United States by following only the minimal standards established by the World Organization for Animal Health (OIE). Citing the OIE as its authority, APHIS states "the APHIS analysis of Japan's FMD status does not extent to exposure and consequence assessments"[6] of Japan's FMD risk.

APHIS' decision to not complete either an exposure assessment or a consequence assessment is a departure from the level of due diligence expected from APHIS when making decisions that could potentially devastate the U.S. livestock industry. In fact, APHIS' Evaluation Process states, "The risk assessment may conclude if the release assessment demonstrates no significant risk. <u>However, some form of exposure and consequence assessment is typically included for completeness</u>."[7] (Emphasis added.)

R-CALF USA is deeply troubled that APHIS persists in making recommendations to expose the U.S. livestock industry to an unnecessary, avoidable and heightened risk of disease introduction

[1] Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking, USDA-APHIS, 2004 (hereafter "Evaluation Process"), attached hereto as Exhibit 1.
[2] *Id*., at 7.
[3] APHIS Evaluation of the Foot and Mouth Disease Status of Japan, USDA-APHIS, April 1, 2011 (hereafter "APHIS Evaluation"), at 5.
[4] *Id*., at 7.
[5] *Id*., at 13.
[6] *Id*., at 35.
[7] Evaluation Process, at 7.

without first quantifying such risks and without completing even the most fundamental of risk analyses.

B. APHIS Provides No Scientific Basis for Recommending the Resumption of Japanese Exports Within only Months Following Japan's Latest FMD Outbreak

APHIS has a long history of miscalculating the risk of FMD outbreaks in foreign countries. For example:

1. APHIS' Risk Evaluation Methodology Resulted in the Miscalculation of FMD Risks in Argentina

In August 1997, APHIS engaged in a high-risk scheme to begin importation of fresh (chilled or frozen) beef from Argentina, even though Argentina was still carrying out vaccination for FMD. *See* 62 Fed. Reg., 56003, col. 2. APHIS claimed that this new scheme "exemplified the opportunity" to regionalize countries with ongoing FMD problems. *See id*. In July 2000, APHIS fully implemented a regionalization scheme for Argentina by prohibiting the importation of beef from animals that had been in specified areas along Argentina's border. *See* 65 Fed. Reg., 82894, col. 1. In August 2000, just days before the effective date of APHIS' regionalization rule, Argentina confirmed a new outbreak of FMD. Nevertheless, APHIS concluded the U.S. could continue to safely import fresh (chilled or frozen) beef from Argentina under its regionalization scheme, despite this new outbreak. *See id*., 82894, col. 3. For nearly a year after its August 2000 outbreak, Argentina remained eligible to export fresh (chilled or frozen) beef to the United States. APHIS, however, was subsequently forced to take emergency, retroactive action in June 2001 to protect U.S. livestock from the introduction of FMD from Argentina because at that time APHIS believed the FMD virus already was present in Argentina for several weeks before Argentina finally reported the first of many new and widespread FMD outbreaks beginning in March 2001. *See* 66 Fed. Reg., 29897, col. 3; 29898, col. 1. APHIS' regionalization scheme for Argentina was an abject failure that could have easily resulted in the introduction of FMD into the United States.

2. APHIS' Risk Evaluation Methodology Resulted in the Miscalculation of FMD Risks in Uruguay

In July 2000, APHIS was allowing fresh (chilled or frozen) beef from Argentina provided it was not from Argentina cattle that had been in close proximity to Uruguay. In October 2000 APHIS regionalized, retroactively, Uruguay by removing only Artigas, a department in Uruguay, from the list of regions considered by the U.S. to be free of FMD. *See* 65 Fed. Reg., 82894, col. 3; *see also* 65 Fed. Reg., 77772, col. 1. APHIS had evaluated Uruguay's risk for FMD and concluded it was safe for the U.S. to continue the importation of fresh (chilled or frozen) beef from Uruguay provided it was not from cattle in Artigas, a region APHIS determined to qualify as a distinct subpopulation for disease control and international trade purposes under its regionalization scheme. *See* 65 Fed. Reg., 77771-773. However, within about four months of USDA's presumed scientific conclusion that it was safe to continue the importation of beef in all regions of Uruguay except Artigas – a conclusion presumably based on a careful, scientific risk analysis –

widespread FMD outbreaks were reported, beginning in April 2001, in numerous Uruguayan departments. *See* 66 Fed. Reg., 36695-697. By June 22, 2001, there were 1,596 new cases of FMD confirmed in 18 separate departments in Uruguay. *Ibid*.

3. APHIS' Risk Evaluation Methodology Resulted in the Miscalculation of FMD Risks in South Africa

After conducting an on-site visit along with a risk evaluation regarding the risks for FMD in South Africa, APHIS, in April 2000, regionalized the Republic of South Africa and declared it, except the FMD-controlled area (which includes Kruger National Park) free of FMD. *See* 64 Fed. Reg., 7819, col. 2 and fn 1; *see also*, 66 Fed. Reg., 9641, col. 1. In September 2000, APHIS was forced to take emergency action to protect U.S. livestock after a FMD outbreak was confirmed in KwaZulu-Natal, a province in the Republic of South Africa. *See* 65 Fed. Reg., 65728, col. 1; 65729, col. 1. APHIS, however, persisted with its regionalization scheme and simply carved out KwoZulu-Natal as a province ineligible to export fresh (chilled or frozen) beef to the U.S. due to FMD. *See* 64 Fed. Reg., 65728, col. 3. Within a matter of months, in November 2000, APHIS was again forced to take emergency action to prevent the introduction of FMD into the U.S. by removing all of the Republic of South Africa from the list of regions considered free of FMD following new outbreaks of the disease in additional provinces.

4. APHIS' Risk Evaluation Methodology Resulted in the Miscalculation of FMD Risks in South Korea

After South Korea experienced outbreaks of FMD in 2000 and 2002, APHIS, in October 2008, completed a comprehensive, 56-page evaluation of the risks for FMD in South Korea and determined South Korea was free of FMD:

> Based on an evaluation of the 11 factors and observations from the site visit, APHIS considers that the Republic of Korea has the legal framework, animal health infrastructure, disease detection capabilities, reporting systems, and emergency response systems that are necessary for maintaining the Republic of Korea as free of FMD.[8]

On December 28, 2009, APHIS issued a final rule declaring South Korea free of FMD and eligible to export fresh (chilled or frozen) beef to the United States beginning January 12, 2010. *See* 74 Fed. Reg., 68478, col. 3; 479, col. 2.

However, on January 6, 2010, just days before the effective date of APHIS' final rule, South Korea had an outbreak of FMD and APHIS was forced to delay indefinitely the effective date of South Korea's FMD-free designation. *See* 75 Fed. Reg., 1697. col. 1.

[8] APHIS Evaluation of the Status of the Republic of Korea Regarding Foot-and-Mouth Disease and Rinderpest, USDA-APHIS, October 2008, at 39.

APHIS was dead wrong and the reality is that South Korea was unable to effectively contain the widespread FMD outbreaks that began Jan. 6, 2010 – outbreaks APHIS concluded were unlikely to occur. The South Korean FMD outbreak devastated South Korea's livestock industry.

5. APHIS' Risk Evaluation Methodology Resulted in the Miscalculation of FMD Risks in Japan

Nine years after APHIS declared Japan free of FMD, based exclusively on OIE standards (*see* 66 Fed. Reg., at 46228, col. 3, *supra*), APHIS was forced to take emergency action to ban beef imports from Japan due to numerous outbreaks of FMD that began in that country in April 2010.[9]

Based on the numerous opportunities for FMD introduction discussed above that were created by APHIS' miscalculation of FMD risks in foreign countries, it would appear prudent for APHIS to establish a significant waiting period following the last FMD case that occurs in a foreign country before APHIS even considers designating that country as FMD free.

R-CALF USA recommends a waiting period of at least three years following the last case of FMD that occurs in a foreign country before considering the resumption of trade in FMD-susceptible products from that country. The APHIS Evaluation provides no scientific basis for resuming trade with a FMD-affected country within less than three years following the country's last FMD case, but it does provide support for R-CALF USA's three-year recommendation. The APHIS Evaluation concludes that Japan should be designated FMD free because, *inter alia*, the 134 burial sites for livestock depopulated during Japan's 2010 FMD outbreak "cannot be disturbed for 3 years."[10]

APHIS is silent on why Japan has established a three-year waiting period before its FMD burial sites can be disturbed, but it is both plausible and logical that this period was established to prevent another FMD outbreak from recurring as a result of the FMD-infected livestock carcasses that are now part of Japan's environment.

APHIS should explain whether the three-year prohibition on disturbing the FMD-infected carcass burial sites is a mitigation strategy to preventing the further spread of FMD as well as what security measures Japan has instituted to prevent the buried carcasses from being prematurely disturbed, e.g., APHIS should explain the security measures in place to prevent wild boars, floods, earthquakes or other natural phenomenon from prematurely disturbing the burial sites within three years and what risks can be expected if those security measures fail.

C. The APHIS Evaluation Contains Overly Optimistic and Unsupported Assumptions Regarding Japan's Ongoing Risk for FMD Outbreaks

[9] *See* U.S. Bans Japan Beef Imports Over FMD Concerns, USAgNet, May 21, 2010 (Reporting that Bloomberg news received an e-mailed statement from USDA regarding the imposition of a U.S. ban on Japanese beef imports), available at http://www.wisconsinagconnection.com/story-national.php?Id=1027&yr=2010
[10] APHIS Evaluation, at 24.

APHIS acknowledges the source of Japan's latest FMD outbreak is not definitively known.[11] APHIS also acknowledges that Japan's import policies are less stringent than those of the United States as they allow the importation of grain straw, hay, cloven-hoofed live animals, genetic materials, and/or meat from countries APHIS does not consider free of FMD.[12] Thus, Japan bears an inherently higher risk for the introduction and spread of FMD than the United States, though the U.S. would assume Japan's higher risk if trade in FMD-susceptible products were resumed.

Notwithstanding Japan's inherent, higher risk for FMD, APHIS summarily dismisses those possible sources for Japan's recent FMD outbreak and for future outbreaks based primarily on Japan's regulatory regime, including its import inspection processes. It is absurd for APHIS to suggest that the U.S. livestock industry must rely on Japan's regulatory regime – a regime the U.S. livestock industry has absolutely no control over – to mitigate what is known to be a highly risky practice – trading in cloven-hoofed animals and their products and grain straw and hay with countries not free of FMD.

In addition, APHIS, relying on Japanese officials, rules out Japan's wildlife population as a probable source or vector for FMD by asserting that the wildlife density in the affected area is low,[13] but at the same time, and in support of the Japanese official's claim, APHIS explains that farmers in the affected prefecture have traditionally erected fencing to prevent wildlife from contacting domestic livestock.[14] Yet, nowhere does APHIS provide any scientific evidence to suggest that FMD cannot be readily transmitted through a fence. And, while APHIS discounts the risks that Japanese wildlife could transmit FMD by explaining that wild boars and sika deer, have limited ranges, no comparable restriction is described for the third species of FMD-susceptible wildlife – the Japanese serow, which also inhabits the FMD-affected region.

The APHIS Evaluation provides no confidence in APHIS' conclusion that Japan's FMD-susceptible wildlife populations and Japan's high-risk import policies are not potential sources and vectors for yet another FMD outbreak in Japan.

D. The APHIS Evaluation Deceives the Public by Falsely Claiming that All FMD-Exposed Livestock in Japan have been Depopulated

In its APHIS Evaluation, APHIS emphatically states:

> All told, FMD infection was confirmed on 292 farms over a period of 11 weeks; all 211,608 infected and susceptible animals residing on those farms were depopulated. All vaccinated animals were also depopulated. (Citations omitted.).

Yet, a careful reading of the APHIS Evaluation reveals that among six bulls that all were on a Japanese farm affected with FMD during the time when FMD likely was incubating (they were

[11] APHIS Evaluation, at 4, 9, 18.
[12] *Id*., at 33.
[13] *Id*., at 18.
[14] *Id*., at 29.

removed just three days before the farm experienced an outbreak[15]), one of the six bulls became infected with FMD and the other five bulls were spared.[16] The APHIS Evaluation is silent on whether the five bulls that were from the FMD-affected farm were vaccinated or what precautions have been taken to ensure that any one of the five bulls that were spared is not a carrier of the disease.

Either R-CALF USA has misinterpreted the APHIS Evaluation, the APHIS Evaluation contains inconsistencies, or APHIS has purposely attempted to deceive the public into believing that Japan had depopulated all infected and susceptible animals residing on farms where FMD outbreaks occurred.

Conclusion

For the reasons stated above, R-CALF USA finds it absurd and irresponsible for APHIS to conclude that "there is no risk barrier to reinstating Japan to the list of regions considered free of FMD."[17] Clearly, there is a risk to resuming trade with Japan and clearly that risk is greater than trading with other countries that have not had two outbreaks of the disease in the last decade alone.

R-CALF USA urges APHIS to reject Japan's request to be designated a country free of FMD.

Sincerely,

Bill Bullard, CEO

Attachment

[15] APHIS considers the average incubation period for cattle to be seven days (APHIS Evaluation at 18), therefore, FMD likely was incubating on the farm prior to the six bulls' departure that occurred three days before a FMD outbreak was confirmed on the farm.
[16] APHIS Evaluation, at 20, 21, 41.
[17] *Id*., at 36.

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.

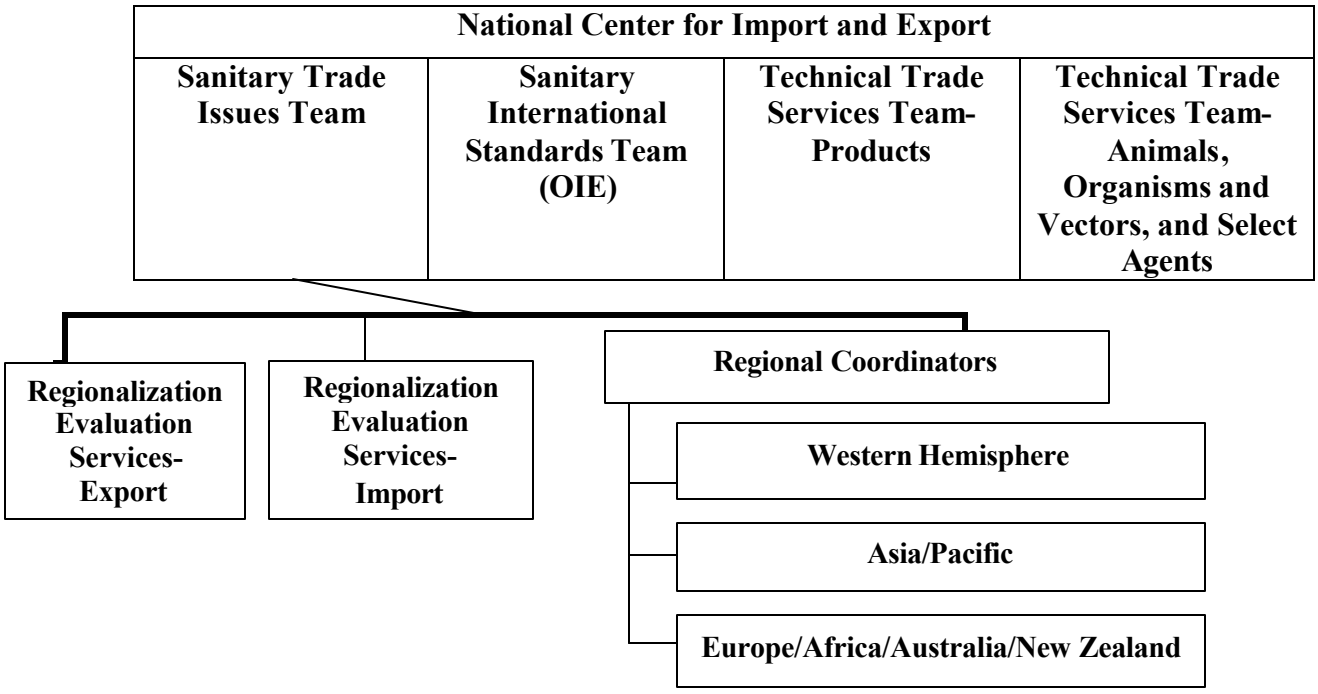
National Center for Import and Export (NCIE): A VS unit that has primary responsibility for issues relating to import and export of animals and animal products. These responsibilities include issuing import permits for animals and animal products, participating in negotiations with foreign governments 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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4. *Administrative Procedures Act, Title 5, U.S. Code, Chapter 5, Administrative Procedure, In: Administrative Conference of the US, Federal Administrative Procedure Sourcebook, Statutes and Related Materials, 2nd Ed., Office of the Chairman, 1992, pp.17-31.*