CHAPTER 6

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Animal Disease Status and Trade

Background

Foreign Animal Disease (FAD) outbreaks can have a profound impact on U.S. trade markets. For example, when some U.S. export markets were closed to U.S. beef and ruminant products due to restrictions implemented because of bovine spongiform encephalopathy (BSE), and when additional markets were closed because of restrictions implemented because of avian influenza (AI), U.S. exports of livestock, poultry, and their products fell approximately 15 percent (from $12.2 billion in 2003 to $10.4 billion in 2004). Guidelines issued by the World Organization for Animal Health (OIE) have been instrumental in reopening these markets.

The OIE is recognized by the World Trade Organization (WTO) as the international standards-setting body for developing health-related standards, guidelines, and recommendations for animal health worldwide. By focusing on OIE guidelines, the U.S. Department of Agriculture's (USDA) Animal Plant and Health Inspection Service (APHIS) and Foreign Agricultural Service (FAS) worked with many partners to facilitate trade of certain products—such as boneless beef, milk and milk products, hides and skins, semen, and embryos—as safe despite current U.S. BSE status. Adhering strictly to OIE guidelines was equally important in regaining poultry markets lost in the wake of the 2004 detection of high-pathogenicity AI (HPAI) in the United States because many countries initially imposed restrictions that exceeded those supported by OIE guidelines.

Import Regionalization

Background

Before a foreign country is allowed to export most live animals or unprocessed animal-origin commodities to the United States, Veterinary Services (VS) personnel carefully evaluate the animal-disease status of the exporting country and the risk of introducing FADs into the United States. This evaluation is often referred to as a regionalization process. This process provides a systematic method for evaluating the likelihood of whether an exporting country, a specific region within the country, or a region consisting of several countries present a danger of introducing FADs into the United States through trade. The presence of an FAD in an exporting country does not necessarily preclude trade with that country if the country employs effective regionalization controls among its own regions or processes its products in a manner known to inactivate the FAD agent of concern. Before a market is opened, APHIS specialists evaluate the country according to regionalization criteria defined in Title 9 Code of Federal Regulations (CFR), Part 92.2, conduct a risk assessment, and define suitable mitigation measures based on the risk. If the risk of introducing an FAD through importation is determined to be sufficiently low, then VS initiates a rulemaking process that defines the appropriate mitigations and culminates in trade of the animals or products.

VS published its new approach to regionalization in the "regionalization rule and policy statement" (APHIS Policy Regarding Importation of Animals and Animal Products. 62 Federal Register 56027–56033, October 28, 1997). The rule stated that regionalization requests would be considered on a region-by-region and commodity-by-commodity basis (Importation of Animals and Animal Products. 62 Federal Register 56000–56026, October 28, 1997). VS also made a commitment to stakeholders to provide guidance regarding its approach. These procedures are explained in more detail in the document "Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis and Rulemaking," available at <http://www.aphis.usda.gov/vs/ncie/reg-request.html>.

The regionalization policy states that the United States will recognize the animal health status of (1) regions within countries or (2) regions composed of groups of countries rather than recognizing only regions defined by national boundaries, as the United States has done in the past.

Initiation of the Regionalization Process

The regionalization process begins when the Deputy Administrator in charge of APHIS' VS receives a request from the chief veterinary officer of a foreign government seeking authorization to export animals, unprocessed animal products, or both to the United States. The request may refer to the entire country or region or may define subregions within the larger region. The request must be accompanied by information addressing the 11 risk factors defined in Title 9 Code of Federal Regulations (CFR), Part 92.2, as they pertain to each subregion under consideration. These risk factors are

- Authority, organization, and infrastructure of the veterinary services organization in the region;
- Disease status of the region;
- Status of adjacent regions with respect to the agent;
- Extent of an active disease-control program;
- Vaccination status of the region;
- Degree to which the region is separated from adjacent regions of higher risk through physical or other barriers;
- Extent to which movement of animals and animal products is controlled from regions of higher risk and the level of biosecurity regarding such movements;
- Livestock demographics and marketing practices in the region;
- Type and extent of disease surveillance in the region;
- Diagnostic laboratory capabilities; and
- Policies and infrastructure for animal disease control in the region (e.g., emergency response capacity).

Data Evaluation Process

The regionalization request and supporting data are forwarded to Regionalization Evaluation Services–Import (RESI), National Center for Import and Export (NCIE). NCIE is the VS unit with primary responsibility for international trade issues. These responsibilities include issuing import permits for animals and animal products, participating in negotiations with foreign governments on provisions for animal-health certificates for animals and animal products, providing a liaison with OIE. RESI is responsible primarily for coordinating the evaluation of animal health status with the import risk analyses for regionalization requests. Case managers coordinate responses to individual requests and serve as primary contact for the requesting countries.

After receiving the initial information, the case manager assembles a review team. Team members are drawn from various sources to obtain a wide range of technical expertise and program representation. Sources include

APHIS' International Services (IS) unit, VS' Centers for Epidemiology and Animal Health and National Veterinary Services Laboratories, and other program staff as appropriate. The team includes individuals with technical expertise on the disease, commodity, and the country making the request.

Team members evaluate submitted information and provide comments to the case manager based on the evaluation and application of the 11 risk factors. Comments (1) address issues related to the risk of exporting disease agents to the United States, (2) identify both the strengths and weaknesses of the requesting country's veterinary system, and (3) identify and define gaps in the information.

The case manager synthesizes the team comments and coordinates an official response to the designated contact in the requesting country. Often, the initial response amounts to a request for additional information.

Verification Through Site Visits

Once the initial review team deems the submitted information sufficient to justify proceeding with the evaluation, a site visit is planned to verify and complement the information provided and review local conditions. The team visits the site prior to completing the risk assessment. When possible, the site-visit team includes members of the initial review team. In addition, when the request is submitted simultaneously to Mexico, Canada, and the United States, the team may include veterinary officials from all three countries. A representative from the office of a State Veterinarian also participates.

Risk Assessments

Risk assessments are conducted using information provided by the requesting country, scientific literature, and information gathered during the site visit. The assessment can be either quantitative or qualitative and is compatible with the general guidelines provided by OIE (Terrestrial Animal Health Code, Part 1, Chapter 1.3.2).

The choice of approach depends on the nature of the request. In this regard, VS historically has conducted qualitative assessments when evaluating a country or region for a particular disease-free status and in many cases for commodity assessments. The qualitative approach is often more appropriate when data are inadequate for numerical evaluation or risk calculations would imply false precision. When appropriate data are available and the situation lends itself to numerical evaluation, the qualitative assessment may be further supported by a quantitative assessment. For example, VS has developed a quantitative model to assess the risk of introducing foot-and-mouth disease (FMD) virus in beef from countries that practice vaccination. The practice of vaccination in a region may mask the active presence of a given disease, and so the quantitative assessment incorporates the influence of vaccination. However, the assessment is conducted against the background of a satisfactory result from an 11-factor qualitative analysis.

Rulemaking

Once a risk assessment is complete, the rulemaking process begins. This process is coordinated by the Regulatory Analysis and Development branch of APHIS' Policy and Program Development unit. The draft rule undergoes legal and policy reviews within APHIS, other USDA offices, and, occasionally, external groups such as the Food and Drug Administration (FDA) and the Office of the U.S. Trade Representative. A proposed rule is published for public comment, and APHIS personnel consider those comments in the next part of the rulemaking process. As part of U.S. obligations under the WTO–Sanitary and Phytosanitary Measures (SPS) agreement, the WTO is notified of all proposed rules that may affect trade to allow U.S. trading partners the opportunity to comment prior to implementation. However, if there is a need to implement an emergency SPS measure to prevent the transmission of a disease or pest from a foreign country, the United States may notify the WTO after implementation.

A proposed rule's provisions usually are implemented by a final rule in which APHIS' analysis of the public comments is presented and the content of the comments is addressed. For a more detailed description of the process, visit the VS–NCIE Web site: <http://www.aphis.usda.gov/vs/ncie/country.html>.

Export (Domestic)

VS is responsible for certifying that animals, animal germplasm, and many animal products exported from the United States meet the animal health requirements of the importing country, including freedom from specific diseases. VS' ability to certify exports is sometimes dependent on the regionalization or zoning of the United States with respect to the animal health status of different geographic areas. Trading partners concerned about animal diseases in the United States often request detailed reports on the occurrence and distribution of a specific disease, including results of epidemiologic investigations, control and surveillance measures in place, laboratory testing methods, quarantine procedures, veterinary infrastructure at the Federal and State level, and regionalization of the disease to defined areas.

The Domestic Regionalization Staff, a unit within the NCIE, has as its mission to gather, analyze, and interpret data relating to specific diseases and to identify epidemiologic, environmental, ecologic, geographic, and other factors associated with the animal health status of regions within the United States. At the request of importing countries seeking information about a specific disease, or proactively in the event of an animal-disease occurrence, the Domestic Regionalization Staff develops information packages describing the veterinary infrastructure of the United States. These packages document surveillance activities, diagnostic procedures, biosecurity measures, and control and eradication efforts for diseases that impact trade.

Table 15 lists the affected commodities and the importing countries for which animal-disease-related issues threatened the continuation of U.S. exports during 2005. Concerns about AI and BSE dominate the list. The information packages prepared by the Domestic Regionalization staff as well as additional efforts of APHIS' VS and IS units and USDA's FAS contributed to "retaining," or continuing, the flow of U.S. exports when disease-related issues were raised by importing countries.

TABLE 15. **Commodities and countries included in disease-related trade issues addressed during 2005**

Commodity	Importing country
Aquaculture (finfish and mollusks)	European Union
Beef and beef products	Chile, Colombia, Egypt, Israel, Hong Kong, Jamaica, Japan, Jordan, Kuwait, Lebanon, Oman, Panama, Peru, Philippines, Romania, St. Lucia, St. Vincent, Singapore, Taiwan, Thailand, United Arab Emirates, Vietnam
Bovine semen and embryos	China, Colombia, European Union, Peru
Bovine serum products	Taiwan
Feeder cattle	Canada
Eggs	Russia, Singapore
Pet food	India, Turkey
Poultry and poultry products	Argentina, China, Costa Rica, Cuba, Hong Kong, India, Indonesia, Israel, Japan, Jordan, Kazakhstan, Kenya, Korea, Kosovo, Kyrgyzstan, Lebanon, Macedonia, Mexico, New Caledonia, Nicaragua, Peru, Qatar, Russia, Singapore, Sri Lanka, Taiwan, Thailand, Ukraine, United Arab Emirates, Uruguay
Rendered fats	Russia
Ruminant and ruminant products	Guatemala
Swine products	India, Taiwan

Trade Rules in 2005

Add Argentina to the List of Regions Considered Free of Exotic Newcastle Disease.

Proposed rule published: August 23, 2005

Federal Register, Vol. 70, No. 162, p. 49200–49207

Importation of Swine and Swine Products from the European Union [Rule proposed new approach, recognizing much of the European Commission CSF regionalization decisions in the 15 original EU Member States.]

Proposed rule published: April 8, 2005

Federal Register, Vol. 70, No. 67, p. 17928–17940

Notice of Availability of Draft Document Concerning the Identification of EU Administrative Unit

Notice published: April 21, 2005

Federal Register, Vol. 70, No. 76, p. 20733–20734

[This was notice that a draft document was available for public comment.]

Notice of Availability of a Risk Analysis Evaluating the Exotic Newcastle Disease Status of Denmark

Notice published: May 5, 2005

Federal Register, Vol. 70, No. 86, p. 23809–23810

Notice of Availability of a Document Concerning the Identification of EU Administrative Units

Notice published: July 29, 2005

Federal Register, Vol. 70, No. 145, p. 43838–43839

[This was notice that the administrative units defined previously could now be considered final and effective.]

Classical Swine Fever Status of Mexican States of Campeche, Quintana Roo, Sonora, and Yucatan

Final rule published: March 28, 2005, effective April 12, 2005

Importation of Whole Cuts of Boneless Beef from Japan

Proposed rule published: August 18, 2005

Federal Register, Vol. 70, p. 48494–48500

Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities

Final rule and notice: January 4, 2005

Federal Register, Vol. 70, No. 2, p. 459–553

U.S. Export Certification Procedures

Overview

VS oversees the export of live animals, their germplasm (including embryos and semen), and also many animal products. VS' export functions include inspections of live animals and products at ports, inspection of export isolation facilities, and certification of live animals, veterinary biologics, and animal products intended for export.

VS also negotiates export protocols with foreign countries for the exportation of U.S. live animals and animal products. APHIS' International Regulation Retrieval System (IREGS) compiles information on foreign country requirements. This information is available online at

- http://www.aphis.usda.gov/NCIE/iregs/products (for animal products), and
- http://www.aphis.usda.gov/NCIE/iregs/animals (for live animals).

U.S. exporters can and should verify that the foreign country's import requirements listed in the IREGS system are current by contacting their State's VS area office at:

- <http://www.aphis.usda.gov/vs/area_offices.htm>, and
- The FAS officer located at the U.S. Embassy in the importing country (see <http://www.fas.usda.gov/scriptsw/fasfield/ovs_directory_search.asp>.)

Exporters should also consult the Food and Agricultural Import Regulations and Standards reports issued by FAS for more than 60 countries, found on the Web at:

- <http://www.fas.usda.gov/itp/ofsts/fairs_by_country.asp>.

For live-animal shipments, a veterinarian accredited by VS conducts required tests and prepares an export health certificate. For animal-product shipments, company officials complete the required export documents. Then the documents are forwarded to the VS area office for review and certification by either the Area Veterinarian-in-Charge or the export veterinary medical officer. However, if the exporter cannot meet all of the importing country's requirements, VS may contact the country's import officials in an attempt to clarify the protocols in question. If a failure to clear customs is due to a new or changed inspection procedure or standard, the exporter is encouraged to contact APHIS–IS or USDA–FAS field officers for the respective country (see <http://www.fas.usda.gov/scriptsw/fasfield/ovs_directory_search.asp>.)

VS also provides technical support when an exported U.S. product is detained at a foreign port. IS officials stationed overseas and FAS officers attempt to verify why the product is being detained to determine what, if anything, can be done to facilitate the shipment and to assist the exporter in obtaining any necessary documentation. Usually the matter is resolved and a waiver issued, allowing the shipment to be released to the importer. In some cases, however, the shipment is returned to the United States or destroyed and disposed of overseas.

Export Health Certificates and Health Statements

Generally, export certificates are issued by the VS Area Office nearest the exporter. Staff at those offices undergo training to ensure consistency in the certification process and to make certain that the import protocols of foreign countries are understood and followed.

VS issues export certificates for many types of products. Normally, certification statements cover issues of particular animal species or diseases. For instance, a statement may document that the United States is free of FMD. Statements also may include limited remarks about if and how a product was processed to eliminate micro-organisms of concern to the importing country.

Embryos, semen, cattle, horses, bison, cervids, sheep, goats, swine, poultry, and pet birds fall under USDA export protocols. Established requirements must be met to export these animals and animal products (see Title 9 Code of Federal Regulations [CFR], Part 91). Except for animals transported by land to Canada and Mexico, cattle, horses, bison, cervids, sheep, goats, and swine must be exported from the United States via an approved port and be accompanied by an export health certificate. In addition, these animals must be transported to the port in vehicles that have been cleaned and disinfected according to APHIS regulations. If for any reason the animals have to be unloaded while en route to the port, unloading must be done under APHIS supervision at cleaned and disinfected facilities approved by VS to ensure that the animals are not exposed to any infectious agents. At the port, animals must enter an approved export inspection facility and remain there for at least 5 hours. While at the export inspection facility, and within 24 hours of export, all animals are inspected by an APHIS veterinarian.

Export health certificates for livestock and poultry must be issued by an accredited veterinarian. Certificates identify each individual animal and include species, breed, sex, age, and, if applicable, breed registration name and number, tag number, tattoo markings, or other natural or acquired markings. The certificate also must state that the animals were inspected and declared healthy. All test results and certification statements required by the importing country must be listed in the export health certificate, and the certificate must be endorsed by an authorized APHIS veterinarian.

When requested, APHIS also provides certification for dogs, cats, and laboratory animals leaving the country. Pertinent regulations appear in 9 CFR 91. VS helps exporters meet the receiving country's import requirements and certifies that the exporter has done so. These export health certificates can be issued by a licensed veterinarian unless the importing country requires specifically that an accredited veterinarian issue the certificates. These certifications also must include proper identification of the animals and animal products in question and must contain testing results and certification statements as required by the importing country.

Many countries require both public-health and animal-health statements before a product is imported. U.S. agencies work together to facilitate this process when jurisdictions overlap. USDA's Agricultural Marketing Service certifies many different types of dairy products and table eggs. USDA's Food Safety and Inspection Service (FSIS) inspects meats, meat products, poultry, poultry products, and different types of egg products intended for human consumption. Again, VS approves the animal-health statements and then FSIS certifies inspected products for export. The FDA and/or the States certify most other types of food for compliance with their laws. The U.S. Department of the Interior's U.S. Fish and Wildlife Service certifies some wild animals and wild-animal products. The U.S. Department of Commerce's National Marine Fisheries Service provides certification for fish meal and some aquaculture and seafood products; FDA and USDA–APHIS certify other aquaculture products.

Biologics and Diagnostics

VS' Center for Veterinary Biologics (CVB) issues Certificates of Licensing and Inspection to biologics manufacturers as an aid to foreign product registration. These certificates confirm that manufacturers are licensed with USDA under the Virus–Serum–Toxin Act, that facilities and products have been inspected by USDA, and that there are no restrictions on the distribution of the manufacturers' products.

CVB licensed two new diagnostic test kits in 2005 with improved ability to detect piroplasmosis in horses. These kits are used as part of an overall testing strategy to ensure that only noninfected horses are imported into the United States. Additionally, CVB specialists reviewed and approved more than 300 export certificates for biologics in 2005, supporting the export of individual serials of product. In 2005, CVB reviewed and approved 2,400 certificates of licensing, facilitating the registration of these U.S.-manufactured veterinary biologics products in more than 50 countries.

CVB partners with IS and the NCIE to facilitate the exportation of veterinary biologics. Foreign governments, in response to the United States' BSE case, restricted importation of U.S.-manufactured veterinary biologics. The CVB Trade Issues Resolution Manager worked with foreign regulators, providing information and participating in onsite audits of licensed U.S. manufacturers. This interaction played a significant role in reducing the trade restrictions imposed.