

Clarification of Information Requested for Recognition of a Historically-free Region

Introduction

This document describes the basic information that the Animal and Plant Health Inspection Service (APHIS) requires to initiate an evaluation of a historically-free region in accordance with title 9, *Code of Federal Regulations*, section 92.2(c). Qualifying regions are those in which the disease under evaluation has not occurred in domestic livestock for at least 25 years, if ever, or in wildlife for at least 10 years. Veterinary authorities seeking APHIS recognition of regions that do not meet these conditions should follow the guidance in 9 CFR 92.2(b).

APHIS recognizes regions (zones) in other countries for the purposes of international trade. A region is defined as a geographical land area identifiable by geological, political, or surveyed land boundaries, that contains an animal subpopulation with a distinct animal health status. Examples include (1) an entire country; (2) part of a country; (3) parts of several countries; and (4) a group of countries. The borders of a region must be clearly defined and the entire region must be accessible to both national veterinary authorities and APHIS personnel.

A regionalization evaluation typically consists of initial information gathering, a site visit, and a risk assessment. Any resulting regulatory action must reflect the risk assessment conclusions. The pace of an APHIS evaluation largely depends on the quality of the information received.

To facilitate the assessment process, please submit all information in English.

1. Scope of the evaluation

- a. Provide a detailed description of the proposed region(s) and maps showing the following:
 - Borders of the region(s)
 - Internal administrative divisions (regional and local)
 - Buffer zones (if any)
 - Main cities and towns
 - Main roads and railways
 - Locations of the following:
 - Headquarters of the veterinary services
 - Regional and local offices of the veterinary services
 - Central and regional official laboratories
 - Approved border inspection posts (airports, seaports, land crossings)
- b. Identify the animal commodities¹ proposed for export to the United States and estimate the annual volume of export for each commodity.
- c. Specify the disease(s) for which an APHIS evaluation is requested (*see* Appendix A).

¹ For the purposes of this document, *animal commodities* are live animals, animal products, and animal by-products.

2. Disease history and vaccination practices

- a. Indicate when each disease under evaluation was last reported in domestic livestock in the region. (Note that this questionnaire may only be used if the disease(s) under evaluation have not been reported for at least 25 years.)
- b. Indicate when each disease under evaluation was last reported in wildlife in the region. (Note that APHIS cannot consider a region historically free if infection has occurred in wildlife in the last 10 years.)
- c. Indicate whether vaccination against the disease(s) under evaluation has occurred in the last 10 years and, if so, provide the following information:
 - Reasons for vaccination
 - Source and type of vaccines used
 - Target populations
 - Recordkeeping requirements
 - Procedures to distinguish vaccinated animals

3. Veterinary control and oversight

The requesting region should provide evidence that the veterinary services in the region have had and continue to have sufficient legal authority, organization, and infrastructure to effectively investigate, diagnose, and report animal diseases, if present.

a. Legal authority for animal health activities

- i. Provide copies (in English) of the legal acts and regulations that afford authority for the official veterinary services to conduct the following animal health activities:
 - On-farm inspections
 - Import, export, and internal movement controls
 - Quarantine of animals or farms
 - Vaccination for the disease(s) under evaluation
 - Surveillance for the disease(s) under evaluation
 - Control and eradication of the disease(s) under evaluation
 - Emergency response activities
 - Seizure, depopulation, and compensation
- ii. Provide copies (in English) of any secondary legislation, enabling regulations, manuals, contingency plans, or guidance documents pertaining to the disease(s) under evaluation.

b. Organizational structure of the veterinary services

- i. Provide an organizational chart of the official veterinary services and describe the chain of command, including to whom the central, regional, and/or local veterinary units report.
- ii. Describe the functions of each unit within the official veterinary services and the division of responsibilities among central, regional, and local veterinary authorities. What procedures are in place to ensure coordination and communication among these entities?

c. Infrastructure and financial resources

- i. Describe the financial resources of the official veterinary services, including the budget for the most recent fiscal year and sources of funding (governmental and nongovernmental).
- ii. If financial or performance audits of the veterinary services are conducted, identify the auditing entity and describe the audit frequency and the results of the most recent audit.

4. Disease reporting

The requesting region should provide evidence that each disease under evaluation has been legally notifiable in the region, for at least the past 10 years.

- a. Describe how notification of the disease(s) under evaluation is ensured within the region, including the methods by which obligated persons are made aware of the reporting requirements and penalties for failure to notify. Provide a copy (in English) of the pertinent legal acts or regulations.
- b. Describe the procedures in place to ensure that the veterinary authorities of the requesting region inform pertinent international entities of a disease outbreak in a timely manner.

5. Disease detection

The requesting region should provide evidence that an effective early detection system has been in place for each disease under evaluation, for at least the past 10 years. An effective early detection system includes, among other things, representative coverage of susceptible animal populations by field services, a training program for detecting and reporting unusual animal health incidents, the ability to undertake effective disease investigation and reporting, and access to laboratories capable of diagnosing and differentiating relevant diseases.

a. Coverage by field services

- i. Complete the table in Appendix B concerning veterinary personnel in the region.
- ii. Indicate the number of private veterinarians and veterinary technicians in the region and the number authorized to conduct official animal health and food safety activities. Describe the procedures for authorization, the policies in place to safeguard against conflicts of interest, and any requirements for official supervision.
- iii. Describe any legal or procedural requirements for routine inspection of livestock premises for animal health, identification, or welfare purposes. Who conducts the inspections and how often do such inspections occur?

b. Training programs

- i. Indicate the minimum qualifications required for veterinary and technical staff employed by the official veterinary services at the central, regional, and local levels. Describe the training requirements for newly recruited and established staff, as well as any pertinent simulation or field exercises conducted in the last 3 years.

- ii. Describe any outreach activities of the official veterinary services designed to increase awareness, recognition, and reporting of the disease(s) under evaluation among producers, industry members, official and private veterinarians, and the general public.

c. Disease investigation and reporting

- i. Describe the type and extent of surveillance activities for the disease(s) under evaluation, in domestic livestock and wildlife. Include both active and passive surveillance, if applicable.
- ii. Indicate the number of suspicious cases of the disease(s) under evaluation reported to the official veterinary services in the past 3 years and describe the follow-up measures taken in each case.
- iii. Provide copies (in English) of any guidance documents for investigation of suspect cases of the disease(s) under evaluation and plans for emergency response.

d. Diagnostic laboratory capabilities

- i. Provide an organizational chart of the animal health laboratory system in the region. Indicate which laboratories conduct screening and/or confirmatory tests for the disease(s) under evaluation. Describe the certification or accreditation requirements for these laboratories.
- ii. Indicate the number of scientists and administrative staff employed in each laboratory, and describe the procedures in place to ensure continued proficiency in diagnostic procedures.
- iii. Indicate the diagnostic tests or procedures used to detect the disease(s) under evaluation. What procedures are conducted for agent isolation, identification, and typing?
- iv. Describe the procedures for reporting test results, including to whom they are reported and the average time between sample collection and reporting. If confirmatory testing is conducted outside of the region, estimate the time required to confirm a diagnosis.

6. Barriers to disease introduction

The requesting region should provide evidence that measures have been in place to prevent introduction of each disease under evaluation, for at least the past 10 years.

- i. Provide a map showing the main geological features of the region. Describe any manmade barriers (e.g., fences, netting) that isolate the region from adjacent regions and indicate how the integrity of these barriers is ensured.
- ii. Provide a map showing the location of all official entry points into the region with veterinary and/or customs inspection. Describe the procedures for veterinary inspection and control of animal commodities that could harbor the disease(s) under evaluation.
- iii. Describe any other procedures at border entry points to exclude prohibited animal commodities (e.g., customs inspections, self-declarations, signs to alert travelers).
- iv. List the countries or regions from which the region under evaluation imports animal commodities that could harbor the disease(s) under evaluation. Indicate the amount and type of such commodities imported from each country or region in the last 3 years.

Appendix A

Select the diseases for which an APHIS evaluation is requested from the table below. Include all diseases potentially affecting the commodities proposed for export in Question 1b, unless APHIS already considers the region free or low risk for a disease.

African horse sickness	Foot and mouth disease
African swine fever	Newcastle disease
Avian influenza	Rinderpest
Bovine brucellosis	Scrapie
Bovine tuberculosis	Swine vesicular disease
Classical swine fever	Other (please specify)
Contagious equine metritis	

Appendix B

Provide the information in the table below concerning veterinary services personnel in the region.

	Veterinarians*		Veterinary technicians		Administrative staff	
	Filled posts	Vacant posts	Filled posts	Vacant posts	Filled posts	Vacant posts
Central service						
Regional service						
Local service						
Border controls						
Laboratory service						

* Veterinarian is defined as having graduated from veterinary school.