

Clarification of Information Requested for Recognition of a Region

Introduction

This document describes the basic information that the Animal and Plant Health Inspection Service (APHIS) requires to initiate a regionalization evaluation in accordance with title 9, *Code of Federal Regulations*, section 92.2(b). Veterinary authorities seeking APHIS recognition of regions could be considered historically free of a disease should follow the guidance in 9 CFR 92.2(c).

APHIS recognizes regions or 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. Veterinary control and oversight

The requesting region should provide sufficient information for APHIS to assess the infrastructure of the official veterinary services and the ability of the veterinary services to oversee animal health activities, monitor for disease, and implement disease control measures. The questions below are designed to provide a comprehensive view of the legal authority for animal health activities in the region; the organizational structure and function of the veterinary services; and the personnel, financial, and physical resources available within and to the veterinary services.

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 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. Describe how notification of reportable diseases is ensured within the region and provide a copy (in English) of the pertinent legal act or regulation.
- iii. Describe compliance monitoring activities and the penalty system for noncompliance.

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?
- iii. Complete the table in Appendix B concerning veterinary services personnel.
- iv. 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.
- v. 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.
- vi. Identify any governmental or nongovernmental entities other than the official veterinary services that participate in, monitor, or provide oversight of official animal health and disease control activities (e.g., accreditation organizations, industry groups). Describe the roles and responsibilities of 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.
- iii. Specify sources of funding for emergency response measures in the event of a disease outbreak, including indemnity and compensation for destroyed animals and/or property.

3. Disease history and vaccination practices

The requesting region should provide sufficient information to enable a thorough understanding of the history of the disease(s) under evaluation in the region, including prior control measures and revisions to those measures as appropriate, to facilitate APHIS' assessment of export risk.

a. History of disease outbreaks in the region

- i. Provide maps showing the location of cases and/or outbreaks of the disease(s) under evaluation, in both wild and domestic species, within the last 5 years. For each outbreak, provide the following information:
 - Species affected
 - Number of animals and premises involved
 - Mechanism by which the outbreak was detected
 - Probable source of infection
 - Results of the epidemiological investigation
 - Control measures implemented
 - Disposition of infected and exposed animals
 - Time required for eradication and control
- ii. Provide a map showing the range of any known wildlife reservoirs of the disease(s) under evaluation.

b. Vaccination practices

- i. Provide the following information concerning vaccination practices against the disease(s) under evaluation:
 - Source and type of vaccines used
 - Schedule or timing of vaccination
 - Target populations
 - Number of animals vaccinated annually
 - Measures in place to regulate vaccine production and use
 - Persons authorized to administer vaccine
 - Required training for authorized personnel
 - Recordkeeping requirements
- ii. Describe the mechanisms in place to distinguish between vaccinated and unvaccinated animals, including animals found to be positive during serological surveillance.

4. Livestock demographics and traceability

The requesting region should provide sufficient information for APHIS to assess the geographic distribution of livestock and wildlife that are susceptible to the disease(s) under evaluation, patterns of livestock movement within the region, and the ability of the region to trace livestock movements in the event of a disease outbreak.

a. Livestock demographics

- i. Indicate the number of livestock and wildlife in the region that are susceptible to the disease(s) under evaluation and provide maps showing the geographical distribution of these species, if possible.
- ii. Provide demographic data on the relative size and type of holdings in the region that have susceptible livestock species and provide maps showing the geographical distribution of these holdings, if possible.
- iii. Describe general patterns of livestock movement and marketing within the region and indicate the location of any major marketing or assembly centers for species susceptible to the disease(s) under evaluation.

b. Identification and registration

- i. Provide copies (in English) of regulations pertaining to animal identification and farm registration, focusing on species susceptible to the disease(s) under evaluation.
- ii. Describe the system used to identify individual animals or groups of animals within the region and identify the implementing authority. Indicate any recordkeeping requirements, including what records are kept, by whom, and where.
- iii. Describe the system for registering livestock holdings. Indicate any recordkeeping requirements, including systems for recording and reporting changes in inventory.
- iv. Describe any official requirements for movement of susceptible livestock species within the region (e.g., a health certificate, permit, or other notification form). Indicate any recordkeeping requirements, including what records are kept, by whom, and where.
- v. Describe compliance monitoring and enforcement activities as they pertain to animal identification, farm registration, and animal movements within the region, as well as the penalty system for noncompliance.

5. Epidemiological separation from potential sources of infection

The requesting region should provide sufficient information to enable APHIS to evaluate the ability of the region to prevent incursions of the disease(s) under evaluation. Relevant risk factors include the presence of the disease(s) in adjacent regions or regions with epidemiological links to the requesting region, natural and manmade barriers to disease introduction, trading practices, and inspection procedures.

a. Disease status of adjacent regions

- i. Describe the status of adjacent regions with regard to the disease(s) under evaluation, including the location and date of the most recent case or outbreak, if known.

- ii. Describe any cooperative agreements or programs with adjacent regions for surveillance, prevention, and/or control of the disease(s) under evaluation.

b. Natural and manmade barriers

- i. Provide a map showing the main geological features of the region (e.g., rivers, mountain ranges). 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. Which entry points receive consignments of animal commodities that could harbor the disease(s) under evaluation?
- iii. Complete the table in Appendix C concerning entry points with veterinary inspection.

c. Import practices and trading partners

- i. 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.
- ii. Describe the procedures by which the region under evaluation ascertains the disease status of other countries or regions and approves exporting establishments therein.

d. Requirements for entry

- i. Describe the documentation required for entry of animal commodities that could harbor the disease(s) under evaluation into the region and provide examples of pertinent documents.
- ii. Describe the quarantine requirements for live animals entering the region, including the length of quarantine, veterinary inspection, and testing for the disease(s) under evaluation. Where are the quarantine facilities located and who maintains oversight?
- iii. Describe the mechanisms in place to track animal commodities in transit within the region and to confirm exit or arrival at the point of destination. How are tracking records maintained and who is responsible for oversight of the tracking system?
- iv. Describe any required biosecurity procedures for live-haul trucks (loaded or empty).

e. Inspection practices and procedures

- i. Describe in detail the procedures for veterinary inspection and control of imported animal commodities, including the system for selecting consignments for physical examination and sampling. Provide copies (in English) of pertinent guidance documents.
- ii. Describe any other procedures at border entry points to exclude prohibited animal commodities (e.g., customs inspections, self-declarations, signs to alert travelers).
- iii. Describe the procedures for disposition of commercial consignments that do not pass veterinary inspection and other prohibited animal commodities seized at entry points.

6. Surveillance

The requesting region should document the existence of a surveillance system sufficient to ensure early detection of the disease(s) under evaluation. A combination of active surveillance and passive surveillance may be necessary to accomplish this goal. Collection and analysis of disease/infection data should be sufficient to provide confidence in the disease status of the region.

a. Active surveillance

- i. Provide the following information regarding active surveillance in domestic livestock and wildlife, for each disease under evaluation:
 - The target population(s)
 - Risk factors considered in the surveillance approach
 - Targeted prevalence for detection
 - Estimated confidence level
 - Sampling plan
 - Types of samples collected
 - Frequency of sampling
- ii. Provide the targeted and actual numbers of samples collected, by species. Indicate the results of screening and confirmatory testing for the past 3 years, including any false positive results. Describe the procedures for investigating positive results.
- iii. Specify the entity or unit responsible for analyzing surveillance data and updating the surveillance plan(s). How often does this occur?

b. Passive surveillance

- i. Describe the type and extent of passive surveillance activities for each disease under evaluation, including who does the reporting, the type of information reported, and how reports are verified.
- 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.
- iii. Provide the number of suspicious cases of each disease under evaluation that were reported to the official veterinary services over the past 3 years and describe the follow-up measures taken in each case.

7. Diagnostic laboratory capabilities

The requesting region should clearly document the animal health laboratory system, diagnostic procedures, and quality assurance measures to demonstrate effective support of surveillance activities for the disease(s) under evaluation.

- a. 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.
- b. 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.

- c. Indicate the diagnostic tests or procedures used to detect the disease agent(s) under evaluation, including the sensitivity and specificity of each. What tests or procedures are conducted for agent isolation, identification, and typing?
- d. Describe how diagnostic tests are approved or licensed for use within the region.
- e. Describe the procedures for sample collection from domestic livestock and wildlife, as well as the procedures for transport of samples to the laboratory.
- f. Describe the biosecurity measures followed while conducting diagnostic tests or procedures to detect the disease(s) under evaluation. Provide copies (in English) of pertinent guidance documents.
- g. 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.
- h. Describe any projections for laboratory resource needs in the event of an outbreak. How would the requesting region meet the projected needs?

8. Emergency preparedness and response

The requesting region should provide sufficient information for APHIS to assess the emergency preparedness measures and response capability and document procedures in place to notify trading partners and other international entities of a disease outbreak.

- a. Provide a copy (in English) of the contingency plan for each disease under evaluation. If not addressed in the contingency plan, please describe the required actions of the official veterinary services and other entities in the event of suspicion or confirmation of a disease outbreak, including the procedures for imposing and releasing quarantines, conducting epidemiological investigations, monitoring and/or depopulating affected premises, disposing of carcasses, and providing indemnity.
- 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.

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.

Appendix C

Provide the information in the table below concerning official entry points into the region.

| | | | | | |
|----------------------------|------------------------|--|--|--|--|
| Entry point name | | | | | |
| Days open each week | | | | | |
| Hours of operation | | | | | |
| Staff | Total | | | | |
| | Veterinarians | | | | |
| | Veterinary technicians | | | | |
| | Administrative | | | | |
| No. consignments received* | | | | | |
| No. refused entry† | | | | | |

*Total number of consignments requiring veterinary inspection received at the entry point in the past 12 months.

†Number of consignments received that were seized, returned, or otherwise denied entry into the region.