

# ***Clarification of Information Requested for Recognition of a Compartment***

## **Introduction**

This document describes the basic information that the Animal and Plant Health Inspection Service (APHIS) requires from official veterinary authorities<sup>1</sup> to initiate a compartmentalization evaluation in accordance with Title 9, *Code of Federal Regulations*, Section 92.2(b).

A compartment is an epidemiologically distinct animal subpopulation defined by husbandry, management, and biosecurity practices, to which a health status for one or more diseases can be assigned. A compartment is made up of at least two sites or facilities, known as “components”. An approved compartment, in an approved compartmentalization program, produces a trade-eligible animal or product known as the “commodity”. For example, components of a compartment whose commodity is hatching eggs or day-old chicks could include a feedmill, farm, hatchery, and/or egg depot.

For the purposes of international trade, APHIS recognizes the compartmentalization program of the official veterinary authority of the requesting region and recognizes individual compartments overseen by the official veterinary authority. For APHIS to approve a compartment, the compartment must be clearly defined and formally recognized by the official veterinary authority.

A compartmentalization evaluation typically consists of initial information gathering, a site visit, and a risk assessment. Any resulting regulatory action to recognize a region’s compartmentalization program, or to recognize individually approved compartments, 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. If submitted information contains confidential business information that would not normally be disclosed to the public, please indicate specifically which words, paragraphs, or pages contain confidential business information. It is APHIS’ intent to protect confidential business information in accordance with legal and regulatory obligations and practices.*

## **1. Scope of the evaluation**

### **a. Provide a detailed description of the proposed compartment and maps showing the following:**

- i. The components of the compartment, including size (by species and number for farms, by commodity and volume produced for other components), and provide maps showing the geographical distribution of the components, if possible.
- ii. Controlled access zones that only authorized personnel or vehicles may enter

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<sup>1</sup> At this time, all components of a compartment must be in one country.

- iii. Biosecure zones in which the high biosecurity standards for the disease(s) of concern apply
- iv. Additional zones and designations (if any)
- v. Main cities and towns within 10 km of any of the compartment components.
- vi. Main roads, railways, and air and sea ports within 10km of any of the compartment components
- vii. Locations of the following entities:
  - Headquarters of the official veterinary authorities of the country in which the compartment operates
  - Headquarters of the entity that oversees the biosecurity and management of the compartment (i.e. company headquarters)
  - Central and regional official laboratories and other laboratories that conduct testing for the disease(s) of concern in the compartment

**b. Identify the animal commodity/ies that the compartment produces that the official veterinary authority requests to remain trade-eligible in the event of a disease outbreak. Estimate the annual production volume of each commodity by the compartment.**

**c. Specify the disease(s) for which an APHIS evaluation is requested. (APHIS will determine the disease(s) to which the compartmentalization request will apply.)**

## **2. Veterinary control and oversight**

*The official veterinary authority of the country in which the compartment operates should provide sufficient information for APHIS to assess the infrastructure of the official veterinary services and the ability of the official veterinary authorities to oversee animal health activities, monitor for disease, and implement disease control measures in the compartment. The questions below are designed to elicit a comprehensive view of the oversight and authority for animal health activities in the compartment; the organizational structure and function of the official veterinary authority; and the personnel, financial, and physical resources available in and to the compartment for veterinary services.*

**a. Describe the organizational structure of the official veterinary authority that oversees the compartmentalization program, and certifies individual compartments.**

**b. Describe the official veterinary authority's system for registering and certifying compartments, and individual components of compartments. Indicate any recordkeeping requirements or practices, including systems for recording and reporting changes in inventory.**

**c. Legal authority for animal health activities related to compartmentalization.**

i. Provide copies (in English) of the legal acts and regulations that grant the authority for the official veterinary services to conduct or audit the following animal health activities:

- Site or facility inspections (e.g. farm)
- Import, export, and internal movement controls (e.g. quarantine)
- 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
- Certification and recognition of the compartment for which the veterinary authority is requesting an APHIS evaluation

**d. Describe how suspicion or confirmation of reportable diseases is communicated by non-compartmentalized and compartmentalized entities to the official veterinary services and provide a copy (in English) of the pertinent legal act or regulation.**

**e. Describe the legal authority of the official veterinary services to dissolve an approved compartment, i.e. to stop trade eligibility of compartment commodities.**

**f. Describe compartment inspection and certification activities conducted by the official veterinary services and the corrective action system for noncompliance with compartmentalization protocols. Provide protocols, if available.**

**g. Describe the financial resources of the official veterinary authority of the country in which the compartment operates that are dedicated to their compartmentalization program. Include the budget for the most recent fiscal year and sources of funding (governmental and nongovernmental).**

**h. Organizational structure of the compartment**

- i. Provide organizational diagram(s) of the entities (e.g. company) that oversee the compartment.
- ii. Describe the functions of each component of the compartment and the division of responsibilities among each of them. What procedures are in place to ensure coordination and communication among these entities?
- iii. Describe human resources (i.e. staffing) and their roles and responsibilities (e.g. auditing).
  - Indicate the minimum qualifications required for veterinary and technical staff employed full-time by the compartment. Describe the training requirements for new and established staff, as well as any pertinent simulation or field exercises conducted in the last 3 years.

- Indicate the number of veterinarians and veterinary technicians that perform work for the compartment but are not full-time employees of the compartment, such as consultants. Describe the procedures for authorization, the policies in place to safeguard against conflicts of interest, and any requirements for supervision by the official veterinary authority.
- vi. Identify any governmental or nongovernmental entities other than the official veterinary authority that participate in, monitor, or provide oversight of official animal health and disease control activities in the compartment. Describe the roles and responsibilities of these entities.
  - v. Describe the compartment's budget for conducting animal health activities, including the budget to support biosecurity practices, vaccines and medications, facilities maintenance and repair, staffing, and transportation.

### **3. Disease history and vaccination practices**

*The official veterinary authority of the country in which the compartment operates should provide sufficient information to enable a thorough understanding of the history of the disease(s) under evaluation in the compartment and its surrounding territory, including prior control measures and revisions to those measures as appropriate, to facilitate APHIS' assessment of export risk.*

#### **a. History of disease outbreaks**

- i. Provide maps showing the location(s) of cases and/or outbreaks of the disease(s) under evaluation, in both wild and domestic species, that have occurred in the country in which the compartment operates within the last 5 years. For each outbreak, provide the following information:
  - Species affected
  - Number of animals and premises involved
  - Mechanism by which the case or outbreak was detected
  - Probable source of infection
  - Results of the epidemiological investigation
  - Control measures implemented
  - Disposition of infected and exposed animals
  - Time required for control and eradication
- ii. Provide a map showing the range of any known wildlife reservoirs of the disease(s) under evaluation.
- iii. Provide maps and a description of the outbreak history within the component AND within the country in which the component operates of the compartment, including biosecurity measures and management practices that have been implemented since the resolution of the last outbreak.

## **b. Vaccination practices**

i. Provide the following information concerning vaccination practices in the compartment AND in the country in which the compartment operates 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 and commodity movement and traceability**

*The official veterinary authority of the country in which the compartment operates should provide sufficient information for APHIS to assess the movement patterns of animals, commodities, people, and other fomites within, into, and out of the compartment.*

### **a. Identification and registration**

- i. Describe how components within the compartment are registered, and how such identification and registration distinguishes them from other facilities in the country. Provide copies (in English) of regulations pertaining to animal identification, commodity traceability, and component registration, focusing on species susceptible to the disease(s) under evaluation.
- ii. Describe the system used to identify individual animals or groups of animals, or individual commodity/ies or groups of commodities, within the compartment and identify the implementing authority. Indicate any recordkeeping requirements or practices, including what records are kept, by whom, where, and for how long.
- iii. Describe compliance monitoring and enforcement activities as they pertain to component registration, animal identification and registration, commodity traceability, as well as the corrective action system for noncompliance.

### **b. Livestock and commodity movement *into* the compartment**

- i. List the type, source, and amount of animals, products (e.g. feed), supplies, and equipment that are brought into the compartment from outside of the compartment, and the frequency of their introduction.

- ii. Provide process diagrams, flow charts, or descriptions showing the movements of these entities into the compartment. Describe the husbandry, management, and biosecurity protocols implemented to prevent the introduction of disease agents into the compartment by these entities.
- iii. Describe the procedures by which the compartment ascertains, documents, and certifies the eligibility, disease status and/or biosecurity measures required for animals, products, supplies, and equipment brought into the compartment from outside of the compartment.
- iv. Describe any quarantine, isolation, or testing practices intended to identify and prevent the introduction of disease agents into the compartment by livestock and commodities.
- v. Describe the mechanisms in place to track live animals or commodities moved into the compartment. How are tracking records maintained and who is responsible for oversight of the tracking system?
- vi. Describe compliance monitoring and enforcement activities as they pertain to animal and commodity movements into the compartment, as well as the corrective action system for noncompliance.

**c. Livestock and commodity movement *within* the compartment.**

- i. List the entities that may come in to contact with the species within the compartment that are susceptible to the disease(s) under evaluation or could contribute to the spread of the hazards under evaluation. These entities may include livestock, wildlife, or other animals; and fomites such as employees, visitors, vehicles, feed, equipment, and others.
- ii. Provide process diagrams, flow charts, or descriptions showing the movements of these entities into the compartment. Describe the husbandry, management, and biosecurity protocols implemented to prevent the introduction of disease agents into the compartment by these entities.
- iii. Describe any official requirements or management practices for movement of susceptible livestock species or commodity/ies from one component to another within the compartment (e.g., a health certificate, permit, or other notification or authorization form). Indicate any recordkeeping requirements, including what records are kept, by whom, where, and for how long.
- iv. Describe compliance monitoring and enforcement activities as they pertain to animal and commodity movements within the compartment, as well as the corrective action system for noncompliance.

**d. Livestock and commodity movement *out of* the compartment**

- i. Identify the exit point/export point for any commodity that would be trade eligible under the approved compartment.

## **5. Epidemiological separation from potential sources of infection**

*The official veterinary authority of the country in which the compartment operates should provide sufficient information to enable APHIS to evaluate the ability of the compartment to prevent incursions of the disease(s) under evaluation. Relevant risk factors include the presence of the disease(s) in the country in which the compartment operates with epidemiological links to the requesting compartment, biosecurity practices to prevent disease introduction, trading practices, and inspection procedures by the official veterinary services.*

### **a. Biosecurity**

- i. Describe the physical separation (e.g. fencing, natural borders) of each component within the compartment.
- ii. Provide process diagrams or flow charts of each component of the compartment that show where and how people, products (e.g. feed), supplies, equipment, and animals can be moved into or out of the component. Provide a description of the methods used to deter unauthorized entry into biosecure areas for each component (e.g. signs, locks, fences).
- iii. Describe the routine biosecurity measures (or other husbandry or management practices) implemented to prevent introduction of disease into the compartment from adjacent holdings or facilities.
- iv. Provide the written routine biosecurity protocols, and documentation of training by all personnel responsible for implementing these protocols.
- v. Are additional biosecurity measures, or other contingencies, implemented during a high risk period (e.g. incidence of disease in the country)? If so, provide protocols and plans, including documentation of training by all personnel responsible for implementing these protocols.
- vi. Describe cleaning, sanitation, and control of vehicles prior to entering biosecure areas.

### **c. Requirements for entry**

- i. Describe disease testing requirements for the disease(s) under evaluation, veterinary inspection requirements, and/or quarantine requirements for live animals entering the compartment. Where are the quarantine facilities located and who maintains oversight?
- ii. Describe the documentation required for entry of commodities or other potential carriers that could harbor agents of the disease(s) under evaluation into the compartment and provide examples of pertinent documents.

### **d. Inspection practices and procedures**

- i. Describe in detail the protocols and standard operating procedures for veterinary inspection and control of animals or commodities or fomites introduced into the compartment from outside of the compartment, including the system for selecting

consignments for physical examination and sampling. Provide copies (in English) of pertinent guidance documents, protocols, and written procedures.

ii. Describe any other procedures at compartment entry points intended to prevent disease incursion through introduction of animals or commodities or other fomites into the compartment.

iii. Describe the procedures for disposition of animals, commodities, or fomites that do not pass official veterinary inspection or are found to be noncompliant with compartment protocols.

## **6. Surveillance**

*The official veterinary authority of the country in which the compartment operates 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 and infection data should be sufficient to provide confidence in the disease status of the country.*

### **a. Active surveillance**

i. Provide planned and actual surveillance data for domestic livestock in the compartment, and livestock and wildlife in the country in which the compartment operates, near the compartment, for each disease under evaluation:

- The target population(s)
- Risk factors considered in the surveillance approach
- Targeted prevalence and confidence level for detection
- Types of samples collected
- Frequency of sampling

ii. Provide the targeted and actual numbers of samples collected and tested 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 within the compartment for each disease(s) 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 and of compartment management 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 authority over the past 3 years and describe the follow-up measures taken in each case.

## **7. Diagnostic laboratory capabilities**

*The official veterinary authority of the country in which the compartment operates 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 that the country uses to conduct surveillance activities for the disease(s) under evaluation. Specify which laboratories test samples from the compartment. Indicate which laboratories conduct screening tests and which laboratories conduct confirmatory tests for the disease(s) under evaluation. Describe the certification or accreditation requirements for these laboratories, and whether those requirements are consistently met.**

**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 agents of the disease(s) under evaluation, or evidence of infection with the agent, including the sensitivity and specificity of each. What tests or procedures are conducted for agent isolation, identification, and typing? Describe how diagnostic tests are approved or licensed for use.**

**d. Describe the procedures for sample collection from domestic livestock and wildlife, as well as the procedures for transport of samples to the laboratory.**

**e. 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.**

**f. Describe the procedures for reporting test results, including to whom they are reported and the average time between sample collection and reporting. Estimate the time required to confirm a diagnosis.**

- g. Describe any projections for laboratory resource needs in the event of an outbreak. How would the requesting country, and the compartment, meet the projected needs.**

## **8. Emergency preparedness and response**

*The official veterinary authority of the country in which the compartment operates 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 compartment component for each disease under evaluation that would be implemented during a high risk period (e.g. disease detection in the country). If not addressed in the compartment/component contingency plan, please describe the required actions of the official veterinary authority of the country in which the compartment operates and all other entities involved in the response to the 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. 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.**
- c. Describe the procedures in place to ensure that the official veterinary authority of the country in which the compartment operates inform pertinent international entities of a disease outbreak in a timely manner.**
- d. Describe enhanced management procedures or biosecurity practices during periods of high risk (e.g.. incidence of the disease in the country). Please provide relevant protocols, in English.**