**Introduction:** A representative of the central competent veterinary authority of any country or countries may request that the Animal and Plant Health Inspection Services (APHIS) classify a region for bovine brucellosis (*Brucella abortus*). A region is defined as a geographical land area identifiable by geological, political, or surveyed land boundaries. 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.

Title 9, *Code of Federal Regulations,* section 93.441 (9 CFR 93.441) describes the process for requesting regional classification for brucellosis. This document clarifies the information required for APHIS to evaluate a region. APHIS will conduct a site visit to verify and complement the information provided. Any resulting regulatory action will reflect the conclusions of the evaluation. The evaluation methodology and criteria are further described in *APHIS Evaluation Procedures for Bovine Brucellosis: Classification of Foreign Regions*.

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

**Regulatory authority:** 9 CFR 93.441, process for requesting regional classification for bovine brucellosis.

# 1. Region boundaries and composition

1.1 Provide a map of the region generated using GPS or similar technology that clearly shows:

* The geographic boundaries;
* The major administrative and/or geopolitical divisions (states, counties, municipalities); and
* Any defining topographic features (rivers, mountain ranges).

1.2 List the major administrative divisions comprising the region. If the region borders cross through any administrative units, provide GPS data sufficient to map the boundary line.

1.3 Describe any higher risk zones[[1]](#footnote-1) associated with the region under evaluation:

* Provide a map and list of administrative divisions for each zone as described in points 1.1 and 1.2;
* Describe surveillance for brucellosis in each higher risk zone using Table 1;
* Estimate the herd brucellosis prevalence within the higher risk zone; and
* Describe any measures in place to reduce the brucellosis prevalence in the higher-risk zone(s).

**Table 1: Surveillance in the higher risk zone(s) and buffer zone(s)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Zone** | **Year** | **Total herds**  | **Total eligible head** | **Herds tested** | **Eligible head tested** | **Infected animals** | **Infected herds** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

1.4 List the adjacent regions and estimate the bovine brucellosis prevalence in each.

1.5 Describe any buffer zones that the region has established with adjacent regions or higher risk zones:

* Provide a map and list of administrative divisions for each zone as described in points 1.1 and 1.2;
* Describe surveillance for bovine brucellosis in each buffer zone using Table 1.

1.6 State the classification level the region is seeking for bovine brucellosis (see also 9 CFR 93.440).

# 2. Veterinary control and oversight (including notification)

## 2.1. Organization and infrastructure

* + 1. Briefly describe the history of brucellosis in the region and development of the control program.

2.1.2 Describe the current organizational structure of the brucellosis control program in the region, including:

* The competent authority (CA) for the brucellosis program;
* Any other entities to which authority for control of brucellosis in the region is delegated; and
* Organizational charts for the CA and other authorized entities.

2.1.3 Describe the procedures and requirements for authorizing and training personnel to conduct activities for the official brucellosis program and provide the pertinent sections of the program standards[[2]](#footnote-2) that establish these parameters.

2.1.4 Summarize the workforce available to implement the brucellosis program in the region, including official veterinarians, authorized private veterinarians, veterinary technicians, and other personnel.

2.1.5 Indicate the financial resources allocated to the brucellosis program in the 3 previous budget cycles, when and how the funds are distributed to the brucellosis program, and how the CA ensures that financial resources are adequate to support brucellosis program activities.

2.1.6 Describe any procedures in place to promote collaboration and standardization of brucellosis eradication efforts in multi-jurisdictional regions (i.e., more than one state, province, country, etc.).

## 2.2 Legal authority

2.2.1 List the legal statutes that authorize the CA and/or other responsible entities to carry out the following actions and provide the pertinent sections (in English):

* Establish buffer zones (if applicable);
* Establish higher-risk zones (if applicable);
* Require notification of and follow-up for suspect and/or confirmed brucellosis cases;
* Inspect bovine animals and obtain records on farm;
* Inspect bovine animals at movement control checkpoints;
* Inspect bovine animals at slaughter;
* Apply brucellosis test to any livestock;
* Establish and enforce quarantine and movement restrictions on animals or herds;
* Establish and enforce disposition processes for infected animals and affected herds;
* Conduct surveillance for brucellosis;
* Require reporting of abortions in bovine animals (if applicable);
* Require vaccination against *B. abortus* (if applicable);
* Control the movement of livestock into, within, and out of the region;
* Authorize, train, and oversee private veterinarians authorized to conduct official program activities;
* Authorize, train, and oversee veterinarians conducting live-animal testing for brucellosis;
* Authorize, train, and oversee veterinarians conducting post-mortem exams for brucellosis;
* Establish and enforce penalties for noncompliance with brucellosis program requirements; and
* Require identification of bovine animals, herds, and premises.
	+ 1. Describe the system(s) in place to detect and correct noncompliance with brucellosis program requirements, including the legal framework to process violations. How many noncompliance actions were processed over the last 3 years and what were the outcomes?

# 3. Prevalence of bovine brucellosis

## 3.1 Animal and herd demographics

3.1.1 List the domestic species subject to regulation under the brucellosis control program.

3.1.2 Summarize the animal and herd demographic data within the region using Table 2 and describe the methodology used to obtain this data, including the dates of the most recent census.

**Table 2: Animal and herd demographics in the region**

|  |  |  |
| --- | --- | --- |
| **Species/Type** | **Total herds** | **Total head** |
| Bison/Buffalo |  |  |
| Dairy cattle |  |  |
| Beef cattle |  |  |
| Mixed-use cattle |  |  |
| **Total** |  |  |

3.1.3 Summarize the production parameters for bovine herds within the region using Table 3.

**Table 3: Production parameters for bovine herds within the region**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species/Type** | **Calving rate** | **Mortality** | **Culling rate** | **Age at weaning** |
| Bison/Buffalo |  |  |  |  |
| Dairy cattle |  |  |  |  |
| Beef cattle |  |  |  |  |
| Mixed-use cattle |  |  |  |  |

## 3.2 Period prevalence calculations

3.2.1 State the criteria used to officially classify the brucellosis status of bovine animals and herds. Provide the pertinent sections of the program standards that establish these criteria (in English).

* + 1. Provide data on all brucellosis-affected herds in the region during the evaluation period[[3]](#footnote-3) using Table 4.

**Table 4: Data on brucellosis-affected herds during the evaluation period**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Herd ID** | **Lab results issued** | **Case initiated** | **Date released** | **Method released¥** |
| **Month** | **Year** | **Month** | **Year** | **Month** | **Year** | **T&R** | **Depop** |
| *Example* | *11* | *18* | *11* | *18* | *3* | *19* |  | *X* |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| *¥T&R = Test and removal; Depop = depopulation* |

## 3.3 Other sources of infection

3.3.1 Describe any known wildlife reservoirs of *B. abortus* within the region, including species, geographic distribution of the affected population, estimated prevalence, and vaccination strategies (if applicable). What measures are in place to mitigate the risk of transmissions to domestic bovine animals?

3.3.2 Describe surveillance for *B. abortus* conducted in other wildlife populations, including the targeted surveillance numbers, number of animals tested over the last 3 years, and results.

3.3.3 Briefly describe *B. abortus* surveillance and control measures in non-bovine domestic species:

* Indicate the number of herds and animals by species;
* Describe the overall surveillance plan and test(s) used;
* Describe the surveillance conducted during the evaluation period (may use Table 1 or 9);
* Indicate the number of brucellosis-affected herds and estimated prevalence; and
* Describe the procedures for managing brucellosis-affected herds.

# 4. Surveillance

## 4.1 Framework

4.1.1 Describe the overall plan for *B. abortus* surveillance in bovine animals in the region, including the main components (e.g., slaughter sampling, first point/market testing, movement testing), target prevalence of detection, and confidence level. What measures are in place to validate each component?

## 4.2 Slaughter surveillance (if applicable)

4.2.1 Provide the program standards for slaughter surveillance (in English), including procedures for:

* Ensuring proper documentation, animal ID, and record keeping;
* Determining test-eligible animals;
* Correlating animal identification with blood and tissue samples;
* Inspecting carcasses for brucellosis;
* Sampling, preserving, and documenting submission of samples for laboratory diagnostics;
* Monitoring compliance of slaughter establishments with surveillance requirements; and
* Official supervision of slaughter inspection and sampling practices.

4.2.2 Summarize slaughter inspection and brucellosis sampling during the evaluation period using Table 5.

**Table 5:** **Cattle slaughtered and blood sample submissions during the evaluation period**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of the plant** | **Location** | **Total cattle slaughtered** | **Intact cattle ≥ 12 months of age** |
| **No. slaughtered** | **No. sampled for brucellosis** | **No. samples positive for brucellosis** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **Total** | **NA** |  |  |  |  |

4.2.3 Indicate the number of intact bovine animals exiting the region during the evaluation period, purpose (feedlot, pasture, breeding, slaughter, etc.), and how many were tested for brucellosis prior to exit.

## 4.3 Live animal testing

4.3.1 Provide the following information for each form of brucellosis surveillance conducted in live bovine animals (e.g., first point or market testing, ownership changes, targeted herd testing):

* Target population(s);
* Samples taken and test(s) used;
* Criteria for test eligibility;
* Training and oversight of the sample collectors;
* Number of tests conducted during the evaluation period and results.

## 4.4 Other surveillance

4.4.1 Describe any other surveillance conducted for *B. abortus* in bovine populations (e.g., abortion screening), including the information in point 4.3.1 as applicable.

# 5. Diagnostic testing for bovine brucellosis

5.1 List the laboratories that conduct brucellosis diagnostic tests for official program purposes.

5.2 Describe the requirements for laboratory accreditation and re-accreditation.

5.3 Indicate the official tests for brucellosis conducted by each laboratory and the purpose/use of each test.

5.4 Describe the testing algorithm(s) for confirming or ruling out *B. abortus*.

5.5 Indicate the personnel training requirements and the quality control measures in place for each test.

5.6 Describe the procedures for competency or proficiency testing of laboratory personnel.

5.7 Describe the procedures for monitoring and reporting on the quality of incoming samples.

5.8 Describe the process for evaluating new tests proposed for official use in the brucellosis program.

# 6. Epidemiological investigations

6.1 Describe the personnel resources available for conducting epidemiological investigations, including organization, staffing, educational and training requirements, and supervision.

6.2 Provide the program standards for conducting epidemiological investigations (in English).

6.3 Describe the procedures for investigating infected animal(s) detected at slaughter, tracing the animal(s) to the most probable herd of origin (MPHO) and confirming or ruling out *B. abortus* infection.

6.4 Provide the data in Table 6 on traceback evaluations during the evaluation period.

**Table 6: Traceback investigations during the evaluation period**

|  |  |  |  |
| --- | --- | --- | --- |
| **Source of cases** | **No. cases** | **No. cases traced and MPHO¥****tested** | **No. MPHOs****confirmed infected** |
| Slaughter cases from herds in the region |  |  |  |
| Slaughter cases reported by another region |  |  |  |
| Other cases (first point, market, movement)  |  |  |  |
| **Total (all cases)** |  |  |  |
| *¥MPHO: Most Probable Herd of Origin* |

6.5 Describe the procedures for investigating non-negative brucellosis test results in a live bovine animal, including any follow-up testing and the disposition of the animal while the status is determined. How many such investigations occurred during the evaluation period?

# 7. Affected herd management

7.1 Describe the procedures for managing brucellosis-affected herds through depopulation.

7.2 Provide the procedures for managing brucellosis-affected herds through test and removal, including the diagnostic test(s) used, disposition of non-negative animals, and testing plan to assure freedom.

7.3 Provide the program standards for managing brucellosis-affected herds (in English).

7.3 Describe the procedures for determining whether wildlife surveillance or testing of susceptible non-program animals is necessary around a known brucellosis-affected herd and the results of such testing.

7.4 Indicate whether vaccination is used to control the spread of brucellosis infection in affected herds. If so, what vaccine is used, what is the vaccination protocol, and how are vaccinates identified?

# 8. Control of livestock movement

## 8.1 Animal identification and traceability

8.1.1 Describe the system(s) in place for bovine animal and herd identification.

* + 1. Describe the system(s) in place to track bovine animal movements (traceability systems).

8.1.3 Describe the system(s) in place to detect and correct noncompliance with animal identification and traceability requirements, including the legal framework to process violations. How many noncompliance actions were processed in the last 3 years and what were the results?

## 8.2 Entry into the region

8.2.1 Describe the requirements for entry of bovine animals into the region, including animal identification, brucellosis testing, and documentation (import permit, health certificate, transit guide, etc.). Provide the pertinent sections of the program standards (in English).

8.2.2 Indicate the number, purpose, and source of bovines entering the region during the evaluation period.

8.2.3 Provide a map of the border ports and/or other inspection facilities established to control the movement of bovine animals into or out of the region under evaluation.

8.2.4 Describe the personnel resources available for inspection of bovine animals at the border ports and/or other inspection facilities, including organization, staffing, supervision, and training requirements.

## 8.3 Export of bovine animals

8.3.1 Detail the procedures and requirements for certification of bovine animals for export, including verification procedures and any training provided to the certifying officials.

8.3.2 Provide the program standards for approval and oversight of facilities where bovine animals are gathered for export (in English). How many of these facilities are there in the region? Who is responsible for official supervision of these facilities and what training do they receive?

## 8.4 Miscellaneous

8.4.1 Provide the program standards for approval and oversight of approved (quarantine) feedlots[[4]](#footnote-4) (in English). How many approved feedlots are there in the region? Who is responsible for official supervision of these facilities and what training do they receive?

8.4.2 Provide the program standards for accreditation (or certification) of brucellosis-free herds in the region (in English), if applicable. How many such herds are there in the region? Who is responsible for ensuring that the requirements for accreditation and re-accreditation are met?

# 9. Vaccination (if applicable)

9.1 Describe the history of vaccination of bovine animals against *B. abortus* in the region, including when vaccination started and the vaccine(s) used historically and currently. Estimate the percentage of the intact bovine population that has been vaccinated.

9.2 Describe the brucellosis vaccination plan, including:

* The eligible population (age of first vaccination and any follow-up vaccination);
* The vaccine used (type, manufacturer, concentration, dosage);
* Identification of vaccinated animals;
* Documentation of vaccination; and
* Differentiation of vaccinated and infected animals (DIVA).
1. Higher risk zone: Zone created by national or subnational authorities which is within or adjacent to the region under evaluation and consists of higher prevalence administrative units under the same national and/or subnational authority. [↑](#footnote-ref-1)
2. Program standards = regulations, manuals, guidelines, instructions, standard operating procedures, etc. [↑](#footnote-ref-2)
3. Evaluation period = previous 24 months for Levels I and II, previous 12 months for Levels III and IV (see also 9 CFR 93.437). [↑](#footnote-ref-3)
4. Approved (quarantine) feedlot = terminal feedlot authorized to receive animals of higher risk for bovine TB. [↑](#footnote-ref-4)