

APHIS Bovine Tuberculosis (TB) Evaluation Questionnaire

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 tuberculosis (TB) caused by *Mycobacterium bovis*. 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 93.438 (9 CFR 93.438) describes the process for requesting regional classification for bovine TB. This document clarifies the information required for APHIS to evaluate a region. Certain definitions and information requirements in this document that are specific to Mexico are designated with an (M). 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 Tuberculosis (TB): Classification of Foreign Regions*.

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

Regulatory authority: 9 CFR 93.438, process for requesting regional classification for tuberculosis.

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 zones¹ 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 bovine TB in each higher risk zone using Table 1;
 - Estimate the herd TB prevalence within the higher risk zone; and
 - Describe any measures in place to reduce the TB 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 head	Herds tested	Head tested	Reactors	Infected herds

- 1.4 List the adjacent regions and estimate the bovine TB prevalence in each.
- 1.5 Describe any buffer zones that the region has established with adjacent regions or higher risk zones:
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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.

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

1.6 State the classification level the region is seeking for bovine TB (see also 9 CFR 93.437).

2. Veterinary control and oversight (including notification)

2.1. Organization and infrastructure

2.1.1 Briefly describe the history of *M. bovis* in the region and development of the control program.

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

- The competent authority (CA) for the bovine TB program;
- Any other entities to which authority for control of bovine TB 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 bovine TB program and provide the pertinent sections of the program standards that establish these parameters.

2.1.4 Summarize the workforce available to implement the bovine TB 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 bovine TB program in the 3 previous budget cycles, when and how the funds are distributed to the TB program, and how the CA ensures that financial resources are adequate to support TB program activities.

2.1.6 Describe any procedures in place to promote collaboration and standardization of TB 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 bovine TB cases;
- Inspect bovine animals and obtain records on farm;
- Inspect bovine animals at movement control checkpoints;
- Inspect bovine animals at slaughter;
- Apply TB 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 bovine TB;
- 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 bovine TB;

- Authorize, train, and oversee veterinarians conducting post-mortem exams for bovine TB;
- Establish and enforce a penalty system for noncompliance with TB program requirements; and
- Require identification of bovine animals, herds, and premises.

2.2.2 Describe the system(s) in place to detect and correct noncompliance with TB 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 TB

3.1 Animal and herd demographics

3.1.1 List the domestic species subject to regulation under the bovine TB 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 TB status of bovine animals and herds. Provide the pertinent sections of the program standards² that establish these criteria (in English).

3.2.2 Provide data on all TB-affected herds in the region during the evaluation period³ using Table 4.

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

Herd ID	Lab results	Case initiated	Date released	Method
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² Program standards = regulations, manuals, guidelines, instructions, standard operating procedures, etc.

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).

	issued						released ^y	
	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 *M. bovis* 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 *M. bovis* 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 *M. bovis* 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 TB-affected herds and estimated prevalence; and
 - Describe the procedures for managing TB-affected herds.

4. Surveillance

4.1 Framework

- 4.1.1 Describe the overall plan for *M. bovis* surveillance in bovine animals in the region, including the main components (e.g., slaughter inspection, tuberculin testing), prevalence of detection, and confidence level. What measures are in place to validate each surveillance component?

4.2 Slaughter surveillance

- 4.2.1 Provide the program standards for slaughter surveillance (in English), including procedures for:
 - Ensuring proper documentation, animal ID, and record keeping;
 - Correlating animal identification with carcass parts during slaughter;
 - Qualifying and training inspectors;
 - Inspection of carcasses for bovine TB;
 - Sampling, preserving, and documenting submission of granulomatous lesions for diagnostics; and
 - Monitoring compliance of slaughter establishments and inspectors.
- 4.2.2 Summarize slaughter inspection and granuloma submissions during the evaluation period using Table 5. At a minimum, include all plants that slaughtered at least 2,000 adult bovine animals (≥ 24 months of age) during this timeframe plus any other plants slaughtering primarily cull dairy cows.

Table 5: Cattle slaughtered and granuloma submissions during the evaluation period

Plant ID	Total cattle killed		Total cattle killed w/inspection	No. Granulomas from regular-kill cattle [*]		No. Granulomas positive for TB	
	Total	From the region		Total	From the region	Histopathology	Bacteriology
<i>Example</i>	2500	2000	2300	1	1	1	1
Total							
<i>*Regular-kill cattle—does not include tuberculin reactors or exposed animals</i>							

4.2.3 If not all plants in the region were included in Table 5, indicate the total number of plants, the number of bovine animals slaughtered during the evaluation period, and the percentage that received postmortem inspection for granulomatous lesions. Who is responsible for official supervision of these facilities and what training do they receive?

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

4.3 Live animal testing

4.3.1 Provide the following information for each form of TB surveillance conducted in live bovine animals:

- Target population(s);
- Samples taken and/or test(s) used;
- Criteria for test eligibility; and
- Training and oversight of the sample collectors.

4.3.2 If tuberculin testing is conducted, state the type(s), concentration(s), and supplier(s) of the tuberculin.

4.3.3 Describe the performance standard for TB testing of live bovine animals and the monitoring procedures in place. How many veterinarians are authorized to conduct TB testing and what percentage meet the performance standard annually?

4.3.4 Summarize the number of surveillance tests conducted during the evaluation period using Table 6.

Table 6: Live animal surveillance conducted during the evaluation period

Reason for testing	Test used	No. Herds	No. Head	No. positive results	No. infected herds

Total					

5. Diagnostic testing for bovine TB

- 5.1 List the laboratories that conduct TB diagnostic tests for official program purposes.
- 5.2 Describe the requirements for laboratory accreditation and re-accreditation.
- 5.3 Indicate the official tests for bovine TB conducted by each laboratory and the purpose/use of each test.
- 5.4 Describe the testing algorithm(s) for confirming or ruling out *M. bovis*.
- 5.5 Provide data on response times in days for each laboratory using Table 7.

Table 7: Laboratory response times during the evaluation period

Measure	[Lab name]		[Lab name]	
	Median	Range	Median	Range
Slaughter to reception				
Reception to histopathology results				
Reception to PCR results				
Reception to bacteriology results				
Reception to typing results				

- 5.6 Provide data on samples submitted and tests conducted by each laboratory using Table 8.

Table 8: Laboratory testing data during the evaluation period

Measure	[Lab name]	[Lab name]
Total number of samples received		
No. histocompatible samples		
No. culture positive samples (<i>Mycobacteria</i> species)		
No. histocompatible samples that were culture positive		
No. histocompatible samples that were culture negative		
No. PCR tests conducted		
No. PCR positive samples (TB complex)		

- 5.7 Indicate the personnel training requirements and the quality control measures in place for each test.
- 5.8 Describe the procedures for competency or proficiency testing of laboratory personnel.
- 5.9 Describe the procedures for monitoring and reporting on the quality of incoming samples.
- 5.10 Describe the process for evaluating new tests proposed for use in the official bovine TB 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 slaughter traceback investigations (in English), describe the criteria used to evaluate the overall performance of this system, and provide the data in Table 9.

Table 9: Slaughter traceback investigations during the evaluation period

Source of cases	No. cases	No. cases traced and MPHOU ^y tested	No. MPHOU confirmed infected
Slaughter cases from herds in the region			
Slaughter cases reported by another region			
(M) Slaughter cases reported by USDA			
Total (all cases)			
^y MPHO: Most Probable Herd of Origin			

- 6.3 Indicate the number of cases detected at slaughter in the region that originated from other regions during the evaluation period. What are the procedures for reporting these cases to the region of origin?
- 6.4 Provide the program standards for investigating non-negative TB test results in live bovine animals. Describe the number of these investigations conducted during the evaluation period and results.

7. Affected herd management

- 7.1 Provide the program standards for managing TB-affected herds through depopulation (in English).
- 7.2 Provide the program standards for managing TB-affected herds through test and removal (in English).
- 7.3 Describe the procedures for determining whether wildlife surveillance or testing of susceptible non-program animals is necessary around a known TB-affected herd and the results of any such testing.
- 7.4 Indicate whether vaccination is used to control the spread of TB infection in affected herds or for other purposes. If so, what vaccine is used 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.
- 8.1.2 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, TB 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 (in English).⁴ 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 of TB-free herds in the region (in English), if applicable. How many accredited herds are there in the region? Who is responsible for ensuring that the requirements for accreditation and re-accreditation are met?
- 8.4.3 (M) Provide the program standards for entry of cattle from certified-free herds. How many animals from certified-free herds entered the region during the evaluation period and from where? Provide the date of entry and the date of post-entry TB testing, as well as the results.

⁴ Approved (quarantine) feedlot = terminal feedlot authorized to receive animals of higher risk for bovine TB.