APHIS Evaluation Procedures for Bovine Tuberculosis (TB) Classification of Foreign Regions

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Introduction

This document describes the process by which APHIS evaluates and classifies foreign regions for tuberculosis (*Mycobacterium bovis*) in bovine animals. The essential considerations for such evaluations are outlined in title 9, Code of Federal Regulations, part 93.438 (CFR 93.438), as follows:

- 1. Region boundaries and composition
- 2. Veterinary control and oversight (including notification)
- 3. Prevalence of bovine TB
- 4. Surveillance
- 5. Diagnostic testing for bovine TB
- 6. Epidemiological investigations
- 7. Affected herd management
- 8. Control of livestock movement

A region seeking APHIS classification and recognition of TB status must demonstrate that it has in place a TB program that meets or exceeds the minimum standards in 9 CFR 93.438. This process starts with the region submitting the *APHIS Bovine Tuberculosis (TB) Evaluation Questionnaire*, which details the information and data required for APHIS to evaluate each factor. Initial information gathering is typically followed by one or more onsite visits to verify and complement the information provided. APHIS teams conduct the onsite visits using the *APHIS Onsite Bovine Tuberculosis Review Template*, which prompts team members to record and analyze critical data and information in a standardized format.

APHIS teams assess both program elements and program implementation. Program elements are the essential building blocks that support program operations, without which the program may be fundamentally flawed (e.g., legal authority, comprehensive program standards,¹ financial and personnel resources, monitoring and oversight systems, etc.). APHIS therefore assesses the existence or absence of a program element as a binary variable: yes or no. APHIS evaluates the quality of a TB program by examining on certain critical actions necessary for program implementation within each factor, using a 5-point scale:

- 1 = Very Poor or Almost Never
- 2 = Poor or Rarely
- 3 = Fair or Sometimes
- 4 = Good or Usually
- 5 = Very Good or Almost Always

APHIS teams record the findings using the *Review Template* and associated checklists as described below. The findings are summarized for each factor in tabular form. A given TB program will optimally have all program elements in place and score above 3 on program execution; however, apparent program deficiencies in one are may be balanced by other findings. The TB status of a region that meets or exceeds the minimum program standards is determined by the herd prevalence, as described in 9 CFR 93.437. Status levels range from Level I with a prevalence less than 0.001 percent to Level IV with a prevalence less than 0.5 percent. APHIS classifies

¹ Program standards = regulations, manuals, guidelines, instructions, standard operating procedures, etc.

regions that it has not evaluated, as well as those in which prevalence is equal to or greater than 0.5 percent or the TB program does not meet the minimum standards in 9 CFR 93.438, as Level V.

The following sections describes the evaluation process in more detail, focusing on each factor in turn. Key program elements and the procedures by which APHIS assesses both program elements and execution are briefly described in each section, along with the corresponding summary table from the *Review Template*.

Note: in rare instances, APHIS may have initiated a TB status evaluation some years before the provisions of 9 CFR 92.438 came into effect and the corresponding evaluation procedures were fully developed. In these cases, APHIS will assess the region against the criteria in 9 CFR 92.438 but the format of the evaluation may differ.

Table of contents

Introduction 2						
valuation factors						
1. Region boundaries and composition						
2. Veterinary control and oversight						
3. Prevalence of bovine TB						
3.1 Animal and herd demographics						
3.2 Herd prevalence						
3.3 Other sources of infection						
4. Surveillance						
5. Diagnostic testing for bovine TB						
6. Epidemiological investigations						
7. Affected herd management 11						
8. Control of livestock movement						
8.1 Animal identification and traceability12						
8.2 Entry into the region						
8.3 Export to the United States14						
8.4 Approved feedlots15						
8.5 Accreditation of TB-free herds						
Appendices						

Evaluation factors

1. Region boundaries and composition

The APHIS team initially examines the geographic extent of the region seeking classification and confirms that the borders are clearly defined along administrative boundaries and/or distinct geographic barriers. The team determines the composition of the region by confirming the administrative units (states, provinces, prefectures, counties, municipalities, etc.) included. If the regional authorities have created a higher-risk zone² by "zoning out" certain higher-prevalence administrative units, the borders and composition of this higher-risk zone must be clearly defined as well. If a border of the higher-risk zone bisects an administrative unit, the subunits included within the region seeking classification must be identified and the border mapped using global positioning system (GPS) data points. The border should not bisect individual premises. Ideally, the TB program has developed and is actively implementing a plan to reduce the TB prevalence in any defined higher-risk zone(s).

The APHIS team identifies the regions adjacent to the region seeking classification and gathers estimates of the TB prevalence of each. The team further assesses the mitigations in place to prevent and/or detect introduction of bovine TB from adjacent higher-risk regions and established higher-risk zones, if present. A buffer zone should be in place along parts of the region border that are not adequately protected by geographic barriers, with annual testing of the herds within the buffer zone to detect TB introduction.

The summary evaluation criteria for region boundaries and composition are listed in Table 1.

Table 1: Evaluation criteria—region boundaries and composition

Program elements
The geographic extent and boundaries of the region are clearly defined.
Buffer zones or other measures to prevent TB introduction are clearly established.
Regular (annual) surveillance of herds adjacent to higher-risk zones and regions is required.
A comprehensive plan is in place to reduce TB prevalence in higher-risk zones.
Program execution
Regular (annual) surveillance of herds adjacent to higher-risk zones and regions is conducted.
The TB program is actively working to reduce TB prevalence in higher-risk zones.

2. Veterinary control and oversight

The APHIS team assesses the organizational structure and resources of the bovine TB program at the central, regional, and local levels, as well as the personnel and financial resources available for program activities. The team interacts with regulatory and supervisory officials at all levels to assess overall qualifications and training, as well as the accountabilities and coordination mechanisms in place for TB program activities, and determine whether the available personnel and financial resources appear to meet the program needs. Specific education and training is assessed in other sections.

² 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.

At a minimum, a region seeking APHIS classification for bovine TB must demonstrate that the disease is compulsorily notifiable. In addition, regulatory officials must have the legal authority to inspect live animals and records; apply diagnostic tests for TB; inspect live animals and carcasses at slaughter; control animal movement into, within, and out of the region; establish quarantines and restrict animal movement; control the disposition of infected animals and affected herds; authorize and oversee private veterinarians to conduct regulatory activities for the TB program; require identification of bovine animals and premises with bovine animals; and enforce TB program requirements and penalize noncompliance. The APHIS team examines all pertinent regulatory acts and assesses the application of these acts to carry out TB program activities, with particularly attention to demonstrated ability or failure to require and enforce compliance with the elements described above. The summary evaluation criteria for veterinary control and oversight are listed in Table 2.

Table 2: Evaluation criteria—veterinary control and oversight

Program elements	
Personnel resources available to the TB program are sufficient to support program activities.	
Financial resources available to the TB program are sufficient to support program activities.	
Roles and responsibilities within the TB program are clearly defined.	
Chains of reporting and communication within the TB program are well established.	
Bovine TB is a compulsorily notifiable disease throughout the region.	
Program officials have sufficient legal authority to carry out an effective bovine TB program.	
Violations and associated sanctions are well defined in the legal and regulatory framework.	
An effective system is in place to track legal cases from the initial report to closure.	

3. Prevalence of bovine TB

3.1 Animal and herd demographics

To calculate the herd prevalence of bovine TB, the APHIS team first gathers data on the number and type of bovine herds in the region. A region seeking classification must have established and maintained an accurate herd census, since this is a critical data point for prevalence calculations. The team notes the date of the last herd census, how it is updated, and progress towards conducting a new herd census (if applicable). The APHIS team also gathers data on production parameters for the various types of cattle operations in the region.

The summary evaluation criteria for animal and herd demographics are listed in Table 3.

Table 3: Evaluation criteria—animal and herd demographics

Program elements

The region has conducted a census of bovine animals and herds.

Systems are in place to update and inform the census over time.

Program execution

Rate the quality of the census data for the purpose of calculating herd prevalence.

3.2 Herd prevalence

The APHIS team then assesses the criteria used to classify the TB status of individual animals and herds and determines the number TB-affected herds during the evaluation period.³ The criteria must be clearly defined and equivalent to APHIS domestic standards. For example, a herd is designated infected when there is laboratory confirmation of *M. bovis* or substantial evidence of *M. bovis* infection, including bacterial identification of *M. bovis*, a polymerase chain reaction test positive for *M. tuberculosis* complex, and/or histopathology-compatible lesions in a known TB-exposed bovine. The team examines data on laboratory sample submissions and results, quarantine herd lists, and case files to determine whether TB program personnel follow the classification criteria.

APHIS defines prevalence as the number of affected herds occurring during the evaluation period (9 CFR 93.400). In some instances, the APHIS Administrator may allow calculation of prevalence based on affected herd-years to avoid penalizing regions with small herd numbers, as described in VS Memorandum 552.38 *Discretionary Bovine Tuberculosis Herd Prevalence Calculations in States or Zones with Small Numbers of Herds*. Any region seeking APHIS classification must first meet the minimum program standards; classification level is then determined according to herd prevalence (see Table 4).

Status level	Prevalence criteria						
Level I	Program that meets APHIS requirements for classification and Level I prevalence of less than 0.001 percent over at least the previous 2 years (24 consecutive months).						
Level II	Level IIProgram that meets APHIS requirements for classification and prevalence equal to or greater than 0.001 percent but less than 0.01 percent, over the previous 2 years (24 consecutive months).						
Program that meets APHIS requirements for classification at prevalence equal to or greater than 0.01 percent but less that 0.1 percent, over the previous year (12 consecutive months).							
Level IV	Program that meets APHIS requirements for classification and prevalence equal to or greater than 0.1 percent but less than 0.5 percent, over the previous year (12 consecutive months).						
Level V	Program that does not meet APHIS requirements for classification, prevalence equal to or greater than 0.5 percent, or unassessed by APHIS with regard to tuberculosis.						

Table 4: Prevalence criteria for TB status classification (from 9 CFR 93.437)

³ Evaluation period = 24 months for Levels I-II, specifically the first 24 months of the previous 26-month period; 12 months for Levels III-IV, specifically the first 12 months of the previous 14-month period.

3.3 Other sources of infection

Finally, the APHIS team gathers and verifies information on other livestock or wildlife sources of *Mycobacterium bovis* within the region and reviews surveillance and control measures with responsible regulatory officials, if applicable. The summary evaluation criteria are listed in Table 5.

Table 5: Evaluation criteria—other sources of infection

Program elements

Surveillance for bovine TB is conducted in susceptible wildlife and non-bovine domestic species.

No wildlife reservoirs of bovine TB have been identified within the region.

The official bovine TB program includes susceptible non-bovine domestic species if necessary.

Program execution

Applied mitigations effectively prevent TB transmission to domestic bovines from other species.

4. Surveillance

The APHIS team examines the official surveillance plan and program standards for slaughter inspection and live animal testing to identify any deficiencies that could negatively impact detection of bovine TB infection in the region. The team evaluates inspection rates and granuloma sample submission data for all slaughter plants in the region and visits several plants to assess the facilities and equipment, the knowledge and competency of the inspectors and supervisors, the systems for correlation of animal identification with carcass parts, and documentation of slaughter samples submitted for laboratory diagnostics. The team assesses compliance with the program standards for slaughter inspection and granuloma submissions using the checklist in <u>Appendix A</u>. The team also reviews individual caudal fold tuberculin (CFT) test data and response rates to assess performance.

At a minimum, a region seeking APHIS classification for bovine TB must demonstrate that (1) comprehensive program standards are in place to guide inspection of bovine animals at slaughter, sampling of granulomatous lesions, submission of samples for laboratory diagnostics, and live animal testing; (2) slaughter inspection and tuberculin testing is conducted by qualified and trained personnel; (3) appropriate minimum standards to validate slaughter and live animal surveillance are established and met; and (4) effective systems are in place for monitoring performance and addressing deficiencies.

As a general benchmark, a region should be able to demonstrate that combined slaughter and live animal surveillance is sufficient to detect a prevalence of 0.05 percent or lower among the resident bovine population with 95 percent confidence. In most cases, at least 95 percent of bovine animals slaughtered should be inspected for lesions indicative of TB. To validate that carcasses are carefully inspected, each slaughter plant should submit suspicious granulomatous lesion(s) from at least one animal in every 2,000 adult bovine animals slaughtered at the facility. Routine slaughter surveillance may not be necessary if a region can substantiate a claim of biological freedom from bovine TB, although targeted or risk-based surveillance should still be conducted as needed to demonstrate continued freedom. APHIS would evaluate these regions on a case-by-case basis. Summary evaluation criteria for surveillance are listed in Table 6.

Table 6: Evaluation criteria—surveillance

Program elements

Program standards: (1) Address the critical actions necessary for TB inspection at slaughter.

(2) Address the critical actions necessary for granuloma sampling and submission.

(3) Address the critical actions necessary for live animal testing for bovine TB.

Appropriate minimum standards are in place to validate slaughter surveillance for bovine TB.

Appropriate monitoring and performance standards are in place for CFT testing.

Program execution

Slaughter inspection for bovine TB occurs in accordance with program standards.

Granuloma sampling and submission occurs in accordance with program standards.

Slaughter inspection processes/techniques are standardized between plants and inspectors.

Slaughter processes promote accurate correlation of animal ID/documents with carcass parts.

Slaughter inspection and lab submissions meets the minimum standards to validate surveillance.

Individuals conducting inspection and sampling receive adequate instruction and training.

Deficiencies in slaughter inspection and sampling are rapidly detected and corrected.

Individuals conducting tuberculin testing receive adequate instruction and training.

Deficiencies in tuberculin testing are rapidly detected and corrected.

5. Diagnostic testing for bovine TB

The APHIS team typically visits the primary diagnostic laboratory for bovine TB in the region under evaluation and assesses the diagnostic techniques and quality assurance measures against APHIS National Veterinary Services Laboratory and international standards, using the checklist in <u>Appendix B</u>. The team also examines the electronic laboratory sample submission database to calculate performance metrics the degree of correlation between histopathology and bacteriology results.

At a minimum, a region seeking APHIS classification for bovine TB must demonstrate that (1) diagnostic laboratories supporting the TB program are equipped to conduct histopathology and culture; (2) at least one laboratory is proficient in other diagnostic techniques for bovine TB such as polymerase chain reaction (PCR) and genotyping; (3) laboratories are accredited according to international standards; (4) an effective quality control system is in place; and (5) interpretation or classification of results is in accordance with international standards. All laboratories should regularly engage in competency or proficiency testing for TB diagnostics.

As general benchmarks, the region should be able to demonstrate that samples are delivered to the laboratory within 10 days of slaughter, the TB program receives histopathology results within 15 days after that, culture results within 90 days, and typing within 120 days. Laboratory personnel should routinely rate the quality of the samples received and provide feedback for the slaughter plant inspectors. There should be a high degree of correlation between histopathology and culture results, as well as histopathology and PCR results. The summary evaluation criteria for laboratory diagnostic testing are listed in Table 7.

Table 7: Evaluation criteria—diagnostic testing

Program elements

The laboratories supporting the TB program are accredited to international standards.

The laboratories supporting the TB program are equipped to conduct the required tests.

The SOPs for conducting official diagnostic tests for TB reflect international standards.

Interpretation/classification of test results is in accordance with international standards.

Accredited laboratories regularly engage in competency/proficiency testing for TB diagnostics.

Program execution

The laboratories report diagnostic results to the TB program in a timely manner.

Rate the degree of correlation between histopathology and bacteriology results. [¥]

Rate the degree of correlation between histopathology and PCR results.[¥]

Laboratory personnel conducting diagnostic tests are adequately qualified and trained to do so.

Quality control measures rapidly detect and correct deficiencies in diagnostic protocols or techniques.

^{*} Greater than 90% = very good; 75-90% = good; 60-75% = fair; 50-60% = poor; less than 50% = very poor.

6. Epidemiological investigations

The APHIS team reviews the program standards for conducting and documenting epidemiological investigations (slaughter traceback, live animal testing, trace-in, trace-out, and contact herds) and assesses them against the checklist in <u>Appendix C</u>, noting any deficiencies that could negatively impact the quality of the investigations. The team also reviews multiple case files to assess implementation of the program standards, evaluate the knowledge and training of the responsible regulatory officials, and determine whether deficiencies in the investigative process are rapidly detected and corrected. The team further correlates the case files with laboratory submission data and quarantine herd lists to ascertain whether the TB program conducts follow-up testing and/or initiates an epidemiological investigation as appropriate.

At a minimum, a region seeking APHIS classification for bovine TB must demonstrate that (1) the program standards address the critical actions for effective and thorough epidemiological investigations; (2) designated officials conduct epidemiological investigations in accordance with the program standards; (3) every slaughter case is subject to investigation; (4) investigators quickly and accurately determine the status of non-negative animals and herds; and (5) movement from herds under investigation is promptly and effectively regulated while the TB status is determined. As a general benchmark, the successful traceback rate—i.e. the percentage of slaughter cases traced to the most probable herd of origin (MPHO) and the MPHO tested—should be at least 75 percent. If the MPHO tests negative, the case file should contain evidence of further traceback investigations based on the slaughter order. Investigations must be well-documented with orderly and complete case files.

The summary evaluation criteria for epidemiological investigations are listed in Table 8.

Table 8: Evaluation criteria—epidemiological investigations

Program elements

Program standards address the critical actions for effective slaughter traceback investigations.

The successful traceback rate meets or exceeds the minimum standard.

Program standards address the critical actions for effective live animal testing investigations.

Program standards address the critical actions for effective investigation of related/implicated herds.

Program standards promote logical, standardized, and well documented case files.

Program execution

Slaughter traceback investigations are conducted in accordance with the program standards.

Slaughter traceback investigations result in detection of a TB-affected herd.

Live animal testing investigations are conducted in accordance with the program standards.

Investigations of related/implicated herds are conducted in accordance with the program standards.

Investigators quickly and accurately determine the status of non-negative animals and herds.

Movement from herds under investigation is effectively regulated while the TB status is determined.

Investigations are well documented with orderly and complete case files.

Program officials conducting epidemiological investigations receive adequate instruction and training. Deficiencies in the investigative process are rapidly detected and corrected.

7. Affected herd management

The APHIS team reviews and assesses the program standards for managing TB-affected herds by depopulation or test-and-remove against the checklist in <u>Appendix D</u>, and notes any deficiencies that could negatively impact the quality of management efforts. The team works through multiple case files to assess implementation of the program standards, evaluate the knowledge and training of the responsible regulatory officials, and determine whether deficiencies in management processes are rapidly detected and corrected.

At a minimum, a region seeking APHIS classification for bovine TB must demonstrate that (1) the program standards address the critical actions for effective management of TB-affected herds; (2) designated officials manage affected herds in accordance with the program standards; (3) movement from affected herds is effectively regulated with periodic inventory reconciliation; and (4) management actions are fully documented.

The summary evaluation criteria for affected herd management are listed in Table 9.

Table 9: Evaluation criteria—affected herd management

Program elements

Program standards address the critical actions necessary to manage herds via depopulation.

Program standards address the critical actions necessary to manage herds via test-and-removal.

Program standards promote logical, standardized, and well documented affected herd case files.

Program standards allow for vaccination against bovine TB.

Program execution

Program officials and affected herd owners are implementing official herd management plans. Management via depopulation is conducted in accordance with the program standards. Program officials account for all animals in the herd at the time of depopulation. Management via test-and-removal is conducted in accordance with program standards. Program officials regularly monitor the inventory of herds undergoing test and removal. Movement from TB-affected herds is effectively regulated while under quarantine. Herd management actions are well documented with orderly and complete case files. Program officials conducting affected herd management receive adequate instruction and training. Deficiencies in herd management processes are rapidly detected and corrected. TB vaccinates are clearly and permanently identified.

8. Control of livestock movement

8.1 Animal identification and traceability

The APHIS team assesses the legal and regulatory framework supporting animal and premises identification and movement control within the region, including compliance enforcement. The team evaluates implementation by examining cattle for official identification and reviewing movement control documents, reviewing and assessing procedures at issuing centers for official identification and movement control documents, and challenging the identification and traceability systems using data gathered from case files and the sites visited (see <u>Table E-1</u> in Appendix E). The team also evaluates enforcement by assessing the systems in place to detect and report noncompliance and reviewing data on the violations reported and the sanctions applied.

At a minimum, a region seeking APHIS classification for bovine TB must demonstrate that (1) official identification of bovine animals and herds is mandatory; (2) documentation of bovine animal movements promotes traceability; and (3) effective compliance monitoring and enforcement systems are in place. Ideally, bovine animals should be individually and uniquely identified prior to leaving the premises of origin. Official animal identification should be accurately linked to a specific owner and premises. Bovine animals should be moved with appropriate documentation of origin, destination, date, and identification, and changes in ownership and location should be captured in a central database. Violations and associated sanctions should be adequately defined in the legal framework with effective systems in place to monitor and enforce compliance.

The summary evaluation criteria for animal identification and traceability are listed in Table 10.

Table 10: Evaluation criteria—animal identification and traceability

Program elements

Official identification of bovine animals is required for movement from the premises of origin.

Official identification of herds / premises and bovine concentration points is required.

Control and distribution of official identification is strictly regulated.

Documentation is required for all movements of bovine animals between premises.

Violations and associated sanctions are clearly defined in the legal or regulatory framework.

Program execution

Bovine animals are officially identified prior to movement.

Herds / premises and bovine concentration points are officially identified.

Movement of bovine animals between premises is fully documented.

Data and documents necessary for tracing bovine animals are readily available to investigators.

Noncompliance is reported, prosecuted, and legal sanctions applied.

8.2 Entry into the region

The APHIS team reviews the requirements for bovine animals to enter into the region and assesses them for equivalence to APHIS import requirements detailed in 9 CFR 93.439, making note of any deficiencies that could negatively impact control of movement into the region or allow legal importation of TB-infected animals. The team also evaluates any program standards established to guide inspection at the points of entry and assesses the placement of movement control checkpoints in relation to the major access routes into the region. Finally, the team evaluates implementation of entry controls by visiting checkpoints and/or ports, interviewing the inspectors, examining documents, and observing inspection procedures (see <u>Table E-2</u> in Appendix E).

At a minimum, a region seeking APHIS classification of bovine TB status must demonstrate that (1) requirements for bovine entry into the region provide risk mitigation equivalent to APHIS requirements; (2) checkpoints are strategically located; (3) any bovine animals that arrive at a checkpoint without proper identification, testing, and documentation are denied entry; (4) checkpoints records are sufficient to promote traceability; and (5) measures are in place to confirm that higher-risk animals arrive at the stated destination. Checkpoint facilities should be in good physical condition, an authorized inspector present whenever the checkpoint is open, and entry effectively prevented if the checkpoint is closed. The summary evaluation criteria for entry into the region are listed in Table 11.

Table 11: Evaluation criteria—entry into the region

Program elements
Program standards clearly describe the entry requirements and inspection procedures.
Requirements for bovine entry into the region are risk based and equivalent to U.S. standards.
Checkpoints are strategically located at the most likely points of entry from higher-risk regions.
Checkpoint are in good condition with appropriate signage, lighting, corrals, etc.
Program execution
All shipments of bovine animals passing through the checkpoint are subject to inspection.
Shipments not fully compliant with the entry requirements are denied entry into the region.
Shipments of higher-risk animals move to destination or transit the region under seal.
Official personnel confirm the arrival of higher-risk animals at destination or point of exit.
Inspectors record the details of all shipments of bovine animals into or through the region.
Movement control measures are effective in preventing illegal entry into the region.
Regulatory officials enforcing movement requirements receive adequate instruction and training.
Deficiencies in the movement control system are rapidly detected and corrected.

8.3 Export to the United States

8.3.1 Export certification

The APHIS team reviews the program standards for export certification, making note of any deficiencies that could negatively impact compliance. The team works through multiple export certificates with the regulatory officials responsible for validating the conditions specified on the certificate, to assess their processes, knowledge, and competency (see <u>Table E-3</u> in Appendix E). The team also takes into account any previously disclosed issues with cattle from the region presented for export to the United States.

At a minimum, a region seeking APHIS classification of bovine TB status must demonstrate that (1) export certificates are prepared by well-trained and authorized regulatory officials in accordance with comprehensive program standards; (2) the regulatory officials verify the accuracy of the information provided by exporters prior to certifying; and (3) a robust review process is in place to rapidly detect and correct any deficiencies in the verification or certification processes.

Summary evaluations criteria for export certification are listed in Table 12.

Table 12: Evaluation criteria—export certification

Program elements

Program standards clearly describe the processes for export certification and review of certificates.

Regulatory officials certifying cattle exports and reviewing certificates are qualified and trained.

Program execution

Export certification is conducted in accordance with the program standards.

Shipments are only certified for export if they meet all requirements of the importing country.

8.3.2 Export gathering centers

Regions seeking classification for bovine TB may have regulated facilities to gather and sort cattle for export to the United States. At a minimum, each such export gathering centers must demonstrate that (1) it is a designated facility which only accepts cattle for export; (2) all animals entering the facility are uniquely identified and accompanied by appropriate documentation; (3) TB testing at the facility is conducted in accordance with APHIS requirements; and (4) biosecurity measures are in place to prevent disease transmission from neighboring herds. Export gathering centers must be approved by the authorized regulatory entity and subject to routine and effective regulatory oversight sufficient to detect and correct noncompliance. If applicable, the export gathering center must maintain a tick immersion bath and conduct tick treatment as required for export to the United States. The APHIS team typically visits several export gathering centers to assess the procedures and practices using the checklist in <u>Table E-4</u> in Appendix E or similar.

Summary evaluation criteria for export gathering centers are listed in Table 13.

Table 13: Evaluation criteria—export gathering centers

Program elements

Program standards for export centers: (1) Clearly define approval requirements.

(2) Clearly define the requirements for animal entry into the facility.

(3) Require unique identification of animals entering the center.

(4) Require the center to keep accurate records of entries, exits, and animal inventory.

(5) Require the center to keep accurate records of testing conducted on the premises.

(6) Require appropriate risk mitigation measures (fencing, biosecurity, etc.).

Export gathering centers are subject to regular (monthly) inspection and supervision.

Program execution

Export centers are approved, operated, and supervised in accordance with the program standards. Regulatory officials responsible for supervision of export centers are qualified and trained to do so. Noncompliance with the program standards is rapidly detected and corrected.

8.4 Approved feedlots

Bovine TB Level I-IV regions may have approved (quarantine) feedlots⁴ which accept cattle from higher-risk regions destined for slaughter and national consumption (not export). The APHIS team reviews the program standards for approval and supervision of approved feedlots, making note of any deficiencies that could allow the spread of bovine TB from these entities. The team reviews the approval and supervisory records with the responsible regulatory officials and visits several approved feedlots to assess implementation of the program standards, supervision, and regulatory oversight. The APHIS team visits several approved feedlots to assess the practices and procedures using the checklist in Table E-5 Appendix E.

At a minimum, a region seeking APHIS classification of bovine TB status must demonstrate that (1) entry of animals into an approved feedlot is strictly controlled; (2) all animals entering the feedlot are uniquely and permanently identified; (3) biosecurity measures are in place to prevent disease spread to neighboring herds; (4) animals exit the feedlot only to slaughter; and (5) approved feedlots are subject to routine and effective regulatory oversight sufficient to detect and correct noncompliance.

Summary evaluation criteria for approved feedlots are listed in Table 14.

⁴ Approved (quarantine) feedlot = terminal feedlot authorized to receive animals of higher risk for tuberculosis/brucellosis.

Table 14: Evaluation criteria—approved feedlots

Program elements

Program standards for approved feedlots: (1) Clearly define approval and supervision requirements.

(2) Require unique identification of animals entering approved feedlots.

(3) Require all animals exiting an approved feedlot to go directly to slaughter.

(4) Require approved feedlots to keep accurate records of entries, exits, and animal inventory.

(5) Require approved feedlots to keep accurate records of births and deaths.

(6) Contain appropriate risk mitigation measures (fencing, biosecurity, etc.).

Approved feedlots are subject to regular (monthly) inspection and supervision.

Regulatory officials responsible for supervision of approved feedlots are qualified and trained to do so.

Program execution

Approved feedlots are approved, operated, and supervised in accordance with the program standards. Noncompliance with the program standards is rapidly detected and corrected.

8.5 Accreditation of TB-free herds

Level I-IV regions may have accredited herds for TB; animals from these herds are generally subject to reduced testing requirements for movement within the region and for export to the United States. The APHIS team reviews the program standards for accreditation of herds for bovine TB against APHIS standards using the checklist in <u>Table E-6</u> in Appendix E and assesses the impact of any differences in accreditation or reaccreditation processes. The team reviews several accredited herd files with the responsible regulatory official(s).

To be considered an accredited herd for the purpose of exporting bovine animals to the United States, the accreditation and reaccreditation processes must be equivalent to U.S. domestic standards. The TB program should maintain a file on each herd with complete documentation of whole-herd testing, inventory reconciliations, and provenance and/or testing of purchased additions. Regions in which the accreditation and reaccreditation practices are not equivalent to U.S. domestic standards are not eligible to export cattle under the reduced testing requirements that would otherwise apply to bovine animals from accredited herds. Summary evaluation criteria for accreditation of TB-free herds are shown in Table 15.

Table 15: Evaluation criteria—accredited herds

Program elements

Program standards for accreditation and reaccreditation: (1) meet APHIS standards for export purposes.

- (2) Require inventory reconciliation at the time of reaccreditation testing.
- (3) Restrict entry to animals from other accredited herds or with appropriate testing.
- (4) Require all testing for (re-) accreditation to be conducted by an authorized veterinarian.

Program execution

Herds are accredited and reaccredited in accordance with APHIS standards for export.

Regulatory officials responsible for oversight of herd files receive adequate instruction and training.

Annual review of accredited herd files results in detection and correction of any deficiencies.

Appendices

Appendix A: Checklist for slaughter inspection and sampling

	Slaughter plant ID:			
Α	General	Info	Info	Info
1	Type of plant (municipal, TIF, other):			
2	Number of cattle killed per week:			
3	Number of days per week the plant operates:			
4	Type of cattle killed (dairy, beef, mixed):			
5	Age of cattle killed (adult >2 years, young):			
6	Origin of cattle killed:			
7	Number of inspectors working at the plant:			
В	Facilities (Y/N)	Score	Score	Score
1	Slaughter plant facilities are in good physical condition:			
2	The slaughter plant has pens to offload and inspect arriving cattle:			
3	Equipment is sufficient for quality inspection (head rack, tables, etc.):			
4	Lighting is sufficient for quality inspection:			
С	Access to pertinent program standards (Y/N)	Score	Score	Score
1	Guidelines for slaughter inspection and sample submission:			
2	A current list of herds under guarantine within the region:			
3	Copies of pertinent laws and regulations:			
D	Entry requirements (5 pt)	Score	Score	Score
1	All animals are officially identified with a unique ID number.			
2	All animals are accompanied by an official transit guide			
3	All animals are accompanied by a health certificate (if required)			
4	A designated person records the owner and ID of all animals upon arrival			
5	Cattle from NA (level IV) regions arrive in sealed conveyances			
a	An authorized official breaks the seals and records the seal numbers			
F	Inspection practices (5 pt)	Score	Score	Score
1	A veterinarian inspects and verifies the health of the cattle prior to slaughter	50010		
2	Postmortem inspection is conducted by trained and authorized inspectors			
2	An affective system is in place to correlate animal ID with all carcase parts			
1	An inspector checks all lymph podes on each carcass (head lyngs viscora)			
-4 E	Training and supervision (5 nt)	Score	Score	Score
r	Inspectors are adoptately gualified and trained for the job	30016	Score	30016
2	A designated official ravious claughter and compling procedures at least monthly			
2	A designated official reviews staughter and sampling procedures at least monthly.			
a L	A designated efficiel ensures that reported deficiencies are corrected			
0	A designated official ensures that reported deficiencies are corrected.	Infe	Info	Infe
1	Sample submissions	ΙΠΤΟ	Into	Into
1	Number of regular-kill samples during the previous 12 months:			
a	Number of regular-kill samples from cattle from the region:			
b	Number of regular-kill samples from cattle from other regions:			
C	Number of regular-kill samples that were positive (histopathology and/or culture):			
2	Granuloma submission rate over previous 12 months:			
H	Sampling practices (5 pt)	Score	Score	Score
1	Sample submission forms are complete (name, age, sex, brand, ID, reactor/exposed).			
2	Samples are adequately preserved for laboratory diagnostics.			
3	Samples are shipped properly and received by the lab within 10 days of collection.			
4	The plant keeps all documents related to a submission (invoices, transit papers, lab results).			

	Laboratory:		
Α	Facilities (Y/N)	Info	Info
1	The laboratory is accredited to national or international standards [by whom and date] (Y/N):		
2	The laboratory has a designated area for conducting histopathology (Y/N):		
3	The laboratory has a designated area for bacterial culture (Y/N):		
4	The laboratory has a designated area for serological testing (Y/N):		
5	All samples are uniquely identified and correlated to the incoming submission (Y/N):		
6	Effective quality monitoring and control systems are in place (Y/N):		
7	From where does the laboratory receive samples? Indicate percentages from each:		
В	Histopathology (5 pt)	Info/Score	Info/Score
1	Number of samples received per year:		
2	Diagnostic test(s) conducted:		
3	The laboratory is properly equipped to conduct the above tests (Y/N):		
4	SOPs for conducting the above tests are available to the technicians (Y/N):		
5	Date of last proficiency or competency testing of technicians:		
6	Technicians are adequately qualified and trained to perform the diagnostic test(s).		
7	The technician records all samples and results as they are received.		
8	Effective measures are in place to prevent cross-contamination.		
9	A designated official conducts periodic supervisory reviews (including QC assays and technician proficiency).		
а	Findings are documented in a formal report provided to the technician.		
b	The designated official ensures that deficiencies are corrected in a timely manner.		
С	Bacteriology (5 pt)	Info/Score	Info/Score
1	Number of samples received per year:		
2	Diagnostic test(s) conducted:		
3	Culture system and media used:		
4	The laboratory is properly equipped to conduct the above tests (Y/N):		
5	SOPs for conducting the above tests are available to the technicians (Y/N):		
6	Date of last proficiency or competency testing of technicians:		
7	Technicians are adequately qualified and trained to perform the diagnostic test(s).		
8	The technician records all samples and results as they are received.		
9	Effective measures are in place to prevent cross-contamination.		
10	A designated official conducts periodic supervisory reviews (including QC assays and technician proficiency).		
а	Findings are documented in a formal report provided to the technician.		
b	The designated official ensures that deficiencies are corrected in a timely manner.		
В	Other testing (PCR, etc.) (5 pt)	Info/Score	Info/Score
1	Number of samples received per year:		
2	Diagnostic test(s) conducted:		
3	The laboratory is properly equipped to conduct the above tests (Y/N):		
4	SOPs for conducting the above tests are available to the technicians (Y/N):		
5	Date of last proficiency or competency testing of technicians:		
6	Technicians are adequately qualified and trained to perform the diagnostic test(s).		
7	The technician records all samples and results as they are received.		
8	Effective measures are in place to prevent cross-contamination.		
9	A designated official conducts periodic supervisory reviews (including QC assays and technician proficiency).		
а	Findings are documented in a formal report provided to the technician.		
b	The designated official ensures that deficiencies are corrected in a timely manner.		

Appendix B: Checklist for diagnostic testing

Appendix C:	Checklist for	epidemiologica	I investigations
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		TB-affected herds Other investigat		stigations			
	Herd ID:						
Α	Live animal testing investigations (5 pt)	Score	Score	Score	Score	Score	Score
1	Disclosure of non-negative animals on primary testing resulted in herd movement restrictions / precautionary quarantine.						
а	Animals only left the MPHO premises to inspected slaughter, necropsy, or approved (quarantine) feedlot.						
b	All movements of animals from the MPHO occurred under seal and/or with official supervision.						
2	All animals non-negative on primary testing were subject to an official secondary test or postmortem examination.						
а	All animals non-negative on secondary testing were retested in an appropriate timeframe or examined postmortem.						
b	All animals non-negative on two consecutive secondary tests were examined postmortem with sampling for lab testing.						
3	All secondary tuberculin testing was conducted by an official veterinarian.						
В	Slaughter traceback investigations (5 pt)	Score	Score	Score	Score	Score	Score
1	An epidemiological investigation was initiated within 15 days of issuance of the lab report.						
2	The MPHO was placed under movement restrictions / precautionary quarantine while the TB status was determined.						
а	Animals only left the MPHO premises to inspected slaughter, necropsy, or approved (quarantine) feedlot.						
b	All movements of animals from the MPHO occurred under seal and/or with official supervision.						
3	The MPHO was subject to a whole-herd test (WHT) of all animals ≥ 6 months of age.						
4	The MPHO was subject to a second WHT prior to quarantine release if the first test was negative.						
5	Additional traceback investigations were conducted based on the slaughter order (3 up and 3 down) if the MPHO was negative.						
6	All primary and secondary tuberculin testing was conducted by an official veterinarian.						
а	All animals non-negative on primary testing were subject to an official secondary test or postmortem examination.						
b	All animals non-negative on secondary testing were retested in an appropriate timeframe or examined postmortem.						
7	The epidemiological investigation was completed within 180 days.						
С	Investigation of herds related to a TB-affected herd (5 pt)	Score	Score	Score	Score	Score	Score
1	All herds adjacent to or in contact with the affected herd were subject to a WHT of all animals \geq 6 months of age.						
2	All herds that contributed animals to the affected herd (trace-ins) were subject to a WHT of all animals ≥ 6 months of age.						
3	All herds that received animals from the affected herd (trace-outs) were subject to a WHT of all animals ≥ 6 months of age.						
4	All animals non-negative on primary testing were subject to an official secondary test or postmortem examination.						
5	All animals non-negative on secondary testing were retested in an appropriate timeframe or examined postmortem.						
6	All primary and secondary tuberculin testing was conducted by an official veterinarian.						
7	All trace-in and trace-out herds were placed under movement restrictions while the TB status was determined.						
а	Animals only left herds under movement restrictions to inspected slaughter, necropsy, or approved (quarantine) feedlot.						
b	All movements of animals from herds under movement restrictions occurred under seal and/or with official supervision.						
D	Documentation in the case file (Y/N)	Score	Score	Score	Score	Score	Score
1	Up-to-date investigative narrative:						
2	Flow diagram of case investigation:						
3	Map of the area including adjacent herds:						
4	Slaughter sample submission form for the case animal (slaughter cases only):						
5	Laboratory results for sample(s) from the case animal (slaughter cases only):						
6	A copy of the order of slaughter from the slaughter plant (slaughter cases only):						
7	Field test charts for all herds tested as part of the investigation (should include ear tag and brand information):						
8	Official test charts for all herds tested as part of the investigation (should include ear tag and brand information):						
9	Pertinent official and field test charts for historical herd tests (prior to the investigation):						
10	Invoices and transit papers used to trace animals involved in the investigation:						
11	Records of quarantines issued and released during the course of the investigation:						
12	Animal inventory records / evidence of inventory reconciliation between herd tests (if applicable):						
13	Permits for animal movement from herd(s) under movement restrictions / quarantine (if applicable):						
14	Documents pertaining to tracing of animals illegally moved while under movement restrictions (if applicable):						
15	Sample submission forms for animals non-negative on tuberculin testing (if applicable):						
16	Laboratory results for samples from animals non-negative to tuberculin testing (if applicable):						

Appendix D: Checklist for affected herd management

	Herd ID:					
Α	Management via depopulation (5 pt)	Score	Score	Score	Score	Score
1	Depopulation of the affected herd occurred in a timely manner.					
2	The affected herd remained under continuous movement restrictions / quarantine until depopulated.					
а	Animals only left the premises to inspected slaughter, necropsy, or approved (quarantine) feedlot.					
b	All movements of animals from the premises occurred under seal and/or with official supervision.					
3	The affected herd underwent a complete herd inventory at the time of depopulation.					
а	All animals present at the time of initial movement restrictions / quarantine were accounted for at depopulation.					
4	Depopulated animals were inspected at slaughter to detect TB lesions.					
5	The affected premises was cleaned and disinfected prior to restocking.					
6	The herd underwent two annual whole-herd tests after restocking (assurance testing).					
В	Management via test and removal (5 pt)	Score	Score	Score	Score	Score
1	The affected herd remained under continuous movement restrictions / quarantine until depopulated.					
а	Animals only left the premises to inspected slaughter, necropsy, or approved (quarantine) feedlot.					
b	All movements of animals from the premises occurred under seal and/or with official supervision.					
2	The affected herd was subject to a regular herd inventories with inventory reconciliation.					
а	All animals present at the time of initial movement restrictions / quarantine were accounted for on reconciliation.					
3	Herd testing occurred or is occurring on an established schedule in accordance with program standards.*					
а	All test-eligible animals were tested during each whole-herd test.					
b	Any CFT responders on the first 2 herd tests were necropsied or slaughtered with inspection.					
с	Any reactors to secondary testing on subsequent herd tests were necropsied or slaughtered with inspection.					
d	The testing protocol was restarted if any gross lesions or histological evidence of mycobacteriosis was disclosed.					
4	The herd underwent two annual whole-herd tests after quarantine release (assurance testing).					
С	Documentation in the case file (Y/N)	Score	Score	Score	Score	Score
1	Field test charts for all testing of animals in the affected herd:					
2	Official test charts for all testing of animals in the affected herd:					
3	Animal inventory records / evidence of inventory reconciliation between herd tests:					
4	Investigation of any animals moved illegally from the affected herd:					
5	A herd plan signed by the herd owner:					

Appendix E: Checklists for control of livestock movement

	Facility ID:			
Α	General	Info	Info	Info
1	Type of facility:			
2	Capacity (no. head):			
3	Current inventory (no. head):			
4	Type of cattle (beef, dairy, mixed):			
5	Cattle origin (source and %):			
6	Cattle destination(s):			
7	Average length of stay:			
В	Facilities (Y/N)	Score	Score	Score
1	Facilities are in good physical condition (particularly fencing):			
2	Facility infrastructure is sufficient to monitor animal movements:			
3	Facilities infrastructure is sufficient to maintain cattle in individual lots if necessary:			
С	Documentation and recordkeeping (5 pt)	Score	Score	Score
1	All animals allowed entry have an official ear tag; and			
а	A brand indicating the original owner; and			
b	An official transit guide; and			
с	Documentation validating the origin and purchase of the animal; and			
d	Proof of TB testing (if applicable); and			
е	An animal health certificate (if applicable).			
2	The official ID and accompanying documentation of each animal is recorded on entry and exit.			
3	The entry and exit records are maintained in a format that allows tracking of individual animals (logbook).			
4	Animals transiting through a lower status region arrive in sealed conveyances.			
а	A designated employee confirms that the seal is unbroken and records the seal number on arrival.			
5	Animals from Level V / NA regions are not permitted entry.			
6	Animals from herds under movement restrictions or quarantine are not permitted entry.			
7	All births on the premises are recorded and newborns officially identified.			
8	All deaths on the premises are recorded (with ID).			
9	All animals leave the facility with an official transit guide.			

Table E-1: Checklist for concentration points

	Checkpoint ID:			
Α	Staffing levels and hours of operation	Info	Info	Info
1	Number of inspectors:			
2	Average number of bovine shipments inspected per month:			
3	Hours of checkpoint operation:			
4	An inspector is on duty whenever the checkpoint is open (Y/N):			
5	Procedures to ensure inspection if the checkpoint is closed (if applicable):			
В	Checkpoint facilities (Y/N)	Score	Score	Score
1	Checkpoint facilities are in good physical condition:			
2	Signage clearly indicates upcoming checkpoint location:			
3	Inspectors have access to pens for off-loading bovine animals:			
4	Lighting is sufficient for inspection at night:			
5	Computer, radio, and phone are onsite or otherwise accessible:			
6	Checkpoint has a designated vehicle or access to vehicular support:			
С	Access to pertinent program standards (Y/N)	Score	Score	Score
1	Up-to-date guarantine herd list:			
2	Movement and testing requirements for entry of bovine animals into the region:			
3	Manual or SOPs for inspection at checkpoints:			
4	(M) List of State statuses according to APHIS:			
5	Copies of pertinent laws and regulations:			
D	General (5 pt)	Score	Score	Score
1	All shipments of bovine animals passing the checkpoint are subject to inspection.			
а	Inspectors visually inspect all boyine animals passing the checkpoint.			
b	Inspectors correlate ID between animals and documents.			
2	Inspectors record all shipments of bovine animals through the checkpoint.			
Е	Personnel resources and supervision (5 pt)	Score	Score	Score
1	Inspectors are adequately qualified and trained for the job.			
2	A designated official conducts a supervisory review at least monthly.			
а	The review include exercises or exams for the inspectors.			
3	Review findings are documented in a formal report provided to the inspectors.			
4	A designated official ensures that reported deficiencies are corrected.			
F	Use of seals (5 pt)	Score	Score	Score
1	Animals for direct slaughter or approved feedlot move to destination under seal.			
2	Imported animals requiring guarantine move to the place of guarantine under seal.			
3	Potentially higher-risk animals transiting the region move under seal.			
4	Inspectors record the numbers of all seals removed and placed.			
G	Tracking of shipments (5 pt)	Score	Score	Score
1	Authorities confirm arrival of direct slaughter animals at the slaughter plant.			
2	Authorities confirm arrival of feeder animals at the approved feedlot.			
3	Authorities confirm exit of higher-risk animals in transit from the region.			
н	Animal ID and documentation (5 pt)	Score	Score	Score
1	All animals are officially identified with a unique ID number.			
2	Inspectors require an official, valid transit guide with origin. destination, and animal IDs.			<u> </u>
3	Officials require proof of appropriate TB testing and/or free herd statutes.			
4	All animals are accompanied by an official health certificate (if required).			<u> </u>
5	All animals are accompanied by an official entry permit (if required by the region).			

Table E-2: Checklist for movement control checkpoints

Table E-3: Checklist for export certification

	Certificate number:			
Α	Documentation in the export file (Y/N)	Score	Score	Score
1	Solicitation for export:			
2	International health certificate:			
3	Test chart for the lot test with the blue metal tag numbers of all animals exported (if applicable):			
4	Test charts for herd of origin testing (if applicable):			
5	Certificate of TB-free herd (if applicable):			
6	Transit guides from the herd of origin to the export center (if applicable):			
7	Herd of origin certificate and annex (if applicable):			
8	Spay certificates for spayed heifers:			
9	Tick treatment Certificate:			
_				
В	Verification by certifying official (5 pt)	Score	Score	Score
B 1	Verification by certifying official (5 pt) The herd of origin certificate accurately lists all animals presented for export.	Score	Score	Score
B 1 2	Verification by certifying official (5 pt) The herd of origin certificate accurately lists all animals presented for export. The herd of origin information for all animals presented for export is accurate.	Score	Score	Score
B 1 2 3	Verification by certifying official (5 pt) The herd of origin certificate accurately lists all animals presented for export. The herd of origin information for all animals presented for export is accurate. Animals that are non-negative to the CFT test on herd or lot testing are prohibited export.	Score	Score	Score
B 1 2 3 4	Verification by certifying official (5 pt) The herd of origin certificate accurately lists all animals presented for export. The herd of origin information for all animals presented for export is accurate. Animals that are non-negative to the CFT test on herd or lot testing are prohibited export. Lot tests were conducted by veterinarians who meet the minimum CFT response rate at the time of testing.	Score	Score	Score
B 1 2 3 4 5	Verification by certifying official (5 pt) The herd of origin certificate accurately lists all animals presented for export. The herd of origin information for all animals presented for export is accurate. Animals that are non-negative to the CFT test on herd or lot testing are prohibited export. Lot tests were conducted by veterinarians who meet the minimum CFT response rate at the time of testing. Herd tests were conducted by veterinarians who meet the minimum CFT response rate (if applicable).	Score	Score	Score
B 1 2 3 4 5 6	Verification by certifying official (5 pt) The herd of origin certificate accurately lists all animals presented for export. The herd of origin information for all animals presented for export is accurate. Animals that are non-negative to the CFT test on herd or lot testing are prohibited export. Lot tests were conducted by veterinarians who meet the minimum CFT response rate at the time of testing. Herd tests were conducted by veterinarians who meet the minimum CFT response rate (if applicable). All CFT tests were read within the 72 hour timeframe (plus or minus 6 hours).	Score	Score	Score
B 1 2 3 4 5 6 7	Verification by certifying official (5 pt) The herd of origin certificate accurately lists all animals presented for export. The herd of origin information for all animals presented for export is accurate. Animals that are non-negative to the CFT test on herd or lot testing are prohibited export. Lot tests were conducted by veterinarians who meet the minimum CFT response rate at the time of testing. Herd tests were conducted by veterinarians who meet the minimum CFT response rate (if applicable). All CFT tests were read within the 72 hour timeframe (plus or minus 6 hours). Heifers were at least 18 months of age at the time of spaying.	Score	Score	Score
B 1 2 3 4 5 6 7 8	Verification by certifying official (5 pt) The herd of origin certificate accurately lists all animals presented for export. The herd of origin information for all animals presented for export is accurate. Animals that are non-negative to the CFT test on herd or lot testing are prohibited export. Lot tests were conducted by veterinarians who meet the minimum CFT response rate at the time of testing. Herd tests were conducted by veterinarians who meet the minimum CFT response rate (if applicable). All CFT tests were read within the 72 hour timeframe (plus or minus 6 hours). Heifers were at least 18 months of age at the time of spaying. Spayed heifers were TB tested before spaying or at least 60 days after spaying.	Score	Score	Score
B 1 2 3 4 5 6 7 8 8	Verification by certifying official (5 pt)The herd of origin certificate accurately lists all animals presented for export.The herd of origin information for all animals presented for export is accurate.Animals that are non-negative to the CFT test on herd or lot testing are prohibited export.Lot tests were conducted by veterinarians who meet the minimum CFT response rate at the time of testing.Herd tests were conducted by veterinarians who meet the minimum CFT response rate (if applicable).All CFT tests were read within the 72 hour timeframe (plus or minus 6 hours).Heifers were at least 18 months of age at the time of spaying.Spayed heifers were TB tested before spaying or at least 60 days after spaying.Tick treatment was by immersion and in accordance with APHIS facility requirements (no vegetation, etc.).	Score	Score	Score

Table E-4: Checklist for export gathering centers

	Center ID:			
Α	Facilities (Y/N)	Score	Score	Score
1	EGCs are only approved by the authorized regulatory entity once all requirements are met:			
2	The entire facility is an export gathering center (not just pens within the facility):			
3	All cattle are maintained on dry lot conditions (no pasturing):			
4	The EGC is surrounded by a perimeter fence with double fencing where there are adjacent herds:			
5	The EGC has a tick immersion bath, handling chute, drying area, and decantation vat:			
а	The EGC is clearly divided physically and by biosecurity between clean and dirty areas:			
6	Clean pens are maintained vegetation-free for a minimum 10m perimeter:			
7	The EGC has a separate pen for caudal fold tuberculin (CFT) test responders and sick animals (10m separation):			
8	All adjacent herds with cattle are tested annually:			
В	Cattle entry and recordkeeping (5 pt)	Score	Score	Score
1	All animals allowed entry into the EGC have an official ear tag; and			
а	A brand indicating the original owner (if applicable); and			
b	An official transit guide; and			
С	Documentation validating the origin and purchase of the animal; and			
d	An animal health certificate (if applicable).			
2	All animals allowed entry into the EGC have resided since birth in an APHIS accredited region.			
3	Animals non-negative to the CFT test on the herd test are not allowed to enter the EGC.			
4	Animals from AP / Level II regions have proof of a valid negative herd test or origin from a TB-free herd.*			
а	Proof of a negative CCT test is provided for any animal that was non-negative on the herd test.			
5	Holstein or Holstein-cross animals are not admitted to the facility or processed for export.			
6	Animals transiting through a lower status region to reach the EGC arrive in sealed conveyances.			
а	A designated EGC employee confirms that the seal is unbroken and records the seal number on arrival.			
7	The EGC ensures that the ID of the animals presented for entry matches that on the accompanying documents.			
8	The EGC records the official ID and control numbers of the corresponding documents for each animal on entry and exit.			
9	The EGC maintains entry and exit records in a format that allows tracking of individual animals (logbook).			
10	The EGC documents all deaths on the premises and records the ID.			
11	All animals leave the EGC within 90 days of entry.			
12	The EGC maintains strict control over records of cattle entry, exit, and origin.			
С	Supervision (5 pt)	Score	Score	Score
1	A designated regulatory official is responsible for oversight and supervision of the EGC.			
2	The designated official conducts a supervisory review at least monthly.			
а	Review findings are documented in a formal report provided to the EGC owner / operator.			
b	The designated official ensures that reported deficiencies are corrected within 30 days.			
D	Tuberculin testing (5 pt)	Score	Score	Score
1	All CFT tests at the EGC are conducted by a vet who is eligible to conduct export testing.			
а	Animals non-negative to the CFT test are uniquely identified and immediately separated to the designated pen.			
b	Non-negative animals are subject to CCT testing by an official vet within 10 days or after 60 days of the CFT test.			
2	CCT reactor animals are immediately removed from the EGC and transported to slaughter under seal.			
а	In-contact animals are only processed for export if the CCT reactor animal is negative on laboratory testing.			
3	CCT suspect animals are slaughtered with sampling or re-tested at least 60 days after inoculation for the first CCT test.			
а	In-contact animals are only processed for export if the CCT suspect animal is negative on laboratory or secondary testing.			
4	CCT negative animals are removed to slaughter or approved (quarantine) feedlot (in-contact animals may be exported).			
E	Tick treatment (5 pt)	Score	Score	Score
1	Cattle for export are treated for ticks using the immersion bath (dip vat).			
2	EGC personnel agitate the bath to mix the solution for at least 30 minutes prior to dipping cattle.			
3	The EGC keeps a record of quality control parameters (pH, agitation, pollution, level of solution, animals dipped, etc.).			

*Valid negative herd test:

The test was conducted within the 11 months immediately prior to entry into the EGC; and

The test was conducted by a veterinarian who met the minimum CFT standard at the time of testing; and

The test included all animals in the herd that were 6 months of age or older; and

All animals in the herd younger than 6 months of age were officially recorded on the test chart; and

At least 1 adult bull was present in the herd and tested.

**Eligible vets are certified by SENASICA as having met the minimum CFT standard for export testing during the current period.

Table E-5: Checklist for approved feedlots

	Feedlot ID:			
Α	Facilities (Y/N)	Score	Score	Score
1	The feedlot was approved by the authorized regulatory entity only after verification that all requirements were met:			
2	The feedlot consists of the entire premises (not just certain pens):			
3	The feedlot is surrounded by a perimeter fence with double fencing where there are adjacent herds:			
4	Animals in the feedlot are confined to dry lot conditions (no pasturing):			
5	Facility infrastructure is sufficient to monitor animal movements:			
6	Any cattle on adjacent premises are TB tested annually:			
В	Cattle entry (5 pt)	Score	Score	Score
1	The origin of all cattle entering the feedlot is recorded with reference to all documentation.			
2	Bovine animals must have a permit issued by the authorized regulatory entity to enter the feedlot.			
3	Animals from regions with NA / Level V TB status arrive to the feedlot under seal.			
а	A designated feedlot official confirms that the seal is unbroken and records the seal number.			
4	Animals arrive to the feedlot with official identification.			
а	Identification is verified and recorded at the time of entry.			
5	Each animal in the feedlot is marked as eligible for slaughter only.			
6	All animals entering the facility tested negative for TB w/in 60 days prior to entry.			
а	TB testing was performed by an official or accredited veterinarian with a test response rate that meets the minimum standard.			
С	Cattle exit (5 pt)	Score	Score	Score
1	The destination of all cattle leaving the feedlot is recorded with reference to all documentation).			
2	All cattle go directly to another approved feedlot or an approved slaughter facility.			
а	Cattle leaving the feedlot do so under seal.			
b	All cattle exits are authorized in writing by the State veterinarian responsible for supervising the feedlot.			
D	Recordkeeping (5 pt)	Score	Score	Score
1	The feedlot maintains entry and exit records in a format that allows tracking of individual animals (logbook).			
2	All births on the feedlot are documented and the newborns officially identified.			
а	Animals born on the feedlot remain there until moved to another approved feedlot or an approved slaughter facility.			
3	The feedlot keeps a record of all animals that die or are euthanized, including identification.			
E	Supervision (5 pt)	Score	Score	Score
1	A designated regulatory official is responsible for oversight and supervision of the EGC.			
2	The designated official conducts a supervisory review at least monthly.			
а	Review findings are documented in a formal report provided to the EGC owner / operator.			
b	The designated official ensures that reported deficiencies are corrected within 30 days.			

Table E-6: Checklist for accredited herds

	Herd ID:			
Α	Accreditation and reaccreditation (5 pt)	Score	Score	Score
1	Initial accreditation was via 2 consecutive negative whole-herd tests (WHTs) conducted 9-15 months apart.			
а	All cattle 6 months of age or older were included in each WHT.			
b	All cattle younger than 6 months were officially identified and recorded on the WHT test chart.			
С	At least 1 adult bull was present and tested during each herd test (unless artificial insemination is used).			
2	All animals non-negative on primary testing were subject to an official secondary test or postmortem examination.			
а	All animals non-negative on secondary testing were retested in an appropriate timeframe or examined postmortem.			
b	All animals non-negative on two consecutive secondary tests were examined postmortem with sampling for lab testing	g.		
с	Accreditation was suspended while the animal and herd status was determined.			
3	Reaccreditation was via a negative WHT conducted within 9-15 months of the anniversary date.			
а	All natural additions to the herd were recorded at the time of reaccreditation.			
b	All purchased additions to the herd were recorded at the time of reaccreditation.			
С	Purchased animals came from an accredited herd or with proof of a negative WHT and individual test.			
4	Each WHT was conducted by an accredited or official vet who met the minimum CFT standard at the time of testing.			
а	All secondary testing was conducted by an official veterinarian.			
В	Documentation in the herd file (Y/N)	Score	Score	Score
1	Complete field and official test charts for each WHT:			
2	Field and official test charts for any secondary tests conducted:			
3	Summary of the herd inventory and TB test history:			
	Evidence of inventory reconciliation between herd tests, including missing and additions:			
4	Entry documentation for purchased additions (e.g., certificate of accreditation, transit guide, test charts):			
5	Certificates of accreditation and re-accreditation:			
6	Documentation of suspension of accreditation (if applicable):			