Proposed Bovine Tuberculosis and Brucellosis Draft Regulatory Framework

Executive Summary

In September 2010, the Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) formed a working group of Federal, State, and Tribal subject matter experts to discuss new directions and flexible, transparent regulations for the bovine tuberculosis (TB) and brucellosis eradication programs. The working group subsequently drafted a regulatory framework of eight interrelated elements for the TB and brucellosis proposed rule. VS will seek comments on the framework through public meetings and on the proposed rule through publication in the *Federal Register*.

VS proposes that the draft framework cover cattle, bison, and captive cervids as targeted host species. Disease agents covered by the framework are defined as *Mycobacterium bovis* for the TB program and *Brucella abortus* for the brucellosis program. The combined overarching regulatory objectives of the programs are to rapidly detect disease, implement actions to prevent further spread in the United States or through importation, eradicate disease (when possible), and document disease status for domestic and international trading partners.

The eight interrelated regulatory elements are:

1. Program (State) requirements
2. Zoning
3. Surveillance
4. Affected herd management and epidemiological investigations
5. Indemnity
6. Interstate movement controls
7. Importation requirements
8. Approval procedures related to official tests and laboratories

While these eight elements are separated and discussed as individual components, items under each element may appear in a different section when VS develops the actual regulatory text and supporting documents. Also, the regulatory language will refer to lists posted on the APHIS Web site and to guidance documents such as program standards and VS Memoranda.

Element 1: Program (State) Requirements

Regulatory Objectives of the Element

1. Eradicate TB and brucellosis from all U.S. livestock herds of cattle, bison, and captive cervids, and mitigate the risk of transmission between livestock and wildlife populations.
2. Provide a structure that ensures consistency in program implementation and compliance across States and Tribes.
3. Provide animal health information and document disease status (i.e., risk) for both domestic and international trading partners.

Regulatory Components for the Element

Component 1: State status

1. VS will implement a three-tiered State status system where a State or Tribe is classified based on its compliance with national standards and the implementation of its animal health plan. The State or Tribe should be able to take immediate action when appropriate.
   Tier 1: Consistent status
   Tier 2: Provisionally consistent status
   (**Note:** A State or Tribe could move directly between consistent and inconsistent status. "Provisionally consistent" status would be used for States or Tribes that need to correct certain deficiencies, within a specified time, to become consistent. Failure to correct deficiencies in the specified time would result in reduced status.)
   Tier 3: Inconsistent status

2. Key criteria used to determine status will include compliance with requirements for surveillance, conducting epidemiological investigations (i.e., response to traces/cases), risk evaluation and mitigation activities, traceability, and enforcement. Thresholds would be established for these key criteria that would trigger a review or change in status.

3. A separate status would be assigned for each disease.

4. VS would conduct, coordinate, or facilitate evaluations for status classification and paper or onsite reviews to audit and verify State and Tribal programs.

5. A control or advisory board consisting of Federal, State, and Tribal experts may be formed to evaluate States and Tribes for compliance with program requirements and to give VS status recommendations.

Component 2: General program requirements

1. The State or Tribe must have in place infrastructure, laws, and regulations to implement and enforce TB and brucellosis programs.

2. The State or Tribe must implement a reportable disease process for TB and brucellosis that includes coordination with animal health, wildlife, and public health officials as appropriate.

3. The State or Tribe must develop and implement a comprehensive animal health plan that meets APHIS performance standards jointly approved by the State or Tribe and the APHIS Administrator. VS will make these animal health plans publicly available.

Component 3: Reporting requirements

1. States and Tribes must meet specific reporting requirements as a component of State status.

2. Transparency (as provided by these reporting requirements) is a foundation for the success and acceptance of this program. These reports will document program compliance.

3. Although States or Tribes would not automatically lose status for failing to submit individual reports, options to reduce a State or Tribe to inconsistent status or to impose other consequences when a State or Tribe habitually fails to submit required reports will be a component of the State status system.

4. The animal health plan should describe how States and Tribes will coordinate their reporting (for example, Tribes may submit reports with the State's report or may submit their own reports).

5. States and Tribes must document implementation of animal health plans to VS, and VS will make review results available to cooperators (such as Federal, State, and Tribal animal health and wildlife officials).
    a. Some degree of regular reporting will be required of all States and Tribes.
    b. The frequency of required reports may be increased or decreased based on the history of disease or current disease events in a State or Tribe.
    c. The program standards must define the information to be included in the required reports and the frequency of reporting for each disease. This would include regular reporting on the measures used as triggers for reviews or change in status.
    d. Electronic data submission would reduce the need for manual reporting and should be supported in the future programs. Ideally, the programs would require standardized electronic reporting, which should reduce or eliminate the need for additional written reports.

6. States and Tribes must provide summaries of epidemiological investigations. VS will make these summaries available to Federal, State, and Tribal animal health and wildlife officials.
    a. This should be a fairly flexible process that allows States and Tribes to provide summaries as they deem appropriate. At a minimum, an initial report and a closing

report must be submitted. Additionally, States and Tribes are encouraged to submit ongoing progress reports.

b. An initial report would be required upon initial classification of an affected herd. This report would include basic information about herd size, type, identification, and other details, but extensive epidemiological information would likely not be available.
c. Progress reports may be submitted during an investigation as deemed appropriate by the State or Tribe. These reports may include (but are not limited to) primary traces, neighboring herds identified for area testing, and other information.
d. A closing report would be required upon case closure. VS recognizes that it could be years before a case is closed.

7. VS will make certain information publicly available on its Web site, including State and Tribal status and the number of affected herds by State. This information will include context, background, and links to individual State and Tribal Web sites when appropriate.

Component 4: Compliance and accountability

1. The status system must include mechanisms to ensure that States and Tribes comply with national standards in implementing their animal health plans. This will ensure the success and acceptance of this program.

2. States and Tribes that document compliance with national standards and successful implementation of their APHIS-approved comprehensive animal health plan (with the exception of restrictions associated with defined risk zones within a State or reservation) will not be subject to Federal interstate movement restrictions or testing requirements for animals that enter interstate commerce.

3. Alternatively, the APHIS Administrator may implement Federal interstate movement restrictions, testing requirements for animals that move interstate, or other remediations in States or Tribes that fail to comply with national standards or fail to implement their APHIS-approved comprehensive animal health plans.

4. When they fail to comply, States or Tribes may be immediately reclassified to inconsistent status or may be given time to address the noncompliance while classified as provisionally consistent. States or Tribes that fail to correct the noncompliance within the defined time will be reclassified as inconsistent.

5. The required remediations associated with failure to comply with the national standards need to be determined on a case-by-case basis. However, the number and severity of these remediations would increase as the status level is lowered.

6. When possible, these remediations should be specific to existing problem areas and may be specific for either species or animal class (testing for feeder cattle; dairy heifers) rather than applied to an entire State.

7. Possible alternative remediations, in addition to or instead of Federal interstate movement and testing requirements, include reduction of cooperative agreement funding, increased surveillance requirements, State quarantine, or increased reporting frequency.

Component 5: Scope of program regulations

1. Program host species should include cattle, bison, and captive cervids for both the brucellosis and TB programs.

2. Non-program host species should continue to be considered during affected herd investigations and response activities, as non-program species may be on the same premises or be exposed to infected program species through commingling or fence line contact. There may also be public health issues associated with these non-program host species that should be addressed.

3. Disease agents covered by the framework will be defined as *Mycobacterium bovis* for the TB program and *Brucella abortus* for the brucellosis program.

   Note: Although it is not a formally included in the brucellosis program as the species of interest, *B. suis* infection in cattle is currently addressed through epidemiological investigations of reactor animals. It will likely continue to be so addressed until improved diagnostic tools that can differentiate *B. suis* from *B. abortus* are developed.

4. The programs should be flexible enough to include additional agent species when producer- or industry-driven initiatives support certification or accreditation efforts. These efforts would enhance current surveillance activities in both programs and may serve as the initial step toward documenting State status for TB and/or brucellosis for those species. Additionally, public health exposures may require that additional species of agents be included in the individual programs.

Element 2: Zoning (As a Component of Response and Containment)

Regulatory Objectives of the Element

1. Rapidly reduce the risk of disease transmission to disease-free populations.
2. Minimize the economic impact of a disease on the disease-free population.
3. Demonstrate to trading partners (domestic and international) that the measures implemented effectively isolate the affected zone.
4. Maintain risk-appropriate market access and business continuity.
5. Focus resources on geographic areas where the disease exists.

Regulatory Components for the Element

Component 1: Short-term containment actions

If an affected herd is detected:

1. A standard epidemiological investigation is conducted (following the protocol outlined in the program standards).

2. The State or Tribe implements short-term containment actions, such as quarantine or zoning, as outlined in its State or Tribal action plan. The containment actions, which should not be limited by geopolitical boundaries, include:
   a. A standard epidemiological investigation (following the protocol outlined in the program standards)
   b. Mandatory testing of all adjacent herds, known contact herds, and potential source herds
   c. Addressing and evaluating wildlife risks
   d. Evaluating and considering all potential risks

3. The goal of the containment action is eradication.

4. VS will coordinate interstate issues to ensure other States are notified and take necessary action, such as testing of herds that received exposed animals.

5. The State or Tribe will communicate all actions with VS and an advisory board to minimize negative effects on animal and product movement interstate and internationally.

6. The State will continually update the action based on epidemiological information collected.

If wildlife infection is identified in the absence of infected herds:

1. The State or Tribe will implement its short-term containment action based on program standards. The action includes standard livestock surveillance conducted with knowledge of wildlife movement.

2. The State or Tribe will communicate all actions with VS and an advisory board to minimize negative effects on animal and product movement interstate and internationally.

3. The goal of the containment action is to protect livestock from exposure to disease.

4. The action is not limited to geopolitical boundaries. VS will coordinate interstate issues to ensure that neighbording States are notified and take action as recommended by VS and the advisory board.

5. The State or Tribe will continually update the action based on epidemiological information collected.

Component 2: Long-term containment actions (>1 year)

1. If the outbreak cannot be eradicated within a year, then the State, Tribe, or identified region will develop a long-term containment plan.

2. VS will assess the plan in consultation with the advisory board. Ultimate approval of the plan will be the responsibility of VS.

3. VS and the advisory board may determine that a risk assessment, conducted by VS with the State, Tribe, or identified region, may be needed to support or modify the containment plan.

4. The long-term containment plan will be incorporated into the State animal health plan for each State involved. VS will evaluate the plans at least annually.

5. The plans can be evaluated through an annual report or as set forth in the program standards.

6. VS will notify other animal health officials regarding the long-term containment plan to minimize negative effects on animal and product movement interstate and internationally.
    a. The long-term containment plan will be based on:
        i. An evaluation of livestock and wildlife movement, geography, population, and demographics collected from the short-term containment action
        ii. The extent of disease in livestock populations and associated wildlife risk as identified by the State or Tribe
        iii. Recognition that some groups within a zoned area represent greater risks, while others represent lesser risks
    b. The long-term containment plan may include a management action such as zoning or other long-term action identified by the State or Tribe or as directed by VS in consultation with the advisory board.
    c. The goal is long-term risk management or containment with the ultimate goal of disease eradication.

7. If zoning is the method for management, boundaries should:
    a. Follow the epidemiological characteristics of the event
    b. Be justifiable and based on science
    c. Be enforceable
    d. Be manageable
    e. Not be limited by geopolitical boundaries unless appropriate

8. The plan must include methods to alter the boundaries or remove the zone.

9. Management of the zone must consider:
    a. Whole herd testing

b. Movement testing, permitting, or certification
c. Wildlife risk
d. Biosecurity evaluation
e. Modified management practices
f. Traceability

10. Requests to modify the zone will be submitted to VS for review and approval in consultation with the advisory board.

11. When the disease has been eradicated, the zone will be dissolved after the advisory board has reviewed and VS has approved the actions taken.

Element 3: Surveillance

Regulatory Objectives of the Element

1. Rapid detection of disease.
2. Ability to estimate the magnitude of the problem (prevalence/incidence).
3. Ability to measure progress toward regulatory goals (eradication/control).
4. Ability to provide metrics to aid in evaluation of compliance with program standards.
5. Ability to give interested stakeholders and decisionmakers timely and relevant actionable information.

Regulatory Components for the Element

Component 1: National surveillance

1. VS and the States and Tribes will collaborate to conduct slaughter and other routine surveillance as defined in the program standards or national plan for all susceptible livestock species.

Component 2: Targeted surveillance

1. Program standards must adequately address at-risk populations through testing, movement controls, slaughter surveillance, or other management practices.

2. The program standards or national plan will define at-risk populations and adequate testing.

3. State and Tribal animal health plans will locate and identify at-risk populations.

Component 3: Other surveillance

1. Other surveillance to support State or Tribal zoning or national plans will include:
   a. Consideration of enhanced surveillance for at-risk zones or populations

b. Testing associated with movement control
c. Testing for other program activities
d. Other methods of disease detection

Component 4: Animal identification

1. Effective surveillance will require unique and official individual identification of animals, consistent with the proposed traceability rule.

2. Official identification is needed for the following categories:
   a. Official vaccinates
   b. Officially tested animals
   c. Suspects and reactors
   d. Animals moving interstate (consistent with the proposed traceability rule)

3. Technologies such as DNA profiling could be used to confirm that a sample is identical to the identified animal.

4. All official identification should be collected and recorded on all program surveillance animals at slaughter by USDA's Food Safety and Inspection Service unless other arrangements are made as provided by the proposed traceability rule.

Element 4: Affected Herd Management and Epidemiological Investigations

Regulatory Objectives of the Element

1. Establish criteria for determining an individual animal as negative, suspect, reactor, exposed, or infected, and a group or groups of animals as affected.
2. Conduct epidemiological investigations to determine where infection may have originated and where it may have spread.
3. Describe the handling and disposition of negative, suspect, reactor, exposed, or infected animals and affected groups.
4. Eliminate infection in affected groups by depopulation, test-and-remove plans, or other means and prevent further transmission to susceptible species.
5. If disease cannot be eliminated, implement mitigations to reduce the risk of further transmission to susceptible species that provide a high level of confidence that further disease transmission will not occur.

Regulatory Components for the Element

1. Provide definitions for livestock, herd, feedlots, heifer raisers, affected herd, affected feedlot, affected heifer raiser, infected individual animal, exposed herd, contact herd, contact feedlot, contact heifer raiser, contact animal, negative animal, responder animal, suspect animal, reactor animal, exposed animal, susceptible species, and program species.

2. Describe how the following will be determined: affected herd, affected feedlot, affected heifer raiser, infected individual animal, exposed herd, contact herd, contact feedlot, contact heifer raiser, contact animal, and exposed animal.

3. Identify personnel to develop and implement a plan to manage affected groups of animals, to include movement restrictions.

4. Provide for the development of investigation and reporting requirements and timelines for epidemiological investigations, including notification of interstate traces associated with an infected individual animal, affected herd, affected feedlot, or affected heifer raiser to determine where the infection originated and where it may have spread.

5. Allow for consequences if epidemiological investigations are not rapidly and properly conducted.

6. Provide conditions for and variances from program requirements and timelines, including epidemiological investigations, notification of interstate traces, and testing.

7. Allow facilities to receive high-risk or restricted-movement animals.

Notes

1. Much of the existing *Code of Federal Regulations* (9 CFR) and many existing guidance documents can be used for this element.

2. Items in individual elements may appear in different sections when the regulatory text and supporting documentation are developed.

Element 5: Indemnity

Regulatory Objectives of the Element

1. Provide Federal legal authority to pay indemnity for animals destroyed because of TB or brucellosis.
2. Describe the use of indemnity in the TB and brucellosis programs and the eligible expenses for indemnity.
3. Describe the process for valuation of individual animals.

Regulatory Components for the Element

1. Define terms specific to indemnity.

2. Indicate that indemnity payments are contingent upon the availability of Federal funds.

3. Describe the approach for indemnity. The indemnity process will be put into program standards so that it can be changed quickly as needed.

4. Describe how indemnity values for individual animals will be determined. Use standardized appraisal tools to determine the animals' fair market value.

    a. VS will develop an appraisal calculator with input from stakeholders.
    b. VS will monitor market prices to ensure that the appraisal calculators remain current.
    c. Key objective parameters, such as age, weight, and milk production (for dairy), would be used to determine fair market value.
    d. Values can be regionalized, but the number of regions should be limited.
    e. VS will determine values for cervids annually with input from industry (or more often if deemed necessary).
    f. Indemnity would be paid at 100 percent of fair market value; however, indemnity payment should be reduced by any realized salvage value.

5. Describe eligible indemnity expenses.

    a. VS will pay up to 100 percent of the following:
        i. Value of the animals destroyed (minus salvage value)
        ii. Transportation costs
        iii. Disposal costs

    b. Payment would not usually include cleaning and disinfection, although disinfection may be paid for on a case-by-case basis.

Element 6: Interstate Movement Controls

Regulatory Objectives of the Element

1. Define "movement controls."
    a. Movement controls are activities intended to reduce the potential for disease transmission and mitigate risk.

2. Describe the purpose of "movement controls."
    a. Prevent the spread of disease from areas of identified risk (such as quarantined facilities or established zones where there is documented disease risk or when there is failure to meet program requirements).
    b. Reduce the risk of disease transmission.

3. Describe why and when movement controls will be invoked.
    a. Movement controls will be applied to identified areas, such as quarantined facilities or established zones, but may also be applied to a risk population without regard to program status in a State, Tribe, or identified area.

b. Movement controls will also be applied to any State, Tribe, or identified area that does not comply with investigation, surveillance standards, or program management.
c. Movement controls will also be applied to animals that originate from known or suspect risk areas or populations.

Regulatory Components for the Element

1. Provide for interstate, Tribal, or area movement controls for animals presenting a risk of disease transmission.

2. Provide the authority to define what types and classes of animals and herds might be subjected to movement controls.

3. Provide consequences for lack of implementation, maintenance, and compliance with risk mitigation measures or restrictions, and provide that active mitigation activities (such as use of terminal feedlots or disease management plans) may preclude or diminish the need for movement controls.

4. Provide that the APHIS Administrator can, in specific cases and in consultation with or advisement by the program regulatory advisory board, consider conditions for variances from the movement restrictions when disease spread has been mitigated.

Notes

1. Much of the existing 9 CFR (parts 77 and 78) and many existing guidance documents can be used for this element.

2. The regulatory framework may refer to lists posted online as well as to guidance documents.

Element 7: Import Requirements

Element 7-A: Preimport

Regulatory Objective of the Element

Minimize the introduction of disease into the United States through the import of live animals.

Regulatory Components for the Element

General requirements

1. Determining the risk of disease in the region of origin. VS will not propose changes to the risk evaluation process described in 9 CFR part 92.

2. Developing, implementing, and verifying measures to ensure that animals offered for import to the United States are disease free.

Modified review/case-based import restrictions

1. VS wil recognize States or zones for export to the United States after the country of origin submits written documentation and VS completes an onsite program review.

2. Import requirements may be increased (up to and including halting all imports) for States or zones after a threshold, such as the number of TB cases found in imported cattle at slaughter, has been reached. Annual report reviews, U.S. slaughter surveillance, and other applicable data sources will document threshold determination.

3. VS may ease import restrictions after the State or zone improves its methods to meet program standards to prevent the introduction of disease into the United States. These improvements may be verified by an onsite program review.

Element 7-B: At Import

Regulatory Objectives of the Element

1. Ensure that animals appear healthy at the time of import to the United States.

2. Ensure that import documentation shows all preimport requirements have been met.

Regulatory Components for the Element

General requirements

1. Documentation accompanying imported animals must indicate that all preimport requirements have been met.

2. Each animal has individual official identification.

3. Any required additional testing must be performed.

4. First point of concentration (mingling) after entry must be identified and documented, and records must be maintained to facilitate tracing of animals. (This requirement may be incorporated into State or Tribal animal health plans or in the State's or Tribe's enacted laws, regulations, or policies.)

5. If animals will be moved interstate from the first point of concentration, the State of destination must be notified before movement takes place.

Element 7-C: PostImport

Regulatory Objectives of the Element

1. To maintain traceability and individual official identification of imported livestock.
2. To prevent the exposure of domestic livestock and native wildlife to diseases carried by imported livestock and wildlife.
3. To ensure that imported livestock do not develop disease after entry.

Regulatory Components for the Element

General requirements

1. Official identification that includes country of origin must be maintained to facilitate identification of imported livestock throughout the production cycle.

2. Interstate movement of animals after the first point of concentration (mingling) will require an inspection of interstate certificates of veterinary inspection (ICVI) or brands. ICVI or brand inspection will indicate the country of origin and purpose or class of the animals.

3. Biosecurity requirements must keep high-risk imported livestock separated from domestic livestock.

4. Long-term testing requirements will be needed for imported livestock outside of food production channels (such as rodeo or other event cattle).

Post-entry restricted movements and long-term followup testing

1. Interstate movement of imported animals will be allowed after an ICVI or brand inspection that indicates the country of origin and purpose or class of the animals.

2. Imported steers must be permanently identified and tested before events and exhibitions and tested periodically thereafter.

3. Steers and spayed heifers imported for food production must be kept separate from domestic breeding cattle during pasturing.

4. Feedlots receiving imported steers or spayed heifers for finishing must establish and maintain biosecurity measures between imported steers and spayed heifers and domestic cattle that may return to the national herd.

5. Imported animals designated for slaughter may not leave a feedlot after entering except to go to slaughter.

6. Animals imported for breeding purposes would be required to have a negative test within 120 to 180 days after entry into the United States.

Element 8: Approval Procedures Related to Official Tests and Laboratories

Regulatory Objective of the Element

Ensure that diagnostic test methods, testing laboratories, testers, and test results meet program requirements and standards.

Regulatory Components for the Element

1. Define official diagnostic test, official testing laboratory, and when appropriate, official tester, among other terms. Definitions will cover the potential use of a penside test methodology.

2. Provide a process of initial approval and recertification of official diagnostic tests, official testing laboratories, and when appropriate, official testers.

3. Provide that changes to the process for program approval of diagnostic tests, official testing laboratories, and official testers will be accomplished through a *Federal Register* notice describing the proposed change and soliciting public comment.

4. Provide a mechanism to withdraw or suspend approval of official diagnostic tests, official testing laboratories, and when appropriate, official testers.

5. Set minimum performance standards for quality assurance and quality control for testing laboratories and proficiency testing of authorized personnel (such as accredited veterinarians) performing official program disease testing.

Notes

1. Much of the existing 9 CFR and many existing guidance documents will be used for this element.

2. We are not proposing any regulatory changes to the Center for Veterinary Biologics (CVB) regulations dealing with the licensure of diagnostic tests and biologicals. A CVB-licensed test still requires program approval.