

# **Veterinary Services Information Sheet: Proposed Bovine Tuberculosis and Brucellosis Draft Regulatory Framework**

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 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

## **Element 1 – Program (State) Requirements**

Program requirements will play a pivotal role in the proposed regulations. Program status for States and Tribal Nations will be based on a three-tiered system, and separate status designations will be used for TB and brucellosis. VS, possibly with the input of an advisory board, will evaluate program status according to key criteria that include compliance with surveillance requirements, ability to conduct epidemiological investigations, risk evaluation and mitigation activities, and enforcement. Unlike the current programs, a State or Tribe's status would no longer depend on disease prevalence.

The framework proposes that each State or Tribal Nation must develop and implement comprehensive animal health plans that meet VS performance standards jointly approved by the

State or Tribal animal health official and VS. A designated animal health official is defined as the chief animal health or wildlife official authorized by a State or Tribe to oversee their respective parts of the program or perform the functions or activities involved.

Accountability and compliance will be core regulatory components to ensure that animal health plans are successfully implemented. For example, States and Tribes would be obligated to meet specific reporting requirements, such as the timely reporting of the initial classification of an affected herd. Such a report would include basic information about herd size, herd type (dairy versus beef), and how the herd was found (slaughter testing, epidemiological investigation, etc.). These reports would be made publicly available on the VS Web site.

### **Element 2 - Zoning**

The animal health plans described in Element 1 will include short- and long-term containment actions for disease events. States or Tribes will implement short-term containment zones to quickly eradicate disease; zones will be established epidemiologically and not solely on geopolitical boundaries. VS will notify other States that may be involved to ensure that appropriate actions, such as mandatory testing of contact and adjacent herds, are taken. States or Tribes will implement long-term containment plans if disease eradication cannot be achieved within one year. Containment would no longer be necessary after disease has been eradicated.

### **Element 3 - Surveillance**

VS will require unique and official identification for program activities, such as vaccination and testing of animals associated with an epidemiological investigation. These requirements will be consistent with the proposed traceability rule. Further, VS will develop TB and brucellosis performance standards for both national slaughter surveillance and targeted surveillance (first point, wildlife, or movement testing) for high-risk areas. Any other surveillance activities conducted by a State or Tribe will also be taken into account when VS evaluates compliance with surveillance standards.

### **Element 4 - Affected herd management and epidemiological investigations**

Common terms (e.g., livestock, herd, feedlots, and heifer raisers) will be defined to ensure consistency in regulatory actions. VS will develop standards for epidemiological investigations, reporting, time frames, and notification of interstate traces associated with affected animals. Many of these standards will be similar to what exists today. Program standards will describe consequences (such as loss of status or increased reporting requirements) if epidemiological investigations are conducted improperly or completed beyond the required time frames.

### **Element 5 - Indemnity**

Indemnity for depopulated herds or diagnostic purchases will be contingent on the availability of Federal funds. VS will develop a national calculator (with input from stakeholders) to determine

an animal's fair market value. Such a calculator will include consideration of the type and age of the animal, stage of milk production for dairy animals, and regional values. To respond to disease situations quickly and to appropriately manage limited funds, there will be no provisions for a separate appraisal or an appeal.

#### **Element 6 - Interstate Movement Controls**

Based on a State's or Tribe's comprehensive animal health plan, risk mitigations in the form of movement controls may be applied for animals originating from areas or populations of higher risk. VS may also implement interstate movement requirements for noncompliance with program management, investigation and surveillance standards, and risk mitigation activities. Program standards will include the types and classifications of animals subject to movement controls.

#### **Element 7 - Importation Requirements**

VS recognizes countries or zones as eligible to export to the United States according to title 9 of the *Code of Federal Regulations* (9 CFR) section 92.2, which defines the requirements for recognition of the animal health status of a region. VS and APHIS International Services will continue to monitor approved countries and zones for any conditions or activities that would trigger a review or change in status.

At the time of import, VS will verify that all pre-import conditions have been met by examining required documentation and official identification for each animal. The first point of concentration after entry (i.e., mingling) will be identified on import documents, and records will be maintained at the facility to enable tracing animals to their next destination. Biosecurity will be required at locations that receive imports to separate high-risk imported livestock from domestic breeding livestock. Further, post-entry interstate movement requirements will be enforced for long-term followup testing of some classes of animals, such as rodeo cattle.

#### **Element 8 - Approval procedures related to official tests and laboratories**

Existing regulations in 9 CFR describing the approval process for official tests and laboratories will remain in place; that is, VS will need to approve any diagnostic test for official program use and all laboratories conducting official program testing. VS will also determine minimum performance standards for quality control, testing laboratories, and proficiency testing of authorized personnel. In addition, the regulations will include definitions for common terms (e.g., official diagnostic test and official laboratory).